Title: A Rapid Resolution and Redress Scheme for Severe Avoidable Brain Injury at Birth **IA No:** 9535 **RPC Reference No:** N/A **Lead department or agency:** Department of Health **Other departments or agencies:** N/A	**Impact Assessment (IA)** **Date:** 02/03/2017 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Other **Contact for enquiries:** RRR-Consultation@dh.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
£m	£m	£m	Not in scope	Qualifying provision

What is the problem under consideration? Why is government intervention necessary?

Evidence tells us that the current system for handling maternity litigation cases is not working as well as it could. The lengthy and adversarial litigation process adds stress and uncertainty for families at a difficult time, and results in escalating NHS litigation costs. Importantly this system is not geared to enable rapid learning to avoid future incidents, improving safety and reducing future claims against the NHS. This issue was considered by the National Maternity Review (Better Births 2016) recommending the Department of Health (DH) consider a Rapid Resolution and Redress scheme to enable improvements in these areas. DH is therefore required to fully assess this policy, for cross-government consideration of a final business case.

What are the policy objectives and the intended effects?

The policy aims to reduce 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. The policy will support wider initiatives designed to improve the safety of maternity care in England. Additionally, it intends to provide a more supportive and open relationship with families affected by severe birth injury, while providing timely and effective compensation to ensure the baby's future care needs are met.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing
Option 2: Clinical eligibility without additional administrative eligibility criteria
Option 3A: Compensation scheme with eligibility criteria based upon experienced specialist test.
Option 3B: Compensation scheme with eligibility criteria based upon reasonable care test.
Option 4: A pilot version of Option 3A with commitment to rolling out more widely.

Option 3 is the preferred option as both sub-options deliver the policy objectives cost-effectively in the majority of scenarios.

Will the policy be reviewed? It will/will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?		N/A		
Are any of these organisations in scope?	**Micro** No	**Small** No	**Medium** No	**Large** No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: _____ Date: _____

Summary: Analysis & Evidence

Policy Option 3A

Description:

FULL ECONOMIC ASSESSMENT INCLUDING OPPORTUNITY COSTS

Price Base Year 2015	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**Best Estimate:** £12.80bn

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	
High	Optional		Optional	
Best Estimate				**-£11.86bn**

Description and scale of key monetised costs by 'main affected groups'

Implementation costs associated with investigations and learning for clinicians. Additional costs from providing compensation greater than the universal state offer to an increased number of people.

Savings delivered to health budgets from reduced numbers of litigations and incidents that receive the universal state offer. Savings on legal fees from reduced litigations.

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	
High	Optional		Optional	
Best Estimate				**£0.95bn**

Description and scale of key monetised benefits by 'main affected groups'

Reduction in the QALYs lost through the prevention of incidents of brain injury.

Other key non-monetised benefits by 'main affected groups'

Improved experience of families through earlier, supportive interaction with clinicians and opportunity to access support and compensation without litigation.

Increased capability in the health system through improved learning and support for clinicians and expected changes in professional culture.

Key assumptions/sensitivities/risks — **Discount rate (%)** 1.5%

Harm reduction: The numbers of avoidable incidents of harm being reduced through the policy is vital to delivering cost savings.

Number of eligible incidents: the number of incidents qualifying for the RRR compensation scheme.

Uptake: the proportion of those who would be eligible for a negligent litigation award that take an RRR compensation package.

BUSINESS ASSESSMENT (Option 3A)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: N/A	**Benefits:** N/A	**Net:** N/A	Not a regulatory provision.

Summary: Analysis & Evidence

Policy Option 3A

Description:

FULL ECONOMIC ASSESSMENT WITHOUT OPPORTUNITY COSTS AND BENEFITS

Price Base Year 2015	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**Best Estimate:** £1.41bn

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	
High	Optional		Optional	
Best Estimate				**-£1.41bn**

Description and scale of key monetised costs by 'main affected groups'

Implementation costs associated with investigations and learning for clinicians. Additional costs from providing compensation greater than the universal state offer to an increased number of people.

Savings delivered to health budgets from reduced numbers of litigations and incidents that receive the universal state offer. Savings on legal fees from reduced litigations.

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	
High	Optional		Optional	
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

Other key non-monetised benefits by 'main affected groups'

Improved experience of families through earlier, supportive interaction with clinicians and opportunity to access support and compensation without litigation.

Increased capability in the health system through improved learning and support for clinicians and expected changes in professional culture.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

Harm reduction: The numbers of avoidable incidents of harm being reduced through the policy is vital to delivering cost savings.
Number of eligible incidents: the number of incidents qualifying for the RRR compensation scheme.
Uptake: the proportion of those who would be eligible for a negligent litigation award that take an RRR compensation package.

BUSINESS ASSESSMENT (Option 3A)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: N/A	**Benefits:** N/A	**Net:** N/A	Not a regulatory provision.

Summary: Analysis & Evidence

Policy Option 3B

Description:

FULL ECONOMIC ASSESSMENT INCLUDING OPPORTUNITY COSTS

Price Base Year 2015	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**Best Estimate:** £19.47bn

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	
High	Optional		Optional	
Best Estimate				**-£18.72bn**

Description and scale of key monetised costs by 'main affected groups'

Implementation costs associated with investigations and learning for clinicians. Additional costs from providing compensation greater than the universal state offer to an increased number of people.

Savings delivered to health budgets from reduced numbers of litigations and incidents that receive the universal state offer. Savings on legal fees from reduced litigations.

Other key non-monetised costs by 'main affected group

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	
High	Optional		Optional	
Best Estimate				**£0.76bn**

Description and scale of key monetised benefits by 'main affected groups'

Reduction in the QALYs lost through the prevention of incidents of brain injury.

Other key non-monetised benefits by 'main affected groups'

Improved experience of families through earlier, supportive interaction with clinicians and opportunity to access support and compensation without litigation.

Increased capability in the health system through improved learning and support for clinicians and expected changes in professional culture.

Key assumptions/sensitivities/risks **Discount rate (%)** 1.5%

Harm reduction: The numbers of avoidable incidents of harm being reduced through the policy is vital to delivering cost savings.
Number of eligible incidents: the number of incidents qualifying for the RRR compensation scheme.
Uptake: the proportion of those who would be eligible for a negligent litigation award that take an RRR compensation package.

BUSINESS ASSESSMENT (Option 3B)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: N/A	**Benefits:** N/A	**Net:** N/A	Not a regulatory provision.

Summary: Analysis & Evidence

Policy Option 3B

Description:

FULL ECONOMIC ASSESSMENT WITHOUT OPPORTUNITY COSTS AND BENEFITS

Price Base Year 2015	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate: £2.24bn

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	
High	Optional		Optional	
Best Estimate				-£2.24bn

Description and scale of key monetised costs by 'main affected groups'

Implementation costs associated with investigations and learning for clinicians. Additional costs from providing compensation greater than the universal state offer to an increased number of people.

Savings delivered to health budgets from reduced numbers of litigations and incidents that receive the universal state offer. Savings on legal fees from reduced litigations.

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	
High	Optional		Optional	
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

Other key non-monetised benefits by 'main affected groups'

Improved experience of families through earlier, supportive interaction with clinicians and opportunity to access support and compensation without litigation.

Increased capability in the health system through improved learning and support for clinicians and expected changes in professional culture.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

Harm reduction: The numbers of avoidable incidents of harm being reduced through the policy is vital to delivering cost savings.
Number of eligible incidents: the number of incidents qualifying for the RRR compensation scheme.
Uptake: the proportion of those who would be eligible for a negligent litigation award that take an RRR compensation package.

BUSINESS ASSESSMENT (Option 3B)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: N/A	**Benefits:** N/A	**Net:** N/A	Not a regulatory provision.

A Rapid Resolution and Redress Scheme for Severe Avoidable Birth Injury: An Impact Assessment

Contents

Executive Summary

Main body of Impact Assessment begins in 20 pages.

This executive summary provides a complete overview of the Rapid Resolution and Redress (RRR) policy being considered in this Impact Assessment (IA). In the main body of the document and Annex A, much greater detail is provided on the policy design, evidence used and the analytical results that are derived.

The figures in this IA are based on the previous personal injury discount rate of 2.5%. On 27th Feb 2017, the Lord Chancellor announced a change to the discount rate to minus 0.75%. Although the change in rate would affect some elements of the Impact Assessment, nonetheless the methodology used and the assumptions serve to illustrate the likely impact of the proposed policy, and we do not think this change in discount rate would alter its broad conclusions and recommendations. Any final IA that is produced will take into account changes in discount rate as appropriate.

Rationale for intervention and policy objectives

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[1] and, the vast majority of the time, the care that mothers and babies receive is excellent. However, in the small number of cases where the NHS is at fault (less than 0.1%)[2] it is important that the system is set up to provide prompt support to families and to ensure that lessons are learned to reduce future harm.

Currently when a negligent incident during labour and delivery results in the most severe forms of birth injury (cerebral palsy/brain damage (CP/BD)), the only means by which families can secure compensation is through the adversarial and often lengthy process of litigation. This process takes time as the Court has to allow the injured child's prognosis to settle before final quantification of the claim can take place in order to award a full and final settlement. Such claims take on average 11.5 years to resolve[3] – adding uncertainty, and stress for the families involved.

Within the context of rising NHS litigation costs, such cases also place a significant financial pressure on the NHS. The current expenditure on maternity claims is nearly £500m per year.[4]

International evidence demonstrates that improvements in investigation and learning can be highly effective in reducing instances of avoidable injury during birth, which can help to reduce the number of claims arising.[5]

Following the recommendation set out in the Report of the National Maternity Review (*Better Births,* February 2016), the RRR proposal aims to deliver the following policy objectives:

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

[1] http://www.publications.parliament.uk/pa/cm201314/cmselect/cmpubacc/776/776.pdf

[2] "The role of insurers in maternity safety", Draycott et al. 2015

[3] NHSLA data

[4] NHSLA data

[5] "Better Births" – National Maternity Review, 2016

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. It is important to note that this is proposed as a voluntary scheme, and the option to pursue litigation would remain open to families at all times. The scheme would only apply to injuries associated with NHS services in England. As such, these proposals do not apply to the Devolved Administrations.

Stage One: rapid independent investigations of all instances of suspected avoidable harm

Stage One focuses on reducing incidents of harm through:

- Early independent investigations of qualifying incidents, including root cause analysis; and
- Systematic learning and adoption of best practice

Stage One also includes improved openness with patients and their families through an immediate acknowledgement that a mistake might have been made, and an explanation of the routes available for understanding and addressing the consequences of harm to the baby.

The evidence underpinning the policy for Stage One is given below in the discussion around the policy design and supporting evidence.

Stage Two: providing a non-adversarial route to accessing compensation

Stage Two focuses on improving the process for families who are entitled to compensation, while also aiming to reduce litigation costs in the long term.

Level of compensation and universal state offer

Stage Two aims to improve the process for eligible claimants to receive support and compensation, and to make more effective use of NHS resources. Eligible claimants would always retain the right to pursue a claim through the litigation process. However, Stage Two seeks to provide eligible claimants with access to necessary services determined by the child's needs, reducing the need of families to pursue litigation.

All babies suffering from severe birth injury, whether negligent or not, are entitled to support through the *universal state offer*. The universal state offer is what is available to us all through either the NHS or Local Authority entitlement based purely upon level of need (and financial circumstance for social care), as opposed to what caused the medical condition.

Modelling of compensation under the RRR scheme was considered with a package proportionate in size relative to the average litigation award. The central assumption in this Impact Assessment is that the package lies at 90% of the litigation award. This figure was informed by analysis of successful litigation cases and a 'bottom up' approach by considering the types of services that are currently available to meet needs.

This was felt to offer a proportionate balance which would be large enough to ensure the family's needs would be met, and to provide a realistic alternative to litigation. Sensitivity analysis is considered around this level (80%-100%) in this IA. 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.

RRR aims to provide the family with appropriate and consistent support to enable the child to live in comfort and security. However, if a family chooses to pursue a claim after an RRR package has been put in place, it is currently proposed that services provided under the scheme would be likely to be scaled down or withdrawn (likely on a phased basis) to make sure the 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.

Policy design and supporting evidence

Harm reduction and compensation eligibility

The origin of RRR arose from the consideration of a 'no-fault/no-blame' approach to clinical accidents, where compensation is awarded even in cases where the incident may not have been caused through medical fault (negligence). Systems that operate in such a way argue that a major cultural barrier to learning is the perceived reluctance of clinicians to be open about the origin and causes of an incident, for fear of litigation or disciplinary/employment concerns.

Requirements for increased openness, such as the Duty of Candour introduced in 2015, have sought to improve this position. Nevertheless, initial feedback gathered by the National Maternity Review indicated anecdotally that factors such as reputation; employment status; a usually complex set of causative factors; and the risk that litigation might be pursued may act as substantial barriers to the openness needed when an incident of harm occurs. Such factors reduce the potential learning that could prevent such events recurring. The consultation accompanying this IA seeks further evidence of whether there are other barriers to learning in the current system.

Sweden

Sweden has operated a no-blame compensation scheme since 1975 based around whether an incident was 'avoidable'. This considers whether the incident could have been expected to have occurred had the relevant decision been taken by an 'Experienced Specialist'. This may be seen as what *could* have been done differently in the given circumstances, in contrast to what *should* have been done differently for cases of negligence. In Sweden, their measure of avoidability is considered to contribute significantly to openness among clinicians.

The Maternity Review considered the work of the Safe Delivery Care Project in Sweden, which begun in 2007 and focussed on understanding the causes of incidents of harm, combined with improved learning. Up to a 50% reduction in the number of settled claims has been observed since 2007, which is attributed to the project. Furthermore it is suggested that the pre-existing no-blame culture was a critical success factor for the Safe Delivery Care project.

Currently the data has not undergone an independent peer review of the harm reduction trend observed, although additional analysis of the data from the subsequent year has indicated that additional claims coming forwards in future years are likely to only have a small impact on the overall level of harm reduction achieved.

Harm reduction through multi-disciplinary learning

Additional robust evidence of harm reduction in birth injury comes from the studies by Bristol University using the method called PROMPT. This method involves a combination of root-cause analysis of the reason for harm, together with multi-disciplinary team learning to avoid such rare incidents in future. They have seen around 50% reduction in potential harm in Southmead

hospital through the intervention.[6][7][8] The method has been used in many other places, both in this country and in other countries. Some areas have found similar levels of reduction, but there has been a range with at least one area seeing no reduction at all (possibly due to cultural factors, but that has not been tested). The National Maternity Review also identified the benefit to harm reduction from including a multi-disciplinary approach to training.

Central estimate of harm reduction from data, learning and compensation

Building on these different experiences and using expert opinion, the National Maternity Review judged that the combined approach of no-blame compensation with a system of rapid investigations including root cause analysis and systematic multi-disciplinary learning, would lead to harm reduction at the level seen in Sweden of around 50%. The Review recommended this approach be adopted in the NHS in England through a Rapid Resolution and Redress scheme.

Bringing together the evidence discussed above and expert advice, a cautious central position is taken in our modelling that the following combined actions would be expected to achieve a reduction of around 25%:

- Investigation of each incident of harm, including root cause analysis;
- Systematic multi-disciplinary team learning to reduce the chance of such incidents in future; and
- Optional access to an RRR scheme to enable increased openness and learning.

Two options for eligibility criteria – 'Experienced Specialist' or 'Reasonable Care'

The central option in the policy is the avoidable harm option, based on avoidable incidents of brain injury at birth, using either the 'Experienced Specialist' or 'Reasonable Care' criterion. The 'Experienced Specialist' test focusses on whether an incident could have been avoided under the guidance of an 'Experienced Specialist', while the 'Reasonable Care' test considers whether the overall care was of a reasonable standard (the level currently used to establish negligence through the court).

The number of incidents estimated to be eligible for compensation based on the 'Experienced Specialist' test is **162** per year. Under the 'Reasonable Care' test, the number of cases per year is estimated at **122**.

The average level of compensation under the scheme has been assumed to be similar to the size of the current average litigation award, meaning that the difference in numbers entering the scheme makes a large difference to total scheme cost. Therefore the 'Experienced Specialist' option has higher initial costs. The argument for this option is that such an approach encourages additional openness and learning, potentially driving greater harm reduction and further reducing the costs of litigation.

It is difficult to put a precise figure on the additional level of harm reduction due to the 'Experienced Specialist' criteria. As such, a cautious approach has been taken by assuming that this offers an additional 5% harm reduction, over the central scenario. Therefore, a policy that

[6] "Does training in obstetric emergencies improve neonatal outcome?" Draycott et al. BJOG. 2006. The study saw a significant reduction in Apgar scores and a non-statistically significant 50% reduction in Hypoxic-Ischemic Encephalopathy rates.

[7] "Improving neonatal outcome through practical shoulder dystocia training." 2008. The study found a 70% reduction in Brachial Plexus Injury (BPI), paralysed arm, given that shoulder dystocia has occurred. The authors also find a 38% reduction in low Apgar scores in cases with shoulder dystocia.

[8] Prevention of brachial plexus injury—12 years of shoulder dystocia training: an interrupted timeseries study. 2015. The study found a reduction in BPI from 7.4% to 2.3% in early training to 1.3% in late training (not included in the previous paper), which is a total reduction of around 80%.

restricted compensation to cases where 'Reasonable Care' was not met (as opposed to one that under an 'Experienced Specialist' criteria) has the central estimate of 20% harm reduction, compared to 25% in the 'Experienced Specialist' case. Sensitivity analysis considers a range of harm reduction for each option generating a range of cost profiles associated with each option, with further details provided in the main text of this IA.

Policy options

Below, a brief overview of each policy option is provided

Option 1: Do nothing

The 'Do Nothing' option assumes that all severe birth injury incidents after 2018/19 continue to have the same availability of compensation – that offered through litigation for negligent cases and the current state provision of services for all non-negligent cases.

Option 2: Clinical eligibility without additional administrative eligibility (no-fault)

Option 2 provides financial support to all families that meet the clinical eligibility criteria in Stage One of the scheme. Such a scheme can be seen as a fully no-fault scheme[9], where there is no additional requirement to prove causation of harm in order to access compensation.

Option 3 (preferred option): Clinical eligibility with avoidable administrative eligibility

Instead of all cases from Stage One being automatically eligible for Stage Two, an additional eligibility test may also be applied to assess whether a case is eligible for compensation. In the litigation process the standard which is applied is clinical negligence. RRR is proposed to operate under a standard of avoidable harm to support greater openness and learning (which could be assessed according to either the 'Experienced Specialist' or 'Reasonable Care' test).

Further testing of these options and additional evidence will be sought during consultation before developing more detailed guidance on the exact criteria for eligibility.

Option 3A: 'Experienced Specialist' test

The 'Experienced Specialist' test is the level for avoidable birth injury that is applied to determine compensated cases in the Swedish system. This scenario would compensate families where the birth injury could have been avoided under optimal clinical practice within the given circumstances, assessed against the standard of an 'Experienced Specialist'.

The estimated pool size eligible for compensation is around 162 cases per annum (projected 2015 figure). Further evidence will be sought regarding the level of this figure in the consultation.

Option 3B: 'Reasonable Care' test

Under this scenario, eligibility into the scheme would be assessed by whether the care provided by the treating clinician met the standard of a reasonable practitioner.

This is similar to the test currently used in the tort route, but applied in an administrative context as a 'Reasonable Care' test.
The estimated pool size eligible for compensation in such a circumstance is 122 cases per annum (projected 2015 figure) and again further evidence supporting this number will be sought in the consultation.

[9] "No-fault compensation schemes: a rapid realist review to develop a context, mechanism outcomes framework", Dickson et al., 2016. EPPI-centre.

Option 4: A piloted version of RRR

A further option is for a form of the RRR policy (with any of the considered Stage Two eligibility thresholds) to be offered as a pilot to a subset of cases in England. An example of running a pilot using the 'Experienced Specialist' test is considered in this IA as Option 4.

An advantage of such an option is that it allows the operational delivery of a significant change to current practice to be pursued on a smaller scale, potentially increasing the likelihood of a successful transition to the scheme more widely.

The benefit of a pilot option is a decreased initial financial burden due to the smaller number of incidents that would need to be considered and managed, reducing initial spending on the policy before being considered for wider roll-out.

The size and duration of a pilot will impact any ability to determine statistically significant differences in harm reduction achieved and it is likely the main benefit of the pilot would be in fine-tuning the operational delivery of the scheme, rather than in testing its long term success in terms of harm-reduction or savings.

The pilot would probably operate most effectively, and could be aligned with existing Maternity Clinical Networks as described in *Better Births*.

Costs and savings

The NHS Litigation Authority (NHSLA) manages all legal cases against the NHS for incidents of severe birth injury (cerebral palsy/brain damage). There are about 129 successful claims per year (around 102 of which would be eligible under RRR given the scheme is proposed to apply only to full-term incidents), with damages paid out varying from over £10m down to around £10k.[10]

The average cost of such successful claims between 2012 and 2015 was around £4.75m per case. This is calculated by the NHSLA at the time of settlement, and averages those cases that receive settlement on a periodical payment basis (i.e. lump sum plus ongoing annual payments) and those that receive a lump sum only (on average these are smaller settlements). The average in present value terms is discounted across the expected lifespan, and takes account of anticipated inflation in health and care costs being greater than the GDP deflator (estimated at 4.2%[11] compared to 2.0%). On top of these are legal costs, both those paid by NHSLA and the payment of legal costs for successful claimants.

There are several factors that result in a change in the amount of in-year state spending that occurs following the introduction of the RRR policy against a counterfactual where there is no policy change.

Note that this Impact Assessment is concerned with the financial and economic impact of the RRR policy, and therefore describes the costs and benefits in these terms, for example using Quality of Life (QOL) calculations (page 10). We recognise that incidents of severe avoidable birth injury have much wider impacts, including the potentially devastating long-term physical and emotional consequences for the affected child and their family, which cannot always be quantified (some of these benefits are identified on page 45). These wider issues are

[10] NHSLA provided data

[11] Long term ASHE 6115 index used by GAD in NHSLA data analysis: the expected rise in pay for workers in health and social care.

considered in the consultation document, and will be vital in developing a policy which meets the needs of families affected by birth injury.

Reduced costs

Savings arise from the following areas, allowing for reinvestment in frontline services:

- *Harm reduction:* A reduction in the number of severe birth injuries results in both a reduction in numbers of litigations and a reduction in state costs for all injured babies.
- *Level of compensation awarded:* As discussed, ignoring inflationary and timing effects, the amount of the award is modelled centrally at around 90% of what would be predicted to be settled through the claims process. This level is being consulted on and sensitivity analysis around this figure is included in this IA.
- *Moving lump sum payments into ongoing payments*: This will reduce the burden on claimants to manage long-term finances, while ensuring that life-long needs are met by providing guaranteed future provision which is responsive to changes in need. The change in approach to providing support (i.e. ongoing needs assessment as opposed to once and for all assessment) means that a greater proportion of payments currently paid as a lump sum through litigation will be provided by way of ongoing payments under RRR. This produces a saving in present value terms and yields cash savings up-front.
- *Claims inflation:* The Government Actuary's Department (GAD) estimates that claims inflation is about 9% per year, almost 5% higher than the 4.2% per year inflation in health and care costs. This has largely been driven by the impact of judicial inflation on claims awards. It is expected that if there is full uptake of compensation, with far fewer cases proceeding to litigation, that at least part of this claims inflation can be reduced (or stopped), leading to potentially major savings.

  Although an alternative mechanism for providing compensation could have a substantial effect in reducing claims inflation, the model does not currently include any such saving except in the period from incident to settlement, where litigation awards are assumed to grow with the central estimate for claims inflation while the RRR compensation grows in line with health and care costs. Sensitivity analysis is included around the level of claims inflation that applies to both the factual and counterfactual.
- *Legal costs:* those in receipt of compensation from RRR no longer have defence and claimant legal fees that need to be paid as a result of lengthy litigation (note that there will still be an option to receive legal advice under the scheme).

Increased costs

The following areas are ones that bring about new costs for either avoidable standard (Options 3A or 3B). The additional cost of the 'Experienced Specialist' option (3A) is provided in the last bullet.

- *Earlier payment:* Court settlements take a long time to be finalised (on average, about 11.5 years after the incident occurs) partly due to the need to allow the injured party's final prognosis to be settled before quantification is agreed as a full and final settlement. Interim payments are made on eligible claims to try and mitigate the impact of this overall delay by providing interim support to families until a claim is settled. An alternative compensation scheme will result in some payments being made earlier; with families being provided with services or payments as it becomes clear that needs were related to the incident at birth.

  However, there are additional costs from early payment due to the 'accordion effect' of paying for each year's incidents earlier, while in the counterfactual these incidents would have been paid in subsequent years. Therefore, in a particular year of compensation payments, the birth

year of the group being compensated becomes out of sync with the factual containing those born more recently.

There are three factors which taken together mitigate this cost. Firstly, although litigation adds delay, much of the delay is due to the time it takes for harm to be manifest and for cost to arise, so an intention to make earlier payment is not expected in practice to lead to payments being made much more than a year earlier than at present (although an early up-front payment and access to an additional support network will ensure that families are supported during the early years until compensation is awarded). The model assumes payment is a year earlier with sensitivity allowed for up to two years earlier. Secondly, the courts add health and care inflation when payments are to be in the future, so the policy adjusts by such inflation when moving payment earlier, using 4.2% as the annual rate rather than the overall claims inflation rate (centrally taken as 6.2%). Thirdly, as noted above, a part of claims inflation is thought to be mitigated by having the compensation amount settled earlier than the court would have done, which taken together with the other mitigations, avoids any extra cost in discounted terms.

One additional key feature that also increases cost of the RRR package is the inclusion of an early lump sum payment of up to £50k-100k, as soon as eligibility for the compensation scheme is established. This payment reflects acknowledgement that an avoidable injury has occurred, and provides the family with the confidence that their case is being considered seriously and that they will get the services and support that they need. This would be categorised under general damages and would enable the family to obtain additional early support if needed.

- *Stage One implementation costs:* Administration and delivery of additional early investigations; a body to analyse and disseminate learning relating to root cause analysis; and provision for additional training for clinicians all require additional spending. These are estimated to come to up to £24m per year, driven by an estimated £15k per case for investigations, and £65k per maternity unit per year for learning.
- *Stage Two implementation costs:* The compensation scheme requires the administering body (currently proposed to be the NHSLA) to coordinate the decision about eligibility, along with assessments to determine the level of need and agree an appropriate level of compensation. For eligibility, the policy currently assumes these decisions would be made by a panel of medical and legal experts to ensure that an independent and informed decision is made. Appropriate costs for all these elements are included in the estimated cost of the policy.
- *Number of successful claims:* The total number of potentially successful litigation claims may be expected to marginally increase through increased awareness among potential claimants of the available options to access financial support/compensation as a result of the early investigation into their incident under RRR. It is assumed this increase is around 10% (sensitivity analysis included), so that with a current average of around 102 successful litigation cases per annum, there would now be around 112 successful litigations. However, with an assumed 90% of families opting into the RRR scheme (central estimate), this would yield a remaining 11 successful litigations per year.
- *Professional support network:* There are four types of support that the RRR compensation scheme introduces.

  a) *Liaison officers or case managers:* This resource would be provided to coordinate the state offer by bringing together the NHS, Local Authority and other services on the family's behalf.

  b) *Assessment officers:* An assessment officer would review the case as and when needed, on an annual basis or more or less frequently as circumstances change. The review would lead to enhanced, amended or reduced services as required. The assessment officer would have a budget in mind, as determined by 90% of the expected settlement, but would recognise that this represents an average and some cases will not need as much, while others will need more.

  c) *Counselling:* Monthly provision of counselling is available (for up to 21 years), aimed at improving the experience for families.

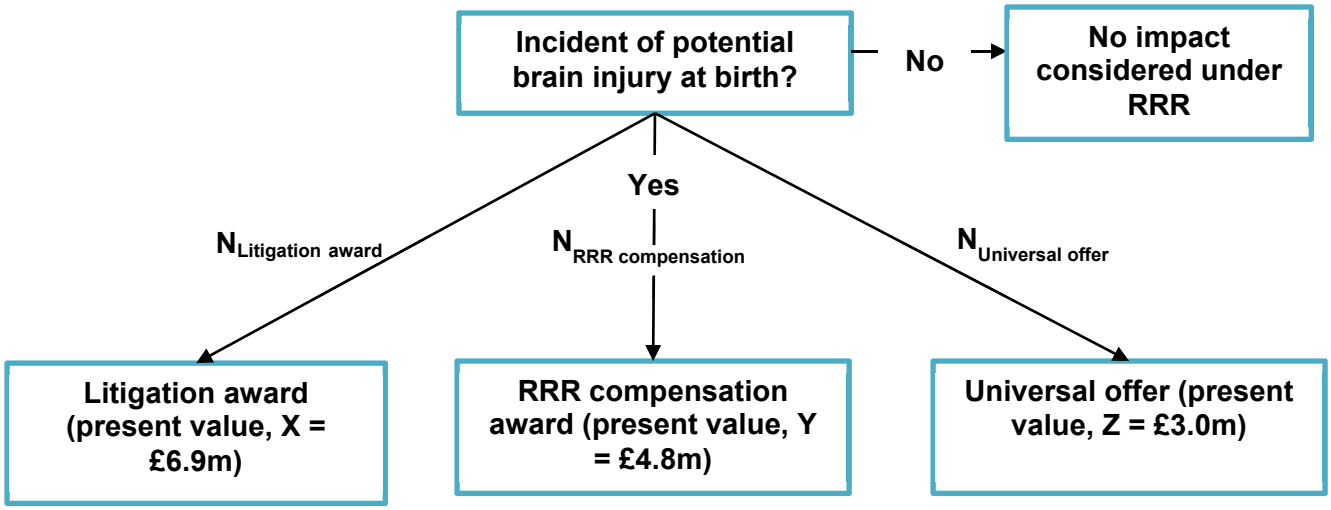
  d) *Independent legal advice:* Legal advice (at £5,000 per eligible incident) is provided to allow families to consider their options.

- *Cost due to the extra cases compensated under the 'Experienced Specialist' avoidable eligibility criterion.* If eligibility for Stage Two is determined with reference to the 'Experienced Specialist' test, this would result in an additional number of cases due to the difference between this test and the current test for negligence in the claims process. This would add around 40 cases annually.

Costs considered by cohort

In order to develop a full economic case, the total discounted spending on the first ten cohorts is considered in order to take into account the costs and benefits gained over the whole lifetime of affected individuals. This allows cross comparability with other government policy and allows the consideration of differential spending across whole lifetimes which could be up to 100 years per cohort.

The below diagram illustrates the different present value of awards that different groups in the policy receive.



The values above correspond to the average present values of awards for any birth that occurs in 2022/23 (when the full level of harm reduction is aimed to be achieved by) and is used in the example calculation below. All spending is discounted at 3.5% in line with Green Book guidance to give present value figures for the cost of each path.[12]

It is worth noting that the average values presented above are aligned from the analytical model used in this IA. These values vary from the average 2014/15 figures derived from data. This is for several reasons:

- The same level of health and social care inflation (4.2% per annum) has been applied in the period 2015 to 2022 in both litigation and RRR compensation awards increasing their real size;
- There is additional claims inflation above health and social care cost inflation included in the litigation award (2% more per annum) but not in the RRR compensation award between the time of incident and settlement; and
- There is also a shift in the distribution for when payments are made in the RRR compensation award affecting the discounted size of the award.

These factors lead to the RRR compensation award figure above having a value less than the 90% figure used to adjust the level of the lump sum and yearly periodical payment in the model

[12] "The Green Book: Appraisal and Evaluation in Central Government", https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/220541/green_book_complete.pdf

– the final proportion being predominantly affected by the gap in inflation between the RRR compensation award and the litigation award over the period from incident to settlement.

A further illustration of how these costs offset each other is given in the example below after the policy has been active for 5 years and harm reduction from the interventions has taken effect.

Inclusion of opportunity costs and benefits

Opportunity costs

All costs and savings are derived from NHS budgets as no additional funding is to be provided for the policy at this stage from HMT. As these are costs to the health system, they are subject to an additional opportunity cost. In accordance with DH guidance, health budgets are assumed to be able to buy 1 QALY for £15k at the margin which carries a societal benefit of £60k. Therefore, any spending also results in an opportunity cost of £45k for every £15k spent or saved as a net of £45k of benefits are foregone. Additionally, a discount rate of 1.5% is used for these costs as they are assumed to relate directly to health outcomes. Some costs under the universal state offer will be provided through social care services but a similar opportunity cost applies in such cases and, for simplicity, is treated in the same way as costs from health budgets. Further detail is provided in the main body of the document.

Benefits

Benefits arising from the policy are derived from the quality of life (QOL) gained by incidents prevented, the change in quality of life provided by spending of compensation awards and those benefits from any parts of the compensation that are financial transfers.

In considering the benefits associated with QOL lost the following three cases can be considered:

1. Healthy individuals are assumed to have a QALY decrease of 0.
2. Those compensated by either a litigation award or RRR compensation has a QALY decrease of P as well as a financial transfer T.
3. Those who are not compensated but only receive the universal offer are assumed to have a QALY decrease of Q.

P and Q are positive quantities representing the discounted QALYs lost over an individual's lifetime.

From considering a sample of litigation awards for severe brain injury, the vast majority of the awards are given specifically in order to be spent on health-related outcomes and are thought to be used for these means. In Appendix A, the typical size of awards across 18 cases is depicted, and only around 10% (general damages and past loss) of the award could be potentially seen as monetary transfers T. Even these are highly likely to be spent in such a way that provides a QOL benefit measureable in terms of QALYs relative to an unharmed individual. Therefore, the above monetary transfer amount T is assumed to be negligible and taken to be T=0.

Therefore, all monetised benefits of the policy are as a result of *any reduction in QALYs lost* by people either through *incidents of harm being prevented* or *additional compensation awarded*. Depending on the change in numbers of each type of incident, the level of this net change in QALY decrease will vary.

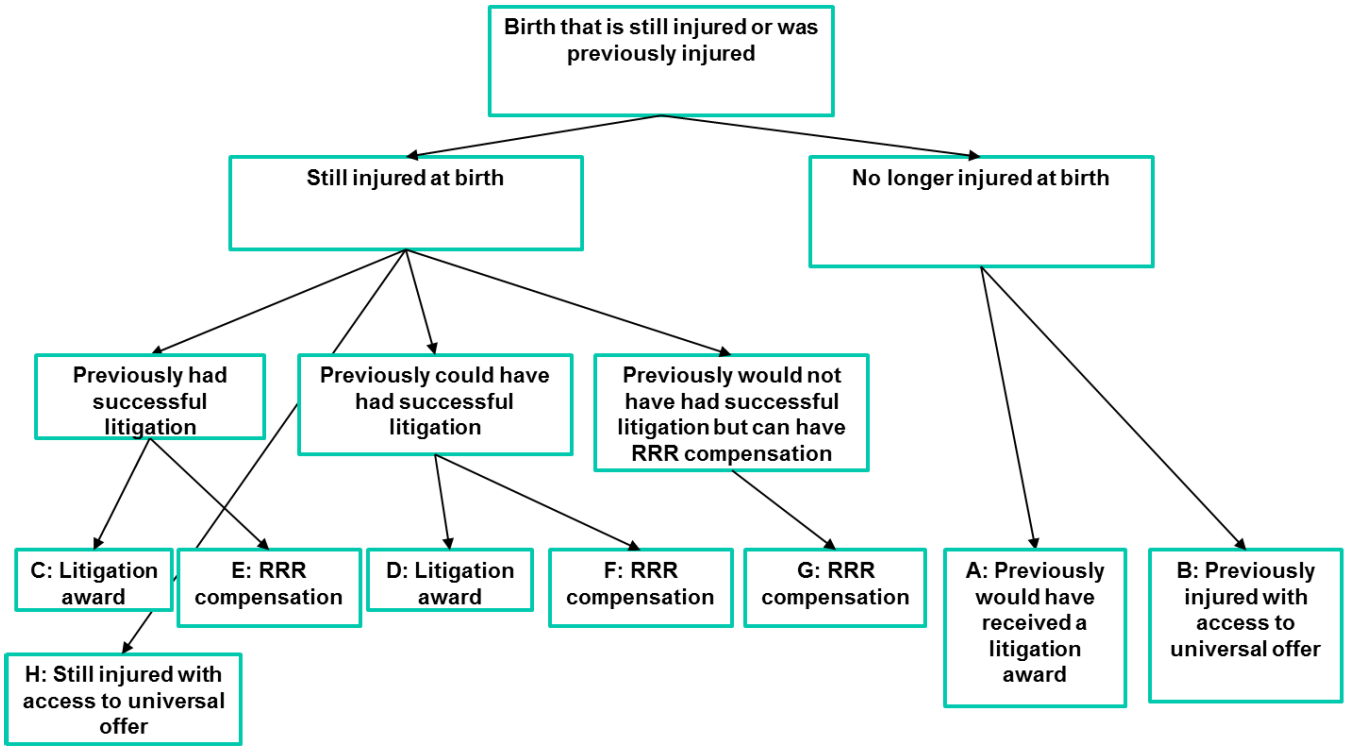
Knowing the size (-P+Q), the number of QALYs gained by individuals compensated, has not been measured in the literature. In the most extreme case, using the result from Leigh et al. that the discounted lifetime QALY decrease for an average person with severe Cerebral Palsy is around Q=50.3 QALYs. Even with P=0, this monetises (£60k per QALY) to around £3m per additional person compensated in benefits. When calculated, the opportunity saving from a single litigation avoided, is around £40m.

For simplicity, and lack of evidence around the level of P, the size of this additional benefit is ignored here as the economics are dominated by the opportunity savings. The consultation provides an opportunity to provide further evidence supporting this approach.

The different groups, the costs and benefits for each group are illustrated in much greater detail in the table below.

Understanding costs and benefits for specific groups

The diagram below illustrates the different groups that have specific costs and benefits that could potentially change following the introduction of RRR. These groups are displayed as leaves at the end of the tree.



In the table below, for each of groups A-H, a specific change in the factual to the counterfactual can be identified. This allows the impact of the policy in terms of costs and benefits to be most easily illustrated. These costs and benefits are considered in the table below with the specific change in DH spending and the change in QALYs experienced by each group.

Category	Example numbers of incidents	Example number	DH spending factual	DH spending counterfactual	QALY decrease factual	QALY decrease counterfactual	Change in DH spending	Change in QALYs	Net costs per case (including opportunity cost)	Net benefits per case
A: Those previously harmed who had a successful litigation who are no longer harmed	25% x 102	25.5	0	X	0	P	**-X**	**P**	**-4X`**	**P**
B: Those no longer harmed who were eligible for state support	25% x 249	62.25	0	Z	0	Q	**-Z**	**Q**	**-4Z`**	**Q**
C: Those still harmed who would have a successful litigation and still go on to litigate	75% x 10% x 102	7.65	X	X	P	P	**0**	**0**	**0**	**0**
D: Those still harmed who would have a successful litigation if they had pursed and now go on to litigate but who did not previously due to lack of awareness	75% x 10% x 10% x102	0.765	X	0	P	Q	**X**	**-P+Q**	**4X`**	**-P+Q**
E: Those still harmed who would have a successful litigation and take RRR compensation instead	75% x 90% x 102	68.85	Y	X	P	P	**Y-X**	**0**	**4(Y`-X`)**	**0**
F: Those still harmed who would have a successful litigation but did not previously due to lack of awareness and take RRR compensation instead	75% x 90% x 10% x 102	6.885	Y	0	P	Q	**Y**	**-P+Q**	**4(Y`-X`)**	**-P+Q**
G: Those still harmed who would not be successful if litigated but are eligible for compensation	75% x (162-110% x 102)	37.35	Y	0	P	Q	**Y**	**-P+Q**	**4Y`**	**-P+Q**
H: Those still harmed who are eligible for state support	75% x 249	186.75	Z	Z	Q	Q	**0**	**0**	**0**	**0**
Implementation costs	N/A		I	0	N/A	N/A	**I**	**N/A**	**4I`**	**0**

X is the monetary cost of litigation while X` is the cost including opportunity cost before accounting for conversion to QALYs (a discount factor of 1.5% is applied to obtain X` compared to 3.5% for X). The same applies to all other quantities distinguished by a "`".The table serves to illustrate that the economic case is dominated by the change in spending and the opportunity saving that arises diminishing the importance of the exact QALY changes that each group experiences (4X` is around £40m compared to Q=£3m). For completeness and due to their being direct evidence in support of the QALYs lost for severe CP cases, the benefits that arise for group B are included in the final economic assessment but are outweighed by the opportunity saving from reducing the incidence.

Example calculation for the 2022/23 cohort

For illustrative purposes the costs for Option 3A in factual and counterfactual by 2022/23 year when harm reduction has reached equilibrium of 25% are described below.

1) *Counterfactual number of incidents and universal state offer*

By 2022/23, it is projected that in the counterfactual, around 250 incidents of potentially avoidable harm are born and survive into early childhood. All of these cases are eligible for universal state offer provided by the NHS and social care systems.

Following inflation from present prices, this is valued at around £3.0m per average incident in present value (PV) terms, notated as Z above. This leads to a cohort cost of around £0.75bn**.**

2) *Factual number of incidents and universal state offer*

In the factual scenario, the total number of incidents is reduced through harm reduction, leading to reduced costs for each avenue where costs are associated. By 2022/23 this harm reduction reaches 25%, resulting in a total 187 incidents, and leading to a total universal state offer cost of £0.56bn**, a saving of £0.19bn compared to the counterfactual.**

3) *Counterfactual number of litigations and total litigation costs*

Around 102 of these cases would receive a successful litigation award (based upon discounting at 3.5% and incorporating claims inflation, this is around £6.9m per case by 2022/23, notated as X above). This incurs a lifetime present value cost for the cohort of around £0.70bn.

4) *Factual number of successful litigations and costs*

Under the new policy there is an expected increase in the number of cases which come forward due to increased awareness. Combining 25% harm reduction with an increase in cases due to more awareness of about 10% leads to 84 negligent cases (compared to the counterfactual of 102). Given the 'Experienced Specialist' threshold operates at a higher bar to the test currently used in the tort route (clinical negligence) it is estimated that the total pool of incidents that would be eligible for compensation ends up at around 162 cases compared to the 112 (including the increased numbers from awareness) in a counterfactual.

Under the central scenario, it is assumed that 90% of the cases that would successfully litigate choose to take the alternative compensation package leaving 10% still choosing to litigate. Therefore, there are around 8 successful litigation cases and 113 cases that receive the alternative compensation package. With 8 incidents litigating, this leads to a PV cost of around £0.06bn. **Therefore, the difference between this and the counterfactual is -£0.64bn.**

5) *Factual number of successful compensations and costs*

The compensation package delivers a lump sum and ongoing payments at 90% of the litigation offer. Under the current system, there is a lengthy gap between birth and settlement (11.5 years on average). Currently this gap undergoes claims inflation. However, under the proposed scheme this effect is removed, and when this is combined with the compensation package being received on average a year earlier. This means that the PV of the package per incident compensated under RRR is around £4.8m (notated as Y above), **leading to a total cost for compensations in 2022/23 of around £0.54bn.**

6) *Combining all cost differentials*

Bringing all these together, the difference between the factual and counterfactual is: ((4) – (3)) + ((2) – (1)) = £0.54bn - £0.64bn - £0.19bn = -£0.29bn.

7) Implementation costs

In addition to the costs from the different forms of compensation, there are also implementation costs of around £0.03bn per year, changes in spending on legal costs and the support network provided for families eligible for RRR compensation. These lifetime costs are much smaller than the saving highlighted above of -£0.29bn.

Summary of costs for first ten cohorts for Option 3A

The table below provides an example of the costs from the first ten cohorts *derived from the modelling process*. Costs are discounted at 3.5% back to the year in which the incident occurs.

Undiscounted costs (£m, 14/15 prices)		17/18	18/19	19/20	20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28	Total
Costs													
	Litigation damages	£0.00	-£0.53	-£0.56	-£0.59	-£0.61	**-£0.64**	-£0.67	-£0.69	-£0.72	-£0.75	-£0.78	-£6.55
	Litigation legal costs	£0.00	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.15
	Compensation damages	£0.00	£0.59	£0.58	£0.57	£0.56	**£0.54**	£0.57	£0.59	£0.61	£0.64	£0.66	£5.90
	Compensation legal costs	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.01
	Support network costs	£0.00	£0.02	£0.02	£0.02	£0.02	£0.01	£0.02	£0.02	£0.02	£0.02	£0.02	£0.16
	Universal state offer	£0.00	-£0.03	-£0.07	-£0.11	-£0.15	**-£0.19**	-£0.19	-£0.19	-£0.20	-£0.20	-£0.21	-£1.54
	Implementation costs	£0.00	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.29
Benefits													
	Reduction in QALYs lost through prevention	£0.00	£0.02	£0.05	£0.07	£0.09	£0.11	£0.10	£0.10	£0.10	£0.09	£0.09	£0.82

The costs highlighted in bold are the largest costs involved and are used in the example calculation discussed in the previous section. It should be noted that these costs do not include opportunity cost of the funds being derived from health budgets. Therefore the costs will be significantly larger than those in bold above due to the discount rate being 1.5% and the multiplying factor of 4 included for opportunity costs. Therefore, the benefits from reduction in QALYs lost are much smaller than the costs highlighted. This is demonstrated in the section below considering the full economic case from a health budgets perspective.

Summary of costs and benefits for first 10 cohorts for Option 3A including opportunity costs and benefits

If the above costs and benefits are expressed to include opportunity costs/savings and discounted fully at 1.5% instead of 3.5% (the appropriate rate for discounting QALY related costs as opposed to purely monetary costs), then the table of costs and benefits below is produced.

Category (discounting at 1.5%, 14/15 prices, £bn)	17/18	18/19	19/20	20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28	Total
Litigation damages	£0.0	-£0.93	-£0.97	-£1.0	-£1.03	-£1.06	-£1.08	-£1.11	-£1.14	-£1.16	-£1.19	-£10.67
Litigation legal costs	£0.0	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.17
Compensation damages	£0.0	£1.05	£1.03	£0.99	£0.96	£0.92	£0.94	£0.97	£0.99	£1.01	£1.04	£9.90

Compensation legal costs	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.01
Support network costs	£0.0	£0.02	£0.02	£0.02	£0.02	£0.02	£0.02	£0.02	£0.02	£0.02	£0.02	£0.21
Universal state offer	£0.0	-£0.06	-£0.12	-£0.18	-£0.25	-£0.31	-£0.31	-£0.31	-£0.31	-£0.32	-£0.32	-£2.50
Implementation costs	£0.0	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.26
Reduction in QALYs lost through prevention	£0.0	£0.03	£0.05	£0.08	£0.10	£0.12	£0.12	£0.12	£0.11	£0.11	£0.11	£0.95
Net Costs (including opportunity cost)	£0.01	£0.36	-£0.12	-£0.63	-£1.15	-£1.68	-£1.70	-£1.71	-£1.73	-£1.75	-£1.77	-£11.86
Net Benefits	£0.0	£0.03	£0.05	£0.08	£0.10	£0.12	£0.12	£0.12	£0.11	£0.11	£0.11	£0.95
Net benefits - Net costs	**-£0.01**	**-£0.34**	**£0.17**	**£0.70**	**£1.24**	**£1.80**	**£1.82**	**£1.83**	**£1.85**	**£1.86**	**£1.88**	**£12.80**
Net benefits - Net costs (without non-litigation state offer)	**-£0.01**	**-£0.58**	**-£0.31**	**-£0.04**	**£0.26**	**£0.56**	**£0.57**	**£0.58**	**£0.59**	**£0.60**	**£0.61**	**£2.81**

Overview of model approach

The simple calculation above illustrates how an economic case can be understood for the new policy. However, understanding associated in-year financial costs is more complicated. This due to the way payments are made in a compensation award. When a case is settled dictates the level of claims inflation applied for a given incident (health and social care costs inflate above GDP while the size of litigation awards inflate further above health and social care cost inflation). Additionally, the whole award is not paid out in its entirety at the date of settlement, with some paid as a lump sum and the remainder as an ongoing payment order.

Therefore, to accurately derive the in-year financial costs, a cohort modelling approach was taken. From considering the main sources of cost above, the main assumptions that influence the modelling outcomes are:

- Level of harm reduction delivered that affects the total number of incidents;
- Size of the compensation and litigation awards;
- Eligible number of incidents for compensation compared to litigation;
- Uptake of compensation instead of litigation; and
- Structure and timing of compensation package compare to litigation

The results from the financial payments in the model are converted back into cohort costs that are presented in the figures and examples above supporting the economic case.

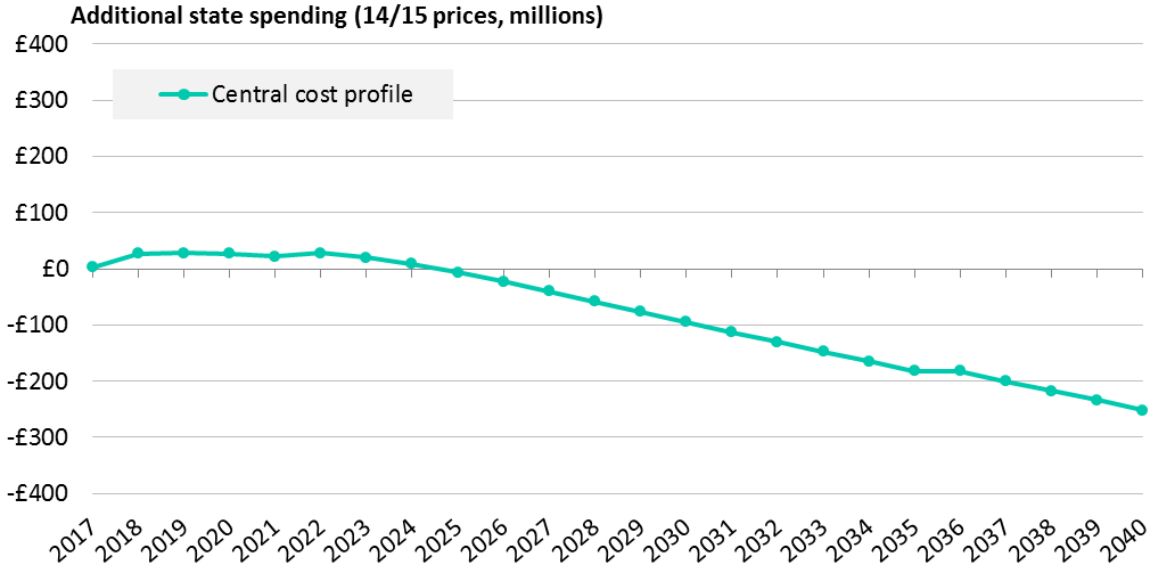
Costs based on in year spending

As discussed above a modelling approach was required to derive in year costs. Below is a description of how these costs arise, the cost profiles derived and a summary of the sensitivity analysis to demonstrate the uncertainty. Further detail is included in the main body of the document.

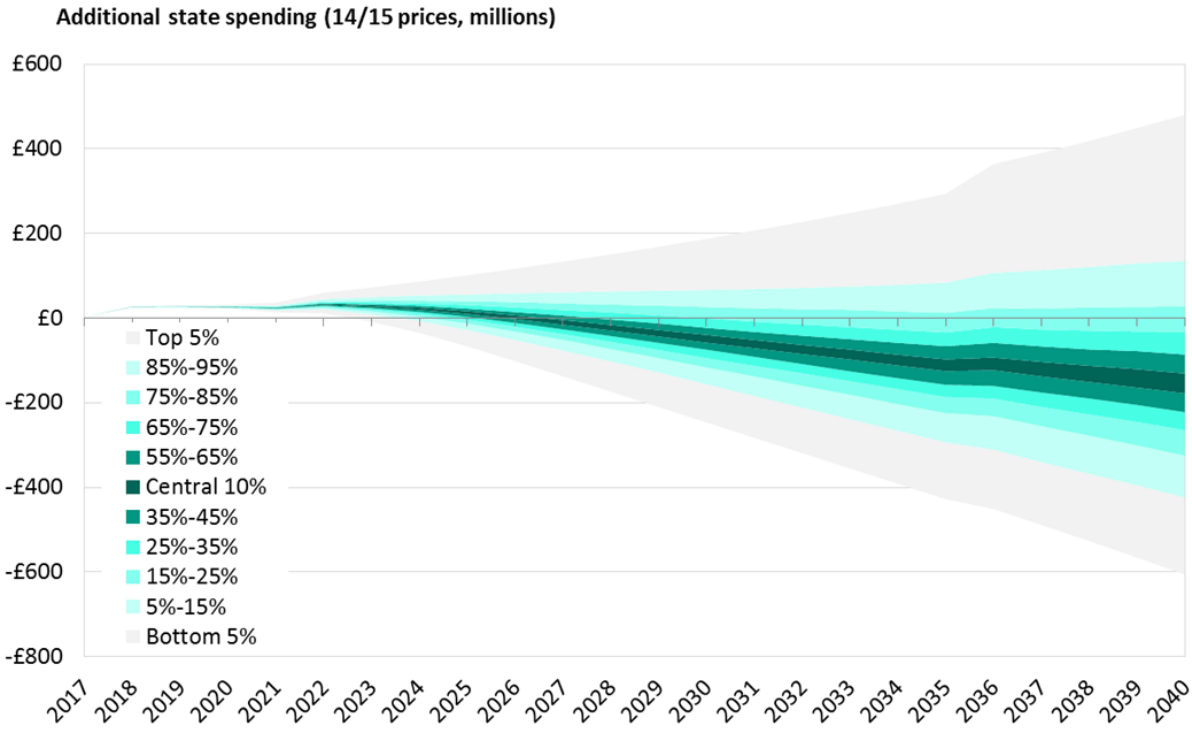
Additional spending in each year

Additional state spending increases initially in order to support the new investigations and learning provided under Stage One. In subsequent years, as the reduction in the number of incidents comes into effect, costs begin to reduce against the counterfactual, in which no additional harm reduction occurs. The reduction is driven by the balance of a reduction in litigation spending on successful claims, the increase in spending on those receiving payments under the new RRR compensation scheme and the reduction in spending on state services for those who are not eligible for either forms of compensation (the potential for harm reduction is considered applicable to these incidents too).

The central cost profile for Option 3A is depicted below in correspondence to the above description.



In the additional figure below are the range of cost profiles that may arise in Option 3A allowing for sensitivity around the central options. The upper and lower ends of the range can be predominantly understood in terms of variation in achieved harm reduction, number of eligible incidents for RRR compensation and the uptake of RRR compensation by those who would be have a successful claim if they chose to pursue one.



Areas of evidence informing assumptions that can be further informed through consultation

During the consultation period, the department aims to further develop the evidence base for the policy and, most importantly, establish the views of the public, service users, charities and professionals (clinicians, lawyers).

In Section 5 of the consultation document, clear guidance is available on the evidence that is particularly being sought. The below table also summarises these key areas of evidence, including what is currently used to inform the policy design:

Area	Current evidence	Likely stakeholder expertise
Evidence around initiatives to reduce harm during labour and delivery	• Root cause analysis, combined with improved learning in Sweden of around 50% reduction over a period of 6-7 years • Multiple sources of evidence of the benefits of multi-disciplinary training (PROMPT) in this country and other countries around the world (range of 18%-50% from this intervention alone)	• Clinicians • Midwives • Academics/experts with relevant expertise
Additional harm reduction generated from the Stage Two eligibility for compensation	• Stakeholder discussion • Primary literature (commissioned EPPI-centre showing the impact of no-blame compensation schemes on clinical culture and practise)	• Clinicians • Midwives • Academics/experts with relevant expertise
Evidence around Initiatives to increase openness and transparency	• Eligibility for compensation being based upon criteria of avoidability rather than negligence • 'A Chinese wall' between compensation and disciplinary procedures enhances openness	• Clinicians • Midwives • Academics/experts with relevant expertise

The level of compensation required to meet the needs of families relative to that provided in a litigation award	• Initial analysis of services that the litigation award may provide • Initial analysis of services provided under the universal state offer through LA provision	• LAs • Families affected • Charities and law firms
Proportionate increase in those eligible incidents for RRR compensation for the 'Experienced Specialist' and 'Reasonable Care' test relative to a negligence based system	• Stakeholder discussions around size of likely pool with CP/BD related to clinical eligibility • Primary literature analysis of outcomes for brain injuries at birth at 18 months • Analysis commissioned by NHSLA analysis of settled claims	• Law firms • Academics/experts with relevant expertise • Clinicians • Midwives
Uptake of compensation RRR compensation package over a litigation award	• Externally commissioned qualitative research from Ipsos MORI • Early discussions with stakeholders	• Families affected • Charities and law firms
The structure and timing of compensation provision for those eligible for the scheme	• Discussions with clinicians and other stakeholders	• Charities • Families affected • Academics/experts with relevant expertise • Clinicians
The administrative structure required to implement RRR, such as the nature of the investigation process, eligibility panels and analysis teams	• Discussions with clinicians and other stakeholders around the size of the teams required to perform investigations, conduct analysis and receive additional training	• Clinicians • Academics/experts with relevant expertise
Mechanisms and measures that will allow the scheme to be effectively evaluated	• Discussions with stakeholders • Government Magenta book around best practice for policy evaluation	• Charities • Families affected • Academics/experts with relevant expertise • Clinicians
Impact on equalities, health inequalities and other considerations for families	• Stakeholder discussions • Academic literature	• Charities • Families affected • Academics/experts with relevant expertise • Clinicians

Summary of options and their final economic NPV

The table below summarises the NPV for each of the options included in the impact assessment, along with commentary for each one:

Option	Net health costs (against counterfactual)	Net health benefits (against counterfactual)	NPV for 10 cohorts including all costs (against counterfactual)	Likelihood of long term positive NPV likelihood in sensitivity analysis with central sensitivity assumptions	Commentary
Option 1	£0.00bn	£0.00bn	£0.00bn	--	This is the "do nothing" option.
Option 2	£11.48bn	£0.95bn	-£10.54bn	--	Providing compensation to all incidents that meet the clinical criteria for an avoidable brain injury at birth produces a significant increase in the eligible cases for compensation and is not cost-effective.
Option 3A	-£11.86bn	£0.95bn	£12.80bn	66%	Increases support to more families and distance between the criteria under which compensation is provided compared to the current negligence, increasing the scope for potential harm reduction. However, with only an additional harm reduction of (5%) from the 'Experienced Specialist' compensation eligibility criterion, compensating additional families is offset by reduced opportunity savings and carries more downside risk if harm reduction is not achieved.
Option 3B	-£18.72bn	£0.76bn	£19.47bn	92%	Compared to Option 3A, reduces financial risk (greater change of a positive long-term NPV when sensitivity analysis is applied to the range of assumptions) through fewer additional cases are compensated and decreased harm reduction is expected due to the smaller pool of incidents that would receive compensation.
Option 4	-£1.11bn	£0.09bn	£1.21bn	--	Piloted version of Option 3A aimed at 10% of incidents. Reduces spending in current SR period and opportunity for fine-tuning operationalization before extending more widely but has limited potential to accurately consider harm reduction or uptake achieved from the scheme in any short time frame.

It should be noted that numbers above may not directly sum due to rounding. From the above table, the most cost-effective option with the current range of central assumptions applied to the policy shows Option 3B as best value for money and with decreased downside risk.

It should be noted that the balance between Option 3A and 3B is determined strongly by the choice of central assumptions. The department is looking to refine the assumptions underlying this analysis through the consultation period before the final policy delivery. Findings in this period may significantly impact the balance between Option 3A and 3B. For example, if the gap between the amount of harm reduction deliverable by Option 3B and Option 3A is greater than 5%, then it is possible that Option 3A could become the more effective net intervention. Additionally the number of additional cases that arise through the differing eligibilities also has a significant effect on the balance between the two.

Additionally, there are other less quantifiable benefits to Option 3A relative to Option 3B, such as wider culture change around the level of practice that could be aspired for. This may indeed have a significantly greater impact on reduction of the number of incidents of harm but caution has be exercised in the expression of this within the central options costed here.

The final policy details will further consider the set of evidence in order to inform the selection of the preferred option.

Main Body of Impact Assessment

Background and rationale for change

Overview

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[1] 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. Inadequate care and serious incidents that occur during birth (labour and delivery) can be profoundly devastating events, in particular, any harm which causes lack of oxygen to the baby during birth can result in severe neurological impairment. Events such as these are terrible for all involved and can be overwhelming for families, as the resulting conditions—potentially lifelong disabilities such as Cerebral Palsy (CP) or other forms of brain damage (BD)—can require comprehensive and lifelong care for the affected babies.

3. When such incidents occur, there is currently significant variation in how the underlying cause is investigated.[2] This leaves many families desperate to find out what happened to their baby during birth. Currently the only way for families who have experienced negligently caused birth injury to receive redress is through a lengthy and adversarial litigation process. The average time of delay from incident to a final settlement on birth injury claims is 11.5 years. For cases where harm was not associated with negligence, a universal state offer (state provided services available to all based on needs) is available but the provision is usually markedly less than a package awarded under litigation.

4. The value of average litigation awards is also increasing well above inflation (by around 9% per year) in comparison to the universal state offer. An alternative compensation scheme could provide a way of managing such inflation, to enable more effective use of health resources.

Policy Objectives

5. The Rapid Resolution and Redress scheme (RRR) aims to introduce a system of consistent, robust, and independent investigations for all instances of severe avoidable birth injury, along with access to compensation through an administrative scheme, with the main aims of:

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

6. DH is committed to working to reduce harm, improve safety and managing the rising costs of NHS litigation. 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 programme of work, which is beyond the scope of this IA.

[1] http://www.publications.parliament.uk/pa/cm201314/cmselect/cmpubacc/776/776.pdf (conclusions, pt. 1)

[2] Royal College of Obstretricians and Gynaecologists. Each Baby Counts. (2016). *Key Messages from 2015*. Available at: https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/rcog-each-baby-counts-report.pdf

Objective One: To reduce the number of avoidable harmful incidents that occur during labour and delivery through increased learning

7. The National Maternity Review[3] commissioned by NHS England and led independently by Baroness Cumberlege, which reported in February 2016, recommended that the Department of Health (DH) looks at introducing a Rapid Resolution and Redress Scheme (RRR) for birth injury and death caused to babies during labour and delivery, and cited evidence from Sweden to support this model.

8. Data from the NHS Litigation Authority (NHSLA), which manages all clinical negligence claims for the NHS, shows that the number of successful negligent claims for severe neurological birth injury has remained relatively static over the last 10 years, with an expected total of around 129 families receiving awards for births in 2015. Using the number of claims as a proxy, this reflects the overall incidence of harm has remained relatively stable at a national level over this period.

9. 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 claims due to late reporting. However, analysis from Swedish colleagues suggests that given the gap between incident and claim is short (3-4 years), therefore this data is a reasonable indication of reduction in incidents per birth.

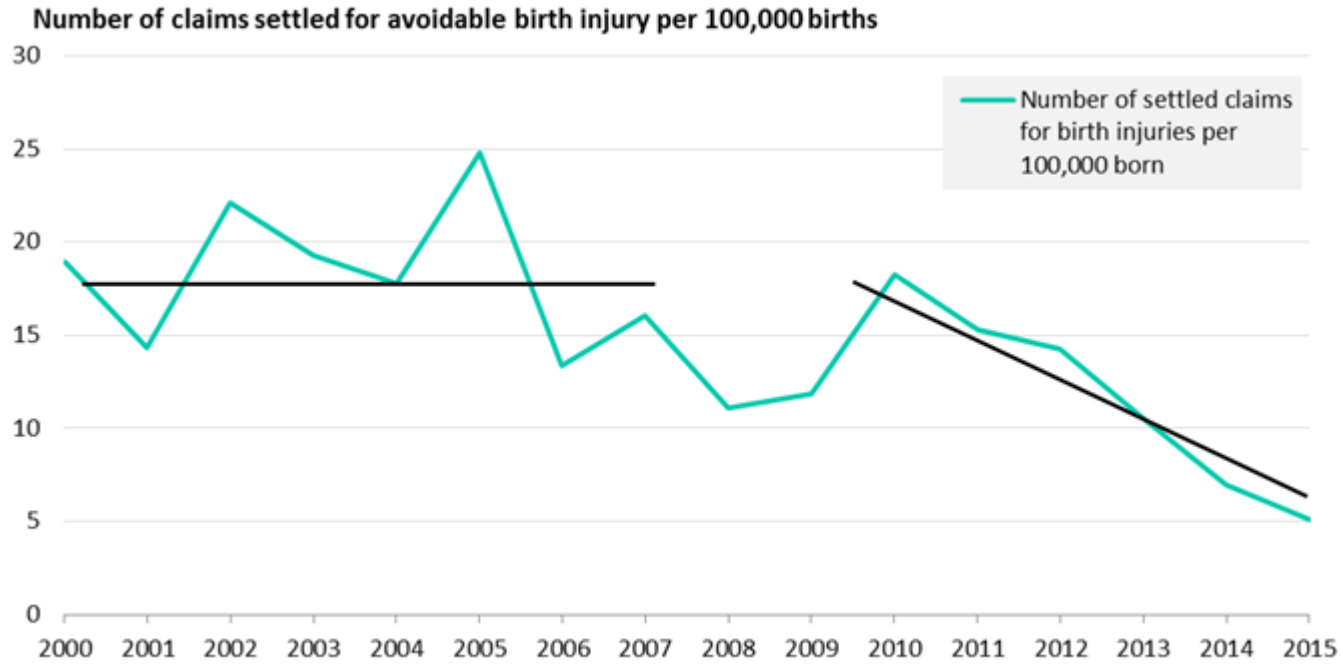


Figure 1: Data from Sweden showing the frequency per 100,000 born of settled claims involving serious birth injuries per year 2000-2015.

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

[3] "Better Births. Improving outcomes of maternity services in England. A Five Year Forward View for maternity care" https://www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf

11. In November 2015, a national ambition for maternity was announced, aiming 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.

Objective Two: To improve the experience for families and clinicians when harm has occurred

12. Currently the only route available to families that experience a 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.

13. 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.

14. Feedback from families, clinicians and other parties tells us the litigation process can be lengthy, stressful and gruelling for families, who are also adapting to a life providing constant and often complex care to their injured child. There is not a consistent process in place for supporting a family when a baby is born with severe neurological injuries and feedback also tells us that investigations into these incidents are not implemented consistently across Trusts. The RCOG (Royal College of Obstetricians and Gynaecologists) 'Each Baby Counts' report[4] found that investigations are currently inconsistent and that parents are neither routinely involved, nor given sufficient information on the investigatory process.

15. Additionally, the limited availability of liability experts often delays the parties from being able to answer key questions – for example, the mechanism of causation of damage. Where liability is established, families are provided with interim compensation payments to help provide them with financial support until final settlement can be agreed. The Courts also adopt a 'once and for all' assessment of quantum meaning that the child's full injury and lifetime needs can only be assessed at around school-age. Compensation is usually calculated on a privately funded basis due to the Common Law principle that the negligent body is responsible for providing compensation which seeks to put the claimant into the same position they would have been in had the negligence not occurred. Furthermore, Section 2(4) of the Law Reform (Personal Injury) Act 1948[5] permits a claimant to recover the costs of private medical treatment, even where this is available to them on the NHS.

16. The experience can also be hugely stressful for the clinicians involved, who may not be well informed about the process of investigation and subsequent litigation. In addition, the label of 'negligence' is suggested to carry connotations of blame on individual practitioner(s), which may mask the opportunity for shared learning and improvements at system level.[6]

17. RRR will aim 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.

[4] https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/rcog-each-baby-counts-report.pdf

[5] http://www.legislation.gov.uk/ukpga/Geo6/11-12/41/section/2

[6] "No-fault compensation schemes: a rapid realist review to develop a context, mechanism outcomes framework", Dickson et al., 2016. EPPI-centre.

Objective Three: Making more effective use of NHS resources

18. The NHSLA has total liabilities (provisions) of £56bn, making it the second largest cross government liability. Annual costs (cash) have increased substantially – last year total annual expenditure on the Clinical Negligence Scheme for Trusts (CNST), the funding mechanism for litigation awards, increased by 32% to £1.5bn in 2015/16 from £1.2bn in 2013/14.[7] Data tells us that maternity care claims tend to be of higher value, and contribute disproportionately to 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.

19. The NHS LA 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.

20. The average settlement of 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 are also achieved through a more efficient and streamlined system which reduces the costs associated with the lengthy litigation process (such as legal fees), and this can then be reinvested back into frontline care.

Policy development

A Rapid Resolution and Redress scheme

21. For clarity, the RRR scheme is described and modelled in a two-stage design, as depicted in Figure 2 below.

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

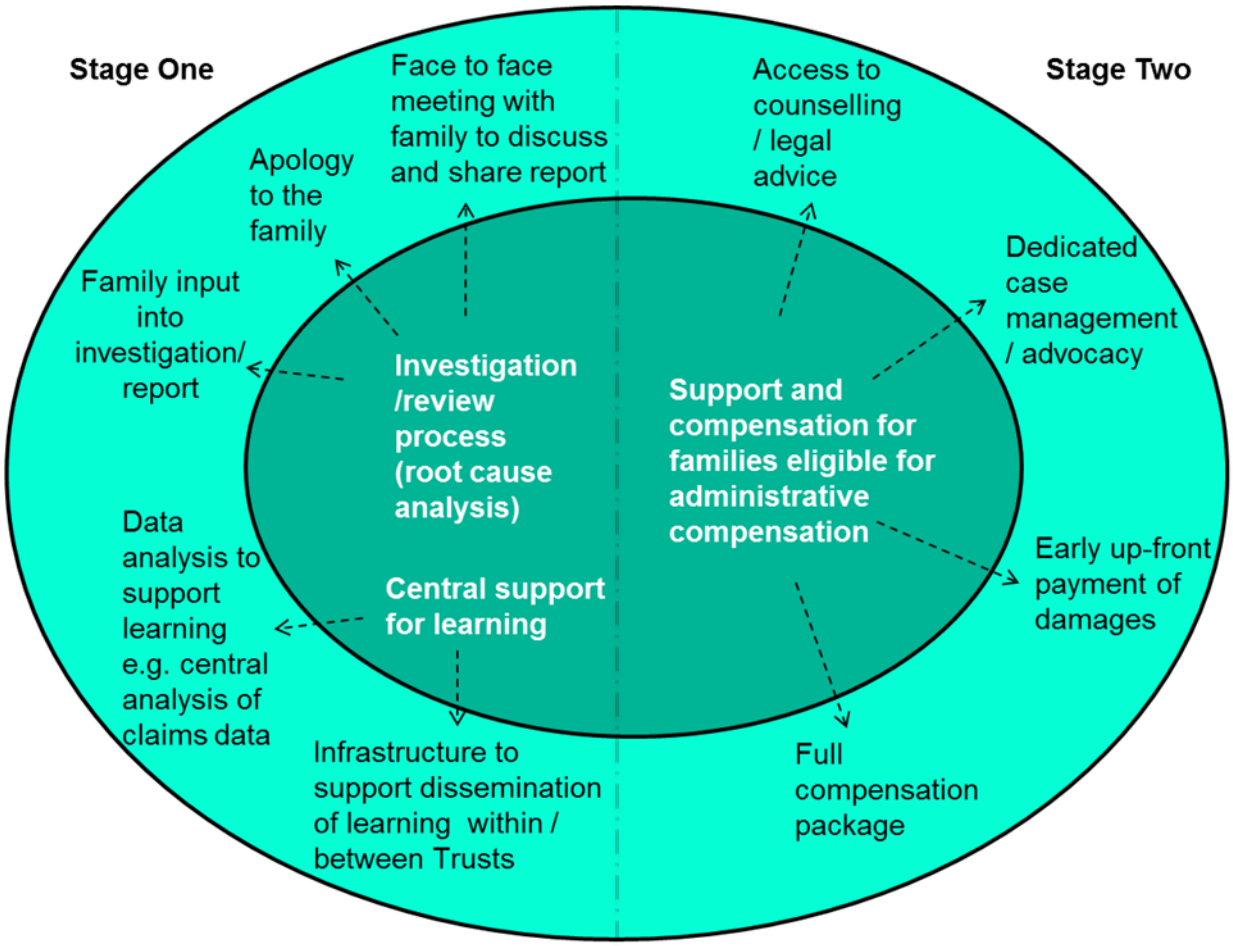


Figure 2: A summary depiction of the different elements of the Rapid Resolution and Redress scheme.

Stage One

22. 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.

23. Importantly, Stage One also includes an early apology to families. This may take the form of an expression of regret for any harm which has occurred and commitment to thoroughly investigating the sequence of events to identify what went wrong and establish whether harm was avoidable

24. The investigation process would provide opportunities for family involvement – firstly in providing evidence as key witnesses, and secondly in discussing the outcomes of the report in a face to face meeting.

25. Implementation of a central system for learning is also proposed, including data analysis of incident and claims data and infrastructure to support dissemination of learning within and between trusts which builds on the Swedish 'Safe Delivery Care Programme'. Further information is provided in Annex C.

Stage Two

26. Stage Two describes the actions which determine whether a baby is eligible for the compensatory package (i.e. the infant has met the clinical eligibility criteria and the incident has met the administrative threshold, as determined by the panel of experts).

27. Stage Two also aims to continue the improved service to families, compared to the current experience they face under the tort route. This would include access to counselling, legal advice, and a dedicated case manager to facilitate provision of service, along with a compensation package to provide for the current and future needs of the injured individual.

Combined effect of Stages One and Two

28. While both stages have been modelled independently, implementation of both stages as a combined policy package is the best way to achieve the full set of policy objectives. Implementing Stage One alone would not sufficiently meet the ambition to provide better support to affected families and offer the opportunity to reduce litigation spend; Stage Two on its own is unlikely to reduce the underlying harm in the system.

29. There are several arguments which support the addition of Stage Two to the policy design:

- A state compensation package that is designed to fairly meet the needs of an affected individual, as assessed by a case manager, has the potential to begin to control claims inflation, which is causing exponential growth in real expenditure on such claims; the size of damages per award has been seen to grow at 9% for the types of cases relevant to RRR over the last 10 years.[8]
- The addition of a compensation scheme which is not attached to the court (without a focus on negligence) improves patient safety by increasing openness during investigations. Increased openness and candour identifies opportunities to learn from mistakes, reducing harm. Separating the compensation mechanism from staff disciplinary action in New Zealand led to an increased speed at which claims could be processed (thus learning could be taken). This was attributed to increased openness amongst clinicians.[9,10]
- There currently exists a legal obligation for clinicians to be open and honest about mistakes that lead to harm (Duty of Candour). However, the additional processes proposed under Stage One for independent and timely investigations, combined with a compensation provision through a non-adversarial process and the mechanisms for achieving system-wide learning described above, can aid the practical application of this duty.
- Implementation of Stage One alone has the potential to increase the volume of claims submitted and the speed at which successful claims proceed due to increased information and awareness of avoidable incidents for families without needing to instigate their own legal investigation. Including Stage Two is the best way of mitigating this potential increase in claims, by offering a credible alternative to litigation.
- Additionally, it could be considered a negative process for families to receive early information from the state relating to the outcome of an early investigation without any further state support or offer of redress. This is managed with the inclusion of Stage Two, which provides assurance over the provision of compensation for cases that are considered avoidable, while maintaining control over when payments are made, maintaining a similar timeframe to that under the litigation award.

Overview of eligibility

30. Eligibility has been considered from two different aspects. Firstly, clinical eligibility, with clinical markers used to determine whether there may have been an avoidable brain injury at birth. Secondly, an additional eligibility requirement for the RRR compensation provided as part of Stage Two.

Clinical eligibility

31. This scheme is designed to provide support and compensation to babies who suffer an avoidable neurological injury at birth. 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

[8] NHSLA data

[9] Bismark, M., & Paterson, R. (2006). No-Fault Compensation In New Zealand: Harmonizing Injury Compensation, Provider Accountability, And Patient Safety. Health Affairs, 25, 278-283.

[10] Wallis, K., & Dovey, S. (2011). No-fault compensation for treatment injury in New Zealand: identifying threats to patient safety in primary care. BMJ Quality & Safety, 20, 587-591.

- 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.

32. The policy focuses on this small subset of birth injury cases since these represent the most complex and high-value claims, and therefore provides the best opportunity to meet the policy intention around improving the experience of families in these most difficult of circumstances and achieving savings. In time it is envisaged that the scheme, if successful, could be extended to cover other types of birth injury, or indeed other categories of clinical negligence claim.

33. In order to define 'Severely Neurologically Injured Baby' we used the clinical marker used in Each Baby Counts (EBC).[11] 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.

34. Eligibility is limited to pregnancies where a complication has not arisen before labour. The current model assumes that only injuries incurred during labour/delivery would be included (i.e. injury associated with pre-natal antenatal care would currently be out of scope). More detail on the eligibility is provided in the Annex A.

35. Babies that show *no* clinical markers of severe injury at birth will *not* be included as the incident would not have any indicator to enable Stage One to be launched. These cases will continue to be covered through existing local investigation procedures.

36. Beginning with a small eligible pool with a strong evidence base for what may be considered avoidable injury, enables the development of a cost-effective policy proposal. The intention would be to evaluate the success of the scheme once it is established, with the aim of widening the pool of eligible infants in future to provide help and support to more families.

Administrative eligibility

37. Under every option explored in this Impact Assessment, every incident during birth which leads to the infant displaying the clinical markers (above) would trigger an investigation in Stage One. Under several of the following options, a panel of independent experts would later decide on whether the incident met the administrative criterion (which varies, detailed below in Figure 3). They would make this decision using evidence from the investigation conducted shortly after the incident occurred.

38. When a panel would be able to decide on an infant's eligibility for compensation under Stage Two 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 long-lasting harm has been caused to the baby.

39. Considering international examples, there are several different ways in which compensatory schemes for medical injury are administered. Many of these schemes have different criteria for eligibility for compensation, usually adjusted around where an incident could have been avoided, but using different tests to determine avoidability. The number of cases which are eligible for compensation is determined by where the threshold is set.

40. The diagram below (Figure 3) sets out two different administrative criteria which could be used. Each has been explored as a potential policy option, detailed in the next section.

[11] The RCOG's page for the project: https://www.rcog.org.uk/eachbabycounts

'Experienced Specialist'	**'Experienced Specialist'** Under this test, a given case would be eligible for compensation if harm could have been avoided under optimal clinical practice, 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.
'Reasonable Care'	**Reasonable care** This test defines the avoidable threshold as a test to: '…whether the care provided by the involved clinicians was akin to that of what would be considered reasonable practice'. Further detail is provided below.

Figure 3: The different potential administrative thresholds for an avoidable compensation scheme that could be used to determine what would be considered an eligible incident under an avoidable compensation scheme.

Policy options

Option 1: Do nothing

41. The 'Do Nothing' option assumes that all incidents after 2018/19 continue to have the same availability of compensation – that offered through litigation for clinically negligent cases and the current state provision of services for all non-negligent cases.
42. It is assumed that no harm reduction for the group under consideration here takes effect, resulting in the number of incidents varying in proportion with the ONS projected numbers of births.
43. Additionally, it is assumed there is no difference in likelihood of uptake of litigation compared to the present and additionally there is no change in timing around payments under litigation awards.
44. Litigation awards are expected to continue to rise at the current rate above health and social care cost inflation, resulting in exponential growth of the size of awards compared to inflation of other prices.

Option 2: Clinical eligibility without additional administrative eligibility (no-fault)

Background

45. The term "no-fault compensation scheme" appears to usually apply to schemes under which a body, e.g. HM Government, accepts responsibility for compensating those who have suffered an injury associated with medical treatment without having to establish negligence or fault. Schemes of this type operate in New Zealand and France.
46. Under a no-fault scheme a claimant would not need to show any legal breach of duty on the part of the treating clinician; it would be irrelevant whether the clinician's act or omission fell below the requisite standard of care. However, claimants would still need to show that the act or omission caused their injuries.
47. Under this option, all infants which met the clinical eligibility (above) would be compensated. Cases would not be tested against an additional administrative threshold.

48. As negligence does not have to be proved for compensation to be awarded under a no-fault scheme, this threshold would capture a much broader number of incidents.

Modelling

49. The modelling showed that for a scenario without any additional administrative eligibility, the potential central reduction in incidents through improved learning and safety was never great enough to offset the cost of compensating the eligible number of people. The economic case for the first 10 cohorts had a Net Present Value of -£10.5bn (with an assumed 25% harm reduction). The additional costs significantly outweigh the benefits.

Option 3 (preferred option): Clinical eligibility with avoidable administrative eligibility

Overview of avoidable eligibility

50. Instead of all cases from Stage One being automatically eligible for Stage Two, an administrative eligibility criterion, to assess whether a case is eligible for compensation, is also included. Currently, this is the criterion of clinical negligence in the context of a successful litigation. Providing compensation to individuals, where harm was considered to be avoidable is likely to achieve greater harm reduction for the reasons outlined below.

51. Negligence is the legal threshold on which eligibility for compensation is assessed in the tort system through establishing a breach in duty of care which caused a reasonably foreseeable injury. This can be seen as when an incident *should* have been avoided if a different course of action had been taken by clinician.

52. It has been suggested that compensation linked to an avoidable criterion could reduce the new scheme's association with individual fault finding and 'blame', re-focusing on system level learning. Avoidable criteria may be considered closer to incidents that *could* have been avoided if a different course had been taken. In Sweden, the no-blame environment has been thought to be a significant factor in recent harm reduction. This is attributed to the greater level of openness that can be achieved during investigations within a no-blame context.

53. An avoidable scheme further separates the compensation process from discipline or individual blame, focusing on wider pathways to harm, viewing the event as a series of failures rather than action or inaction by individual staff. This may help to further facilitate the openness required by the Duty of Candour. Any changes that affect the cultural attitudes in a trust could also be expected to improve dissemination of learning within a trust, contributing to improved patient safety.

54. Few clinicians experience more than one negligent type event in their careers, but within a maternity unit, there will be more avoidable incidents. Extending to cover avoidable incidents increases the sample size of incidents to learn from which could translate to broader opportunities for learning.

55. Investigations under an avoidable eligibility threshold will need to assess and collect information to support the panel to determine whether the incident is eligible. This would allow for wider information to feed into the analysis and dissemination, compared to investigations only considering incidents from a negligent perspective.

56. The threshold that is used to define administrative eligibility varies internationally among those that have an avoidable harm type scheme. There are two options for thresholds considered below as part of RRR. **Further testing of these options will occur during consultation before developing more detailed guidance on the exact criteria for eligibility.**

Option 3A: 'Experienced Specialist' test

57. The 'Experienced Specialist' test is the level for avoidable birth injury that is applied to determine compensated cases in the Swedish system. This scenario would compensate families where the birth injury could have been avoided under optimal clinical practice within the given circumstances, assessed against the standard of an 'Experienced Specialist'.

58. The estimated pool size eligible for compensation is around **162 cases per annum** (projected 2015 figure), further details on the calculation of eligible incidents provided in Annex A.

59. A review of the Scandinavian schemes concluded that applying an avoidable criteria is a more efficient standard to apply as deciding what could have been done by an 'Experienced Specialist' was viewed as simpler than judging whether the actions fell below a standard of 'Reasonable Care'.[12]

60. A threshold that is a greater distance from the current definition of clinical negligence may also achieve greater uptake among eligible families (i.e. fewer families choosing to pursue litigation), as there would be a less direct link between the scheme and the standard applied by the court.

Option 3B: 'Reasonable Care' test

61. Under this scenario, eligibility for 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.

62. This is similar to the test currently used in the tort route, but applied in an administrative context as a 'Reasonable Care' test, 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. Again, taking a system-level view considers the roles of all clinicians involved, their interactions and even any additional circumstances that may have led to what previously had been identified as a single clinician at fault.

63. The estimated pool size eligible for compensation in such a circumstance is **122 cases per annum**, further details on the calculation of eligible incidents is provided in Annex A.

Option 4: A piloted version of RRR

64. 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, which covers a subset of the eligible cases in England. The structure and size of any pilot would be informed by responses to the consultation.

65. A pilot would only help in testing operational delivery and is unlikely to measure long-term impact in terms of uptake and harm reduction.

66. 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.

67. The pilot would probably be most effective at regional level for operational delivery purposes. 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 per year to establish a significant trend within a reasonable time period. 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. Any cases not included in the pilot would be able to proceed through litigation to receive compensation through existing arrangements.

68. 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).

Overview of modelling

69. The analytical model is built on a number of key assumptions outlined further below. Each of these assumptions is informed by past data as well as expert judgement and advice gathered through the pre-consultation phase.

[12] "Beyond Negligence: Avoidability and Medical Injury Compensation", Kachalia et al 2008.

70. Each assumption has a central estimate that is considered the most likely outcome from the policy in place but it is recognised that there is uncertainty in the actual outcome and a range of potential values are given to each assumption.

71. As well as presenting the central financial outcome, sensitivity analysis, including simulation across a range of potential outcomes for the key assumptions, is included. This allows the likelihood of cost profiles and NPVs for the policy to be evaluated (within the scope of the additional assumptions made with regard to the probability distributions assigned to individual assumptions).

72. This section proceeds with discussion of the key assumptions driving the modelled costs, before considering the financial case with associated sensitivity analysis. Finally, the economic case is presented for the first 10 cohorts associated with each policy option. **As described in the Executive Summary, please note that this Impact Assessment is concerned with the financial and economic impact of the RRR policy, and therefore describes the costs and benefits in these terms, for example using Quality of Life (QOL) calculations. We recognise that incidents of severe avoidable birth injury have much wider impacts, which cannot always be quantified. These wider issues are considered in the consultation document, and will be vital in developing a policy which meets the needs of families affected by birth injury**.

Key assumptions and uncertainty

Total incidents

73. The clinical eligibility defines the main pool from which harm reduction may potentially be achieved through RRR. With respect to costs, these are most influenced by the expected number of injured babies that survive into early childhood with lasting neurological damage.

74. An estimate of the number of these cases that arise through some element of intrapartum causation is based upon the UK-wide prevalence of avoidable birth injuries that the Royal College of Obstetricians and Gynaecologists (RCOG) measured in 2015 with their Each Baby Counts (EBC) research regarding the prevalence of avoidable birth injury.

75. The number of incidents that meet the RCOG criteria for avoidable clinical eligibility and survive beyond 7 days is 559 cases. The central estimate for the number of incidents that persist with neurological abnormalities with some element of intrapartum causation into early childhood is estimated as 249, based on the evidence of three trials of outcomes at 18 months for those born with potential brain injuries.[13] An upper bound of 307 and lower bound 210 are used in line with findings from these trials, discussed in further detail in Annex A.

Harm reduction

76. Delivery of harm reduction is a key policy objective of RRR, and is the most important driver of costs and benefits in the model. A central assumption of 25% harm reduction achieved over a period of 5 years between 2018 and 2022 is assumed. This is estimate based on the balance of evidence and is slightly on the low side accounting for optimism bias. Sweden achieved around 50% reduction in harm over a 7 year period through improved root cause analysis and the dissemination of findings to trusts, all wrapped up within their no-blame environment where litigation is not the primary route of access to financial redress.[14] Other evidence from trusts in England and Canada has indicated a range of 18%-50% achievable through improved multi-disciplinary training, which is included in the funding model for RRR.[15]

[13] "Neurological outcomes at 18 months of age after moderate hypothermia for perinatal hypoxic ischaemic encephalopathy: synthesis and meta-analysis of trial data", Edwards et al., BMJ 2010

[14] Better Births. Improving outcomes of maternity services in England. A Five Year Forward View for maternity care https://www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf

[15] Does training in obstetric emergencies improve neonatal outcome? Draycott et al. BJOG. 2006.
Nguyen, X., et al. Outcomes of the introduction of the MORE^{OB} continuing education program in Alberta.J Obstet Gnaecol Can 2010;32(8):749-755.

77. Sensitivity analysis around the central scenario of 25% harm reduction is provided, with a lower and upper bound of 0% and 50% respectively. In this analysis, as the central estimate is considered much more likely to occur than the extreme scenarios, a triangular distribution is used to model the assumption with the likelihood of 0% or 50% harm reduction occurring tailing off to 0.

Successful litigation pool

78. The expected number of successfully litigated cases is derived from NHSLA data and combined with ONS 2012 birth projections for estimating future numbers. The projected number of notifications combined with the ratio of successful to unsuccessful cases determines the number of projected successfully litigated cases compared to the total incident numbers. For 2015, the number of notifications in England, that would be eligible for the RRR scheme, is projected to be 173 with the number of successful cases falling within the scheme's clinical eligibility criteria being 102.

79. A scheme with robust investigations is likely to lead to greater awareness of litigation and may bring additional cases before the courts. A judgement was made from discussion with clinicians and stakeholders in the context of the total number of potential incidents (249) and current notification numbers (173) that a proportionate increase of 10% more negligent cases should be assumed to potentially be brought forward within the context of the new scheme (10 cases more than the 102 of the previous paragraph). Sensitivity analysis considers a range of 0%-20%.

Eligible incidents for RRR scheme

80. A compensation scheme based on an avoidable eligibility threshold will result in more compensated cases than the current threshold based upon negligence.

81. Based on 2015 data, it is estimated that around 162 cases per year would be eligible for the new scheme. This figure was reached through 11 law firms employed by the NHSLA looking at previous cases which had been unsuccessful in court (under the negligence test). The firms assessed whether this range of cases would have been eligible for compensation under the avoidable criterion (set out above). The possible answers were "Yes", "Possibly" and "No". The proportion that were "Yes" or "Possibly" were used to attribute an additional proportion of successful claims under the new criterion. Along with the assumption of the 10% increase in negligent incidents from cases that were previously not notified due to increased awareness, this led to 162 cases.

82. For sensitivity analysis, to gain a low estimate for the number of eligible cases, only the responses that came back as "Yes" were considered. This leads to a number of 134. To arrive at an upper estimate, given the central projected total incident numbers of 249, a conservative estimate of 230 cases is used. This is based on the consideration that the number will inevitably be reduced significantly from imposing the 'Experienced Specialist' administrative threshold on the set of incidents that meet the clinical eligibility criteria. This is because, for many of these cases, there may have been very little that could actually have been done differently. As the central estimate is considered more likely to occur than the extreme scenarios, a triangular distribution is used for modelling purposes.

Compensation package value

83. Currently, there are two ways in which people can receive compensation. These are either through a lump sum payment, or through a Periodical Payment Order (PPO). A PPO is a payment order that provides a legal guarantee of staged regular payments over an individual's lifetime. Presently in successfully litigated cases settled on a PPO basis, families receive lump sum payments (interim payments and a final lump sum payment) followed by periodical payments (PPs) spread over the person's lifetime.

84. Modelling of the compensation under the RRR scheme is provided with a package proportionate in size relative to the average litigation award. The central assumption is that the package lies at 90% of the litigation award in terms of lump sum and PPO sizes before accounting for claims inflation from incident to settlement. This is informed by analysis of successful litigation cases; a 'bottom up' approach to analysing current provision of care for people with cerebral palsy; and discussion with stakeholders; with the aim of offering a proportionate package which enables people's needs to be

met, therefore encouraging a high uptake. Sensitivity analysis considered a range of 80%-100% drawn from a uniform distribution across the range.

85. Payments/provision of equivalent services in the model are generally made at a similar time as under the litigation route – the distribution guiding the payments has its mean shifted earlier by a year in the central scenario, with periodical payments also beginning at this time point. The expected reduction in average time before compensation payments are made is due to an administrative scheme expediting the determination and size of compensation liability associated with an incident, relative to the legal system. In sensitivity analysis, a range of 0-2 years is used drawn from a uniform distribution.

86. The following changes are made to the structure of the package compared to the litigation award:

- An early partial general damages payment is made acknowledging an initial indication of avoidable harm (£100k for PPO cases, £50k for non-PPO cases).
- A proportion of the lump sum moved into periodical payments (50% under the central scenario).
- Provision of a support network of case management, counselling and needs assessments provided to all eligible cases.

87. Further details are available in Annex A regarding the derivation of the compensation package against a litigation award.

Lump sum

88. One uncertain aspect of the compensation package that can be varied under different scenarios is the proportion of lump sum that is paid up-front relative to the litigation award. In sensitivity analysis, a range of 75%-25% is considered, drawn from a uniform range.

Universal state offer

89. Regardless of whether an incident was avoidable or compensated through a legal award, a universal state offer of services is available. These are health and care services available to anyone with a CP/BD as part of the universal NHS and social care offer provided by the state.

90. To calculate the cost profile for the universal state offer for those with CP/BD that do not receive a litigation award, a bottom-up approach was taken. Support for people with cerebral palsy at the most severe end—severity 5 on the Gross Motor Function Classification System (GMFCS)—are considered from the point of view of the costs of the care and health services that are typically offered by Local Authorities (LAs), NHS and the voluntary sector, with evidence gathered from primary research materials.[16]

91. The cost profile is predominantly driven by health and social care costs at around 67% of the total lifetime costs. **As before, please note that this IA describes the financial and economic impact of the policy, which is based on calculations of care costs in the counterfactual. We recognise that the impacts of the long-term care needs associated with cerebral/palsy brain damage on affected individuals and families are much wider. A range of these are captured in non-monetised benefits (page 45) and are explored further in the consultation document.**

92. To convert the Severity 5 case to an 'average' case on the GMFCS scale, 100% of the cost profile is assumed for Severity 5 cases, 66% for severity cases and 33% for Severity 1-3. A weighted average is then taken over the population prevalence of each severity[17] to generate an average profile. This approximation is necessary as additional data on the expected amount received by groups with lower severity is not available.

93. In the modelling, as it is not fully known to what extent there is use of these services by those who receive a litigation award; it is assumed that all incidents considered make use of the costed

[16] "Calculating costs of Children's Continuing Care", Holmes et al. ('Loughborough report') and PSSRU unit cost handbook 2014/15

[17] "The incidence and implications of cerebral palsy following potentially avoidable obstetric complications: a preliminary burden of disease study", Leigh et al. 2014

universal state offer accessible to those with harm that is also unavoidable. This is an approximation. With respect to impact on costing, sensitivity analysis is included as discussed below.

94. Savings on incidents that receive no compensation at all occur through the level of state provision for non-litigation cases. This is because the improvements expected in trusts through early investigations and learnings would be expected to also reduce the likelihood of incidents that may not fully meet the eligibility criteria for Stage Two compensation.

95. There is uncertainty around the nature of the payment profile for services available for a case of typical severity. Sensitivity analysis with 50% of the payment profile in a low scenario and 150% of the value in a high scenario are included. It should be noted that the corresponding adjustments are made to the counterfactual too for the level of the universal state offer in such a case.

Uptake of compensation package

96. Uptake refers to the proportion of those who can and do take the RRR compensation package and do not litigate. Based on early conversations with stakeholders, the policy aims to achieve very high uptake (90% under the central scenario) given it is available to a very specific cohort of cases (the most severe avoidable birth injury). The compensation package on offer will aim to sufficiently meet families' needs, removing the need for families to pursue litigation, therefore achieving the large uptake associated with the central assumption.

97. Sensitivity analysis acknowledges that such a high level of uptake may not be achieved and considers a conservative range of 0%-100% for the cases that would be negligent if litigation was pursued, while assuming there is 100% uptake among the cases that are avoidable but not negligent. Given the unlikelihood of either extreme, a triangular distribution is used in evaluating the sensitivity analysis.

Inflation

98. Above real inflation is assumed across all costs. This is because costs in the health and social care sector typically grow faster than GDP inflation. A cash increase of 4.2% (ASHE 6115 index) is assumed compared to a yearly GDP deflator of 2% under the central scenario. Additional claims size inflation is assumed for the litigation route (and the size of the RRR package so the relative size is preserved).

99. An assumption is made around the relationship of health and social care cost inflation over time in comparison to the GDP deflator, which introduces a change in 'real' relative prices. Around the central scenario of 4.2% health and social care inflation against a 2% GDP deflator (leading to a relative price change of 2.2%), both 0% (low) and 4% (high) relative price inflation was tested.

100. Litigation awards have been observed to have a level of 9% inflation per annum in cash terms over all cases closed in the last 10 years[18]. As discussed above, 4.2% of this could be considered attributable to year on year rising health and social care costs. However, this leaves a remaining 4%-5% unaccounted for.

Implicit assumptions

Litigated Cases

101. The likelihood of an incident being negligent, given it is notified, is a projection from the last 3 years of closed data and remains constant over time.

102. The proportion of notifications against the backdrop of total incident numbers remains constant over time and therefore the number of notifications moves in line with birth projections.

103. The distribution of incident to settlement time, based on the last 3 years of successful closed cases, remains constant over time.

104. The time of settlement is a good indicator of when state payments are made to families, which is supported from analysis of NHSLA data (additional detail in Annex A).

[18] GAD analysis of NHSLA data

Compensation package

105. Compensation services and payments can be structured in relation to a litigation award, both in terms of timing and size of award. Implicitly in this, the assumptions that are assumed for the litigation award are also considered to be true for RRR compensation cases, aside from described adjustments.

Universal state offer payment profile

106. The average universal state offer profile can be applied to all incidents in considering what a state offer would be for a typical incident.

107. It is equally applied to all compensated cases too. This is for several reasons:

- Currently we have insufficient data on the exact average severity of state and litigation cases. Compensation for one average case will not equal compensation for the average state offer.
- There is uncertainty around the level of the average universal state award at each age.
- There is uncertainty around the age at which there would be a transfer to services from a compensation package instead of a state offer available to all.

Inflation

108. Costs related to health and social care will inflate at a rate greater than the GDP deflator, defined by GAD's analysis of the long-term expected ASHE 6115 inflation (this is the index used to uplift the majority of PPs in PPO settlements), resulting in a real growth in health and social care costs for the policy.

109. It is assumed that claims inflation will continue at a constant but reduced rate in comparison to past observations. Choosing a reduced level for claims inflation compared to past trends allows a conservative approach towards savings generated due to the uncertainty in the exact drivers of claims inflation. Sensitivity analysis considers a range of values.

Overview of cost drivers

110. The main drivers of cost are the number of incidents that receive a compensation award, the size of the compensation award and the inflation of the award over time.

111. A simple calculation for a given cohort can consider an average award size in present value terms (discounted over their lifetime from the date of award), combined with the number of eligible incidents, to derive the order of magnitude expected for each cohort. As the average court settlement is approximately £5m (when including both severe and less severe brain injury cases) and there are around 100 cases per year, there is an approximate liability of around £500m per cohort. With 25% harm reduction after 5 years, this saves around £125m per cohort giving an order of magnitude for savings in economic terms.

112. However, as discussed above under key assumptions, there are several factors that make the situation much more complicated, necessitating a modelling approach for figures beyond order of magnitude estimates.

113. Firstly, the financial case does not match the economic one. Litigation awards and RRR compensation awards are split into lump sum and ongoing payments, which requires a cohort tracking approach. Secondly, above GDP inflation, along with claims inflation and the distribution of times from incident to settlement (when the award is made), mean that different incidents within a cohort receive payment and start receiving ongoing payments at different times and receive different size awards due to claims inflation affecting the real size of the award over time. Thirdly, the policy proposes to compensate a greater number of people through an avoidable threshold for eligibility as opposed to a negligent one. Finally, there is a question around the appropriate discount factors to use. Health and social care costs under a litigation award contribute to direct health outcomes and therefore are converted into QALYs and discounted at a lower rate for the economic case than they would be in determining the present value size of the award in monetary terms.

Impact of Option 3A

Financial costs of Option 3A

Stage One Implementation costs

114. Costs associated with Stage One are derived from the cost of developing a reporting tool, consistent independent investigations and their coordination, dissemination of learning from such investigations and the provision of additional learning/training (based upon multi-disciplinary training, although there would be flexibility for trusts around how this budgeted funding was exactly spent). Further details on each of these sources of costs are provided in Annex A.

115. The cost profile for these implementation costs is detailed below and assumes costs rise with health and social care costs (ASHE 6115 index).

Stage Two Implementation costs

116. Implementation costs associated with Stage Two are derived from additional independent expert advice used to determine eligibility, additional administration associated with delivering the RRR compensation package and increased running costs associated with the administering body (potentially the NHSLA) in providing the case management and financial delivery required.

117. The origins and analytical detail of these costs are detailed further in Annex A. The cost profile for in-year spending until 2028/29 is shown below.

Table 1: Implementation costs for financial case for Option 3A.

Net change (14/15 prices, millions)	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Implementation												
Stage 1 implementation costs	£2	£24	£25	£25	£26	£26	£27	£28	£28	£29	£29	£30
Stage 2 implementation costs	£1	£2	£2	£2	£2	£2	£2	£2	£2	£2	£2	£2

Litigation costs

118. Changes in litigation costs arise from changes in damages payments and legal costs. This is directly linked to the number of incidents that occur and choose to litigate, as well as the uptake of an alternative compensation scheme.

119. Changes to existing cash flows are assumed to be redirected into compensation packages or through reduced premiums paid by trusts through reduced CNST payments to the NHSLA as claim numbers reduce in favour of RRR uptake. This is because, if there are fewer successful claims, there will be a reduction in the amount required to be brought in to fund expected claims.

120. Legal costs associated with successful claims are assumed to be paid out at settlement. Defence legal costs associated with unsuccessful claims are negligible and are not included in the modelling results.

121. Below is the cost profile associated with changes in litigation damages payments and associated legal costs.

Table 2: Litigation costs under Option 3A in addition to the counterfactual for the financial case.

Net change (14/15 prices, millions)	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Litigated Cases												
Litigation damages	£0	£0	£0	-£3	-£10	-£22	-£42	-£66	-£93	-£123	-£154	-£186
Litigation legal costs	£0	£0	£0	-£1	-£2	-£4	-£7	-£10	-£13	-£16	-£19	-£22

RRR compensation scheme costs

122. Incidents that are deemed eligible for Stage Two following the investigations receive a compensation package under the RRR scheme. As well as being open to the pool that would be successful if they litigated, under the preferred option, the package also includes the same average offer to cases that meet the new avoidable criterion.

123. Currently the compensation package is modelled relative to the litigation award, making the assumption that payment and services can be structured in a manner that relates to the way payments are made following litigation. Further details of the compensation package are provided in Annex A.

124. In addition to the damages payments/services provided in relation a successful litigation, a *professional support network* is made available to families. The aim of the support network is to contribute towards the policy objective of providing a better experience to families, as well as ensuring the compensation package is delivered in accordance with policy intention. Further details of the support network can be found in Annex A.

125. The cost profile for payments associated with the compensation package and the associated support network are shown in the table below.

Table 3: RRR compensation scheme costs in addition to the counterfactual.

Net change (14/15 prices, millions)	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Compensation												
Compensation damages	£0	£0	£0	£2	£6	£29	£46	£65	£86	£107	£129	£151
Support network costs	£0	£2	£2	£3	£4	£5	£5	£6	£7	£8	£9	£10
Needs assessments	£0	£0	£0	£0	£1	£1	£1	£1	£1	£1	£2	£2

NHS and social care costs for incidents without compensation

126. Incidents that are neither negligent nor avoidable but have some element of intrapartum harm are also considered to be reduced in equal proportion as a result of the harm reduction introduced from the RRR policy.

127. Such cases are assumed to be of average CP severity and have an associated lifetime cost profile from associated health and social care costs. Further details of this cost profile and the way in which it is derived are provided in Annex A.

128. The cost profile under the central option for the change in spending for this group is shown below.

Net change (14/15 prices, millions)	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
NHS and other state costs												
Non-litigation state offer	£0	£0	-£1	-£3	-£5	-£8	-£12	-£17	-£23	-£30	-£37	-£44

Total projected costs

129. The graph and tables below summarise the total costs arising from all the policy elements discussed above.

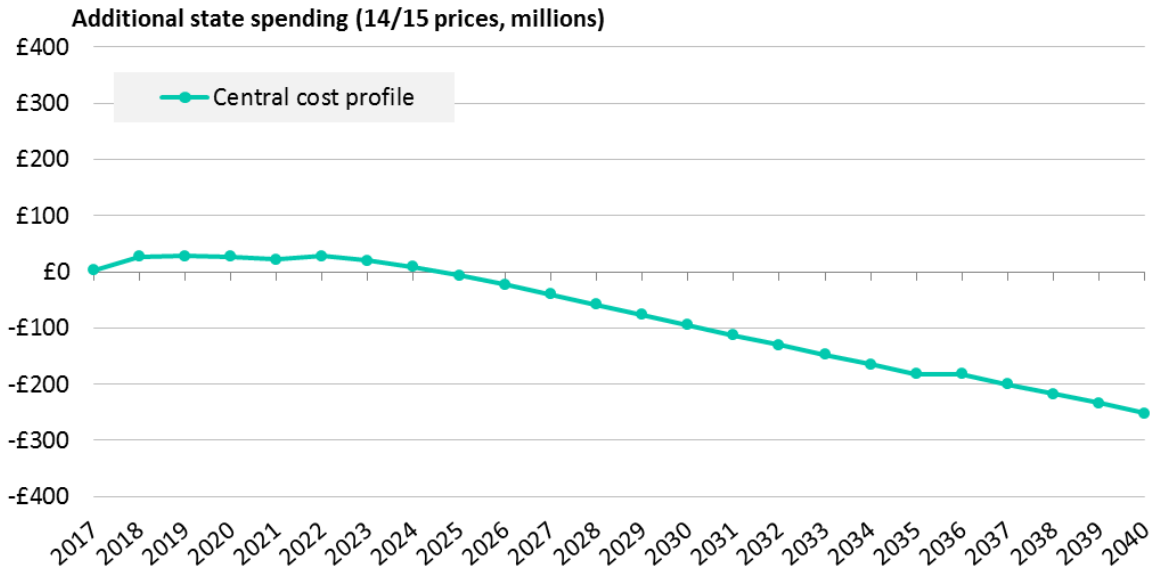


Figure 4: Overall cost profile of central option

Table 4: Summary tables of financial implications for central option.

	17/18	18/19	19/20	20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28
Central	**£3.0**	**£27.1**	**£27.6**	**£26.5**	**£21.8**	**£28.4**	**£20.1**	**£8.6**	**-£6.0**	**-£22.8**	**-£40.3**

	Cost NPV at				Max additional spending		Max cumulative spending	
	By 2030/31	15 years	20 years	Final	Amount	Year	Amount	Year
Central	**£0**	**£280**	**£750**	**+**	**£30**	**2022**	**£160**	**2024**

130. The first table above corresponds to the financial cost profile over the first 10 years of the policy.

131. The second table calculates the NPV for costs in 2030/31, after 15 years and after 20 years simply from a cost perspective. The other columns illustrate the maximum downside in-year spending and the maximum cumulative spending under the central scenario, as well as the years in which these figures occur.

Sensitivity analysis

Sensitivity to individual assumptions

132. The sensitivity analysis presented above can be summarised into the following graphs below showing the financial impact by 2030/31 and 15 years after the policy introduction. The financial impact is measured in terms of the NPV associated with the policy costs alone.

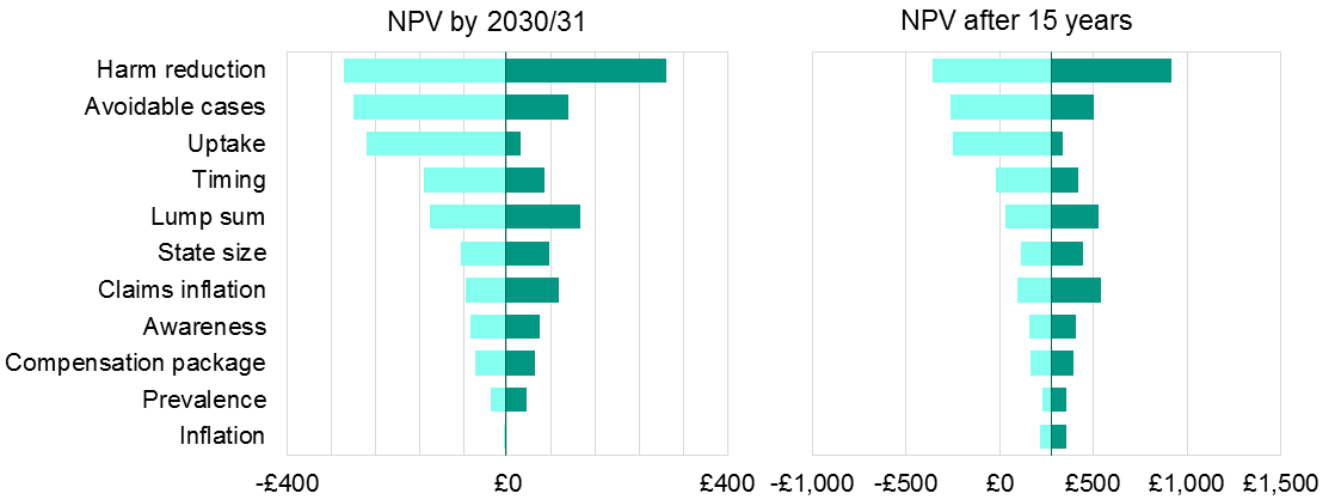


Figure 5: Sensitivity analysis of individual assumptions

133. Harm reduction, number of eligible incidents and uptake are the only factors that significantly prevent a positive NPV inside 15 years (and in the long run), while shifting the payment profile associated with the compensation package, the size of the lump sum and uptake are the largest other factors reducing the NPV at any point in time.

134. These assumptions have the largest associated overall uncertainties and the actual statistical likelihood of combinations of outcomes should be considered for an accurate perspective on these uncertainties, which is achieved through using a Monte Carlo sensitivity analysis described in the next section.

Cost profile and NPV likelihoods

135. To evaluate the likelihood of outcomes given the uncertainty around the assumptions feeding into the model, random combinations of assumptions where chosen and run as scenarios with the outcomes measured. A Monte Carlo sensitivity analysis (1,000 runs) was performed, drawing from distributions of the top 6 assumptions that the modelling outcomes are most sensitive to.

136. Below a cost profile with bands of likelihood is depicted, along with probability distributions for the likelihood of generating positive NPVs overall and within given timeframes.

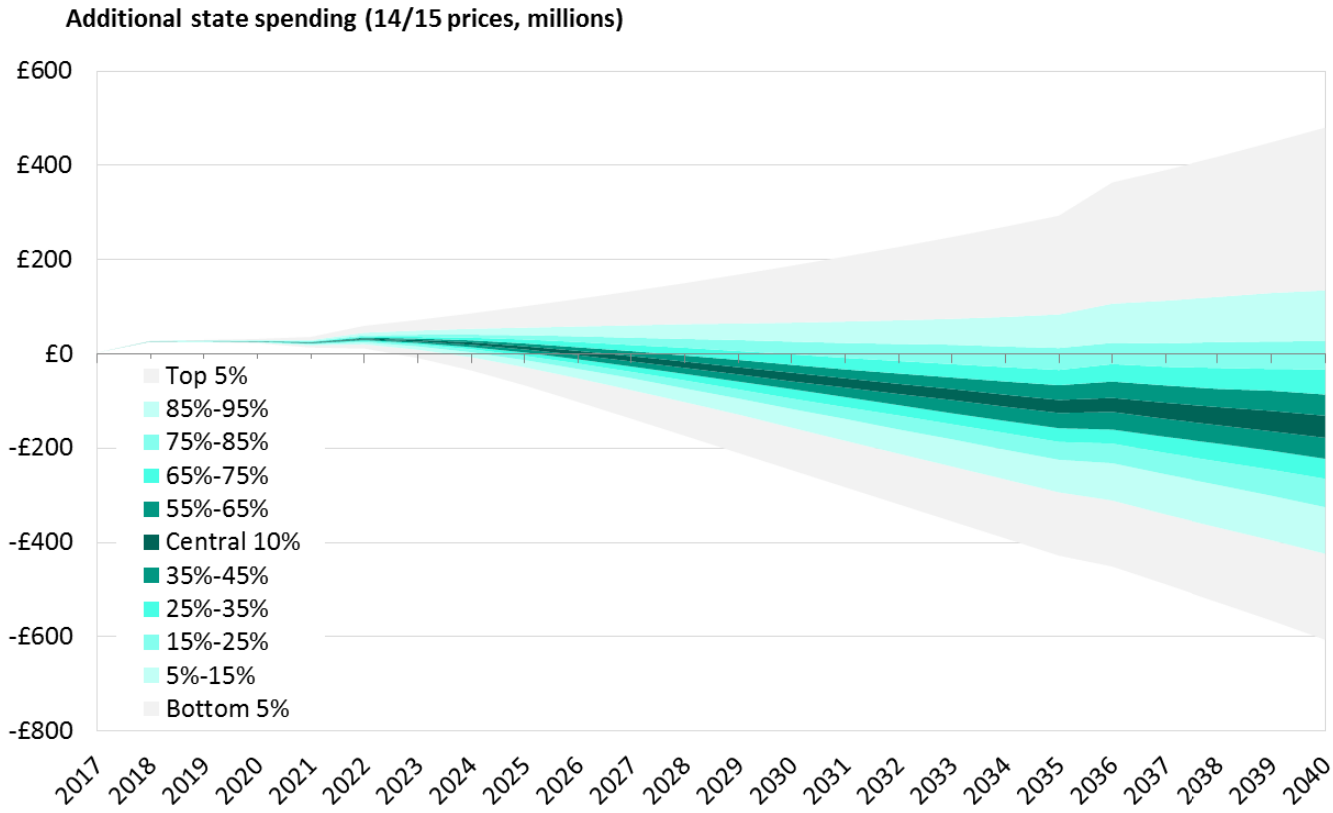


Figure 6: Monte Carlo sensitivity analysis across most significant assumptions showing likelihood of different cost range

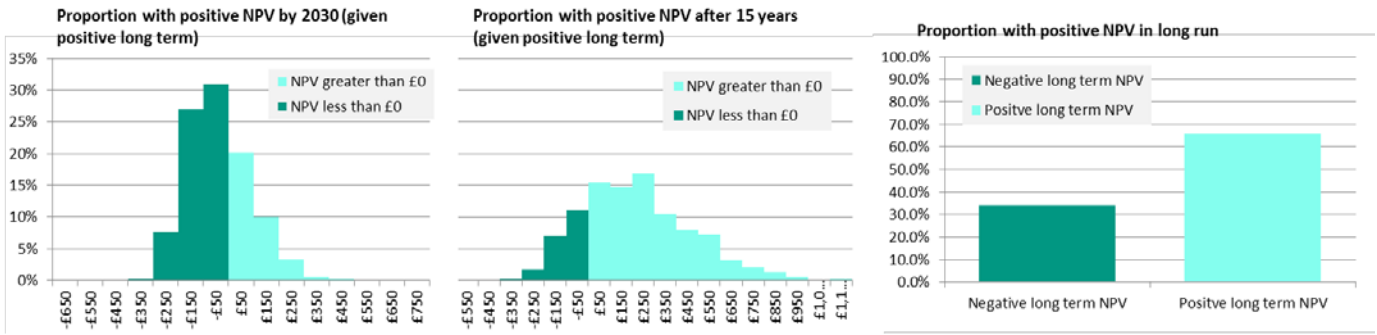


Figure 7: Summary of Monte Carlo sensitivity analysis on NPV at 2030, after 15 years and the final NPV sign. Around 66% of cases generate a long-term positive NPV, with 80% of those that do so achieving this within 15 years and 34% by 2030.

Economic case

Costs under economic case

137. The above analysis focusses on the cost profiles over time of additional state spending and saving assuming the policy carries on without stopping.

138. For realistic comparisons with other policies, as well as escaping the fact that costs for a cohort are played out over the lifetime of individuals (up to 100 year period), the economic case considers the costs differently from the perspective of the lifetime costs of a cohort. In particular, the first ten cohorts are considered alone to enable comparison with other department policy.

139. As the groups under consideration in the model are predominantly funded through NHSE budgets, either through insurance premiums paid by trusts for compensation or through healthcare provision for those under the universal state offer, a discount factor of 1.5% to all costs, instead of the Green Book guidance of 3.5%, with opportunity costs applied. The reason for this arises from the opportunity cost in spending from health budgets. The value of a single QALY is not expected to diminish over time, unlike monetary costs where a growth in GDP per capita of 2% reduces the value of £1 in the future. This leads to the discount factor of 1.5% being used instead of 3.5% (the

2% GDP per capita growth is removed), and a single QALY is assumed to have a fixed value to society of £60k.

140. In addition, deriving opportunity costs from health spending, at the margins, a £15k investment by the department returns a QALY of benefits. How this value varies over time depends on a multitude of factors, from how departmental budgets will vary over time, to the efficiencies that may come about, to the inflationary factors associated with the ability for departmental budgets to deliver such marginal QALY gains. The current departmental position is for the £15k to be treated as constant over time in fixed prices. Therefore, combined with the £60k societal gain from a QALY, a factor of 4 is applied to all costs/savings (with the costs discounted at 1.5%), in order to derive the associated opportunity cost/savings arising from the spending/saving associated with RRR.

141. In the table below, the costs for the first 10 cohorts of the policy are shown (cohort costs are discounted at 1.5% back to incident date). This number of cohorts is chosen for consistency with other policies considered in the department.

Table 5: Summary of discounted costs (at 1.5%) for economic case of Option 3A.

Discounted category	17/18	18/19	19/20	20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28	Total
Litigation damages	£0	-£935	-£965	-£996	-£1,027	-£1,059	-£1,084	-£1,111	-£1,137	-£1,164	-£1,193	-£10,671
Litigation legal costs	£0	-£18	-£18	-£18	-£17	-£17	-£17	-£17	-£16	-£16	-£16	-£170
Compensation damages	£0	£1,055	£1,026	£994	£958	£921	£943	£966	£989	£1,013	£1,037	£9,901
Compensation legal costs	£0	£1	£1	£1	£1	£1	£1	£1	£0	£0	£0	£6
Support network costs	£0	£24	£23	£22	£20	£19	£19	£19	£20	£20	£20	£206
Universal state offer	£0	-£61	-£122	-£185	-£247	-£310	-£312	-£313	-£314	-£315	-£317	-£2,497
Implementation costs	£3	£25	£25	£25	£26	£26	£26	£26	£26	£26	£27	£261

Monetised Benefits

142. The benefits derived from the policy arise from two different sources. For those no longer harmed, any quality of life that was lacking is no longer the case so there is an expected lifetime QALY gain for this group. For those still harmed, those that receive additional compensation may have an improvement in quality of life following the compensation.

143. The following expected QALY decreases are assumed for each group (where P and Q are positive numbers and P is greater than Q).

Group	Expected lifetime QALYs lost
Healthy	0
Compensated family	P
Non-compensated family	Q

144. Discounting at 1.5%, for each incident of CP that occurs, there is an associated expected discounted lifetime QALY decrease to the individual of 35.3 QALYs.[19] It is assumed that this is the QALY decrease experienced by the non-compensated family (Q=35.3). Further, it is assumed that the average incident of CP has the same QALY decrease as for a BD case in the absence of

[19] Derived from data published in: "The incidence and implications of cerebral palsy following potentially avoidable obstetric complications: a preliminary burden of disease study", Leigh et al. 2014

further evidence. Averaging over the more severe levels of CP (severity 3-5 on the GMFCS scale), the QALY decrease is even greater at 50.3.

145. Monetising the QALYs lost at £15k per QALY (what the department can buy QALYs for), shows that for the average non-compensated case, the department would at the margin be able to gain this many QALYs from spending less than £530k. This is much smaller than the average settlement which, when discounted, comes to around £10m (discounting at 1.5% in line with health budgets).

146. At best a compensation package allows families to no longer lose any QALYs (P=0). Even in this case though, the size of the compensation package is much larger than what could be delivered through the opportunity funding presented for each case saved.

147. This highlights that the predominant driver of net benefits arising from the policy are derived from savings to compensation and universal state provision, rather than through QALYs gained by families through expanding the pool to a greater number for compensation, due to the opportunity cost in any funds saved.

QALYs gained from prevention of incidents

148. As there is uncertainty around the level of QALYs gained from the provision of compensation to families and the much smaller magnitude of benefit compared to the opportunity saving arising, the only source of QALY gain included in the benefits here are the QALYs gained from the harm reduction achieved in the central scenario.

149. As an approximation, the level of harm reduction for a given cohort is applied to the whole cohort and the average QALYs lost per case are attributed. This is an overestimate because some of this group receive compensation through litigation and therefore only gain “P” QALYs. However, given the additional benefits of QALYs gained through increased compensations and the margin of error that is considered acceptable for this aspect of the economic case, this overestimate may be considered acceptable.

150. The profile for the monetised QALY change over time is shown below. Each QALY is valued at £60,000 and discounted at 1.5% to gain the total NPV from the 10 cohorts.

Table 6: Summary of discounted benefits for Option 3A.

Discounted category	17/18	18/19	19/20	20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28	Total
Reduction in QALYs lost through prevention	£0	£26	£51	£75	£98	£121	£119	£117	£115	£113	£111	£945

Summary of economic case

151. The full economic case for Option 3A is summarised below and has a final NPV of £12.8bn

Table 7: Summary of economic case for Option 3A with final NPV in bold.

Discounted category (14/15 prices, £bns)	17/18	18/19	19/20	20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28	Total
Litigation damages	£0.0	-£0.93	-£0.97	-£1.0	-£1.03	-£1.06	-£1.08	-£1.11	-£1.14	-£1.16	-£1.19	-£10.67
Litigation legal costs	£0.0	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.17
Compensation damages	£0.0	£1.05	£1.03	£0.99	£0.96	£0.92	£0.94	£0.97	£0.99	£1.01	£1.04	£9.90
Compensation legal costs	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.01
Support network costs	£0.0	£0.02	£0.02	£0.02	£0.02	£0.02	£0.02	£0.02	£0.02	£0.02	£0.02	£0.21
Universal state offer	£0.0	-£0.06	-£0.12	-£0.18	-£0.25	-£0.31	-£0.31	-£0.31	-£0.31	-£0.32	-£0.32	-£2.50
Implementation costs	£0.0	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.03	£0.26
Reduction in QALYs lost through prevention	£0.0	£0.03	£0.05	£0.08	£0.10	£0.12	£0.12	£0.12	£0.11	£0.11	£0.11	£0.95

Net Costs (including opportunity cost)	£0.01	£0.36	-£0.12	-£0.63	-£1.15	-£1.68	-£1.70	-£1.71	-£1.73	-£1.75	-£1.77	-£11.86
Net Benefits	£0.0	£0.03	£0.05	£0.08	£0.10	£0.12	£0.12	£0.12	£0.11	£0.11	£0.11	£0.95
Net benefits - Net costs	**-£0.01**	**-£0.34**	**£0.17**	**£0.70**	**£1.24**	**£1.80**	**£1.82**	**£1.83**	**£1.85**	**£1.86**	**£1.88**	**£12.80**
Net benefits - Net costs (without non-litigation state offer)	**-£0.01**	**-£0.58**	**-£0.31**	**-£0.04**	**£0.26**	**£0.56**	**£0.57**	**£0.58**	**£0.59**	**£0.60**	**£0.61**	**£2.81**

Impact of option 3B

Assumptions

152. For Option 3B, an alternative administrative threshold for Stage Two is based upon an eligibility criterion for incidents that could have been avoided under 'Reasonable Care' as opposed to that expected from an 'Experienced Specialist'. This results in a reduction in the number of cases that are projected to be eligible for Stage Two. The expected number eligible would be similar to the number expected to be successfully litigated cases but with an increase of 10% (around 10 cases) to account for the additional eligibility from an administrative scheme.

Costs of Option 3B

153. In the Figure below, the cost profile generated for Option 3B is depicted, showing a greater reduction in costs over time. This is due to the fewer number of additional cases eligible for the RRR compensation scheme while significant harm reduction may still be expected.

154. A positive cost NPV is generated within 10 years if 20% harm reduction is delivered, with break-even harm reduction under this criterion occurring for 9% harm reduction.

155. Compared to Option 3A, however, there is less harm reduction and a reduced translation of savings generated through savings to people who have been harmed through potentially avoidable incidents. This is captured in the economic case below.

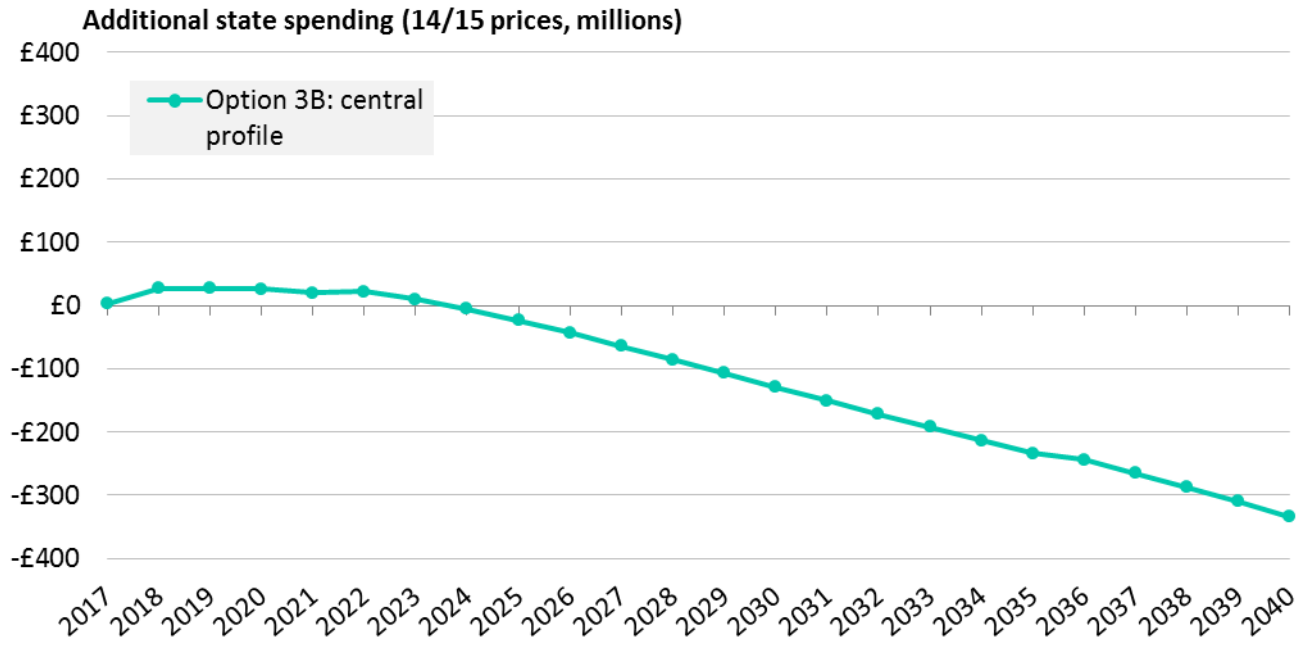


Figure 8: Central financial cost profile for Option 3B.

Table 8: Financial cost profile until 2027/28 for Option 3B.

	17/18	18/19	19/20	20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28
Central	**£3.0**	**£26.8**	**£27.1**	**£25.7**	**£20.2**	**£21.5**	**£9.9**	**-£5.2**	**-£23.3**	**-£43.4**	**-£64.4**

Table 9: Metrics for the financial case associated with Option 3B.

	Cost NPV at				Max additional spending		Max cumulative spending	
	By 2030/31	15 years	20 years	Final	Amount	Year	Amount	Year
Central	**£100**	**£480**	**£1,100**	**+**	**£30**	**2019**	**£130**	**2023**

156. Performing the same sensitivity analysis combined with a Monte Carlo approach, over 1,000 scenarios constructed from drawing the assumption distributions, the figure below shows the range of potential costs that may occur in a particular year. Across all scenarios, 92% returned a positive NPV in the long run.

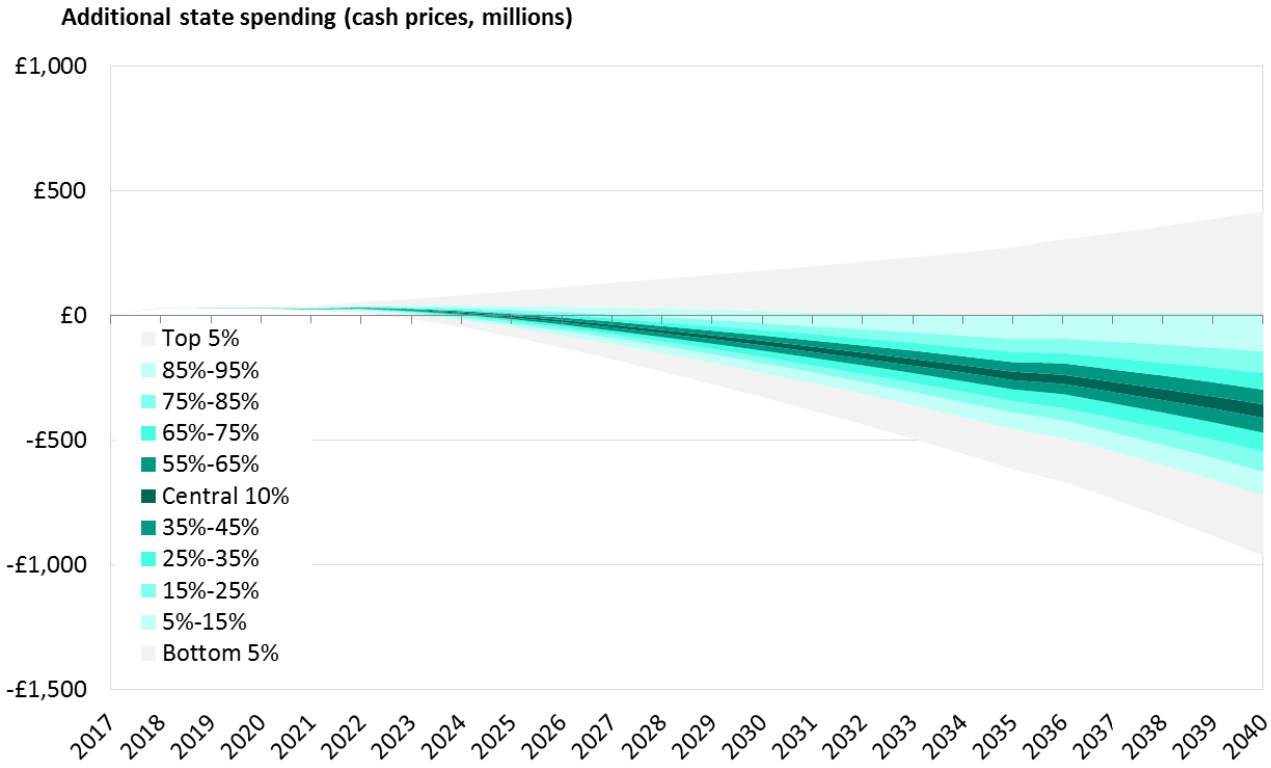


Figure 9: Range of costs in a given year for Option 3B arising from sensitivity analysis.

Economic case

157. A summary of the economic case for Option 3B is shown in the table below. The same methodology was used as for Option 3A in order to determine costs and benefits. A final NPV for this option is shown in bold.

Table 10: Summary of economic case for Option 3B with final NPV in bold.

Discounted category (14/15 prices, £bns)	17/18	18/19	19/20	20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28	Total
Litigation damages	£0.0	-£0.93	-£0.96	-£0.99	-£1.02	-£1.05	-£1.08	-£1.10	-£1.13	-£1.16	-£1.19	-£10.62
Litigation legal costs	£0.0	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.17
Compensation damages	£0.0	£0.79	£0.77	£0.76	£0.74	£0.72	£0.74	£0.76	£0.78	£0.80	£0.82	£7.68
Compensation legal costs	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0
Support network costs	£0.0	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.02	-£0.16
Universal state offer	£0.0	-£0.05	-£0.10	-£0.15	-£0.20	-£0.25	-£0.25	-£0.25	-£0.25	-£0.25	-£0.25	-£2.0
Implementation costs	£0.0	-£0.03	-£0.03	-£0.03	-£0.03	-£0.03	-£0.03	-£0.03	-£0.03	-£0.03	-£0.03	-£0.26
Reduction in QALYs lost through prevention	£0.0	£0.02	£0.04	£0.06	£0.08	£0.10	£0.10	£0.09	£0.09	£0.09	£0.09	£0.76
Net Costs (including opportunity cost)	£0.01	-£0.68	-£1.05	-£1.42	-£1.81	-£2.21	-£2.24	-£2.28	-£2.31	-£2.35	-£2.38	-£18.72
Net Benefits	£0.0	£0.02	£0.04	£0.06	£0.08	£0.10	£0.10	£0.09	£0.09	£0.09	£0.09	£0.76
Net benefits - Net costs	**-£0.01**	**£0.70**	**£1.09**	**£1.48**	**£1.89**	**£2.30**	**£2.34**	**£2.37**	**£2.40**	**£2.44**	**£2.47**	**£19.47**
Net benefits - Net costs (without non-litigation state offer)	**-£0.01**	**£0.51**	**£0.70**	**£0.89**	**£1.10**	**£1.31**	**£1.34**	**£1.37**	**£1.40**	**£1.43**	**£1.46**	**£11.48**

Impact of piloted option

Assumptions

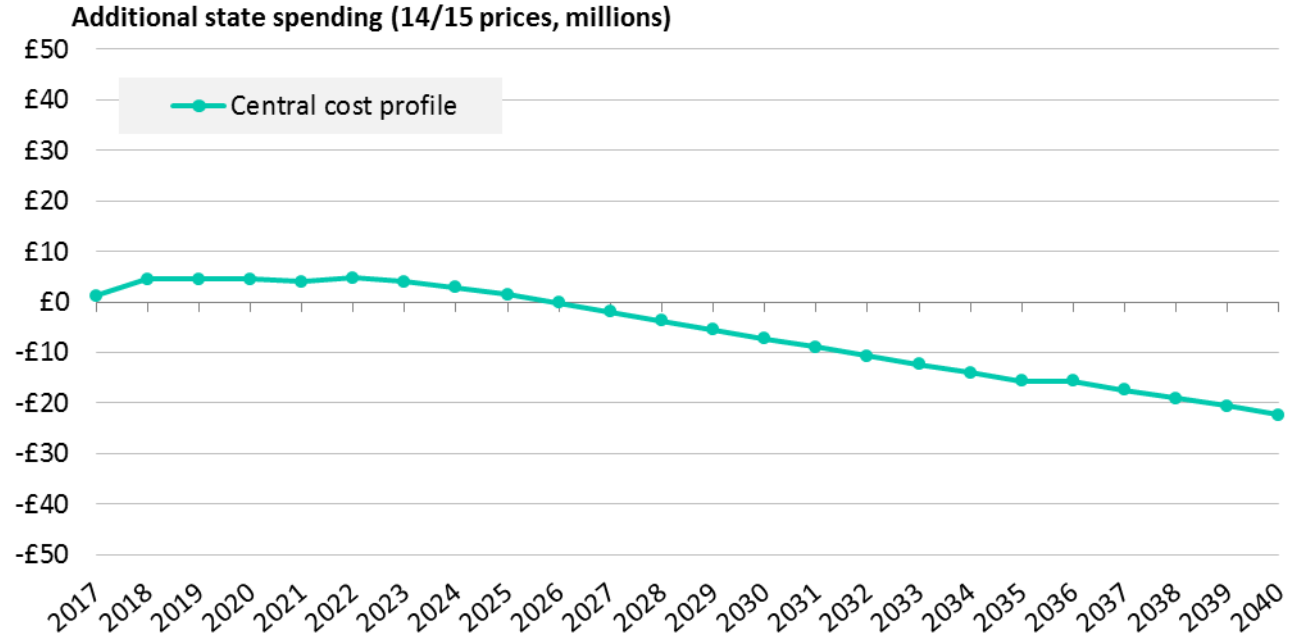
158. In order to test the operational delivery of the scheme, such as the processes involved in deploying investigations and learning, a smaller sample of incidents could be offered access to a pilot scheme. This would likely be organised on a regional basis. Any cases not included in the pilot would be able to proceed through litigation to receive compensation through existing arrangements.

159. It is assumed that 10% of maternity units could be included in such a pilot, which would reduce the expected case load of the pilot RRR scheme proportionately.

160. In deriving the implementation costs, it is assumed that some costs do not scale at all and would still need to be provided in full, while for others they would be proportionate but with an additional amount due to the inverse effect of economies of scale. For the 10% number of incidents a factor of (1+1/3) is applied giving a scaling of 13% of the costs for investigations and learning.[20]

Summary of financial case

161. The financial cost profile associated with a piloted version of the scheme is depicted below with the associated central year on year spending profile and cost NPVs.



	17/18	18/19	19/20	20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28
Central	£1	£4	£5	£4	£4	£5	£4	£3	£1	£0	-£2

	Cost NPV at				Max additional spending		Max cumulative spending	
	By 2030/31	15 years	20 years	Final	Amount	Year	Amount	Year
Central	-£19	£3	£44	+	£5	2022	£32	2025

162. Sensitivity analysis around the assumptions for Option 4, produces a similar range of cost profiles over time compared to Option 3A, with the order of spending reduced by a factor of around 10, given the pilot only applies to 10% of incidents.

[20] PSSRU unit costs: guidance on adjustment for pilot schemes

Summary of economic case

163. A summary of the economic case for Option 4 is shown in the table below. The same methodology was used as for Option 3A in order to determine costs and benefits. A final NPV for this option is shown in bold.

Table 11: Summary of economic case for Option 4 (pilot version of Option 3A) with final NPV in bold.

Discounted category (14/15 prices, £bns)	17/18	18/19	19/20	20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28	Total
Litigation damages	£0.0	-£0.09	-£0.10	-£0.10	-£0.10	-£0.11	-£0.11	-£0.11	-£0.11	-£0.12	-£0.12	-£1.07
Litigation legal costs	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	-£0.02
Compensation damages	£0.0	£0.11	£0.10	£0.10	£0.10	£0.09	£0.09	£0.10	£0.10	£0.10	£0.10	£0.99
Compensation legal costs	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0
Support network costs	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.02
Universal state offer	£0.0	-£0.01	-£0.01	-£0.02	-£0.02	-£0.03	-£0.03	-£0.03	-£0.03	-£0.03	-£0.03	-£0.25
Implementation costs	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	£0.04
Reduction in QALYs lost through prevention	£0.0	£0.0	£0.01	£0.01	£0.01	£0.01	£0.01	£0.01	£0.01	£0.01	£0.01	£0.09
Net Costs (including opportunity cost)	£0.0	£0.04	-£0.01	-£0.06	-£0.11	-£0.16	-£0.16	-£0.16	-£0.17	-£0.17	-£0.17	-£1.11
Net Benefits	£0.0	£0.0	£0.01	£0.01	£0.01	£0.01	£0.01	£0.01	£0.01	£0.01	£0.01	£0.09
Net benefits - Net costs	**£0.0**	**-£0.04**	**£0.01**	**£0.06**	**£0.12**	**£0.17**	**£0.17**	**£0.18**	**£0.18**	**£0.18**	**£0.18**	**£1.21**
Net benefits - Net costs (without non-litigation state offer)	**£0.0**	**-£0.06**	**-£0.04**	**-£0.01**	**£0.02**	**£0.05**	**£0.05**	**£0.05**	**£0.05**	**£0.05**	**£0.05**	**£0.21**

Non-monetised Benefits

An improved experience for families outside of litigation

164. There are many factors that influence a family's decision to pursue litigation following suspected birth injury. While securing compensation is a primary aim, families are also likely to be motivated by the wish to understand in full the events which led to the injury, and to feel confident that lessons have been learned. It is estimated that 25- 35% of families initiate a claim to fully understand what occurred during birth and whether this could have been avoided.[21] Families, mothers in particular, will often blame themselves.[22]

165. Long term care provision is a great concern for families, as many children with brain injuries live long lives and will outlive their parents. The use of periodic payments commits to a long-term provision of services and provides further reassurance to families that care needs can be met.

166. An alternative compensation scheme that includes a robust independent investigation will support families in learning what has happened, reducing the anxiety associated with self-blame and uncertainty; while compensation in the form of periodic payments with ongoing needs assessment will mitigate strain on families looking for security that long term care needs will be met. The pursuit of litigation may achieve these outcomes for families with a successful claim; however the litigation

[21] "Why do parents litigate and what does it do for the family". Rosenbloom, L., BMJ 2014

[22] "Learning from mistakes, enhancing quality and safety of care, and reducing the cost of litigation." Gardosi, J. Perinatal institute. 2015.

process is a stressful time for families, with a great deal of uncertainty, which would be minimised under Rapid Resolution and Redress.

An improved experience for families through early interaction

167. Stage Two of RRR policy includes an improved and timely network of support provided to families, including a case manager, personalised needs assessment throughout the injured party's life, counselling to families and legal advice.

168. The support network provided under stage two of RRR will meet the needs of families, provide security that care needs will be met and improve the mental health and wellbeing of family members supporting an injured child.

An improved experience for a wider group of families

169. At present, only individuals with an injury as a result of negligent care are compensated, via successful litigation. Those who pursued a claim but were unsuccessful would likely experience additional stress and anxiety having gone through the experience of litigation, as would those involved in the case, including the solicitor, physicians and even those involved in determining eligibility.

170. A scheme providing compensation to families, who experienced avoidable harm, as proposed under RRR, would lessen the stress associated with uncertainty from families. This would provide the non-monetised benefits described above to a wider group of individuals.

Increased capacity in the system

171. One of the overall intentions of this policy is to reduce the occurrence of future incidents of cerebral palsy and brain damage. Investigations, data analysis, dissemination and learning under stage one of the policy are designed to support this objective.

172. Harm reduction, and a decrease in future incidents has been accounted for under monetised benefits, however, a reduction in incidents will also free up capacity within a strained care system, allowing others to benefit from this increased capacity.

Risks

Inability to achieve harm reduction

173. A key driver in the ability to fund additional cases for compensation at a level greater than the current state offer for non-litigated cases is the harm reduction delivered from the policy.

174. There is a risk that the system does not have capacity to respond to opportunities for learning provided by a new scheme. Provision of additional funding for learning, included in Stage One, will allow maternity units to respond to identified opportunities. However, it may not provide full capacity to respond, potentially impacting the scheme's ability to achieve harm reduction. This may be compounded if RRR is insufficient to achieve full openness and transparency (for example if knowledge that the Stage One investigation will be linked to a decision concerning eligibility for compensation in Stage Two might result in less openness during the course of the investigation). This may be mitigated by aligning RRR strongly with other policy developments designed to promote openness, such as the Duty of Candour and associated alignment with professional and regulatory procedures.

Compensation in practice

175. There may be risks in translating the timing of payments as reflected in the model into practice – for example practicalities of providing payment when it is needed to secure essential support such as accommodation.

176. Striking the balance between under-provision (leading to litigation) and over-provision (paying as much as is currently provided through litigation) is required. A particular challenge here may arise from earlier admission of breach of duty and potentially causation arising from the early investigations necessarily leading to provision of services.

177. There are risks around ensuring families receive the right level of care; an important aspect of compensation under the scheme is that it complements existing other potential state provision, including systems of state-funded children and young people's continuing care and social care, and NHS Continuing Healthcare (for ages 18 and over). To mitigate this, our working scheme design includes regular review of care needs which would take into account all elements of state provision. Other issues include portability (including a move overseas); how the package would be delivered by local commissioners and providers (including remuneration mechanism); and how a package would take into account existing local provision and level of need (e.g. geographical variation in cost of accommodation) in agreeing a 'best practice' level of compensation.

Risk of low uptake for compensation package in favour of litigation

178. There are several other potential factors that could reduce uptake of the compensation package, for example:

- A lack of trust in the NHS following such a severe event may lead to the rejection of the scheme;
- The regular assessment of need may be perceived to provide less security than the court award; and
- A family may decide to pursue a higher damages award through the Court – particularly in a case where negligence is easy to establish.

179. Addressing the above issues through comprehensive apology, early support, a case manager to coordinate services and guarantees of future provision will help to potentially mitigate this risk.

Equity considerations

180. The principle of providing 'best practice' state support to eligible individuals, in comparison to the level and timeliness of state support to non-eligible individuals, potentially creates a two-tiered system. This is mitigated by the policy rationale which describes the intention to develop this scheme as a pilot / 'test bed' for a new approach, which could in time be extended to other cohorts.

Increase in claim numbers

181. There is an inherent risk associated with investigations that individuals may be more aware of harm and the overall propensity to claim may increase, potentially increasing the number of successful claims. We have accounted for an estimate of this, which is reflected in our modelling.

Direct costs and benefits to business calculations (following BIT methodology)

182. There are no direct costs or benefits to business. Consequently, there are no direct outcomes that are forced upon any legal firms.

Equalities and the Public Sector Equalities Duty

183. The Public Sector Equalities Duty (PSED), as found in Section 149 of the Equalities Act 2010, states that a public authority must have due regard to the need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act;
- Advance equality of opportunity between people who share a protected characteristic and those who do not; and
- Foster good relations between people who share a protected characteristic and those who do not.

184. The Family Test[23] aims to ensure that potential impacts on family relationships and functioning are made explicit and recognised in the process of developing new policy. As set out in the Test, this may be viewed as complementary to the PSED.

185. In preparing for this consultation, DH conducted initial engagement with stakeholders and clinicians; and commissioned external research to engage further with families with experience of birth injury and the general public. This has informed consideration of the emerging policy design against the requirements set out in PSED and the Family Test, as set out below.

186. It is important to note that this is a voluntary scheme, and that litigation will remain open as an option to families at all times (including those not eligible for this scheme).

Eliminating unlawful discrimination

187. Eligibility for this proposed scheme will not discriminate on the basis of protected characteristics of age, disability (aside from the clinical markers described above for eligibility into the scheme), gender reassignment, pregnancy and maternity, race, sexual orientation, sex or religion or belief. This scheme proposes an alternative compensation route for individuals where their disability has arisen from birth injury which could be been avoided (further details provided under the disability headline below).

188. Those participating in the scheme will reflect clinical eligibility and meet the definition for avoidable harm – as such compensated individuals will be disabled, with a diagnosis of avoidable neurological birth injury (CP/BD) and predominantly children (at least at the point at which eligibility is established, although support will continue to be provided across the life-course).

189. It is likely that this scheme may have a high proportion of individuals from minority groups and lower socioeconomic status, as these are identified risk factors for cerebral palsy (though not necessarily risk factors for cerebral palsy as a result of intrapartum harm).

190. Through further engagement with stakeholders, externally commissioned research and the consultation we will work to identify and eliminate inadvertent consequences of the scheme eligibility (both Stage One and Stage Two eligibility threshold).

Advancing equality of opportunity

191. The scheme will offer an alternative source of compensation for families who would otherwise have to endure a prolonged and expensive tort process. This opens up the possibility of compensation to families that may not have been able to afford initial legal advice, or to afford the financial and other risks of pursuing the tort route.

192. Under the proposed scheme, eligible families may receive early support and, when avoidability can be established, an early up-front payment, and periodical payments, earlier on average than they would have done through the tort route. This increased speed of compensation may enable families to provide greater levels of support to the disabled child at an earlier stage.

[23] The Family Test: Guidance for Government Departments, Department for Work and Pensions, October 2014

193. The scheme may offer families less compensation than they would receive under the tort route. It may be argued that what is allocated through the tort route is the amount required to bring the injured child as close as possible to the life they would have had had they not been disabled.

Fostering good relations

194. The proposed scheme aims to improve relations by reducing the need for families to pursue an often adversarial litigation process. In doing this, it aims to create a more positive, collaborative approach between the injured party and the relevant health professionals, fostering good relations with the NHS.

195. The Public Sector Equalities Duty is unclear as to whether it requires fostering good relations between people with protected characteristics. If it does, it may be pointed out that the scheme is only intended to cover a certain group of disabled people – those with severe avoidable birth injuries. While this is true for the current iteration of the scheme, if the scheme proves successful consideration may be given as to whether it can be extended to cover other types of avoidable injury.

Specific impact tests

Equalities

196. The Department of Health conducted initial engagement with stakeholders and clinicians; and commissioned external research to engage further with families with experience of birth injury and the general public.

197. Eligibility for this proposed scheme will not discriminate on the basis of protected characteristics of age, disability, gender reassignment, pregnancy and maternity, race, sexual orientation, sex or religion or belief. This scheme proposes an alternative compensation route for individuals where their disability has arisen from avoidable birth injury; this is considered to be a legitimate aim, further details provided under the disability headline below.

198. Those receiving the alternative compensation will reflect clinical eligibility and meet the definition for avoidable harm – as such compensated individuals will be disabled, with a diagnosis of avoidable neurological birth injury (CP/BD) and predominantly children.

199. During antenatal care, expectant mothers are assessed based on risk factors. A woman with ‘complex social factors’ may be more likely to receive a high risk label. We will be considering any differential impacts upon individuals with high risk assessment when consulting on the detail of implementing this scheme, and the responses will inform the final policy design.

200. It is likely that this scheme may have a high proportion of individuals from minority groups and lower socioeconomic status, as these are identified risk factors for CP (though not specifically risk factors for CP as a result of intrapartum harm).

201. Through further engagement with stakeholders, externally commissioned research and the consultation we will work to identify and eliminate inadvertent consequences of the scheme eligibility (both Stage One and Stage Two eligibility threshold).

202. The impact of this scheme on specific characteristics is listed below.

Disability

203. Rapid Resolution and Redress aims to provide non-adversarial compensation to severely neurologically injured babies (where the harm was avoidable), and to improve the experience of families when harm has occurred.

204. This policy restricts eligibility to individuals with neurological injury (CP/BD) as a result of avoidable birth injury, and therefore the majority of those with CP/BD would not be eligible (most cases of CP/BD have no element of intrapartum causation).

205. The option to pursue litigation remains open to those individuals who don't meet the criteria of this scheme (e.g. babies born before 37 weeks, brain injury attributed to antenatal or postpartum causes), and the injury is considered a result of negligent care.

206. For those where the injury is not a result of negligent care and are ineligible for this scheme, existing care under the provision of existing care arrangements would remain available.

207. We recognise that many other children with similar impairment related to causes ineligible for the scheme, and those with other disabilities not covered by this scheme, would not receive compensation. DH proposes that Rapid Resolution and Redress begins with a very narrow pool of eligible incidents until the scheme is well established, and then to consider future options to potentially expand this further to expand wider.

208. Through further engagement with stakeholders, externally commissioned research and the consultation we will work to identify and eliminate inadvertent consequences of the scheme eligibility (both Stage One and Stage Two eligibility threshold).

Age

209. Rollout of this scheme would begin with a cohort of infants; uptake will be restricted to individuals born after the scheme start date.

Sex

210. Literature indicates that there may be neurobiological differences between male and female brain development and response to trauma; male sex is considered a risk factor for CP.[24][25]While sex is not considered on the eligibility criteria, it is possible that there may be a higher proportion of male infants eligible for this scheme.

Race

211. Black infants have been found to have a higher rate of CP than white infants, which is attributed to their higher risk of low birth weight. This association may be confounded by association between cerebral palsy and socioeconomic status (and an underlying relationship between antenatal care and level of maternal education). There may therefore be a higher proportion of black individuals in the counterfactual, and those who would be eligible for this scheme; our policy recommends monitoring of eligibility and uptake by race.[26]

Religion or Belief

212. Under this policy, individuals and families who are adverse to litigation due to religion or personal beliefs would now have an alternative route to access compensation. Some evidence from America indicates that those with a weaker relationship with religion are more likely to pursue litigation following medical error.[27]

213. Eligibility for the scheme is unlikely to be biased towards a particular religion/belief but may lead to higher uptake of the scheme by those who previously would not have pursued litigation, influenced by their religion or belief system.

Gender Reassignment, Sexual Orientation and Marriage and Civil Partnership

214. The proposed alternative compensation scheme will not impact differentially on these groups and all would benefit equally from inclusion in the scheme.

Pregnancy and maternity

---

[24] Johnston, M. V. and Hagberg, H. (2007), Sex and the pathogenesis of cerebral palsy. Developmental Medicine & Child Neurology, 49: 74–78. doi: 10.1017/S0012162207000199.x

[25] Chounti, A., et al. "Sex differences in cerebral palsy incidence and functional ability: a total population study." *Acta Paediatrica* 102.7 (2013): 712-717.

[26] Wu, Yvonne W., et al. "Racial, ethnic, and socioeconomic disparities in the prevalence of cerebral palsy." *Pediatrics* 127.3 (2011): e674-e681.

[27] Tsimtsiou, Z., et al. "What is the profile of patients thinking of litigation? Results from the hospitalized and outpatients' profile and expectations study." *Hippokratia* 18.2 (2014): 139.

215. This policy is targeted at a subset of women who experience adverse outcomes during pregnancy and maternal care.

Socio-economic status

216. There is a strong association between socioeconomic status and CP, even after adjusting for low birth weight and gestational age. As there may be a higher proportion of individuals from low socio-economic status in the counterfactual, it is anticipated that there is likely to be a higher proportion eligible for this scheme.[28]

217. International evidence indicates that individuals from low socio-economic status are less likely to litigate, however these studies are not specific to maternal care, brain injury or based on UK populations. If these trends do exist within the UK, this scheme would in principle be addressing this disparity by socio-economic status, as access to the scheme would not require the family to actively pursue litigation.[29]

Family

218. The proposed scheme is intended to improve the experience of families following severe avoidable birth injury. Under the current scheme design, families would have the option to enter into a voluntary compensation scheme as an alternative to the court route.

219. Eligible families may receive early support and, when avoidability can be established, an early up-front payment, and periodical payments, earlier on average than they would have done through the tort route. This increased speed of compensation may enable families to provide greater levels of support to the disabled child at an earlier stage.

220. We are consulting on options around the threshold for compensation. We expect that at least as many families would be compensated via the RRR scheme as would be compensated via the courts, and depending on the threshold chosen, potentially more would be compensated and therefore receive support with caring for the injured child.

221. The scheme may offer families less compensation than they would receive under the tort route. The compensation awarded under the scheme is intended to provide for reasonable levels of care and support for families. We will be reviewing further evidence received as part of the consultation process in order to finalise this and other operational aspects of the scheme, and consider fully the impact on families.

One in, three out

222. The impacts presented in this impact assessment do not fall under the one in, three out rule as the compensation is offered as an alternative to litigation and does not involve new burdens on business or civil society.

Micro enterprise exemption from regulation

223. Rapid Resolution and Redress does not involve new regulation on business or civil society.

Small Firms Impact Test

224. Rapid Resolution and Redress will provide a voluntary alternative to litigation for eligible families, and would not mandate any required action for private businesses such as legal firms.

Competition

225. Rapid Resolution and Redress itself has no direct impact on the operation of competition.

---

[28] Sundrum, R., et al. "Cerebral palsy and socioeconomic status: a retrospective cohort study." Archives of Disease in Childhood 90.1 (2005): 15-18.

[29] "No-fault compensation schemes: a rapid realist review to develop a context, mechanism outcomes framework", Dickson et al., 2016. EPPI-centre.

Environmental and sustainability impacts

226. This scheme has no impact upon the environment or sustainability.

Human rights

227. As Rapid Resolution and Redress is an alternative compensation scheme and does not restrict access to the tort route, the proposals are believed to be compliant with the UK's obligations under the European Convention on Human Rights.

Justice system impacts

228. This scheme is likely to impact civil litigation, as its purpose is to provide an attractive alternative to families who would be eligible to pursue litigation.

229. Dependent on uptake of the scheme, there may be fewer cases that proceed to civil litigation.

Rural proofing

230. RRR will benefit everyone regardless of where they are within the country. Investigations, eligibility and case managers in this scheme are proposed to operate in regional teams, which seek to meet the needs of individuals in all communities.

231. There is a risk that support and services are not available in the immediate area. Case managers would need to take into account the services provided in the area and adjust the compensation accordingly (e.g. families in London may see a higher level of compensation for accommodation due to the cost of housing in London, however families in rural areas may see higher provision under transportation recognising that services may not be available in the immediate community).

Annex A: Analytical details

Investigations and learnings costings

Reporting tool and root cause analysis of incidents

232. The cost modelling allows provision for a national maternity data analysis, reflecting the 'Safe Delivery Care' initiative in Sweden. Analysis of data from maternity units in England could identify appropriate opportunities for learning and interventions which are fed-back to Trusts to implement at a local level, building on existing platforms such as the National Reporting and Learning System (NRLS) database.

233. There are two cost elements included for the reporting tool: the set-up and development of the tool estimated at around £225,000, estimating the consultancy fee for the design and development of the software, along with a yearly running cost associated with the maintenance of the tool costed on the basis of 1-2 civil servants at £78,000.

234. There is potential that the scheme could be tied into already existing platforms for reporting incidents, such as the Royal College of Obstetricians and Gynaecologists (RCOG) Each Baby Counts (EBC) campaign for severe brain injury or the National Reporting and Learning System mentioned above. However, the approach outlined above allows for the instance that incorporation into existing tools may not be possible and a separate reporting tool would need to be commissioned and maintained.

235. For the analysis of incidents that take place, provision is made for a team of two analysts. The role would include having oversight of the data collection, the consideration of local and national patterns and the preparation of material that could be used for training purposes. The additional costs for the analysts are estimated to be £178,000 per year.

Investigations

236. Early investigations play a crucial role in meeting policy objectives, providing the first step to gathering information in an independent manner around what may have gone wrong, as well as allowing early support for families.

237. A bottom-up approach to calculating the costs of investigations has been taken. Discussions with NHS England indicate that an appropriate team for external investigations would include three clinical staff members, which are taken to be a neonatologist, obstetrician and midwife. Additionally it is assumed there would be a consultant and registrar among the obstetrician and neonatologist.

238. Using the average length of investigation from Stanford PEARL scheme[30], it is assumed that the investigations take seven days.

239. Bringing together the seven day length of investigation combined with the daily unit costs for a consultant, registrar and midwife[31], a cost per investigation of £14,200 is derived.

240. For the administration of the investigations, it is proposed that three investigation teams are allocated to each of the four NHS Areas, with administration at the NHS Area level. An associated administration cost of £700,000 is derived based on two administrative staff in each of the four NHS regions to orchestrate and deploy the investigation teams.

Dissemination of learning from investigations

241. Dissemination of knowledge within a maternity unit, within a Trust and across the NHS is fundamental for achieving harm reduction. Costs associated with dissemination incorporate dissemination and implementation of learning within a maternity unit.

242. An additional 45 minutes of time to disseminate the findings to on average 8 members of the trust specifically is included in costings (estimated at £540 per trust for the backfill). However, the findings would be expected to feature in the wider learning and development already in place for the involved individuals in the trust.

[30] http://www.stanfordchildrens.org/content-public/pdf/pearl.pdf

[31] PSSRU unit costs 2014/15

243. For the wider distribution of the findings from a particular investigation to trusts around the country, two full-time administrative roles have been included in costs at a total of £228,000 per year.

Wider provision for learning

244. The costing for implementation of learning is informed by the costs of running PROMPT2[32] annually in each maternity unit in England. We propose that maternity units implement learning appropriate to their needs, informed by data analysis described above and lessons from the RCOG/Health Education England working group reviewing multi-disciplinary training and any specific incidents that may occur in individual trusts. This has been costed on the basis of an additional day of staff time for all members of staff in each maternity unit around the country each year and is estimated to be an additional £13.4m across the country in order to directly provide staff to backfill.

Incident numbers and types

Overview

245. There are three types of incident that need to be modelled. These are the:

A. Number that present clinical symptoms at birth that need to be investigated. These are termed Stage One incidents;

B. Number of incidents surviving to early childhood where any lasting harm may have occurred as a result of the delivery process; and

C. Number of incidents that would be eligible for compensation under a new compensation scheme.

246. The figure below summarises the type of incident that may occur.

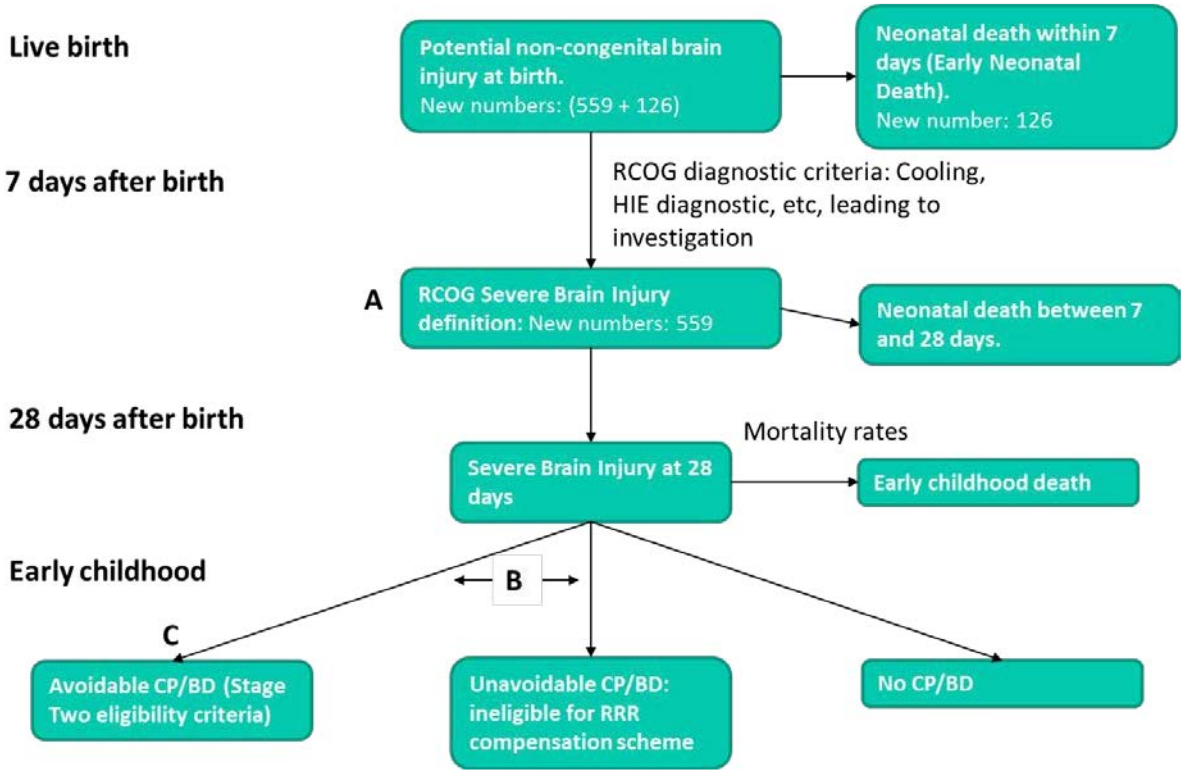


Figure 10: The above flow chart illustrates how a given incident of brain injury at birth can progress into early childhood, with the relevant numbers for the modelling labelled A-C.

Numbers of investigations

247. In order to model the number of Stage One incidents, the policy makes use of the extensive research that RCOG have performed in order to provide a consistent definition of avoidable birth

[32] PROMPT: http://www.promptmaternity.org/

injury through their Each Baby Counts campaign. The criteria used, which are recorded in the national BadgerNet database too, are the following:

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

- With Hypoxic-Ischemic Encephalopathy grade 3 (an indicator of asphyxia related neonatal neurological abnormality)[33]

  OR

- With decreased central tone AND is comatose AND has seizures (of any kind)[34]

  OR

- Any baby which receives active therapeutic cooling treatment

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

248. This set of criteria is proposed to be used to trigger investigations under Stage One of the scheme.

249. The RCOG EBC 2015 report collated a total of 921 incidents: 120 stillbirths, 147 early neonatal deaths and 654 incidents of severe brain injury (SBI) with survival beyond 7 days. ONS 2012 population projections show that 85.4% of UK births were in England, which leads to an estimate of 559 cases of SBI in England for 2015. It is assumed that investigations take place 7 days after the birth and therefore the number of investigations required each year is 559 after scaling with ONS birth projections each year.

Survival of Stage One incidents into early childhood with lasting brain injury

250. Incidents of brain injury can have several outcomes, as illustrated in Figure 10. The child may not survive until early childhood (18 months) or may survive without any abnormal neurological function. However, for RRR, it is the cases that survive with lasting neurological damage that the policy aims to reduce and which may be eligible for the scheme.

251. Several studies have considered the outcomes of infants into early childhood after a moderate to severe brain injury identified at birth. Edwards et al.[35] performed a meta-analysis collating the likelihood of particular outcomes at 18 months. The three trials that were considered were TOBY, NICHD and CoolCap. The primary purpose of the underlying trials was in comparing outcomes for babies that underwent cooling and those who did not – cooling is considered a potentially effective treatment at birth for improved childhood outcomes.

252. Below we show the proportion of outcomes for both cooled and non-cooled groups in the source research.

Table 12: The proportion of the cooled and non-cooled groups that have a specific outcome after 18 months.

Group	Outcomes at 18 months	TOBY	NICHD	CoolCap	All
Cooled group	Survival	74%	76%	62%	71%
	Survival and abnormal neurological function	30%	45%	37%	36%
	Survival and CP	20%	15%	20%	19%
	Survival and major neurodevelopmental disability	20%	21%	20%	20%
Non-cooled group	Survival	72%	61%	58%	65%
	Survival and abnormal neurological function	44%	41%	41%	42%
	Survival and CP	30%	18%	25%	25%

[33] 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.

[34] 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

[35] "Neurological outcomes at 18 months of age after moderate hypothermia for perinatal hypoxic ischaemic encephalopathy: synthesis and meta-analysis of trial data", Edwards et al., BMJ 2010

Survival and major neurodevelopmental disability	26%	25%	26%	26%

253. The results are summarised below for each trial assuming the underlying number of incidents is equal to the total number of severe brain injury and early neonatal death identified in the RCOG's 2015 results. This reported number is 684 for England and it is assumed that 96% are cooled which leads to the following projected outcomes at 18 months.

Table 13: Summary of outcomes at 18 months for the 685 incidents of live brain injury projected from the EBC 2015 data.

Outcomes at 18 months	TOBY	NICHD	CoolCap	All
Survival	503	519	423	483
Survival and abnormal neurological function	**210**	**307**	**255**	**249**
Survival and CP	141	101	137	**129**
Survival and major neurodevelopmental disability	136	142	137	138

254. The results lead us to a central estimate of 249 incidents in 2015 that will survive to 18 months and then undergo expected mortality rates for CP/BD cases. In Figure 10, this number is ascribed to B as a central estimate with 210-307 as the range around the central estimate.

255. Further evidence is available on the expected outcomes following moderate to severe injury at birth in term babies.[36] The authors performed a study looking at expected outcomes following cooling where all infants also received morphine treatment. The table below shows a summary of the proportions of specific outcomes for cooled and non-cooled groups and the resulting projected outcomes at 18 months assuming a baseline equivalent to the numbers of avoidable live birth injuries from Each Baby Counts.

Table 14: Summary of outcomes for cooled and non-cooled groups and EBC projections using analysis from Simbruner et al.

	Probability of outcome		
Outcomes at 18 months	**Cooled group**	**Non-cooled group**	**EBC projected outcome**
Survival	62%	43%	421
Survival with severe disability	13%	26%	94
Survival with CP (upper bound)	9%	24%	69

256. This analysis shows far lower estimates for incidents of severe disability and CP than those from the meta-analysis performed by Edwards *et al.* despite having the same inclusion criteria, cooling treatment (as TOBY and NICHD), follow-up period and definition of severe disability. One potential explanation is inclusion of morphine as part of the treatment which could be reducing adverse outcomes in both the treatment and control groups by reducing stress in response to the hypothermia. This additional evidence may also suggest that the projected numbers from the meta-analysis may be conservative.

Eligibility for Stage Two into early childhood

257. Eligibility for compensation under Stage Two is set by a policy decision, informed by the volume of incidents a given eligibility threshold could result in.

258. An initial eligibility decision will be made following the Stage One investigation and the level, justification and need for compensation will be considered over time. For example, initial harm may

[36] "Systemic Hypothermia After Neonatal Encephalopathy: Outcomes of neo.nEURO.network RCT". Simbruner et al. (2010) Pediatrics.

be judged as having been avoidable but if the type of harm that occurs into early childhood is different and would be considered not avoidable/negligent given the facts of the case, then the compensation and eligibility at this stage may differ.

Current number of successful claims and increased uptake

259. The number of incidents that are considered negligent under the current legal system is derived through consideration of successful claims in NHSLA data. The methodology for this calculation is described in further detail below. Using this evidence, the total number of full-term negligent cases is projected to be 102 for 2015.

260. There are some cases that may be negligent but are not currently brought forward to litigation. This could be for several reasons but is expected to be predominantly due to a lack of awareness or an attitude of not wishing to litigate. As a result of the RRR policy introduction, there is an assumption of an additional 10% of cases that would come forward. This would mean a total of 112 possible negligent cases in 2015.

'Experienced Specialist' test eligible numbers

261. In modelling the number of avoidable incidents under the Swedish test for eligibility, incidents that could have been avoided if it had been under the care of an 'Experienced Specialist', evidence has been gathered from two primary sources. Firstly, the RCOG EBC total discussed above provides an upper bound on what could ever be eligible. However, this is likely to include many cases that would not sufficiently meet the criteria for avoidable harm described above. This is because:

- It may be that a case would not be considered avoidable once further factors are taken into consideration; and
- The type of harm that later becomes manifest may not have been linked to the action at birth that meant that the incident was classed as avoidable.

262. To derive a more accurate picture of the number of cases that would be eligible, a number of unsuccessful cases on NHSLA's records were considered across 11 different law firms. They gave responses around whether a given case would have been eligible for compensation under an avoidable eligibility criterion. It should be noted that the law firms applying the "avoidable" criterion would have been unfamiliar with how to do so as there are no English legal precedents for them to call upon. The possible answers were "Yes", "Possibly" and "No". The proportion that were "Yes" or "Possibly" were used to attribute an additional proportion of successful claims under the new criterion. Along with the assumption of the 10% increase in notified incidents from cases that were previously not notified as a results of increased awareness, **this led to 162 as a central scenario for the number of cases expected into childhood.**

263. To gain a lower estimate for the number of eligible cases, only the responses that came back as "Yes" were considered. **This leads to 134 avoidable cases as a lower bound.**

'Reasonable Care' test

264. Under a 'Reasonable Care' test compensation eligibility, an assumption of an additional 10% of cases is assumed on top of the increase of 10% due to litigation. Against the projected 102 successful litigation cases for 2015, this leads to an additional 10 from flexibility in the eligibility criteria and a further 10 from awareness among those who would have had a successfully litigated case had they chosen to pursue that route but were previously unaware. This leads to a central estimate of **122 cases in 2015** under a scheme with a 'Reasonable Care' test threshold.

Summary charts of incident types and eligibility

265. The chart below depicts how current incidents are broken down into ones that are currently notified to NHSLA and become successfully litigated cases, those that are notified but are unsuccessful and those of which NHSLA are not made aware.

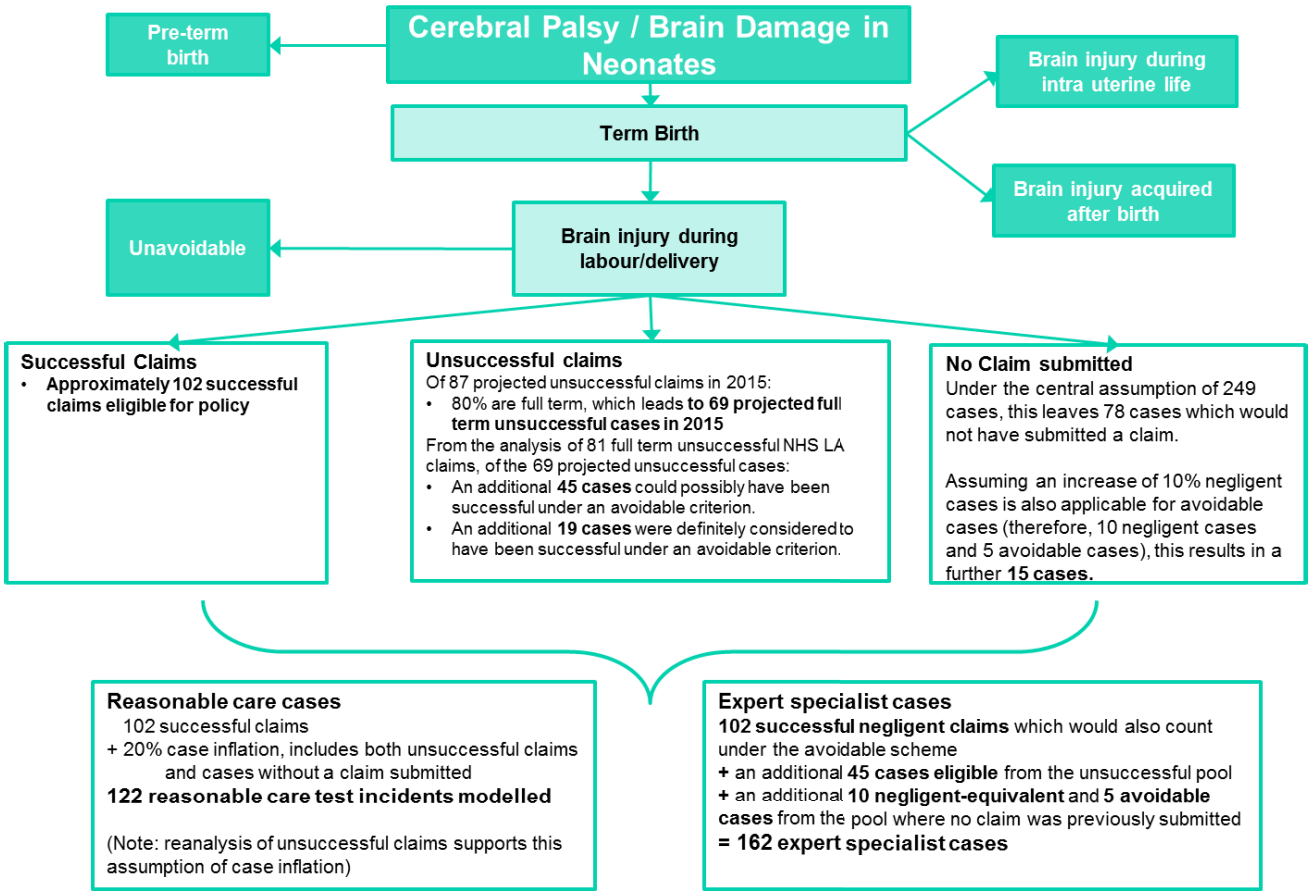


Figure 11: The above flow chart illustrates how an incident of CP/BD can be classified and the specific subset of cases that are under consideration for RRR. The means by which the central estimates of the number of cases is also highlighted.

266. Below a summary chart of the different types of incidence of CP/BD is shown along with the relationship this bears to eligibility for Stage Two of RRR. Alongside this there is a chart showing the effect of cooling on the estimated number of cases of CP caused by asphyxiation. We would expect to see 23 fewer cases of CP thanks to cooling.

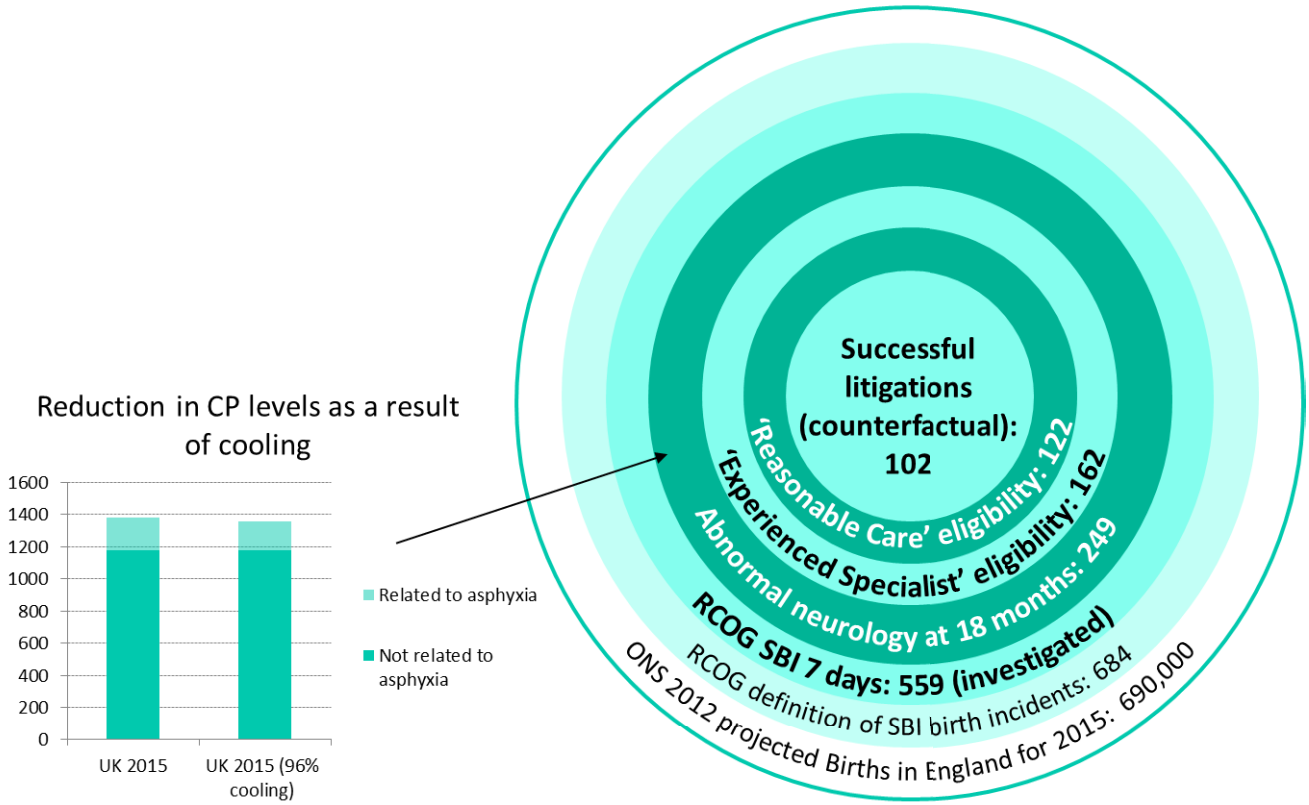


Figure 12: A summary of incident types relevant to RRR along with how other evidence around Cerebral Palsy prevalence fits in with the incidents under consideration in the policy. This shows that the majority of cerebral palsy cases are not linked to cooling. Therefore, 96% cooling compared to 0% cooling will result in 23 fewer cases of cerebral palsy which is a 1.7% fall in total CP levels.

Harm reduction

Summary

267. The evidence base for harm reduction deliverable by RRR has been informed by a number of sources, including published literature, practicing clinicians, stakeholders and communication with Swedish contacts associated with the 'Safe Delivery Care Project'.

268. It is very challenging to identify with certainty the level of harm reduction that England would see by introducing a non-adversarial compensation scheme. However, while this may not be quantifiable with certainty, from the evidence it is reasonable to expect some level of harm reduction through having a more open and learning-based approach to dealing with incidents.

269. The lower bound of harm reduction is assumed to be zero, which demonstrates the impact of the scheme in the worst case scenario for harm reduction. The upper limit is modelled at 50%, which is a reflection of how the harm reduction observed in Sweden could be applied to an English context. Latest evidence from Swedish data (2015 inclusive) potentially indicates that even more extreme levels of harm reduction may be achievable (up to 50%). In sensitivity analysis, a triangular distribution has been used to account for the fact that some harm reduction is expected with greater likelihood than either of the extremes, with a central estimate of 25% and low and highs of 0% and 50% respectively.

Drivers for harm reduction

270. RRR operates in a two stage process but both are considered to influence harm reduction.

271. Stage one contributes to harm reduction through investigations, a reporting tool and data analysis, dissemination and learning.

Investigations

272. Independent, standardised investigations of incidents would lead to a more accurate reflection of the underlying cause of harm. Investigations which apply an accident causation model will collect data that relates to the underlying causes and factors which contribute to the occurrence of an adverse event[37]. This transforms the focus from blaming the individual clinician to collecting robust information that supports learning and identifying areas where care could be improved, thus preventing future adverse events.

Reporting tool and data analysis

273. National maternity data analysis will reflect the 'Safe Delivery Care' initiative in Sweden. Analysis of data from maternity units in England to identify appropriate opportunities for learning and intervention will then be fed-back to trusts to implement at a local level, building on existing platforms such as the National Reporting and Learning System (NRLS) database.

274. The 'Safe Delivery Care' initiative in Sweden has achieved harm reduction of around 50% between 2007 and 2015 across all serious birth injuries. The model of care and socio-demographic differences between Sweden and England do not make this level of harm reduction directly applicable to the English context. However, this 50% reduction indicates that implementation of the reporting tool and data analysis, along with an alternative compensation scheme, will lead to harm reduction in England.

275. Given that the gap between incident and claim in the Swedish system is purported to be short (3-4 years), this is a reasonable indication of reduction in incidents per birth. Conclusions from the English system are not comparable due to the increased lag period between incident and claim success (around 11.5 years). As claims data for past incidents is collected in future years, there may be a slight increase in incidents from the given birth year due to late reporting. Analysis by Swedish colleagues has indicated only a small effect on the 50% reduction.

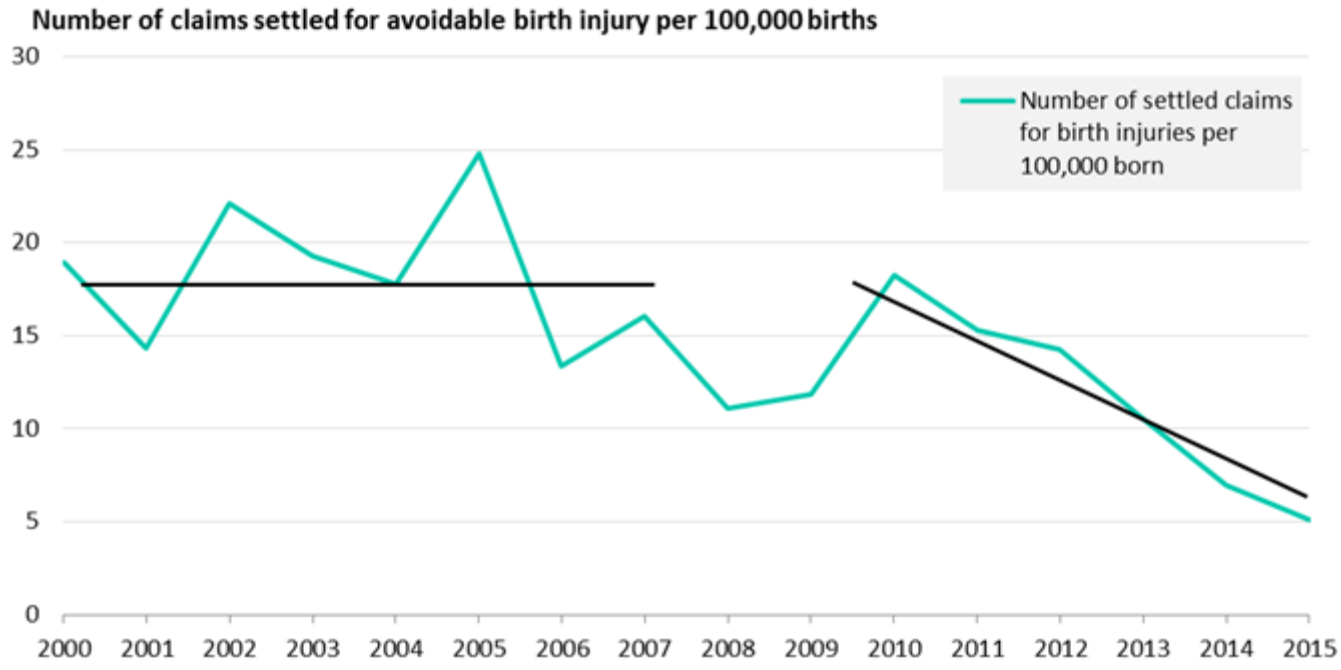


Figure 13: Data from Sweden showing the frequency per 100,000 born of settled claims involving serious birth injuries per incident 2000-2015.

Dissemination and learning

276. Dissemination of knowledge within a maternity unit, within a Trust and across the NHS is fundamental for achieving harm reduction. Costs associated with dissemination incorporate dissemination and implementation of learning within a maternity unit.

277. The costing for dissemination and learning in the model was informed by the costs of implementing PROMPT in every maternity unit in England. While the policy does not make a recommendation of

[37] Elliott, M., et al. Reason's accident causation model: application to adverse events in acute care. Contemporary Nurse, 2012. 43(1):22-28.

the type of learning a trust should implement, training which improves teamwork and communication has been demonstrated to reduce adverse obstetric events. Literature suggests that over 70% of sentinel events in obstetrics are associated with failures in teamwork and communication.[38]

278. Implementation of multidisciplinary simulation training at Southmead Hospital in Bristol led to a significant reduction in neonatal injury at birth with shoulder dystocia (relative risk 0.25, CI 0.11-0.57) comparing incidents in the three year period before the implementation of training to the three year period following training.[39] A statistically significant decrease in the incidence of HIE from 27.3 to 13.6 per 10,000 births was observed during a similar time period following implementation of training.[40] The results were not statistically significant for the moderate to severe HIE groups, reflecting the fact that these are more rare.

279. The program has also been implemented in other trusts in the UK and Australia with some improvements seen in clinical practice and outcomes.[41]

280. In the Canadian context, the implementation of MORE^{OB} in Alberta was associated with an 18% reduction in the incidence of severe neonatal morbidity. This was during a time where the province experienced unprecedented population growth and associated increase in births; the hospitals were not staffed to appropriately deal with the increased demand. Additionally, the implementation of MORE^{OB} was staggered, which led to an impact on the sample size in the case-control methodology. It is anticipated that the implementation of MORE^{OB} would have led to a higher level of harm reduction, if implementation did not overlap with the population boom, and that additional measures of harm reduction would have been statistically significant if not for the staggered implementation.[42]

281. The implementation of training in Bristol and Canada led to significant reductions in incidents which was observed within a three year period. There is additional evidence in support of positive outcomes elsewhere. Our central estimate for harm reduction is modelled at 25% recognising that there may be additional factors influencing the successful implementation PROMPT and MORE^{OB}.

Modelling litigation

Overview of litigation process

282. After an incident of CP/BD occurs, a notification can occur with NHSLA notified either directly from the trust who suspect a case may be brought or by a claimant lawyer after having vetted the case following contact from a family.

283. Following a notification, investigations are considered by both sides and a letter of intent to pursue a claim is submitted, followed by a claim being lodged (for cases where a case is brought).

284. There are four important aspects that are involved in the determination of a successful claim:

- There was a duty of care owed to the claimant
- There was a breach of this duty of care
- The breach of duty of care was the probable cause of the harm
- The extent of the harm caused by the breach of duty that was the probable cause of the harm

285. In the case of a successful claim, it is most common for a settlement to be reached without the need for the case to go to trial. Once a breach of duty has been established, a negotiation occurs between the defence and the claimant around the level of damages payable as it will depend on a number of factors including the severity of the injury, likely future prognosis and the extent of the support required.

---

[38] Guise, JM. And Segel, S. Teamwork in obstetric critical care. Best Practice Res Clin Obstet Gynaecol. 2008 Oct;22(5)937-51.

[39] Draycott T, et al. Improving neonatal outcome through practical shoulder dystocia training. Obstet Gynecol. 2008 Jul;112(1):14-20.

[40] Draycott, T., et al. Does training in obstetric emergencies improve neonatal outcome? BJOG. 2006 Feb;113(2):177-82,

[41] Shoushtarian, M *et al.* Impact of introducing Practical Obstetric Multi-Professional Training (PROMPT) into maternity units in Victoria, Australia. 2014

[42] Nguyen, X., et al. Outcomes of the introduction of the MORE^{OB} continuing education program in Alberta.J Obstet Gnaecol Can 2010;32(8):749-755.

Notifications

286. The number of cases which arise in a given year are modelled using NHSLA data between 2012-2015. Based on discussion with NHSLA, this period is considered best for forecasting future trends as litigation patterns in recent years are expected to more closely map on to future expectations.

287. Between the years 2012-2015 there was an average of 216.3 notifications per year of relevant CP/BD cases.[43] As the average time from incident to notification for such cases is around 3 years, it is assumed that this number of notifications occurs as a result of births from 2012. This is an approximation, but a reasonable one as birth rates varied over a range of only around 2% over the period. [44]The number of notifications per year is projected forwards using the ONS 2012 principal projection for the number of births in England.

Successfully litigated cases

288. From the number of notifications we would like to know the proportion that will proceed to become successfully litigated cases, as well as whether the successful litigation outcome includes periodical payments.

289. In order to calculate this, all cases closed from 2012-2015 are considered and the proportion of successful cases is taken as the probability that a notification becomes a successful litigation. Data indicates that this average is 59.5% with 69.2% of these including a PPO.[45] These project forwards in line with the number of notifications as the proportion is assumed to stay constant over time.

290. In addition to the number of successful cases, the size of the average award is also required to calculate associated costs with each successful case. Again using data of closed cases from 2012-2015, the average lump sum payment and average size of legal fees are calculated and displayed in the table below. Claims inflation of 9%, in line with GAD's handling of NHSLA data, is used to put all closed cases on the same basis in terms of price year.

Table 15: The average lump sum awarded and legal costs paid for successful PPO and non-PPO settlements. The lump sum for PPOs is informed by GAD analysis of NHSLA data as opposed to the direct analysis of NHSLA data undertaken in the other cases

	PPO	Non-PPO
Total lump sum (14/15 prices)	£2,250,000[46]	£880,000
Total legal costs (14/15 prices)	£510,000	£230,000
Number of cases	277	126

291. In addition to lump sums that are paid out in successful cases, those with PPOs have a yearly amount paid to them which is dependent upon their age. A total of 106 cases where PPO payments are still being made were chosen and the average amount being received at a given age is derived. The sample includes settlements from different years and is therefore inflated using claims inflation to get all cases to be on the same terms as a 2015 settlement. The resulting distribution of payments is displayed below.

[43] NHSLA notification case data 2012-2015.

[44] ONS 2012 birth projections

[45] NHSLA closed case data between 2012-2015

[46] GAD analysis of NHSLA data 2014/15: not the PPO analysis includes a larger set of cases than CP/BD obstetrics only. However, this is considered by NHSLA the best approximation to be used for modelling the pay-outs for such cases going forwards.

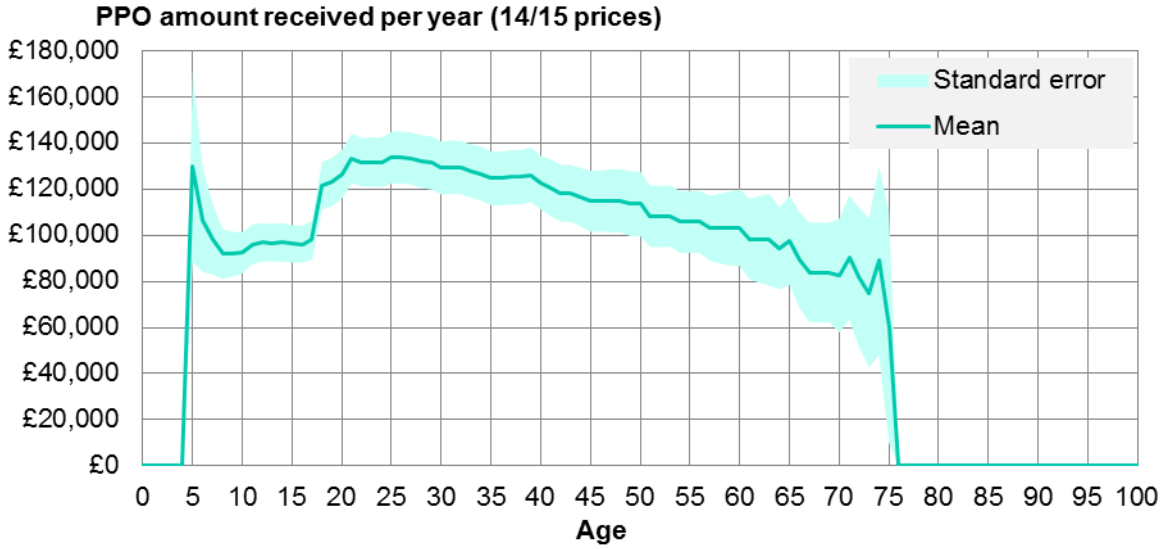


Figure 14: From a sample of 106 PPO CP/BD cases, the average PPO payment, given the recipient is alive or expected to be alive is plotted against age. The shaded region represents a single standard error on the mean for each age.

Incident to settlement time distribution

292. Payments and the size of awards are made at a distribution of times following the incident. When settlement occurs typically dictates when the lump sum payment is made, legal fees are paid and PPO payments begin. There are, on some occasions, interim payments before a final settlement is reached but a breach of duty has been acknowledged. In such cases, the final settlement may not be reached until later due to the harm not being fully manifest.

293. The graph below illustrates the proportion of the lump sum in an award that is paid against the proportion of time from incident to settlement for the set of cases closed from 2012-2015. The step-like nature of the data supports the modelling assumption that payment of lump sum can be considered to occur approximately at the settlement date.

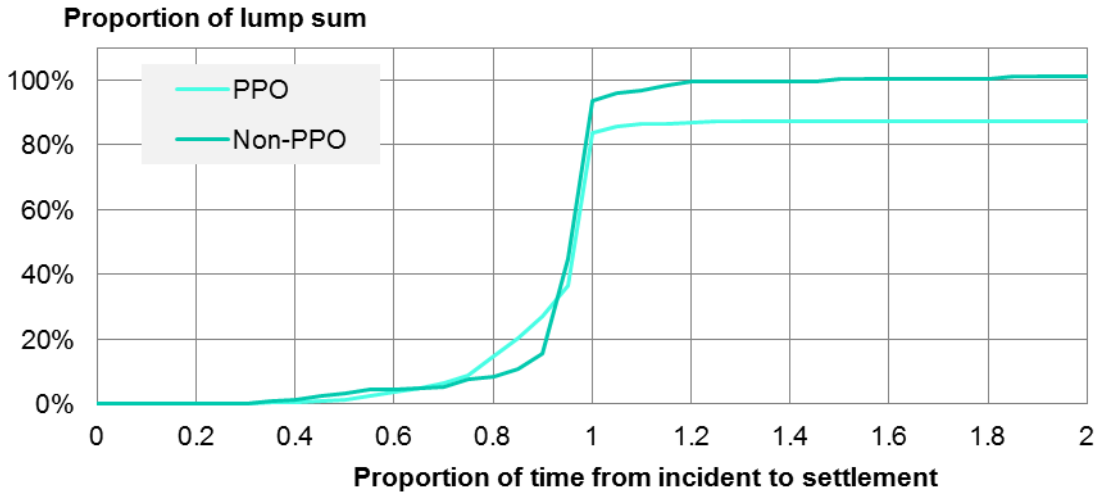


Figure 15: The proportion of lump sum paid as a proportion of time from incident to settlement. The graph indicates that typically lump sum payments are made around the time of settlement.

294. Following on from the assumption that the critical time is from incident to settlement, all closed cases from 2012-2015 are again considered in order to derive a distribution of incident to settlement. The distribution for both PPO and non-PPO cases is shown below.

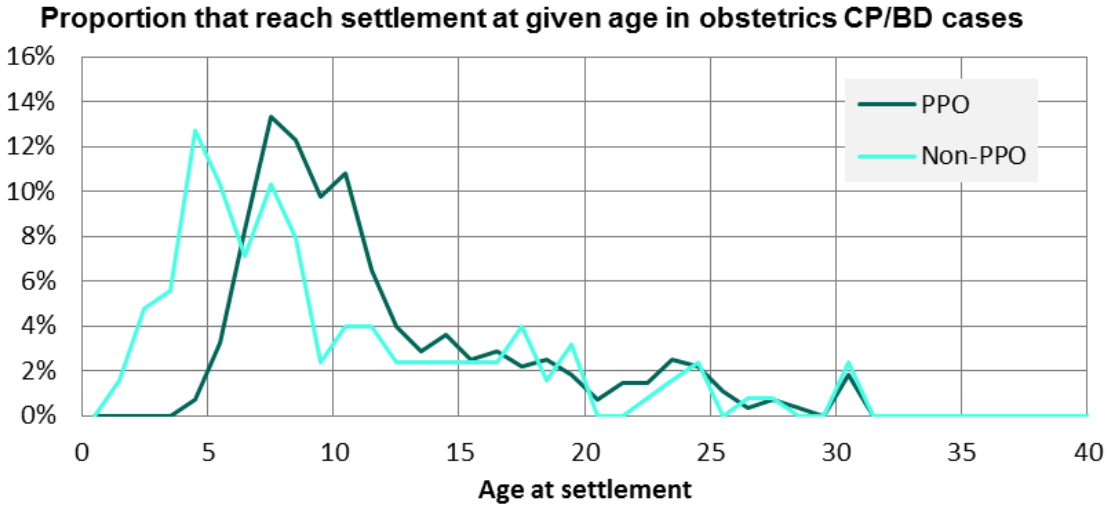


Figure 16: The distribution of time from birth to settlement in all closed cases from 2012-2015 broken down into PPO and non-PPO settlements.

295. Given the small sample size involved and similarity between the distributions, the time from incident to settlement is modelled as the same distribution for both PPO and non-PPO cases.

296. The following factors affect the time from incident to settlement:

- The time it takes to establish breach of duty
- The time for harm to become fully manifest
- The length of time before notification, which may be affected by harm manifestation and the knowledge of litigation as an option.

297. Given the nature of the above distributions, an approximately skewed normal distribution, a fit is performed by aligning the average and mean of the raw data with the log-normal distribution. Deriving a fit aids sensitivity analysis.

298. It is likely that there are underlying aspects of the incident to settlement process that results in such a distribution being derived, although those mechanisms are not considered in further detail here, but rather an argument is made that it is plausible that the distribution should follow this approximate functional form up to small perturbations of the mean and standard deviation which define a given instance of a log-normal distribution. A combined PPO and non-PPO distribution and log-normal fit are displayed in the graph below:

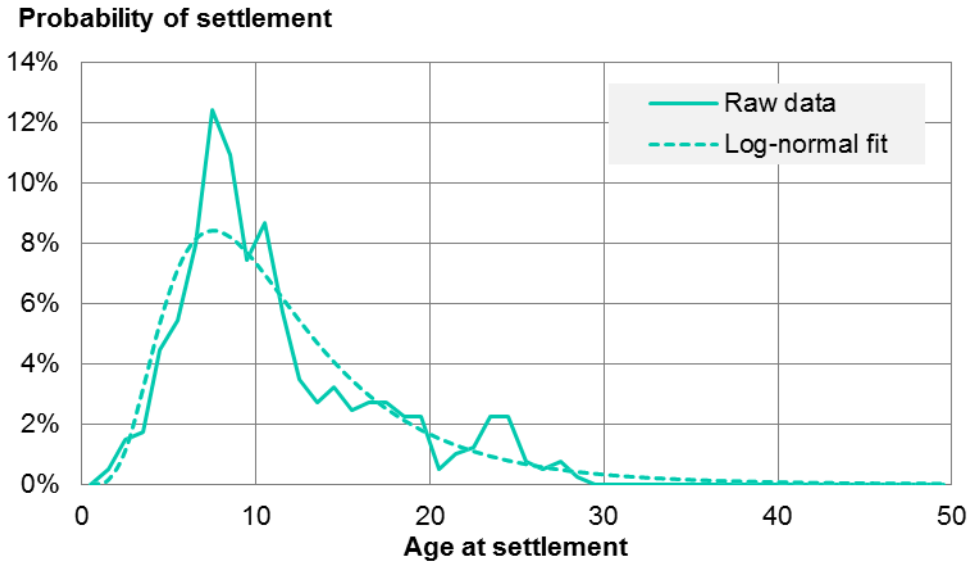


Figure 17: The log-normal fit used for the distribution of settlement at a particular age. The fit allows transformations, such as shifting the mean of the distribution, to be more easily applied compared to manipulating the raw data.

299. Using a χ^2 distribution to evaluate the quality of the fit, the log-normal fit has a p-value=10% and a reduced $\chi^2_{\text{red}} = 1.3$ which, when taken together, indicates a reasonable model fit. Analysis of results generated by the model show only marginal variation between using the distribution directly from the data compared with the log-normal fit, also providing evidence that the modelled distribution is a reasonable approach.

300. In addition to using the log-normal fit of the average incident to settlement time, two other distributions are also used in order to model the timing of payments under the RRR compensation package. These distributions involve shifting the mean of the log-normal distribution earlier by one and two years, with one year providing the central timing distribution. In changing the mean of a log-normal distribution alone, the proportion of cases that are settled early is also affected. Given the requirement for harm manifestation in order to determine both eligibility and causation, the standard deviation of the distribution is manipulated in order to maintain the same proportion of cases receiving payments before the age of 5. This is an age that has been informed through discussions with medical and legal experts regarding harm manifestation.

301. The manipulated distributions are shown below alongside the original fitted distribution.

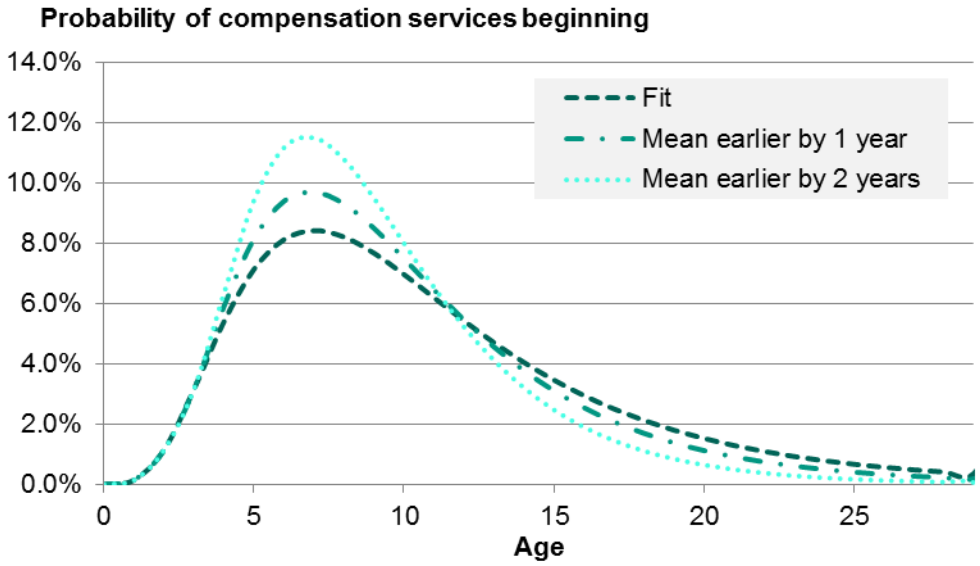


Figure 18: Log-normal distributions for when compensation package services equivalent to a litigation award would begin. The central distribution is a year earlier, with upper and lower ranges

302. A further key assumption is the independence of settlement award and the time from incident to settlement. This assumption allows the cohort to simply be split up by time from incident to settlement and average awards paid out at those times as opposed to also considering an additional distribution for awards as a function of settlement time.

303. In the below graph, for all relevant cases closed from 2012-2015, the total size of award is plotted against time from incident to settlement. The corresponding R-squared for the plot is 0.015, providing strong support for treating these variables as independent.

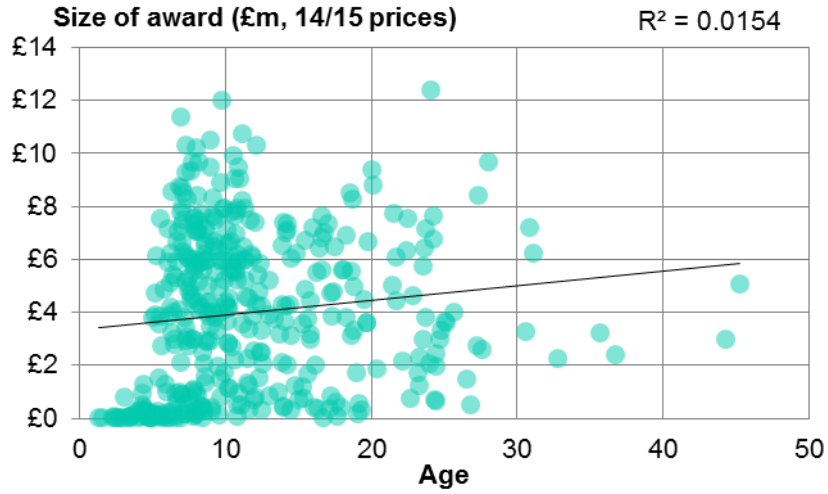


Figure 19: Size of award is plotted against age at which settlement is reached. Overall there is very little correlation between the size of award and the age at which settlement is reached, with an r^2=0.0154 and corresponding correlation coefficient of roughly r=0.12.

Modelling RRR Compensation

Overview of modelling options

304. The alternative compensation package offered under Stage Two can be modelled with two distinct approaches:

- A bottom-up approach with direct consideration of the services that are needed by those who would be eligible for the scheme.
- A top-down approach with consideration for the size of the current litigation award and relating payments under a new compensation scheme to this baseline.

305. In deciding upon the appropriate modelling approach, the primary factor is the availability and reliability of information at hand. The bottom-up approach is more closely aligned to how the compensation would be delivered but suffers from a lack of greater data around the needs of different severities of CP/BD in order for families to feel pursuit of litigation was not necessary.

306. The available data around litigation awards is currently greater than the level of provision under the universal state offer and hence a top-down approach is more appropriate for modelling at this stage.

307. This is justifiable on the basis that the processes underpinning the way timings of payments occur will be similar under the compensation scheme to a successful litigation award. Once breach of duty is established, interim payments and services will be provided before it is clear the extent of the harm that has been incurred. Roughly in line with when settlements are made, further compensation guarantees could be made.

308. An initial bottom-up approach indicated that the level of the universal state award is around 50-60% of an average litigation award, while a larger package aimed at fully meeting the needs of affected families could be around 80-90% of a litigation award. These findings support the top-down approach taken in the modelling, and is an area for further development in support of the policy parameters chosen.

Description of modelling approach

309. Implementing the top-down, litigation based model has the following key elements, that have both size and timing properties:

- Lump sums
- Ongoing payments
- Any earlier damages lump sum payments

310. The key levers for manipulating these with respect to the litigation award are consequently:

- The overall size of compensation award relative to the litigation award
- Proportion of any lump sum that can be moved into ongoing payments
- The inclusion of any earlier damages lump sum that can be subtracted from the lump sum payment made in accordance with the time from incident to settlement distribution.
- Manipulation of the time from incident to settlement (payment) distribution

311. The central assumption for the size of the compensation award is 90% of the litigation route. This number is arrived at through considering the reduction that can be made through alternative provision of services to meet reasonable needs. It also accounts for the advantage for families being able to access compensation without having to pursue the adversarial legal route. Finally, in order to pursue litigation with an uncertain outcome, families may lose access to services under the RRR package. At 90% the expected pay-out from this gamble is negative, suggesting, where additional information regarding the likelihood of a successful litigation, the economically rational choice would to be to retain the 90% compensation package.

312. Sensitivity around this level is accounted for in high and low scenarios of 100% and 80% respectively in the main body as the figure is uncertain and will be influenced by further evidence and responses to the consultation.

313. The first of three of the levers discussed above are illustrated in the diagram below to show visually how the size of the award changes under each transformation to reach the central assumption used in the RRR package.

314. The compensation package under the litigation award can be represented in terms of lump sum and ongoing payment amounts.

315. The area in the chart below can be used to represent the size of the award. The height of each block is used to represent the length of time over which it is paid. The average size of a PPO case is used in the relative sizes below (around £6.25m total size with £2.25m lump sum).

316. The central option for the RRR compensation package is shown as a result of three transformations (moving a proportion of the lump sum to PPOs, reducing the whole package size by 10% and adding in an early damages payment from the lump sum).

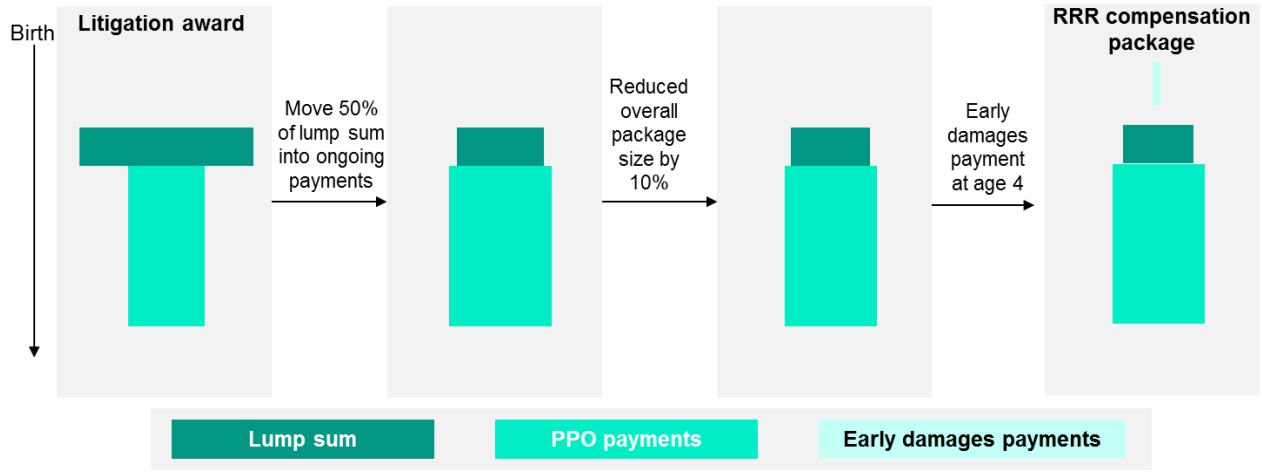


Figure 20: A graphical depiction of how the litigation award is adjusted to arrive at the RRR compensation package. The area of each bar is proportional to its relative size in present value terms, while the vertical axis is the time from birth. The lump sum is shown to reduce by 50% with the amount being moved into periodical payments. The overall size is reduced by 10%. Finally, a small proportion (£100k out of £1.125m) is moved into an early damages payment closer to the time of the incident.

317. The central assumption of the modelling uses the same time distribution of incident to settlement but with the mean shifted to be one year earlier. This is driven by the understanding that settlements/payments are predominantly made when services are needed, with interim payments being relatively small and close to settlement date. Sensitivity analysis where the average length of

time in the distribution is manipulated to be both a total of 2 years longer and 0 years longer is included and the distributions are shown above.

318. The central assumption for proportion of lump sum which can be moved for cases uses 50% as the proportion. This is informed by the table below indicating the current structure of a set of 18 randomly chosen PPO settlements. Discussions with NHSLA and other stakeholders indicate this is an appropriate level. This is in line with the change in mechanism of compensation under RRR where the assessment of damages is not a 'once and for all' process and allows for the assessment reviews.

319. The shifting of the lump sum to ongoing payments in the average of these 18 cases is shown below.

Table 16: The table shows the average amounts payable under each head of loss across a sample of 18 brain injury cases and whether the payment is currently allowed for as a lump sum or PPO. We highlight categories where lump sums can potentially be moved to periodical payments, providing support for the proportionate reduction of lump sum payment by 50% under the central option of the RRR compensation award.

Head of Loss	Court Award Sample (18 sample cases)			RRR	
	Amount	Lump/PPO	% of package	Lump/PPO	% of package
General damages for pain, suffering and loss of amenity	£236,000	Lump	4%	Lump	4%
Past loss	£306,000	Lump	5%	PPO	5%
Loss of earnings	£326,000	PPO	5%	PPO	5%
Treatment and therapies	£209,000	PPO	3%	PPO	3%
Travel and transport	£156,000	PPO	2%	PPO	2%
Aids and equipment	£228,000	Lump	4%	PPO	4%
Education	£31,000	Lump	0%	PPO	0%
Accommodation	£696,000	Lump	11%	Lump	11%
IT	£133,000	Lump	2%	PPO	2%
Holidays	£132,000	PPO	2%	PPO	2%
Deputyship	£191,000	PPO	3%	PPO	3%
Care, health and case management	£3,740,000	PPO	58%	PPO	58%
Miscellaneous	£52,000	PPO	1%	PPO	1%
Total / Number of Heads of Loss paid as lump sum	**£6,431,000**				

	Court award sample	RRR	Percentage reduction in RRR lump sum with respect to court award
Proportion of award that is lump sum	25%	14%	43%

320. Sensitivity analysis around this assumption is provided with bounds of 25% and 75%.

321. Finally, assuming early investigations are able to establish any breach of duty earlier, as soon as any harm becomes manifest, it is appropriate that earlier compensation of general damages is made to compensate families for the incident. As a central assumption, £50,000 is proposed in non-PPO type cases and £100,000 for PPO cases at the age of 4, an age by which any initial harm would be expected to be typically apparent. These amounts are less than what may be expected as the final amount for general damages payments because additional harm may become apparent as the child develops.

Professional support network

Overview

322. In addition to the payments and services provided through the compensation award which are considered similar to those in a litigation award, part of Stage Two of the RRR policy involves

greater immediate and continued state support for families through a 'support network'. The main elements of the support network are the following:

- **Case manager:** An essential part of arriving at the quanta under each head of loss in a successful litigation is the case manager who has an awareness of the services and cost of these services. As such, in being able to provide an RRR compensation package that effectively meets people's needs, each family having access to a case manager who can quantify payments necessary or arrange for services to be provided is essential.
- **Assessments:** Yearly assessments to review the level of need that families have to ensure that services are being provided and needs are being met. The assessment officer would be expected to strongly interact with the case manager.
- **Counselling:** Regular counselling sessions would be offered to families following the incident and these would be ongoing for the duration of the person's childhood. There would be a greater proportion available at particular times, and again, the case manager will play a significant role in establishing that this service is available as and when necessary.
- **Legal advice:** A provision of £5,000 is made from the time of incident for impartial legal advice for families. Senior legal advice can be obtained at around £200 per hour, meaning this provides around 25 hours of legal advice. In comparison to the 7 hours for determination of eligibility following the investigation of an incident, this provides a significant additional service to families.

Costs

323. Due to the complicated and individual nature of each case, equivalent service provision for the support network is assumed over the first 21 years of each incident. This is likely an overestimate of the level of support needed, but given the RRR package aims to deliver a "Best Practice" package, this seems justified and the costs represent a small fraction of the overall damages.
324. Loughborough report £2600 per year case management for severity 5, multiplier of 1.5 for 'Best practice'. This remains the same for every year until 21.
325. Counselling of 12 incidents per year, costing £122 per session (PSSRU unit costs).
326. The Loughborough report indicates that a yearly cost of around £998 is spent on assessing a family's needs at 4 time points over the year. This is possibly an overestimate of the amount to attribute to this area.

Inflation factors

327. There are several elements to inflation that are important to consider in the modelling approach. There are three types of distinct inflationary rates taken account of in the model.
328. **Whole economy inflation:** Inflation of entire economy taken to rise with a GDP deflator of approximately 2% per year[47].
329. **Health and social care price inflation:** As the health and social care sector typically relies upon people delivering its outcomes via people providing care, there has been shown to be less scope for efficiency improvements compared to other sectors. In litigation settlements, above inflation changes in prices is accounted for by including a stipulation that ongoing payments should increase either with RPI or ASHE 6115 (care worker earnings) inflation. In GAD's analysis of the ongoing liabilities of NHSLA finances, ASHE 6115 inflation at 4.2% was used for evaluating expected future payments and the same inflationary factor was used in this model where prices could be expected to rise with in line with care costs. This is accounted for in the modelling by allowing a relative price increase of $\frac{1+4.2\%}{1+2\%} - 1 \approx 2.2\%$ for costs associated with health and care.
330. **Claims inflation:** This type of inflation describes the increase in the size of litigation awards over time. In GAD's analysis of NHSLA finances, the size of awards has been observed to increase at an average of 9% per annum for 2005-2015. Claims inflation includes health and social care cost

[47] Average GDP deflator over past 20 years is around 2%, and in the range 0.3% to 4.1%.

inflation, but as discussed above this is only around 4.2% in cash terms, leaving around 4-5% additional inflation unexplained. Engagement with stakeholders and analysis of life expectancy over the period indicates that the likely source of inflation is an increased expectation of care and provision of damages from precedents set in trials where judges have accepted arguments that extend the established boundaries of what is considered reasonable to meet the needs of families. Such judgements further impact future negotiated settlements.

331. There is uncertainty around whether this level of claims can be expected to continue in the future – it may be expected rather that a plateau in the acceptable level of award will be reached. The central assumption assumes an above health and social care cost of litigation and compensation package inflation of 2%, rather than the 4-5% suggested from past data. Sensitivity for both 0% and 4% above health and social care cost inflation is provided in sensitivity analysis.

332. A modelling effect known as catch-up inflation arises from differential treatment of litigation and RRR compensation awards. Catch-up inflation can be understood by considering two people, person A and person B. Both have the same severity of CP/BD attributable to the breach of duty that occurred. However, person A reaches a settlement two years before person B and therefore has the size of their litigation award fixed two years earlier. Given the discussion of claims inflation above, the size of the award person A receives is smaller by two years of claims inflation. With the compensation award considered from the time of incident compared to a litigation award which is provided an average of 11 years later (at settlement date), this means that the overall compensation package is on average also smaller by 11 years of claims inflation if no additional claims inflation is applied to the RRR compensation award over this average period. The effect is considered a valid restriction on the size of the package as the level of the services received and damages provided in an alternative litigation will not be known. This effect is removed if claims inflation is set to 0% in the modelling and such a scenario is considered in sensitivity analysis.

Discount factors

333. Throughout the analysis, discount factors in line with the Green Book[48] are used and applied to real state spending in fixed 14/15 prices in order to derive any discounted spending. NPV is calculated from 2016/17 as the present year.

334. The NHSLA's provision figure (the balance sheet value of known and likely future claims at the accounting date) is calculated using the discount rate for general provisions as set out in the Public Expenditure System (PES) notice from HM Treasury. GAD uses this discount rate to convert likely future payments (e.g. future lump sums or annual PPs payment streams) into a NPV figure. However, as the approach taken in the modelling here makes use of up-front cash sums in successfully litigated cases, as well as specific cash amounts in fixed prices for ongoing payments, combined with the fact that state spending occurs on a 'pay as you go' basis, there is no issue concerning any discrepancy between the two methods of discounting. The PES method is concerned with calculating provisions and therefore is ultimately linked to return on investment, while the Green Book methodology takes a different approach.

The figures in this IA are based on the previous personal injury discount rate of 2.5%. On 27th Feb 2017, the Lord Chancellor announced a change to the discount rate to minus 0.75%. Although the change in rate would affect some elements of the Impact Assessment, nonetheless the methodology used and the assumptions serve to illustrate the likely impact of the proposed policy, and we do not think this change in discount rate would alter its broad conclusions and recommendations. Any final IA that is produced will take into account changes in discount rate as appropriate.

[48] "The Green Book: Appraisal and Evaluation in Central Government",
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/220541/green_book_complete.pdf

Universal state offer

335. To calculate the cost profile for the universal state offer for those with CP/BD that do not receive a litigation award, a bottom-up approach is taken. An assumption is made that all cases may be considered with Cerebral Palsy needs alone, and the level of need is related to the Gross Motor Function Classification System (GMFCS), which classes motor impairment on a scale of 1-5. The services available for those with a GMFCS of 5 are considered and the costs of the care and health services that are offered at each age are calculated based upon primary research materials.[49]

336. The cost profile is predominantly driven by health and social care costs at around 67% of the lifetime award and treatments making up a further 22% of the award.

337. To convert the Severity 5 case to an 'average' case, 100% of the cost profile is assumed when GMFCS is 5, 66% when GMFCS is 4 and 33% where GMFCS is 3. A weighted average is then taken over the population prevalence of each severity[50] to generate an average profile, displayed in the graph below. This approximation is necessary as additional data on the expected amount received by groups with lower severity is not currently available but is an area where the evidence base is looking to be expanded in the final policy design.

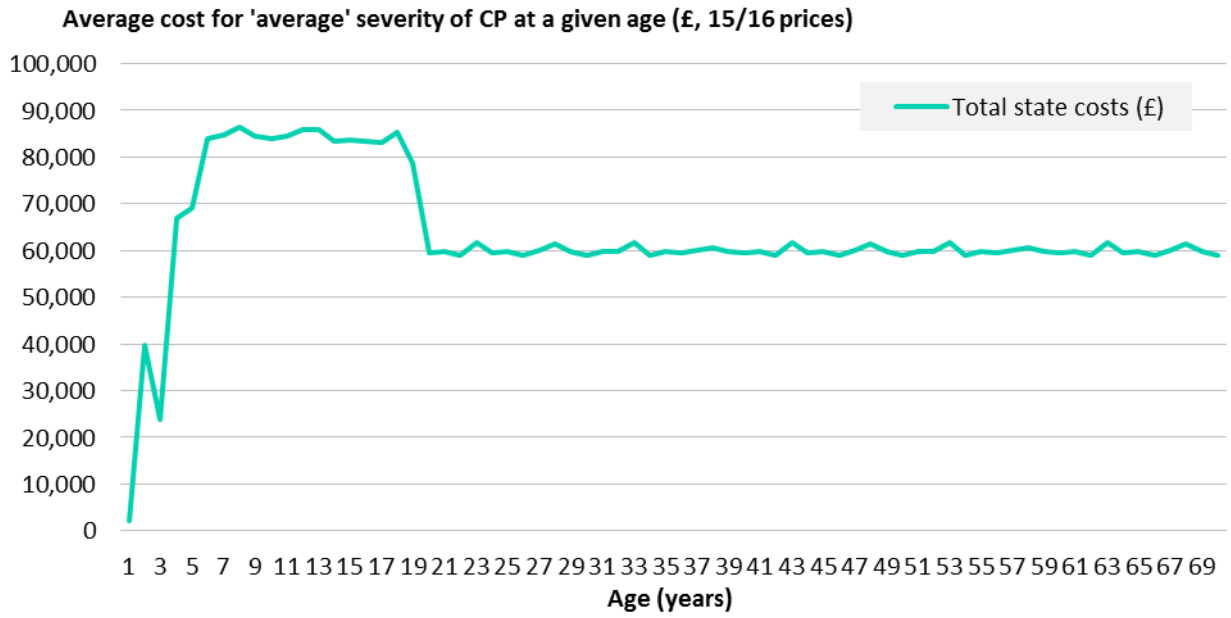


Figure 21: The cost profile at a given age for a person with an average severity of CP. NHS, social care and other costs are derived from primary research materials for the costs in the most severe cases. Lesser severities of CP have a reduction factor applied and the average is derived from considering population-level prevalence of each severity.

Cohort modelling and survival curves

338. For each incident, there are five possible broad classifiers that determine the costs over the person's lifetime. These are:

- Successful litigation with lump sum only;
- Successful litigation with lump sum and PPO;
- RRR compensated (lump sum only if they had litigated);
- RRR compensated (lump sum and PPO if they had litigated); and
- Non-compensated cases who only have access to the universal state offer.

[49] "Calculating costs of Children's Continuing Care", Holmes et al. ('Loughborough report') and PSSRU unit cost handbook 2014/15

[50] Leigh et al. 2014: "The incidence and implications of cerebral palsy following potentially avoidable obstetric complications: a preliminary burden of disease study"

339. Each year, the number of incidents is split over these groups according to the probabilities derived from the data and assumptions around uptake and total eligible numbers. Each cohort then depletes in size according to survival probabilities that are assigned to each group.[51] All compensated groups are assumed to be of a greater severity (GMFCS 3-5) while the non-compensated group is assumed to be of average severity (GMFCS 1-5), with these severities used to determine the survival probability curve at a given age.

340. The below diagram illustrates the modelling process, splitting an incident from a particular cohort of births (a specific year) into outcomes that occur with different time lags and are ultimately linked to different payment timelines.

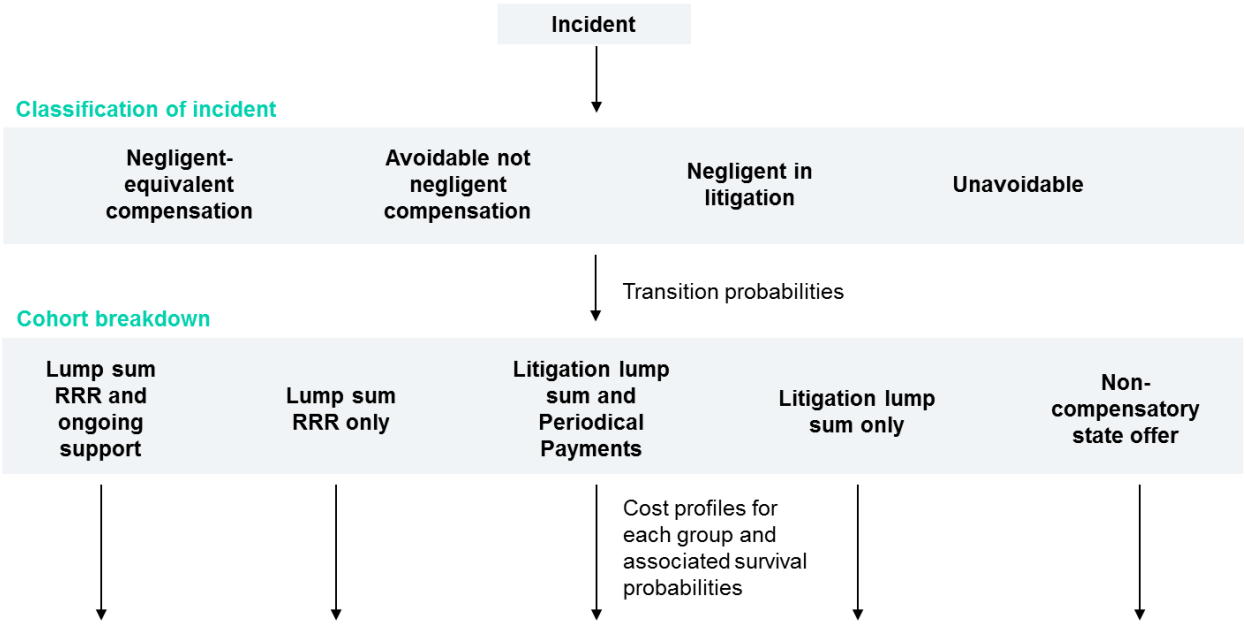


Figure 22: An illustration of how a cohort of incidents translates into different groups which have their own associated cost profiles and survival probabilities.

[51] Leigh et al. 2014: "The incidence and implications of cerebral palsy following potentially avoidable obstetric complications: a preliminary burden of disease study"

Annex B: Glossary of terms

- **ALB** – Arm's Length Body of the Department of Health.
- **ASHE 6115 index –** Inflationary index based on the average earnings increase for health and social care workers.
- **BadgerNet Maternity Service –** The BadgerNet Maternity Service allows for an end-to-end electronic record of all aspects of maternity care.
- **Brachial Plexus Injury –** damage to the
- **Brain hypothermia –** the induced state through cooling of a neonate's brain as a treatment for HIE.
- **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.
- **Clinical Negligence Scheme for Trusts (CNST)** – The CNST scheme indemnifies members for clinical negligence claims.
- **Cerebral Palsy/Brain Damage (CP/BD)** – the collective types of birth injury that will be potentially compensated under such a scheme.
- **Counterfactual –** the case used to represent what has not happened in order to consider the factual against.
- **Damages** - This is the value of the claim, as agreed with the parties, or valued by the court, if no agreement is possible. It is the financial compensation the claimant receives for the injuries and losses suffered as a result of the negligent treatment.
- **Defendant** – The party against whom a claim is made, usually an NHS Trust or GP in clinical negligence claims.
- **DH** – Department of Health.
- **Early Neonatal death (END) –** death within first 7 days of life.
- **EBC –** Each Baby Counts, the RCOG maternity quality improvement programme.
- **Evidence for Policy and Practice Information and Coordinating Centre (EPPI-Centre) –** research centre dedicated to providing evidence to inform policy.
- **Factual –** the expected future
- **Full-term –** is used to describe births that occur on or after 37 weeks.
- **GMFCS --** Gross Motor Function Classification System, which characterises the level of motor impairment in those with cerebral palsy or brain damage.
- **Head of loss –** the categories of damages that comprise a litigation award. Includes categories such as education, care and case management, treatments, accommodation among others.
- **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:
    - 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.

    - 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.
- **Neonatal encephalopathy –** abnormal neurological function in newborns.
- **NHSLA** – National Health Service Litigation Authority
- **Notification –** 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.
- **RCOG** – Royal College of Obstetricians and Gynaecologists
- **RRR –** Rapid Resolution and Redress scheme.
- **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