Title: Coronial investigations of stillbirths IA No: MoJ030/2019 RPC reference Number: N/A Lead department or agency: Ministry of Justice (MoJ) Other departments or agencies: Department of Health and Social Care (DHSC)	Impact Assessment (IA) Date: 20/02/2019 Stage: Consultation Source of intervention: Domestic Type of measure: Primary legislation Contact for enquiries: general.queries@justice.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: N/A

Cost of Preferred (or more likely) Option				
Total Net Present Value **-£152m** (Valued at opportunity cost and not including unquantified costs and benefits)	**Business Net Present Value** **N/A**	**Net cost to business per year** (EANCB on 2014 prices) **N/A**	**In scope of One-In, Three-Out?** **N/A**	**Measure qualifies as Not a regulatory provision**

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

In 2016, there were 3,112 stillbirths (babies delivered ≥ 24^{+0} weeks of pregnancy who did not at any time breathe or show any other signs of life) in England and Wales – a rate of 4.4 per 1,000 total births. Whilst the annual rate of stillbirths has been decreasing since the 1980s and is at an historically low level, England and Wales lag behind some other comparable countries whose stillbirth rates are lower and have been declining faster.

The stillbirth of a baby is a distressing experience for parents and families. At such a difficult time, we recognise that bereaved parents may want to find out why their baby was not born alive and to know that where lessons can be learned changes in clinical care are made.

At present, the causes of stillbirth are reviewed via investigations undertaken or commissioned by local NHS providers and/or commissioners of care. Since April 2018, the Healthcare Safety Investigation Branch (HSIB) has also begun to investigate certain intrapartum stillbirths. HSIB is operationally independent of the NHS and funded by the Department for Health and Social Care (DHSC) via NHS Improvement. Whilst parents are made aware of and consulted during these reviews and will receive a report of the outcome, there has been criticism that they are insufficiently independent, that the process lacks transparency and there is a lack of confidence that lessons are learned and practice improvements implemented.

In England and Wales coroners have no jurisdiction to investigate deaths where a baby did not have life independent of the mother. A system of stillbirth case investigations that is wholly independent of the NHS is required to deliver trusted accounts to parents of why their baby was stillborn and to contribute to system-wide learning and improvement for all maternity service providers.

What are the policy objectives and the intended effects?

The objectives are to: 1) provide an independent assessment of the facts and causes of stillbirths; 2) provide for transparent investigations, and; 3) contribute to system-wide learning. The intended effect is that parents who have lost a baby to stillbirth would gain reassurance from an independent account of why their baby was stillborn and that findings and recommendations inform improvements to maternity care leading to further reductions in stillbirth rates.

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

- **Option 0**: Base case (do nothing)
- **Option 1**: To legislate for coronial investigations in all cases of full and post-term stillbirth, providing an account of the stillbirth and identifying any required improvements to maternity care and safety.

Option 1 is the preferred option as it best meets the Government's policy objectives.

Will the policy be reviewed? Yes, this policy will be reviewed in light of consultation responses

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** **N/A**	**< 20** **N/A**	**Small** **N/A**	**Medium** **N/A**	**Large** **N/A**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

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 25 March 2019

Summary: Analysis & Evidence — Policy Option 1

Description: Bring forward legislation to introduce coronial investigations of all cases of full- and post-term stillbirth (i.e. all stillbirths that take place on or from 37^{+0} weeks of gestation) in England and Wales.

FULL ECONOMIC ASSESSMENT

Price Base Year 2016/17	PV Base Year 2016/17	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: - £152m** (Valued at opportunity cost and not including unquantified costs and benefits)

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate	Not quantified		£16.4m	**£152m**

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

-Costs to local authorities, funded via the DHSC, for a new cohort of coronial investigations are estimated to be around £3.7m in year 1 (opportunity cost of £14.7m in year 1).
-Costs to maternity service providers of their staff participating in coronial investigations of stillbirths are estimated to be up to £1.5m in year 1 (opportunity cost of £6m in year 1).

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

- Some parents may object to or be distressed by the coroner's investigation and/or the post-mortem examinations that are requested as part of that investigation.
- Coronial investigations may lead to increased public disclosure of the circumstances surrounding stillbirths. This may initially encourage more clinical negligence claims against the NHS to be made than would otherwise be the case.
- There could be costs to providers of maternity services of implementing improvement actions generated from the coronial investigations.
-These proposals would increase the workload of perinatal and paediatric pathologists and there is a national shortage of consultants with this specialist training. Work would thus be necessary to address the expected shortfall in workforce capacity and review funding arrangements for coronial post-mortems to ensure that there is sufficient incentive for pathologists to undertake a significant increase in the volume of post-mortems commissioned from coroners.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate	Not Quantified		Not quantified	**Not quantified**

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

Given a lack of evidence, it has not been possible to quantify benefits.

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

-The primary intended benefit would be fewer stillbirths (and, secondarily, other adverse outcomes such as neonatal deaths) in the future brought about by lessons learned through coronial investigations and subsequent improvements in clinical practice.
- Additionally, bereaved families may benefit from an independent account of how it was that their baby was stillborn, potentially helping them through the grieving process and contributing resilience against developing some mental health problems. It could also help to inform care in future pregnancies and contribute to wider confidence in maternity services.

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

- Costs are estimated assuming the volume of stillbirths follows its current trend of decreasing year on year by an average of 5%.
- It is assumed that all investigations would require a post-mortem examination and an inquest.
- Opportunity costs are calculated on the basis that funding will come from health budgets
-There is a risk that Option 1 would significantly increase the burden on perinatal and paediatric pathologists. There is already a shortage of pathologists qualified to carry out post-mortem examinations of stillbirths.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs:	**Benefits:**	**Net:**	No	Not a regulatory provision

Evidence Base

A. Background

1. In 2016, there were 3,112 stillbirths (babies born at ≥ 24^{+0} weeks of pregnancy who did not at any time breathe or show any other signs of life) in England and Wales – a rate of 4.4 per 1,000 total births - 936 of which occurred at or post term (≥ 37^{+0} weeks' gestation).[1] Whilst the annual stillbirth rate has been decreasing since the 1980s and is at an historically low level, England and Wales lag behind some other comparable countries whose stillbirth rates are lower and have been falling faster.[2]

2. The stillbirth of a baby is a distressing experience for parents and families. At such a difficult time, we recognise that bereaved parents want to find out why their baby was not born alive. It is also crucial for maternity service providers to understand the causes, especially if a stillbirth was avoidable, so that improvements in clinical care can be made.

3. At present, the causes of stillbirths are reviewed via investigations undertaken or commissioned by local NHS providers and/or commissioners of care. Since April 2018, the Healthcare Safety Investigations Branch (HSIB) has also begun to investigate certain intrapartum stillbirths i.e. babies thought to be alive at the start of labour but who are born showing no signs of life at a gestational age of ≥37^{+0} weeks. However, in England and Wales, coroners cannot investigate cases where the baby was not born alive. If there is any doubt whether a baby was born alive or not, a coroner can undertake preliminary inquiries as to whether there is a duty to investigate but they have no powers to investigate further if they conclude that the baby was stillborn.

4. In October 2015, the then Secretary of State for Health set a national ambition to halve the 2010 rates of stillbirths, neonatal and maternal deaths and brain injuries that occur during or soon after birth by 2030. In November 2017, he published Safer Maternity Care – Progress and Next Steps, the Government's refreshed Maternity Safety Strategy, and brought forward the target date to achieve the National Maternity Safety Ambition from 2030 to 2025.

5. As part of this announcement, the Department of Health and Social Care (DHSC) committed to work with the Ministry of Justice (MoJ) to develop proposals for coroners to investigate stillbirths:

   As part of the work to improve the investigation of and learning from stillbirths and neonatal deaths, the Government will consider with interested parties how coroners could carry out an investigation into those babies who are stillborn at term, i.e. at 37 weeks gestation and over. In doing so, we will engage with Welsh colleagues on how this would impact the Devolved Administration in Wales.

   Safer Maternity Care – Progress and Next Steps, November 2017[3]

6. Improvements in local investigations and the introduction of HSIB maternity investigations alongside initiatives such as the Perinatal Mortality Review Tool have already led to significant progress in systematising and streamlining learning about the causes of stillbirths. However, despite HSIB's operational independence from the NHS and its explicit learning focus, some bereaved parents, charities and other interested parties remain concerned that existing reviews lack the degree of independence and transparency that could be realised through the independent judicial office of the coroner. The options described in this Impact Assessment (IA) look at the ways in which this could be achieved.

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[1] https://www.ons.gov.uk/file?uri=/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/childmortalitystatisticschildhoodinfantandperinatalchildhoodinfantandperinatalmortalityinenglandandwales/2016/cms2016corrected.xls

[2] Lawn JE, et al. Stillbirths: rates, risk factors, and acceleration towards 2030. The Lancet 2016;387(10018): 587–603

[3] Available at: https://www.gov.uk/government/publications/safer-maternity-care-progress-and-next-steps

B. Policy Rationale and Objectives

Economic rationale

7. The conventional economic approaches to Government intervention are based on efficiency or equity arguments. Governments may consider intervening if there are strong enough failures in the way markets operate (e.g. monopolies overcharging consumers) or there are strong enough failures in existing Government interventions (e.g. waste generated by misdirected rules) where the proposed new interventions avoid creating a further set of disproportionate costs and distortions. The Government may also intervene for equity (fairness) and distributional reasons (e.g. to reallocate goods and services to more needy groups in society).

8. The options considered in this IA are, however, primarily justified on the grounds of providing better information to bereaved parents about how their baby came to be stillborn and to health care providers about changes to clinical practice that could prevent future stillbirths.

Policy rationale

9. The associated policy objectives are to provide for an independent assessment of the facts and causes of the stillbirth being investigated as well as for a transparent investigatory process, and to contribute to system-wide learning about the causes of stillbirths and the circumstances leading up to them, with a view to contributing to the wider health-system efforts being made to improve maternity outcomes and reduce rates of stillbirth.

10. In recent years, investigations undertaken by local health services into serious incidents have become increasingly transparent and supported by an ever-stronger range of procedural safeguards. However, national review programmes such as the MBRRACE-UK Perinatal Mortality and Morbidity Confidential Enquiries[4] and the Royal College of Obstetricians and Gynaecologists' Each Baby Counts programme[5] have identified that there is scope to improve the quality of investigations into the circumstances that have led to avoidable stillbirths occurring.

11. Furthermore, whilst significant progress has been made in systematising and streamlining learning about the causes of all stillbirths, further work is required to improve the learning that can be made from each stillbirth so that, where changes to maternity care can be made to prevent similar avoidable stillbirths, these are disseminated and adopted by all maternity service providers

12. From April 2019, medical examiners will be introduced in England and Wales to scrutinise the cause of death recorded on the Medical Certificate of Cause of Death (MCCD). The ambition is that, in time, all non-coronial deaths will be reviewed by a medical examiner. The new system will provide a service to the bereaved, increasing transparency and offering them the opportunity to raise concerns. As currently proposed however, such independent scrutiny will not extend to stillbirths.

C. Affected stakeholder groups, organisations and sectors

13. The following groups are expected to be most affected by the options assessed in this IA. In the costs and benefits section (section E) if a particular group is considered to be unaffected they have not been included. A brief description is included below outlining the role of each group in this area:

- **Parents of stillborn babies** – would be expected to benefit from an independent account of how their baby came to be stillborn but would not have a choice about whether the coroner should investigate and would no longer be required to consent to a post-mortem examination.

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[4] Draper ES, Kurinczuk JJ, Kenyon S (Eds.) on behalf of MBRRACE-UK. MBRRACE-UK 2017 Perinatal Confidential Enquiry: Term, singleton, intrapartum stillbirth and intrapartum-related neonatal death. The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester: Leicester, 2017.

[5] Royal College of Obstetricians and Gynaecologists (2017), *Each Baby Counts – 2015 full report*

- **Coroners, their officers and staff** – introducing coronial jurisdiction for term stillbirths would increase coroners' workloads. Currently, coroners can make preliminary inquiries as to whether there is a duty to investigate if there is any doubt whether a baby was born alive or not but they have no powers to investigate if they conclude that the baby was stillborn.

- **The Chief Coroner** – responsible for organising training for coroners, their officers and other staff, and providing guidance to them. If coronial investigations of stillbirths were introduced, additional training will be required.

- **Local Authorities (LAs)** – coroner services are funded and resourced by LAs therefore any increase in the coroners' workload would impact LAs.

- **The General Register Office (GRO) and local registrars (for births and deaths)** – responsible for the registration of all stillbirths. Introducing coronial jurisdiction for all stillbirths at or post-term (≥ 37^{+0} weeks gestation) might cause delays to registration and require minor changes to the process of registration.

- **The Office for National Statistics (ONS)** – responsible for publishing official statistics on stillbirths. Any delays in registration would make it difficult to release stillbirth statistics at current publication schedules. ONS would however benefit from higher quality data on causes of stillbirths.

- **NHS pathology services** – an additional demand for perinatal and paediatric pathologists, plus any associated impacts on national bodies such as Health Education England, NHS England and their equivalents in Wales to ensure the required workforce is in place.

- **Providers of maternity services and staff** - including obstetricians, midwives and others requested to provide evidence and/or to attend an inquest, and those responsible for interpreting and acting on the additional learning that is expected to derive from the proposed policy.

- **NHS Improvement** - responsible for delivering its two statutory patient safety duties across the NHS in England: collecting information about what goes wrong in healthcare, and; using information from incident reports and other sources to develop policy and provide advice and guidance.

- **The Healthcare Safety Investigation Branch** – staff may be requested to provide documentary evidence and/or to attend an inquest

- **NHS Resolution (England) and NHS Wales Shared Services Partnership (NWSSP) Legal & Risk Services** – offer financial settlements where evidence suggests that clinical negligence may have contributed to causing a stillbirth.

- **Wider society** – would benefit from fewer stillbirths in future, brought about by additional learning and actions generated by coronial investigations

14. The following groups might also be affected by the options considered in this IA but have been excluded from the cost and benefit analysis (section E) as the impacts to them are expected to be minimal (for example, minor changes and updates to their published guidelines): the Royal College of Obstetricians and Gynaecologists (RCOG), the Royal College of Midwives (RCM), the Royal College of Nursing (RCN), the Royal College of Paediatrics and Child Health (RCPCH), the Royal College of Pathologists, the Nursing and Midwifery Council (NMC), the British Association of Perinatal Medicine (BAPM), the British Medical Association (BMA), the General Medical Council (GMC), the Coroners' Society of England and Wales (CSEW). We also estimate minor impacts to the Legal Aid Agency (LAA), and independently funded maternity service providers due to low volumes impacted. We welcome views on our assumption that these groups will only be marginally impacted.

D. Description of options considered

15. To meet the Government's policy objectives, the following options are considered in this IA:

- **Option 0**: Base case (do nothing)
- **Option 1:** Bring forward legislation to introduce coronial investigations of all cases of stillbirth that occur on or after 37^{+0} weeks of gestation.

16. Option 1 is the preferred option for consultation.

Option 0: Base case (do nothing)

17. Under the "do nothing" base case, the current system would continue to apply where the coroner's duty to investigate only extends to persons who have first been born alive and whose death was unnatural, violent or of unknown cause, or otherwise took place in custody or under state detention. Coroners would continue to make preliminary inquiries to establish whether they have a duty to investigate in cases where there is any doubt whether a baby was born alive or not but they will have no powers to investigate if they conclude that the baby was stillborn.

18. Stillbirths would continue to be reviewed and investigated according to the Serious Incident framework using the Perinatal Mortality Review Tool and/or by HSIB (for term intrapartum stillbirths).

Option 1

19. As judicial office-holders, coroners make an independent scrutiny of every death they have a statutory duty to investigate, ascertaining the facts leading up to, and the circumstances surrounding that death. Their duty is supported by a number of powers and safeguards set out in statute, which support an independent and transparent process. Where the investigation reveals a risk that deaths may occur under similar circumstances to the death being investigated, coroners may also report to organisations and individuals who may be able to mitigate that risk.

20. It is therefore our view that coroners possess the skills and experience from their existing statutory functions that make them ideally qualified to take forward a revised approach to investigating stillbirths. We believe this approach would deliver independence, transparency and add value to both local and national maternity system quality improvement processes.

21. Under Option 1, the coroner's duty to investigate would include all term and post-term stillbirths ($\geq 37^{+0}$ weeks gestation), with no further distinction or criteria other than where the legislation provides that an inquest be suspended or should not otherwise take place. This duty would apply wherever the gestational age criterion is met such that the opening of an investigation would not be subject to the consent of any third party. The coroner would have at their disposal an equivalent range of powers to those which they exercise when investigating deaths which will also be subject to equivalent conditions and restrictions.

22. Coroners would be required to determine: who the baby's mother is; the baby's name where they have been given one; how it was that the baby was not born alive and; when and where the fetal death (likely) occurred and, when and where the baby was stillborn. Coroners would be expected to consider whether any lessons can be learned which could prevent future stillbirths or otherwise improve the safety of, and care provided to, pregnant women. They would also be expected to make recommendations to all relevant parties.

Other Options Considered

23. As this consultation follows on from a specific commitment to consider the introduction of coronial investigations into stillbirth cases, other options for investigating stillbirths have not been considered. However, a number of different options for the inclusion criteria for this intervention

were considered which, for the reasons described below, have not been assessed in this IA. These options included:

- **Introducing coronial investigations of all stillbirths regardless of gestational age**

  The clinical experts that we have spoken to generally agree that the cohort of term stillbirth cases offers the best potential for coroners to (a) identify the causes of stillbirth and (b) recommend changes to clinical practice that are likely to reduce the risk of similar losses in the future.

- **Introducing coronial investigations only to cases of stillbirths which occur at full- or post-term and are intrapartum**

  Evidence shows that term and post-term intrapartum stillbirths (i.e. when the baby was known to be alive at the start of onset of care in labour but was born with no signs of life) may be more likely to be judged to have been 'avoidable' i.e. are cases for which alternative care might have resulted in a different outcome. However, many cases of 'avoidable' stillbirths also take place after 37^{+0} weeks but before labour and we would not want these to fall outside coronial jurisdiction given the wider benefits of learning.

- **Introducing coronial investigations only to cases of stillbirths which fulfil a given criterion, in addition to taking place at a certain gestational age (e.g. limiting investigations to stillbirths of 'unnatural' cause or stillbirths 'amenable to care')**

  If coroners were to investigate stillbirths, we think they should investigate all stillbirths that may have been amenable to care in order to identify any lessons learnt. 'Amenability to care' is where different care would have altered the outcome. We have therefore considered whether a coronial duty to investigate could exclude deaths that were not 'amenable to care', but in practical terms the determination of this would require inquiries equivalent to an inquest.

  Likewise, we consider that the existing distinction between natural and unnatural deaths, currently applied by coroners, would be impracticable if applied to stillbirths.

- **Conditioning investigations into stillbirths to a third-party consent requirement, in particular from parents**

  We have considered whether the opening of a coronial investigation should be subject to the consent or the request of a third party, such as the stillborn baby's parents or the clinicians involved in the mother's antenatal care. We have also considered whether the exercise of powers, such as ordering of post-mortem examinations, should be subject to consent. There is a risk that this would compromise the judicial independence of coroners by giving a third party control in a judicial process and could introduce an unjustifiable differentiation between coronial powers in investigating neonatal (and other) deaths and stillbirths.

E. Cost and Benefit Analysis

24. This IA follows the procedures and criteria set out in the IA Guidance and is consistent with the HM Treasury Green Book. As specified in the Green Book guidance we have valued costs in terms of their best alternative use – i.e. at their so-called opportunity cost. Since it is assumed that DHSC would meet the additional costs of the proposed policy and given that evidence suggests that DHSC's resources generate health gain in the form of Quality Adjusted Life Years (QALYs) at a marginal cost of £15,000 per QALY and QALYs are valued by society at £60,000, we multiply all quantified costs by 4 to represent the social opportunity cost of using existing resources to fund a new policy. Furthermore, we apply a discount rate of 1.5% rather than 3.5%, in recognition that the next best alternative use of these resources is to generate health benefits (conventionally discounted at a lower rate).

25. Where possible, IAs identify both monetised and non-monetised impacts on individuals, groups and businesses in the UK with the aim of understanding what the overall impact on society might be

from the proposals under consideration. IAs place a strong focus on the monetisation of costs and benefits. There are often, however, important impacts that cannot sensibly be monetised. These might be impacts on certain groups of society or some data privacy impacts, positive or negative. The costs and benefits of each proposal are compared to option 0, the do nothing or 'baseline' case. As the 'baseline' option is compared to itself, the costs and benefits are necessarily zero, as is its Net Present Value (NPV).

26. The following rounding conventions have been applied to the figures in this IA:

Estimated volumes:

- greater than 100 and less than 1,000 have been rounded to the nearest 100,
- greater than 1,000 have been rounded to the nearest 1,000

Estimated costs:

- greater than £1,000 and less than £100,000 have been rounded to the nearest £1,000
- greater than £100,000 have been rounded to the nearest £100,000

Key Assumptions

27. The consequences of stillbirth, especially for parents and families, are profound. It is recognised that estimating the economic costs of such consequences is emotive although this is necessary when evaluating the impact of policy proposals. For the purposes of this IA we have estimated the average economic costs associated with a single stillbirth investigation and the annual costs of all additional stillbirth investigations in England and Wales.

28. As coroners do not currently investigate stillbirths, very little data were available to assess the impact of the preferred options. Stakeholders, primarily senior coroners and paediatric pathologists, were contacted to help devise the assumptions which have been used in this IA.

29. Where data or evidence are limited, we have taken a conservative approach to estimating costs, accepting the risk of over-estimation in order to reduce the chances of under-estimation.

30. The key assumptions and the rationale for these are set out in table 1 below. While we would welcome views and further evidence on all of the assumptions, we have highlighted particular assumptions that we would appreciate more detailed data or feedback on.

Table 1: Main Assumptions used in this IA

No.	Main figures and assumptions	Rationale for assumption	Feedback (ideally with data) on this assumption X = Yes
1	900 additional coronial investigations would be instigated in the first year but the volume would be expected to decrease by around 5% each year in	ONS child mortality statistics show that in 2016 there were 936 stillbirths in England and Wales with gestational age of 37^{+0} weeks or more.[6] Although another more recent ONS data release[7] shows that the number of term stillbirths in England and Wales has declined to ~800, this will not be confirmed until the release of ONS child mortality statistics in March 2019. To avoid the risk	

6 https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/childmortalitystatisticschildhoodinfantandperinatalchildhoodinfantandperinatalmortalityinenglandandwales (table 9)

7 https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/datasets/birthcharacteristicsinenglandandwales (tables 8 and 10)

	line with trends in stillbirth rates over the last decade.	of underestimating the impact of Option 1 we draw on 2016 statistics. A 5% reduction is in line with trends in stillbirth rates over the last decade.[8] The policy aim is that there would be an additional reduction on top of the current trend, therefore this is considered to be a conservative baseline.	
2	100% of investigations are estimated to need a post-mortem examination	Based on responses from coroners and pathologists. Most coroners suggested that the majority of investigations would require a post-mortem, however, responses were variable and not all reported 100%. Pathologists have indicated that there is almost always benefit in undertaking a post-mortem especially if the overall aim is to generate wider learning. An upper bound estimate of 100% has been used in this IA.	x
3	£2,000 is an upper bound estimate of the cost of a post-mortem examination for this cohort	Based on responses from coroners and perinatal pathologists. The total cost of a post-mortem examination depends on staff resources (i.e. consultant, mortuary technician, laboratory assistant and admin support time) and tests (i.e. x-ray, genetics, virology, toxicology, microbiology, biochemistry tests and placental histology etc.). Our estimate of £2,000 is also broadly consistent with academic work in this area.[9] However, this cost varies considerably from service provider to service provider.	x
4	100% of cases would require an inquest	Based on responses from coroners. As the policy proposal is that we would need to generate maximum lessons learnt and recommendations, it was concluded that this could not be done without an inquest for every stillbirth within the cohort.	
5	80% of inquests would require witnesses to attend and provide oral evidence and 20% would be conducted solely on the basis of written evidence (referred to as 'documentary' inquests)	Based on responses from coroners. Responses varied with the majority indicating that most inquests would involve calling witnesses to attend and provide oral evidence on the assumption there would be limited medical data available and most families would have questions. However, in contrast, some coroners suggested that very few inquests may involve witnesses providing oral evidence. These coroners suggested that if they had no further concerns and sufficient information following the issuing of reviews undertaken through the PMRT and/or HSIB, they may be able to conduct a 'documentary' inquest. To address the wide range of responses, sensitivity analyses have been carried out on this assumption.	x
6	£3,000 is the average cost of an inquest involving witnesses attending and providing oral evidence (includes coroner costs, investigating officer costs,	Responses from coroners varied as cases differ in complexity, but the average cost is estimated to be around £3,000.	x

[8] https://www.ons.gov.uk/file?uri=/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/childmortalitystatisticschildhoodinfantandperinatalchildhoodinfantandperinatalmortalityinenglandandwales/2016/cms2016corrected.xls

[9] Mistry et al. A structured review and exploration of the healthcare costs associated with stillbirth and a subsequent pregnancy in England and Wales. BMC Pregnancy and Childbirth 2013; 13:236.
Campbell et al. Healthcare and wider societal implications of stillbirth: a population-based cost-of-illness study BJOG 2018; 125:108-17

	witness costs and court building costs)		
7	£400 is the average cost of a ‘documentary’ inquest	Based on responses from coroners	x
8	The average aggregate time taken to conclude an investigation of a stillbirth (including any preliminary inquiries but not court hearing) is 4 hours for a coroner and 15 hours for a coroner’s investigating officer.	Based on responses from coroners	x
9	As stillbirth cases are likely to be complex, it is assumed that Senior/Area Coroners would undertake these investigations. As there is a fixed number of Senior Coroners, it is assumed additional Assistant Coroners’ hours would be needed to take on some of the less complex work currently undertaken by Senior Coroners. We have assumed Senior/Area coroners and Assistant coroners would take the same number of hours on these cases redistributed to Assistant coroners.	Anecdotal views from stakeholders	x
10	Average Assistant Coroner’s cost per hour is around £60 and coroner’s investigating officer’s cost per hour is around £13 In addition to the costs per hour, we also take account of overhead costs including costs of additional office equipment and supplies (5% of the additional wage costs), employer’s National Insurance (NI) contributions (13.8% of earnings above £162 per week) and employer’s pension contributions (20% of the additional wage costs)	Based on responses from coroners and Coroners pay agreement. £13 estimate is based on the annual salary of £25,000 (assuming a coroner’s officer works 37 hours per week and there are 261 working days in a calendar year) Overhead costs for additional office equipment and supplies are calculated by applying an arbitrary 5% of the additional wage costs, NI costs are based on the employer costs under the NI scheme, pension contribution costs are those likely to apply to civil servants.	
11	There are around 50 consultant paediatric pathologist posts in England and Wales	Royal College of Pathologists’ representative alongside informal advice from HEE and NHS England	

12	1 full-time equivalent (FTE) perinatal and paediatric pathologist is capable of undertaking between 100 and 200 stillbirth post-mortems a year. To meet the demand of an additional 450 post-mortems per year would require between 2.25 and 4.5 additional FTE perinatal pathologists	Informal advice from HEE and NHS England	
13	A coronial investigation of a stillbirth that involves witnesses attending and providing oral evidence could require up to a maximum of 6 members of NHS staff (medical consultant, junior doctor, 3 midwives/nurses and an NHS manager) to each provide up to 7 hours of their time. The estimated cost to local authorities of a 'documentary' inquest is 13.3% of the estimated cost of an inquest involving oral evidence and so we assume a similar proportional difference for costs related to NHS staff time	Based on responses from coroners	x

Option 1: Bring forward legislation to introduce coronial investigations of all cases of stillbirth that occur on or after 37^{+0} weeks of gestation

Monetised and Non-Monetised costs of Option 1

Cost to Local Authorities (LAs) of increased coronial investigations (funded via DHSC)

31. There would be costs to LAs of funding and resourcing any additional work for coroners. Currently, coroners undertake a very small number of preliminary inquiries in cases that are later confirmed as stillbirths. An MBRRACE-UK Perinatal Mortality Surveillance Report found that in 2016, less than 5% of all term stillbirth cases were discussed with a coroner, with just 9 cases where there was sufficient doubt as to whether the baby was born alive or stillborn being investigated by a coroner in England and Wales.[10]

32. Under this option, coroners would have to undertake around 900 stillbirths' inquests in the first year following implementation (see Table 1, assumption 1). In 2017, 229,700 deaths were reported to coroners[11] while only 31,500 inquests were opened. The 900 additional stillbirth inquests represent a 3% increase in the volume of inquests in year 1. However, as detailed below, these stillbirth

[10] https://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/MBRRACE-UK%20Perinatal%20Surveillance%20Full%20Report%20for%202016%20-%20June%202018.pdf
[11] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/760123/Coroners_Statistics_Bulletin_2017.pdf

inquests are all likely to require post-mortems; in 2017 there were 85,500 total post-mortems carried out,[12] suggesting this will increase by 0.5% in year 1.

33. Given the complexity of stillbirth cases, it is assumed that the majority of additional work on stillbirths would be undertaken by Senior and Area Coroners rather than by Assistant Coroners (who provide support to Senior/Area coroners in delivering high quality coronial services). As this would be an additional workload for them, it is assumed that this would be offset by part of their current work on less complex cases being undertaken by the fee-paid Assistant Coroners. This assumes that local authorities would spend more on Assistant Coroners rather than increase their Senior Coroner/Area Coroner resources (especially as there can only be a fixed number of Senior Coroners). Since a stillbirth case is complex in nature, it is estimated, based on responses from coroners (see Table 1, assumption 8), that it would take around 4 hours of coroner's time and 15 hours of coroner's investigating officer's time (who work under the direction of coroners and liaise with bereaved families) to investigate such cases. The coroners' pay agreement for 2019/20 suggests that an Assistant Coroner would be paid around £60 per hour. It is estimated that a coroner's officer is paid around £13 per hour. The total cost of coroner's and coroner's investigating officer's time required to investigate 900 additional stillbirth cases is therefore estimated to be around £400,000 in year 1. In addition, overhead costs for office equipment and supplies are estimated to be around £20,000 (around 5% of the additional wage costs). Employer's national insurance (NI) contributions are estimated to be around £42,000, made up of: contributions to coroner's investigating officers' NI of around £16,000 and contributions to assistant coroners' NI of around £26,000. Employer's pension contributions are estimated to be around £78,000 (around 20% of the additional wage costs). See Table 1, assumption 10 for the rationale of these assumptions. The total overhead costs are therefore estimated to be around £140,000 in year 1. **The total cost of coroner's and coroner's investigating officer's time required to investigate (including any preliminary inquiries but not an inquest involving witnesses attending and providing oral evidence) 900 additional stillbirth cases is estimated to be around £500,000 in year 1 (see C, table A1, Annex A), equivalent to an opportunity cost of £2.1m**.

34. As part of coronial investigations, coroners decide whether to request a post-mortem examination, which pathologists undertake. Due to the nature of these cases, it is assumed that all the additional 900 investigations would require a post-mortem examination. The upper bound estimate of the cost of a post-mortem examination is around £2,000. Currently, post-mortems are offered in nearly all cases of term stillbirth but only around 50% of parents consent to this.[13] These are funded by the NHS. This implies that around 450 additional post-mortems would be undertaken. **Costs of additional post-mortems resulting from this option are therefore estimated to be around £900,000 in year 1 (see A, table A1, Annex A), equivalent to an opportunity cost of £3.6m.**

35. Coroners are required to undertake an inquest in all cases for which they have a duty to investigate. An inquest is a fact-finding inquiry held in public by the coroner in order to establish who died and how, when and where the death occurred. It forms part of the coroner's investigation. As set out in the assumptions table (see assumption no. 2, table 1), it is assumed that all stillbirth cases would require an inquest. However, if written evidence is sufficient whereby there is no requirement to take oral evidence from witnesses and interested parties the coroner may conduct an inquest 'on the papers' sometimes referred to as a 'documentary' inquest. A 'documentary' inquest is held in public but it is heard without the attendance of witnesses.

36. Based on responses from coroners (see Table 1, assumption 5), it is estimated that 'documentary' inquests would be conducted in around 20% of stillbirth investigations and the remaining 80% would require witnesses to attend and provide oral evidence. It is assumed that the average cost of a 'documentary' inquest is around £400 and the average cost of an inquest involving witnesses providing oral evidence is around £3,000.

[12] There are an additional 8,660 deaths reported where an inquest may be opened

[13] Source: https://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/MBRRACE-UK%20Perinatal%20Surveillance%20Full%20Report%20for%202016%20-%20June%202018.pdf
While only half of parents' consent to a PM, there is strong evidence that there is a link between how parents are asked (and how the process is explained to them) and the rate of consent (see, for example, https://www.researchgate.net/publication/45439030_Interventions_to_improve_rates_of_post-mortem_examination_after_stillbirth).

37. The cost of 'documentary' inquests required as a result of this proposal is therefore estimated to be around £72,000[14] in year 1, and the total cost of an inquest involving oral evidence is estimated to be around £2.2m.[15] **Combined this gives a total estimated cost of stillbirth inquests of £2.2m in year 1 (see B, table A1, Annex A), equivalent to an opportunity cost of £8.9m.**

38. **Based on the above, the total cost to LAs of increased coronial investigations is estimated to be around £3.7m in year 1, equivalent to an opportunity cost of £14.7m.**

Parents of stillborn babies

39. At present, post-mortem examinations of stillborn babies can only be undertaken with parental consent. In 2016, the majority (97.8%) of parents in the UK who experienced a stillbirth were offered a post-mortem and around half of them (49.4%) consented.[13] Under this option, coroners would be required to open an investigation into every stillbirth that occurs at a gestational age of 37^{+0} weeks or above and would have powers to request a post-mortem without seeking parental consent. Whilst coroners would discuss with the bereaved parents how they will conduct their investigation including why a post-mortem is being ordered this may result in additional emotional distress. For example, findings from the Stillbirth and Neonatal Death (Sands) charity's survey[16] which included responses from 552 people, over two thirds of whom had had a stillborn baby, showed that 72% of respondents were concerned or very concerned about the fact that coroners do not require parental consent to order a post-mortem. This is expected to be a particular issue for those parents who would not have chosen to consent to a post-mortem especially if this decision would have been made on religious grounds.

The Chief Coroner

40. The Chief Coroner is responsible for organising and coordinating training required for coroners. The Chief Coroner also provides detailed guidance to coroners on various matters relating to law and practice. This guidance has been written to assist coroners in discharging their legal duties, and to provide advice on policy and practice. As this option would extend coronial jurisdiction to stillbirths, there would be an additional non-monetised opportunity cost of time spent by the Chief Coroner in providing guidance to coroners. As investigating stillbirths and identifying lessons that could be learnt in this area would be a new duty for coroners, there would also be additional training required for them. We have assumed that this would be primarily take the form of a one-day training exercise undertaken by all senior and area coroners. These training costs are therefore expected to be minimal. We will continue working to estimate these costs, and aim to include them in consultation response IA if possible.

The General Register Office (GRO) and Office for National Statistics (ONS)

41. It is currently a statutory requirement that stillbirths are registered within 42 days. The registered data on stillbirths are collated by the GRO and are shared with the ONS who compile official national statistics on stillbirths. Extending coronial jurisdiction to stillbirths may lead to delays in the registration of stillbirths especially if they can only be registered after the inquest (which would often be expected to extend beyond 42 days) is concluded.

42. Data published by the ONS[17] show that in 2017, 97% of stillbirths had been registered within one month of the event, compared with 84% of neonatal deaths. Only 0.5% of stillbirths were registered more than three months after the event, compared with 11.6% of neonatal deaths (with 3.3% of neonatal deaths not registered until over 1 year later). As we can assume that the majority of delays in registering neonatal deaths relate to inquest cases, we expect that the introduction of coronial inquests of term stillbirths may cause delays in registration of these events that would impact on the ONS and their reporting timelines.

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[14] 900 stillbirth inquests * 20% documentary inquests * £400 cost.

[15] 900 stillbirth inquests * 80% full inquest with hearing * £3000 cost

[16] Source: Sand's UK Survey Results, *Coroners and Stillbirths*

[17] https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/stillbirths/adhocs/009414registrationdelaysonneonataldeathsandstillbirths2015to2017

43. In terms of impacts to the GRO, registrars would require additional training on stillbirth registration to inform them of the changes in process of registering stillbirths including differences dependent on gestational age; stillbirths that occur between 24^{+0} and 36^{+6} weeks would continue to be registered using the current process while stillbirths that occur at 37^{+0} weeks or more would be registered using coroners' reports. These training costs are expected to be minimal.

Pathologists

44. Medical examinations of stillborn babies are complex and need to be undertaken by paediatric and perinatal pathologists. There is a national shortage of pathologists with this specialist training and Option 1 would significantly increase their workload. To help quantify the scale of this increase and its impacts, informal advice has been sought from a number of paediatric pathologists and representatives from NHS England and Health Education England.

45. Paediatric and perinatal pathologists currently undertake post-mortems of stillborn babies where parental consent is provided (i.e. in ~50% of cases[18]). If we assume that coroners would request a post-mortem in all cases, this could double the number of post-mortems of full-term stillborn babies that would need to be undertaken each year from ~450 to ~900.

46. Unpublished reports suggest that there are currently around 50 consultant paediatric and perinatal pathologist posts in England and Wales, of which around 10 are vacant. In addition, it is expected that a number of paediatric and perinatal pathologists will retire within the next 2-5 years, creating a shortfall in the supply of available trainees to fill the existing posts over that period. This does not include the impact of any increased demand for paediatric and perinatal pathology services brought about by this and/or any other future policy proposals.

47. If we assume that 1 FTE perinatal and paediatric pathologist is capable of undertaking between 100 and 200 post-mortems a year and that coronial investigations of stillbirths would result in an additional 450 post-mortems per year, between 2.25 and 4.5 additional FTEs would be required to meet the anticipated additional workload. This would need to be spread over a larger headcount requirement to avoid regional imbalance in capacity relative to demand. Taking the overall average cost of a surgical consultant (including on-costs, overheads and capital costs)[19] and, not including the costs of training, this additional workforce requirement would be expected to cost between £500,000 and £900,000 per year.

48. Further work is required to assess the extent to which this increased workforce requirement could be met by staff retention, international recruitment or training and the additional costs and timeframes associated with each of these different options. However, it is recognised that there is a 4 to 5 year-lag between advertising a training position and the earliest point at which a consultant post may be filled.

49. There is considerable regional variation in the capacity of current paediatric and perinatal pathology services to: a) meet overall existing demand for post-mortems commissioned from any source; and b) more specifically, to respond to existing demand for post-mortems from coroners. For example, there is evidence to suggest that more than 50% of the pathology departments currently providing perinatal pathology services in England are reporting a workload per consultant in excess of 25% above the recommended level, with some of these in excess of 100%.

50. Furthermore, as there is no requirement for pathologists to undertake post-mortems commissioned by coroners, it may be necessary to consider changes to the funding structures for the ~900 pathological examinations of full-term stillbirths per year, were option 1 to be implemented – initial feedback from a small sample of pathologists suggests that the incentives currently provided are very unlikely to be sufficient to encourage pathologists to undertake this additional coronial work. For example, the costs of undertaking pathological examinations of stillborn babies are considerably

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[18] Draper ES, Gallimore ID, Kurinczuk JJ, Smith PW, Boby T, Smith LK, Manktelow BN, on behalf of the MBRRACE-UK Collaboration. MBRRACE-UK Perinatal Mortality Surveillance Report, UK Perinatal Deaths for Births from January to December 2016. Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester. 2018.

[19] https://www.pssru.ac.uk/pub/uc/uc2018/hospital-based-health-care-staff.pdf; table 14

higher than the fees of £276.90 and £313 currently issued by coroners for pathology and histology, respectively.

51. At the very least, this suggests that, alongside the work that would be necessary to address the expected shortfall in workforce capacity, existing funding arrangements for coronial post-mortems would need to be reviewed to ensure that there is sufficient incentive for pathologists to undertake a significant increase in the volume of post-mortems commissioned from coroners. Depending on what such a review concludes, and in order to ensure security of supply, it may be necessary to consider alternative, more direct methods of commissioning post-mortems of stillbirths.

Other NHS staff

52. NHS staff involved in the care of those who experience a stillbirth and other representatives from their NHS trusts would be required to provide evidence as part of any coronial investigation.

53. It is difficult to quantify the costs involved with this activity as each investigation would be different and so levels of staff involvement would vary from case to case. However, if we assume, based on estimates provided by several coroners, that a coronial investigation of a stillbirth that involves witnesses being called to provide oral evidence could require a maximum of 6 members of staff (medical consultant, junior doctor, 3 midwives/nurses and an NHS manager) to each provide up to 7 hours of their time, that would amount to 42 staff hours per stillbirth.

54. Based on average unit costs for NHS staff in 2016, we estimate the direct costs of participating in coronial investigations of stillbirths with an inquest requiring NHS staff to attend and/or provide oral evidence at hearings for NHS providers could be approximately £2,000 per stillbirth (see sum of bottom row of table 2).

Table 2 – Cost of NHS staff

	Consultant medical	Doctor (FY2)	Midwife entry level (band 5)	Midwife (band 6)	Midwife consultant (lower level) (band 8a)	NHS manager (band 8b)*
Cost per working hour	£104	£29	£35	£44	£62	£27
Cost per 7h	£728	£203	£245	£308	£434	£189

Source: Unit Costs of Health and Social Care 2016[20]
*https://www.healthcareers.nhs.uk/about/careers-nhs/nhs-pay-and-benefits/agenda-change-pay-rates[21]

55. 'Documentary' inquests should require less NHS staff involvement than inquests that require oral evidence to be presented at a hearing. The estimated cost to local authorities of a 'documentary' inquest is 13.3% of the estimated cost of an inquest with oral evidence. If we assume a similar proportional difference for costs to NHS staff, this would suggest that the direct costs for NHS providers of their staff participating in coronial investigations of stillbirths with a 'documentary' inquest could be up to approximately £300 per stillbirth.

56. Based on the assumption that 80% of coronial investigations of stillbirths would involve an inquest with oral evidence and 20% would involve a 'documentary' inquest we therefore estimate that **the direct costs of participating in coronial investigations of stillbirths for NHS providers could be up to £1.5m per annum (see D, table A1, Annex A), equivalent to an opportunity cost of £6m.**

57. For NHS staff invited to give evidence at an inquest, it is possible that this would cause stress and anxiety (which we do not propose to quantify).

Providers of maternity services

58. The aim of Option 1 is for the learning generated by coronial investigations to help providers of

[20] Curtis, L. & Burns, A. (2016) Unit Costs of Health and Social Care 2016, Personal Social Services Research Unit, University of Kent, Canterbury
[21] Using the annual salary for band 8b, we have calculated an hourly wage assuming a 37 hour working week

maternity services to take further and more informed action to reduce the risk of stillbirths.

59. While it is not possible to second-guess the actions that the NHS and other maternity service providers might take in response to the findings arising from coronial investigations of stillbirths, below (in the Risks and Sensitivities section) we provide some context for the reduction in number of stillbirths that would be required, net of any associated costs, for the establishment of coronial investigations of stillbirths to prove cost-effective (notwithstanding other non-monetised costs and benefits); and we show what level of additional spending on initiatives would be required to deliver this level of net benefit, depending on the average cost-effectiveness of the initiatives adopted.

NHS Resolution (England) and NHS Wales Shared Services Partnership (NWSSP) Legal & Risk Services

60. As coronial investigations may lead to increased public disclosure of the circumstances surrounding stillbirths this may initially encourage more clinical negligence claims against the NHS to be made than would otherwise be the case.

61. NHS litigation authority data show that between April 2000 and March 2010,[22] around 250 claims relating to stillbirths made against the NHS resulted in litigation costs with a total value of around £15,713,000. This includes compensation payments and all legal costs. Assuming claims are evenly distributed over the period and there are no changes in the real average settlement (on the basis of the GDP deflator at market prices), this can be expressed as around £19,480,000 in 2016/17 prices; an average value of around £78,000 per stillbirth.[23] Between 2000 and 2009 (inclusive), there were around 33,000 stillbirths recorded in England[24] suggesting that 0.8% of all stillbirths led to a claim against the NHS. If we assumed that: i) the value of claims per stillbirth have remained at a similar level over time; ii) are similar in England and Wales and; iii) rates of claims may initially double, this would result in an additional 7 claims with an associated total litigation cost of approximately £500,000.

62. Offsetting this rather speculative estimate of a possible increase in litigation costs, there are two possible mechanisms through which litigation costs may be reduced. First, coronial investigations of all term stillbirths may establish facts in cases that would otherwise have been subjected to less or no investigative scrutiny which may lead to redress and/or resolution at a local level rather than a decision to pursue a claim for clinical negligence. Secondly, to the extent that option 1 delivers its intended benefits in reducing future stillbirths, the future costs of litigation should fall (all else equal).

63. The net effect on litigation costs, taking these three separate effects into account, is therefore very uncertain. In addition, the published figures cited above include both compensation payments and claimant and defendant legal costs, with no indication of the relative split. This is important because changes to compensation payments represent a resource transfer – i.e. any increase (decrease) in compensation paid to individuals is offset by an equal decrease (increase) in resources allocated to others – whereas the legal costs associated with settling claims are a net cost. We have therefore not been able to reliably quantify the overall net costs of this potential impact.

Local and national investigations led by the NHS and Healthcare Safety Investigation Branch (HSIB)

64. As NHS trusts and HSIB already undertake investigations of stillbirths (in the case of HSIB, it is those which meet RCOG's Each Baby Counts criteria i.e. term intrapartum stillbirths; estimated to represent <10% of all cases of term stillbirth[25]), there may be an opportunity cost for the NHS and

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[22] NHS Litigation Authority. Ten years of maternity claims – an analysis of NHS litigation authority data. London: NHSLA 2012 https://resolution.nhs.uk/wp-content/uploads/2018/11/Ten-years-of-Maternity-Claims-Final-Report-final-2.pdf (accessed 2 January 2019)

[23] Analysis of more recent, unpublished claims data from NHS Resolution indicates that the average settlement per stillbirth is in line with the figure derived from the 2000-2010 published figures, after accounting for general price inflation.

[24] https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/datasets/vitalstatisticspopulationandhealthreferencetables

[25] Based on estimates reported in: Draper ES, Gallimore ID, Kurinczuk JJ, Smith PW, Boby T, Smith LK, Manktelow BN, on behalf of the MBRRACE-UK Collaboration. MBRRACE-UK Perinatal Mortality Surveillance Report, UK Perinatal Deaths for Births from January to December 2016. Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester. 2018. [https://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/MBRRACE-UK%20Perinatal%20Surveillance%20Full%20Report%20for%202016%20-%20June%202018.pdf (accessed on 3rd January 2019)]

HSIB of time spent cooperating with coroners and providing detailed reports in a timely manner to avoid unnecessary delays in coronial investigations.

65. The extent to which the cost of carrying out coronial investigations into stillbirths represents a net increase in investigative costs as a whole depends on the extent to which coronial investigations would substitute for or be undertaken in addition to these other investigation activities currently undertaken by NHS trusts and HSIB. This is not something that is known with certainty at this stage.

Overall costs of option 1.

66. Stillbirth rates have decreased year on year by an average of 5% for at least the last decade and, given the stated national ambition to halve 2010 rates of stillbirth by 2025, this decrease is expected to continue. Overall costs for years 2 to 10 have been calculated taking this average decrease in annual rates into account.

67. **Overall the monetised costs are estimated to be around £5.2m in year 1.**

Monetised and Non-Monetised benefits of Option 1

68. The primary intended benefits of this option would be that parents who have lost a baby to stillbirth would gain reassurance from an independent account of why their baby was stillborn and that findings and recommendations would inform system wide improvements in maternity care leading to further reductions in stillbirth rates.

Parents of stillborn babies

69. The stillbirth of a baby is a distressing experience for parents and families. This option provides a benefit to bereaved families as they would receive an independent account of why their baby was stillborn. This may help inform clinical care in future pregnancies. In addition, knowing lessons have been learnt and changes made if necessary might be reassuring. This could help families through the grieving process and contribute some resilience against developing mental health problems.

Reduced incidence of stillbirths

70. In conducting their investigations, coroners would be expected to consider whether any lessons can be learned which could prevent a future stillbirth or otherwise improve the safety of, and care provided to, pregnant women. If the coroner concludes that there are lessons to be learned, it is expected that they will make appropriate recommendations to any person or organisation (including those not involved in the case) that would benefit from those recommendations and to anyone the coroner has identified as having power or authority to implement them.

71. Detailed proposals for how the lessons learned would be disseminated effectively to all relevant parties across the system will be developed during the next phase of policy development. However, it is assumed that this system-wide learning will generate actions that result in an additional reduction in stillbirth rates.

72. In 2013, a landmark case led to a ruling by the Northern Ireland Court of Appeal that coroners there (who operate under different legislation to those in England and Wales) should have jurisdiction to conduct inquests of stillbirth cases.[26] While anecdotal evidence of the benefits of this ruling have been reported, only a small number of coronial inquests of stillbirths have subsequently been conducted and we are not aware of any empirical evidence generated that can be used to help quantify the expected effect of introducing coronial investigations of stillbirths in England and Wales on future stillbirth rates. In addition, there are some important differences between the changes implemented in Northern Ireland and the outlined proposal for England and Wales.

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[26] https://www.parliament.uk/documents/commons-library/The-investigation-of-stillbirth-CBP-8167.pdf

73. Despite the absence of any empirical evidence linking coronial investigations of stillbirths to a reduction in stillbirth rates, should it materialise, reduced incidence of stillbirths would provide benefits to a range of stakeholders, as described below.

Wider society

74. Each avoided stillbirth results in the live birth of a baby. It is expected that there will be benefits to society of the contributions that each such baby will make across their lifetime. Preventing future stillbirths could also bring wider economic benefits to society as it may result in increased productivity of healthcare professionals and parents.

Medical staff and providers of maternity services

75. Pathologists, other NHS staff and providers of maternity services would incur none of the additional costs associated with each stillbirth avoided, e.g. costs of undertaking and responding to post-mortems, being involved in coronial investigations and offering bereavement/counselling services to parents.

NHS Resolution (England) and NHS Wales Shared Services Partnership (NWSSP) Legal & Risk Services

76. Fewer stillbirths would, in the longer term, likely lead to fewer claims for clinical negligence.

ONS

77. Option 1 would also be expected to improve the quality of data on the causes of stillbirth compiled and published by the ONS, thus supporting wider learning.

Quantification of benefits

78. The majority of the potential benefits described above derive from any reduction in stillbirths brought about by the actionable learning that results from coronial investigation of stillbirths.

79. In the absence of any empirical evidence linking coronial investigation of stillbirths and subsequent reduced incidence of stillbirths, this IA instead estimates the level of benefit required to offset the quantified cost.

80. As shown in the summary of quantified costs, coronial investigations of stillbirths are estimated to cost around £5.2m in year 1. An equivalent level of resources deployed in the NHS (at a marginal cost effectiveness of £15,000 per Quality Adjusted Life Year (QALY)) would generate around 350 QALYs. Therefore, any alternative use of such a level of DHSC resources otherwise assumed to be deployed in the NHS would have to generate at least 350 QALYs to be cost effective.

81. On the assumption that an avoided stillbirth leads to the live birth of a baby who is expected to live for the population average quality and duration of life at birth (i.e. a quality-adjusted life expectancy of around 69 years), 350 QALYs is equivalent to around 5 stillbirths avoided, or 0.6% of the annual number of term stillbirths in 2016.

82. In other words, the proposal to introduce coronial investigations of full- and post-term stillbirths is expected to be cost effective if it generates learning that leads to a further 0.6% stillbirths being avoided each year, not including the costs and benefits that it has not been possible to quantify.

Overall benefits of option 1

83. Overall benefits of Option 1 cannot be monetised.

Summary of Costs and Benefits – Net Impact of Option 1

84. The total estimated annual cost of introducing coronial investigations of full- and post-term stillbirths is expected to be around £5.2m in year 1. Total benefits, denominated in terms of the proportion of

stillbirths avoided, would need to be 0.6% per year (on top of the trend reduction of 5% a year) to offset the estimated costs.

85. The Net Present Value of this policy is estimated to be around -£152m (taking account of the opportunity cost to the NHS). Please see table A1 in the annex for details on how this was derived.

F. Risks & Sensitivity Analysis

Risks

86. The following key risks apply to the assessment of expected costs and benefits of Option 1:

- There is a national shortage of paediatric and perinatal pathologists and they currently have minimal capacity to undertake additional work. This proposal could impose additional pressures on this workforce, which could work against the policy's intentions.
- There is a risk that some paediatric pathologists would stop undertaking post-mortems of stillbirths if they are commissioned via the coronial route.
- There is a risk for the NHS and wider public that coronial inquests, conducted in public, lead to more claims for clinical negligence and therefore increased costs to the NHS.
- There is a risk that placing coroners, at least initially, in the lead role for investigating stillbirths could undermine existing working relationships between the various parts of the system currently involved in investigations of stillbirths.
- The learning generated by coronial investigation of stillbirths – and, in particular, the recommended actions arising from the learning – may impose additional costs on providers of maternity services. As such, these indirect, second-order costs represent a risk to the ultimate success of the preferred option – the higher the cost of implementing the actions arising from the additional learning, the less likely providers of maternity services are to take them up. It is not possible to quantify the additional cost because we cannot foresee the additional learning that might be generated, the actions arising from such learning or the costs and effectiveness of the recommended actions.

Sensitivity Analysis

87. We have not undertaken sensitivity analyses for all assumptions used in this IA but instead have focused on just one key assumption; the proportion of investigations that are likely to have a 'documentary' inquest versus an inquest requiring witnesses to attend and provide oral evidence. Sensitivity analyses have been carried out on this specific assumption as we received very mixed responses from coroners on the proportions in each category, and these differences would have a large impact on the overall estimated costs of the preferred option. The sensitivity analysis only considers the impacts on the main groups affected. For simplicity, opportunity costs are not factored in to the sensitivity analysis as these do not impact on the relative comparisons across the different sensitivity options considered.

Sensitivity 1: The proportion of investigations that have i) a 'documentary' inquest and ii) an inquest involving witnesses attending and providing oral evidence.

88. This consultation stage IA assumes that 20% of stillbirth cases would require a 'documentary' inquest and 80% an inquest with oral evidence. Whilst the majority of coroners indicated that most

investigations would require inquests with witnesses attending and providing oral evidence, some coroners did suggest that the majority of cases would involve 'documentary' inquests.

89. In this sensitivity analyses we have considered the following:
    - The **base case** assumes that 20% of stillbirth cases would require a 'documentary' inquest and 80% would require an inquest with oral evidence.
    - **Sensitivity 1.a** assumes that 80% of stillbirth cases would require a 'documentary' inquest and 20% would require an inquest with oral evidence.
    - **Sensitivity 1.b** assumes that 50% of stillbirth cases would have a 'documentary' inquest and the remaining 50% would have an inquest with oral evidence.

90. Table 3 summarises the results. The difference in the total costs is a decrease of around £1.4m for 1.a and a decrease of around £1.2m for 1.b. The differences in total benefits required to offset these reduced costs are decreases of 0.3% and 0.2% in the annual number of term stillbirths for sensitivity 1.a and 1.b, respectively. This illustrates that the total costs are proportional to the proportion of cases that require a 'documentary' inquest and an inquest with oral evidence. Given that 'documentary' inquests are considerably cheaper, the higher the proportion of 'documentary' inquests the lower the total costs.

Table 3: Sensitivity analysis

Scenario	Total Cost to LAs	Total Cost of NHS staff	Total Cost[27]	% of term stillbirths that need to be avoided each year to offset the total cost
Base case (Option 1)	£3.7m	£1.5m	£5.2m	0.6%
Sensitivity 1.a - 20% - inquest with oral evidence, 80% 'documentary' inquest	£2.3m	£0.6m	£3.8m	0.3%
Sensitivity 1.b - 50% - inquest with oral evidence, 50% 'documentary' inquest	£3m	£1m	£4m	0.4%

G. Business Impact Target (BIT)

91. The business impact target does not apply to these proposals as they are not regulatory measures.

H. Specific Impact Tests

Equalities Statement

92. Please see the Equalities Statement in chapter 8 of the consultation document.

Health assessment

93. The health impacts are set out in the main body of this impact assessment.

Justice Impact Test

94. The justice impacts are set out in the main body of this impact assessment.

[27] Total costs do not sum exactly to individual costs combined due to rounding

New Burdens doctrine

95. The new burdens impacts are set out in the main body of this impact assessment.

Privacy impact assessment

96. We appreciate that a coroner's investigation into a stillbirth may involve the exchange, sharing and/or use of private information. In particular, this would be the case where the coroner requests the medical records of the mother to be used as evidence (where relevant and appropriate). Save for any exception provided for in statute, all or part of the information used as evidence could be shared by the coroner with any interested person (within the meaning of the Coroners and Justice Act 2009). Inquests are held publicly and any evidence heard at the inquest would also be included in the record of inquest, which the coroner should likewise make available upon request from an interested person.
97. The potential effects of the options on privacy and the way private information could be used as a result will be closely considered if, following the consultation, the decision is taken to implement this policy.

Family test

98. The proposals consulted on (under option 1) are expected to benefit parents experiencing stillbirth and going through bereavement, as well as their wider family. A coronial investigation would provide parents with an independent review of the facts leading up to and the circumstances surrounding the loss, which may help with the grieving process. It would offer a robust and careful account of how the stillbirth happened, whilst ensuring that no question about how it happened remains unanswered which, when that is not the case, we recognise can lead to further distress.

99. Similarly, as interested persons (within the meaning of the Coroners and Justice Act 2009), parents would have an active role in the investigatory process, and would have an opportunity to share their views, present evidence and air any concerns. They could also be given the opportunity to hear the views of other interested persons, such as clinicians, midwives or nurses, as well as those of any experts who may give evidence. This would give parents the reassurance that their views have been acknowledged and considered, and that all opinions have been carefully heard, which may again help with the grieving process.

100. We also recognise that poor mental health can damage family relationships. The proposals could contribute to reducing that risk since coronial investigations may provide resilience against developing mental health problems (such as post-traumatic stress disorder) or help lower their intensity, particularly in mothers and fathers, especially those who are predisposed to such conditions or are already suffering from mental health problems.

101. Crucially, we also expect coroner's findings to help inform women's clinical care in future pregnancies, which would benefit expectant mothers but also couples approaching pregnancy. The proposals are also intended to contribute to general learning about the causes of stillbirths and prompt improvements to maternity care provision and therefore to maternity outcomes. They would therefore benefit any parents expecting a baby, and help allay any anxiety in approaching pregnancy, pregnancy choices, as well as labour and birth, which can be a particularly stressful period for parents and families.

102. The proposals may however have an adverse effect on families where one or both parents do not wish a coronial investigation or post-mortem examination to be undertaken. This may add to some parent's distress, and could also create anxiety in families whose faith involves specific requirements for how bodies can be handled after death or stillbirth.

103. These potential adverse effects will be closely considered if, following the consultation, the decision is taken to implement this policy.

Welsh language requirements

104. Coronial law and policy being a reserved matter in Wales, the proposals set out for consultation would affect Welsh speakers. The consultation document has therefore been produced in both

English and Welsh. Both versions are available at https://consult.justice.gov.uk/digital-communications/coronial-investigations-of-stillbirths.

105. Guidance on coroner services produced by the MoJ are published in Welsh and should coroners undertake the investigation of stillbirths these would be amended to provide relevant guidance.

I. Monitoring and evaluation

106. As this is a consultation IA, the data that will need to be collected in the future are the responses and feedback to the points raised in this document. This shall be completed via the process described in the consultation document. The evaluation process shall follow appropriate guidelines.

Annex A

Table A1: Summary of quantified costs

Year:	0	1	2	3	4	5	6	7	8	9	10	**10 year NPV period**
Net additional post-mortems (A)	0	900,000	800,000	800,000	700,000	700,000	700,000	600,000	600,000	500,000	500,000	**6,800,000**
Coroner inquests - with oral evidence (B)	0	2,200,000	2,100,000	1,900,000	1,900,000	1,800,000	1,700,000	1,600,000	1,500,000	1,400,000	1,400,000	**17,300,000**
Coroner inquests - 'documentary' (B)	0	72,000	68,400	65,000	61,700	58,600	55,700	52,900	50,300	47,800	45,400	**600,000**
Additional coroner time (C)	0	500,000	500,000	500,000	500,000	400,000	400,000	400,000	400,000	400,000	300,000	**4,300,000**
NHS staff time (D)	0	1,500,000	1,400,000	1,300,000	1,300,000	1,200,000	1,200,000	1,100,000	1,000,000	1,000,000	900,000	**11,900,000**
Total cost (undiscounted)	**0**	**5,200,000**	**4,900,000**	**4,600,000**	**4,400,000**	**4,200,000**	**3,900,000**	**3,700,000**	**3,500,000**	**3,400,000**	**3,200,000**	**41,000,000**
Total cost (discounted at 3.5%)	**0**	**5,000,000**	**4,600,000**	**4,200,000**	**3,800,000**	**3,500,000**	**3,200,000**	**2,900,000**	**2,700,000**	**2,500,000**	**2,300,000**	**34,600,000**
Opportunity cost (undiscounted)	**0**	**20,600,000**	**19,600,000**	**18,500,000**	**17,600,000**	**16,700,000**	**15,800,000**	**15,000,000**	**14,200,000**	**13,400,000**	**12,700,000**	**164,100,000**
Opportunity cost (discounted at 1.5%)	**0**	**20,300,000**	**19,000,000**	**17,700,000**	**16,600,000**	**15,500,000**	**14,400,000**	**13,500,000**	**12,600,000**	**11,700,000**	**11,000,000**	**152,300,000**

Note: Figures in 2016/2017 prices