

Title: Introduction of Medical Examiners and Death Certification Reform in England IA No: DHSC5007 RPC Reference No: N/A Lead department or agency: Department of Health and Social Care (DHSC) Other departments or agencies:	Impact Assessment (IA)			
	Date: June 2018			
	Stage: Final			
	Source of intervention: Domestic			
	Type of measure: Secondary legislation			
	Contact for enquiries: deathcertification@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 2016 prices)	One-In, Three-Out	Business Impact Target Status
-£105.5m	-	-	Not in scope	Not a regulatory provision

What is the problem under consideration? Why is government intervention necessary?
 The arrangements for scrutinising Medical Certificates for Cause of Death (MCCDs) have remained largely unchanged for over 50 years yet there are concerns about their efficacy and efficiency, particularly for those cases which are not referred to a coroner. For cremation there is currently a level of scrutiny but the system for burials does not include any additional scrutiny of the quality or accuracy of the MCCD. The Shipman Inquiry concluded that it was no longer suitable to have a different certification processes for cremations and burials, and that all MCCDs should be subject to independent medical scrutiny.

What are the policy objectives and the intended effects?
 To ensure that a reformed system for certifying non-coronial deaths improves the quality and accuracy of MCCDs and provides adequate scrutiny to identify and deter criminal activity or poor practice. This should be achieved without imposing undue delays on the bereaved or undue burdens on medical practitioners and others involved in the process.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base) Three policy options have been considered:
Option 1: Do nothing.
Option 2: Extend the current system, including the fees, for cremations to burials.
Option 3: (preferred): Reform the current system for cremations and burials by introducing a new universal check by a Medical Examiner (ME) applicable to all non-coronial deaths. The system will initially be funded through cremation form fee revenues sourced from efficiencies in the system and DHSC. Following the interim period the ME system would be primarily funded through a fee for cremations and burials.
 Option 3 is the preferred option as it will improve the assurance and crime deterrence aspects of death certification and provide the same level of scrutiny for both burial and cremation cases.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Tbc; the policy will be reviewed post implementation in April 2019 in relation to legislative requirements and or within 18 months to review the impact on coroners.

Does implementation go beyond minimum EU requirements?	No			
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 (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: Lord O'Shaughnessy **Date** 5 June 2018

Summary: Analysis & Evidence

Policy Option 1

Description: **Busines As Usual (do nothing)**

BASELINE

Price Base Year 2018	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate: -

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

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

This option represents the baseline against which other options are compared.

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

This option represents the baseline against which other options are compared.

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

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

This option represents the baseline against which other options are compared.

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

This option represents the baseline against which other options are compared.

Key assumptions/sensitivities/risks

This option represents the baseline against which other options are compared.

Discount rate (%) 3.5%

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	Benefits:	Net:	

Summary: Analysis & Evidence

Policy Option 2

Description: Extend the current system, including the fees, for cremations to burials.

FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate: -117.7

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	-	-	-
High	-	-	-
Best Estimate	0	15.5	117.7

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

The introduction of scrutiny for all non-coronial deaths represents a new cost for the bereaved of those buried (in the current system burials are not subject to the same fees as cremations).

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	-	-	-
High	-	-	-
Best Estimate	-	-	-

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

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

- Additional scrutiny and improved patient safety
- Improved level of assurance for the bereaved in burial cases

Key assumptions/sensitivities/risks

Discount rate (%) 3.5%

Assumed central costs and central death projections (ONS 2016 principal population projection). Current cremation form fees assumed to be applied to burials. No change in scrutiny or assurance for bereaved families in cremation cases.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	Benefits:	Net:	

Summary: Analysis & Evidence

Policy Option 3

Description: Implementation of Medical Examiner (ME) System funded by a fee on cremations and burials

FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	High: -227.4	Best Estimate: -105.5

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	-	-	-
High	78.7	14.3	227.4
Best Estimate	78.7	-0.5	105.5

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

- The running costs of the new ME system will primarily be funded by the public (typically the informant who registers the death) through the payment of a fee. This represents a saving for families of those cremated but a new cost for families of those buried.
- The costs of establishing the ME system, cost of child deaths, cases referred from MEs to coroners and initially burials will be funded by DHSC. The opportunity cost of DHSC spend is accounted for in terms of quality-adjusted life years (QALYs) forgone.

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

- The additional burden on coroner services due to a greater number of complex cases (though fewer cases sent to the coroner unnecessarily)
- The effect on NHS Litigation liability

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

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

Other key non-monetised benefits by 'main affected groups' See benefits section on page 31 for details

- Improved scrutiny of death certification which can help improve clinical governance as well as detect and deter crime and malpractice, and prevent any costs associated with that crime
- Improved quality and accuracy of MCCDs and potential to identify trends in unexpected causes of death
- Improved level of assurance for the bereaved

Key assumptions/sensitivities/risks

Discount rate (%) 3.5%

QALYs discounted at 1.5%. ONS 2016 based population projections. Main cost estimates above based on central death projections, and central and high costs. Sensitivity analysis included in this document (Annex B) presents cost estimates for low and high death projections. The impact on coroners will be reviewed 18 months after implementation.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m: W			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	Benefits:	Net:	

Evidence Base

Summary cost tables – Option 3

Table 1 presents the financial costs, based on the set-up and running costs and revenue. These are then calculated taking into account cost savings with respect to the status quo (as presented on an average annual basis in Table 13), then uplifted to take account of inflation, and presented per year over the policy time period. Table 2 is the economic costs, with prices discounted from 2018 prices and opportunity costs taken into account (as presented in an average annual basis in Table 14).

Table 1: Annual profile of financial costs (£m) current prices: Option 3 with respect to Do Nothing Option (1) – Central Estimate

£millions	Year 0 (Y ₀)	Y ₁	Y ₂	Y ₃	Y ₄	Y ₅	Y ₆	Y ₇	Y ₈	Y ₉
Set-up costs (DHSC)	19.7									
Running costs (DHSC)		15.7	13.9	4.1	4.2	4.3	4.4	4.5	4.7	4.8
Running costs (public)		18.7	18.8	30.9	31.7	32.5	33.4	34.4	35.4	36.4
Change in Cremation form fees paid (public)		0.0	0.0	-64.6	-66.2	-68.0	-70.0	-72.1	-74.3	-76.6
Total annual costs	19.7	34.5	32.6	-29.6	-30.4	-31.2	-32.2	-33.2	-34.2	-35.3

Table 2: Annual profile of economic costs (£m, accounting for the opportunity cost of DHSC spend in terms of QALYs forgone) discounted prices: Option 3 with respect to Do Nothing Option (1) – Central Estimate

£millions	Year 0 (Y ₀)	Y ₁	Y ₂	Y ₃	Y ₄	Y ₅	Y ₆	Y ₇	Y ₈	Y ₉
Set-up costs (DHSC)	78.7									
Annual cost (DHSC)		61.1	52.2	14.8	14.7	14.6	14.5	14.4	14.3	14.3
Annual cost (public)		17.9	17.0	26.6	25.8	25.1	24.4	23.8	23.2	22.7
Annual resource impact from changes to cremation forms		-17.9	-17.0	-55.5	-54.0	-52.5	-51.2	-49.9	-48.8	-47.6
Total annual costs	78.7	61.1	52.2	-14.1	-13.5	-12.9	-12.3	-11.7	-11.2	-10.7

May not sum due to rounding

Effect on coroners left unquantified in this IA and will be assessed 18 months after implementation

B. What is the problem under consideration?

Characterisation of the underlying problem

Background

1. The system for death certification in England has remained largely unchanged for over 50 years. The current arrangements require that, for all deaths, the doctor who attended the patient in their final illness should complete a Medical Certificate of Cause of Death (MCCD). Additional certification is required before bodies can be released for cremation. Currently around 80% of deaths are followed by cremation¹.
2. However, there are concerns that the death certification process does not provide enough independent scrutiny on the accuracy and completeness of the MCCD for those deaths where the cause is not unknown and therefore not referred to a coroner. In the case of burials, this is due to the fact that only one doctor is involved in completing the MCCD and no other doctor is involved in checking this document. In the case of cremation cases, there are also concerns that the scrutiny may not always be independent enough to be effective.
3. These concerns were put into focus by the Shipman Inquiry. Harold Shipman was a General Practitioner (GP) who murdered hundreds of his patients and wrote MCCDs that reported the cause of death as being due to natural causes. This was not detected and he continued his criminal activities over several decades.
4. In its Third Report, the Shipman Inquiry examined the process of death certification and the coroner system². It looked at written evidence as well as oral testimony, both on the Shipman case itself but also the functioning of the death certification system as a whole.
5. The Shipman Inquiry concluded that the current system of death certification was confusing and provided inadequate safeguards, particularly against the possibility that (as in Shipman's case) the doctor completing the MCCD was himself responsible for the patient's death.
6. Over the last 10-15 years there have been several studies that have examined the evidence on the functioning of the death certification system. A Fundamental Review presented to the Home Office in June 2003, came to broadly similar conclusions about the shortcomings of the current arrangements³.
7. The Government accepted the Shipman Inquiry's conclusions, and its action programme in response to the Inquiry's recommendations outlined proposals for creating a new rigorous, unified system of death certification for both burials and cremations in England⁴.
8. The conclusion from this evidence is that the weaknesses of the current death certification system identified by the Shipman Inquiry can be mitigated or eliminated by the introduction of medical examiners (MEs). Renewed calls for MEs were made by the Francis Inquiry into Mid Staffordshire⁵ and Bill Kirkup's Inquiry into Morecambe Bay⁶. These reports imply that the reforms will help identify poor care and protect patients. Two different options for reform are presented and discussed in this Impact Assessment (IA).

Description of the problem

9. The main aim of the proposed intervention is to prevent future Shipman type crime/malpractice. This type of crime is best described as situational because it depends on the existence of an opportunity that occurs when there is a suitable target (the patient), a likely offender (the doctor), and a lack of a suitable 'guardian' to detect the crime (an ME).

¹ Cremation Society of Great Britain, (provisional) National Cremation Statistics 2016 ([http://www.cremation.org.uk/annual-statistics-1960-2016#accessed May2018](http://www.cremation.org.uk/annual-statistics-1960-2016#accessed%20May2018)) and ONS registered deaths (see footnote 8)

² The Shipman Inquiry, Third Report – Death Certification and the Investigation of Deaths by Coroners, 2003

³ Death Certification and the Coroner Services in England, Wales and Northern Ireland: The Report of the Fundamental Review, June 2003

⁴ Learning from Tragedy, Keeping Patients Safe, February 2007

⁵ The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Robert Francis QC, Feb 2013

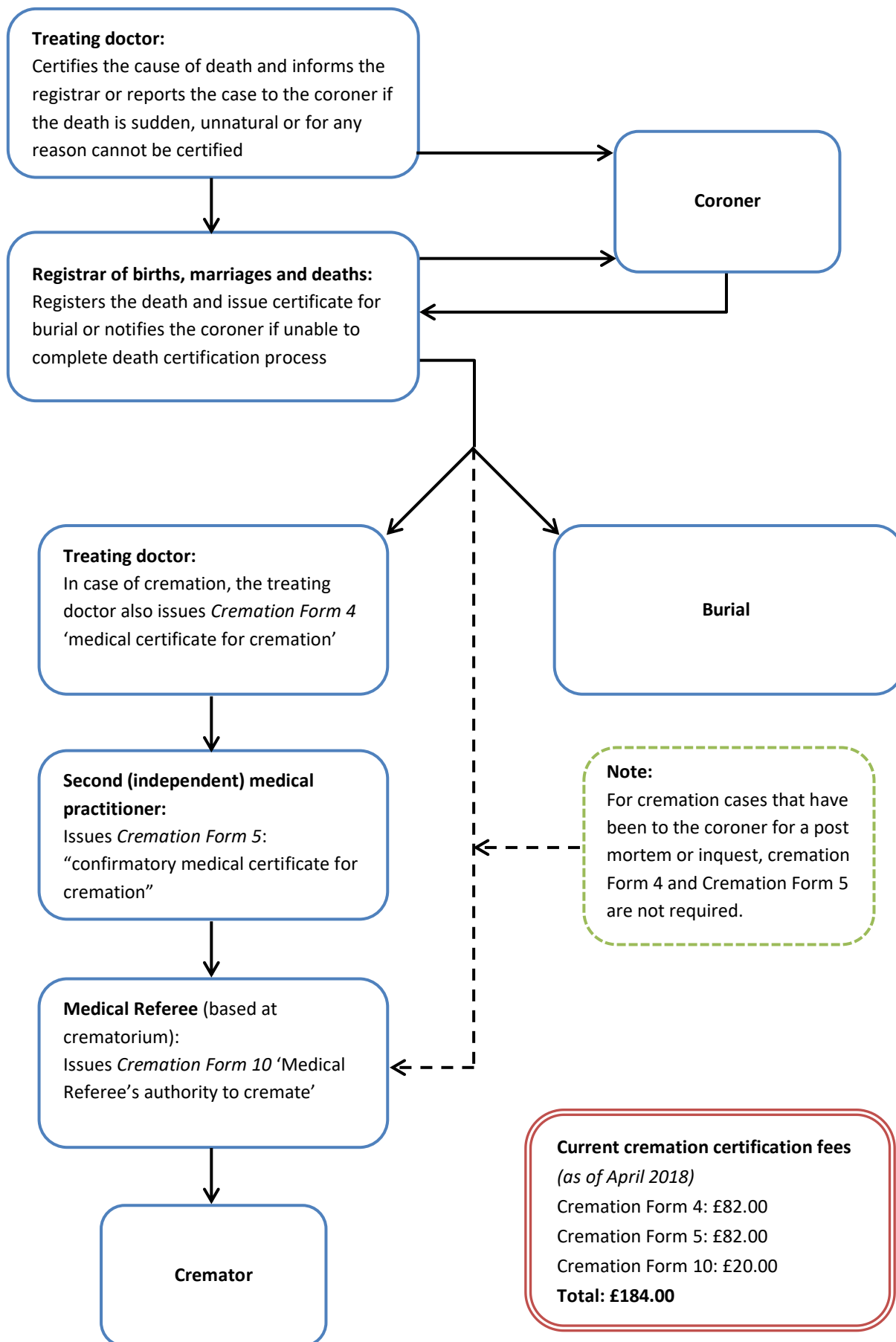
⁶ The Report of the Morecombe Bay Investigation, Dr Bill Kirkup, March 2015

10. There is evidence, as presented in the Third Report of the Shipman Inquiry, that the current death certification accountability mechanism has several weaknesses that mean its effectiveness is compromised².
11. These weaknesses relate in particular to the registration of the 56% of registered deaths (resident in England) that are not seen by coroners which, using 2016 Coroner Statistics figures and 2016 ONS Death Registrations, are 275,463 ^{7 8}.
12. Figure 1 outlines the main features of the current system.

⁷ Coroner statistics 2016, Ministry of Justice, May 2017

⁸ Deaths registered in England and Wales: 2016, Office for National Statistics, July 2017. Using death proportions in England and Wales to estimate England only figures.

Figure 1: Main features of the current system



Burial cases: Lack of scrutiny

13. There is no additional medical scrutiny for burial cases (20% of the total in 2016) once the MCCD has been completed¹. The Registrar does an administrative check on all MCCDs, and has a legal duty to refer to the Coroner in certain circumstances. However, the Registrar is not medically qualified and does not have access to supporting information such as medical notes. The Registrar is therefore not in a position to make effective judgements about the reliability of the cause of death recorded on the MCCD.
14. The lack of scrutiny of burial cases stems from the possibility of exhumation and the scope for malpractice to be detected at some point in the future. However, this only allows for burial cases to be used as evidence to support already open investigations; it does not help to raise suspicion over any new cases. Equally, the evidence actually available from exhumed bodies may not be sufficient to identify signs that could be detected at a time closer to death.
15. According to the Shipman Inquiry (Third Report, page 3, paragraph 13):

“The current procedure has three very real advantages; it is speedy, cheap and convenient. However, it has a number of disadvantages. The most serious of these is that it is dependent on the integrity and judgement of a single medical practitioner. That medical practitioner, if s/he has attended the deceased during the last illness, must decide whether s/he should report the death to the coroner or whether s/he can properly issue the medical certificate of cause of death (MCCD)”².
16. The risk to patient safety is that, without independent monitoring, the potential for malpractice by doctors is not checked. This makes it difficult to detect cases such as Shipman’s where the doctor is responsible for the death of the patient, as well as more minor medical faults and errors.
17. It is difficult to quantify to what extent any such abuses are prevalent, given the lack of data. The benefits section of this IA describes the existing evidence.

Cremation cases: Scrutiny may not be independent despite onerous system

18. In contrast to burial cases, cremation cases are subject to the completion of cremation forms. For the purposes for this document Cremation Forms 4 and 5.
19. However, before the additional safeguards added by the Cremation (England and Wales) Regulations 2008 and Ministry of Justice (MoJ) guidance to doctors and medical referees, the additional scrutiny on cremation cases was not always sufficiently independent of the doctor signing the MCCD and is not subject to effective quality assurance:

“the second certifying doctor may be chosen by the first certifying doctor from any doctor of his acquaintance, provided they are not directly related and they do not share the same employer”³
20. This lack of independence played an important role in the failure to detect Harold Shipman’s crimes:

“the Hyde doctors related how, when they were to complete a Form C for Shipman, he would visit them in their surgery and would give a very full account of the deceased person’s medical history and the events leading up to the death. Shipman was a plausible historian and gave a full and persuasive account of events. The Form C doctor would not see the medical records”²

This can be compounded by the fact that the doctors may not be experts in examining MCCDs.
21. The crematorium referee, who is attached to the crematorium completes cremation form 10. While this medical referee is expected to be independent from the doctor signing the MCCD, in practice before the 2008 changes the crematorium referees often receive the papers at too late a stage for any intervention to be practicable, so their scrutiny was often not effective³. The 2008 changes introduced revised Cremation Forms 4, 5 and 10 (replacing Forms A, B and C) with strengthened guidance for doctors and medical referees completing these forms.
22. Despite being resource-intensive and involving three different people, the system may therefore fail to provide effective independent scrutiny and is liable to the risks outlined in the preceding section.

Low quality and accuracy of MCCDs: Scrutiny may not be effective

23. There are reasons to believe that the lack of independent scrutiny explained above also has an impact on the quality and accuracy of completed MCCDs. However, there are additional factors leading to low quality MCCDs.
24. The study “Death certification: an audit of practice entering the 21st century” looks at a sample of 1,000 completed certificate counterfoils⁹. The main findings are that “only 55% of the MCCDs were completed to a minimally accepted standard, although many of these failed to provide relevant information to allow adequate ICD-10 coding” and “nearly 10% were completed to a poor standard, being illogical or inappropriately completed”. This can be compared to the ME system in Finland, where 71.4% of MCCDs were validated as giving the correct ICD-9 code¹⁰.
25. The reasons the authors give for this low level of quality are:
 - Completing MCCDs is often delegated to junior doctors
 - Lack of training and knowledge in completing the MCCD
 - Lack of care by doctors when completing the form, perhaps due to other time pressures
26. It can further be argued that currently the lack of effective scrutiny of MCCDs (as described in this and the preceding section) signals that mistakes in MCCDs will not be detected and will not have any consequences.
27. Inaccurate MCCDs can have a negative effect on health outcomes and the provision of health care. MCCDs are the source of mortality statistics. These inform medical research, public health and healthcare policy, and in some cases the financing of health systems. Inaccuracies in MCCDs can therefore have a negative effect on all of these aspects. There is some empirical literature on these effects, including “Death certification in fractured neck of femur”, which looks at the potential misallocation of health care-related resources due to such inaccuracies¹¹.

C. Policy objectives and intended effects

28. The aims of the policy are:
 - To ensure that the system for certifying all non-coronial deaths provides adequate scrutiny to identify and deter criminal activity or poor practice;
 - To rationalise the existing system to ensure that the level of scrutiny is proportionate and does not impose undue delays on the bereaved¹² or undue burdens on medical practitioners and others involved in the process;
 - To provide a common death certification procedure that ensures the same level of scrutiny and assurance, irrespective of the choice of burial or cremation.
29. If the level of scrutiny is appropriate, the number of situations where doctors can manipulate MCCDs will be reduced. This is expected to lead to a reduction in the number of problems as well as a better detection of any problems requiring referral to a coroner. An improvement to patient safety could therefore be expected.
30. Similarly, the confidence of the bereaved in the death certification process should improve with the mandatory requirement that the bereaved are offered an opportunity to raise any matter related to the death and an explanation of the cause of death stated on the MCCD. Both the reduction in cases and a more transparent system should contribute to increased confidence that all due process has been followed.

⁹ “Death certification: an audit of practice entering the 21st century” (Swift and West, 2002, *Journal of Clinical Pathology*, 2002;55:275-279)

¹⁰ From Findings to Statistics: An Assessment of Finnish Medical Cause-of-death Information in Relation to Underlying-cause Coding (Lahti, 2005), available at <http://ethesis.helsinki.fi/julkaisut/laa/oikeu/vk/lahti/fromfind.pdf>

¹¹ “Death certification in fractured neck of femur” (Donaldson, Parsons and Cook, 1989), available at: <http://www.sciencedirect.com/science/article/pii/S0033350689800368#cor1>

¹² The use of the term bereaved throughout this document means the informant responsible for the person who has died

31. Additionally, death certification provides the proof of legal death for the legal system and generates data for epidemiological studies and future health care provision. MCCDs of improved quality should have a positive impact on these activities.

D. Underlying causes of the problem

32. The agency problem described above is intrinsic to the situation of medical practice and as such cannot be eliminated fully. It is however possible to achieve a second best solution by introducing an appropriate mechanism to monitor compliance. Improved scrutiny of MCCDs by an ME can provide the necessary incentives for better performance.

E. The Do Nothing Option (Option 1) and Derivation of Other Options

i. Baseline (Do Nothing Option – Option 1), against which other options are assessed

33. The current process and its drawbacks are set out above.
34. According to the “Review into death certification. Home Office”, “The benefits of death certification are varied and include the proof of legal death, the generation of data for epidemiological studies or future health care provision, and the deterrence of crime”. The current problems of the death certification system identified above, if not rectified, have consequences on all of these areas¹³.

Cost of current system

35. In order to compare different options against the current system, it is necessary to quantify the costs of the existing system. This can be estimated by multiplying the number of forms currently completed by the fees charged for them. Cremation Form 4 is completed by a registered medical practitioner (RMP); Cremation Form 5 is a ‘confirmatory medical certificate’ completed by a RMP of at least five years’ standing and independent of the deceased, and of the Form 4 doctor. The Form 5 doctor carries out some checks. Cremation Form 10 is authorisation of cremation of the deceased by a medical referee.
36. In April 2018, the fees for Forms 4 and 5 were £82 each¹⁴. The average fee for cremation form 10 is around £20¹⁵. For cremation cases where coroner investigations were not performed, all three forms were required. For cremation cases where coroner investigations were performed, only form 10 was required.
37. According to data from MoJ and ONS, in 2016 there were 490,791 registered deaths for those usually residing in England, of which 90,404 were investigated (either by post mortem, inquest or both) by coroners and 400,386 were either returned or did not feature any involvement by coroners^{7 8}. Figures from the Cremation Society of Great Britain show that in 2016 for England the proportion of registered deaths that resulted in cremations was 80%¹. This would give 72,465 cremation cases investigated by coroners and 320,937 cremation cases not investigated by coroners. Therefore the total annual cost of the current system in 2016 was approximately £60.5m (based on 320,937 deaths with a fee of £184 and 72,465 deaths with a fee of £20). The costs of carrying out the cremation forms are assumed to be constant in real terms over the 10 year period.
38. However, since amendments to the Coroners and Justice Act 2009 came into force on 1 April 2017, the duty to conduct a coronial inquest for all cases where the deceased was deprived of their liberty (DoLs) under the Mental Capacity Act 2005 have been removed. As such, the

¹³ *Review into death certification*. Home Office. London: HMSO, 2000

¹⁴ *Cremation fees and guidance*, BMA, <https://www.bma.org.uk/advice/employment/fees/cremation> (accessed April 2018)

¹⁵ Based on advice from the Ministry of Justice (MoJ)

appropriate counterfactual is the scenario in which the current system is maintained, without compulsory inquests into all DoLs cases.

39. There were approximately 11,376 deaths subject to DoLs reported to coroners in 2016⁷. Assuming that these are no longer automatically subject to an inquest by the coroner, the estimated future annual average cost of Option 1 would be £62.6m based on ONS death projections.
40. This calculation assumes that the current system is funded fully and precisely through the fees paid by the bereaved. That is, the fees do not provide a surplus to those who provide scrutiny (in which case the resource costs of the system would be over-estimated by this calculation), nor, on the other hand, does the system currently need to be covered in any part by the salary of those who provide scrutiny (in which case the resource costs of the system would be underestimated by this calculation). However, it may be that the existing fees do provide a transfer to doctors.
41. Consultation responses highlighted the fact that cremation form fees are often waived following the death of a child. Given the assumptions made above, this does not alter the cost of the system as the usual service is still provided by doctors.

ii. Derivation of the short-listed options

42. Design and implementation of the reforms to improve scrutiny of MCCDs had been co-ordinated by the Death Certification National Steering Group (formerly known as the Tackling Concerns Locally – Death Certification Sub-Group). The Steering Group was established to provide direction on progress of the Programme and to take overall responsibility for key decisions on deliverables, including acting as ‘field experts’ giving guidance on the practical implications of proposals for the new death certification process.
43. The programme has been informed by clinicians and representatives from professional and regulatory bodies in the NHS, as well as coroners, funeral industry representatives and colleagues from local government and other government departments. From February 2013, an Implementation Board comprising of delivery partners advised on matters relating to implementation. The Steering Group became a Reference Group of all stakeholders and delivery partners advising on wider issues. The current governance for the programme includes a Strategic Programme Board.
44. Following the publication of DH’s Shared Delivery Plan 2015 - 2020, in which introducing medical examiners to a reformed system of death certification is a key deliverable under the strategic objective ‘Creating the safest, highest quality healthcare services’, new governance arrangements have been put in place. In addition in DHSC’s Single Department Plan a key objective is to ‘support the NHS to deliver high quality, safe and sustainable hospital care and secure the right workforce, the introduction of the ME system is essential to being able to deliver this.
45. The main proposal that has been considered is to establish a new system based on MEs, specially trained doctors that scrutinise MCCDs. The proposed new local ME system was developed through this engagement process. It has been piloted in a number of different locations in England and Wales. An initial Pathfinder Pilot was established in March 2008 at the Sheffield Teaching Hospitals NHS Foundation Trust in collaboration with HM Coroner for South Yorkshire (West) to test and evaluate the proposed role of the ME in scrutinising MCCDs in hospitals. The report of the first three months of the pilot concluded by saying:

“Including a ME in the MCCD process improves quality, accuracy, and the service to the bereaved, without introducing delays in certificate issue. There is an overall reduction in the number of referrals to the Coroner, but preservation of appropriate referrals”¹⁶

¹⁶ Sheffield Medical Examiner Pathfinder Pilot Report, August 2008

Trusts were invited to become pilots. The pilots listed below were chosen to represent a true cross-section of society representing all religions and beliefs.

- Sheffield
- Gloucestershire
- Powys
- Mid Essex
- Brighton & Hove
- Leicester Faith Community
- Inner North London

46. Having demonstrated that the new system can work in a range of settings, in hospital and in the community, in urban and in rural areas, the majority of piloting has been completed across England and Wales. The work of the two flagship pilots in Gloucestershire and Sheffield has been extended to enable the pilots to operate on an urban and rural basis to test the new ME service at a scale that will be required for implementation nationally. The two sites now act as implementation resource to observe a fully operational ME service.

47. This option has been further shaped by evidence from the death certification pilots. The starting point for developing policies for the new death certification process is the conclusions and recommendations of the Shipman Inquiry's Third report². The new ME process and its associated policies have been designed with the Inquiry in mind and with advice from a steering group of professionals and pilots who proposed improvements, in particular the practicality of specific procedures and prescribed forms.

48. One of the aspects where the policy has evolved has been the question of who should perform the non-forensic external examination of the body. Initially, it was proposed that a new duty should be introduced on the certifying doctor to examine the body for all deaths (to replace the current requirement for external examinations prior to cremation only, which is performed by a separate doctor who completes cremation form 5 confirmatory medical certificate). However, the experience of the pilots suggested that examination of the body by the ME was impractical for deaths in the community where the doctor would have to travel to where the body lay and potentially lead to delays. It was also suggested by the British Medical Association (BMA) that introducing such a duty would require a fee similar to that which the bereaved pay for completion of cremation forms. The cost of an examination by a doctor is greater than for one performed by a non-medical and the experience of the pilots suggests there is no additional benefit of a doctor viewing the body over a person with suitable expertise and appropriate training.

49. On the whole, consultation responses have confirmed that whether a non-forensic external examination of the body is necessary should be left to the discretion of the ME. Responses were inconclusive on the question as to whether a non-medical with suitable expertise and sufficient independence can undertake the examination.

50. The response to the consultation demonstrates that there is widespread support for the aims of the reforms and for the introduction of medical examiners but there were concerns about some aspects of the proposals. In particular, concerns were raised about how the proposed model based in local authorities, would work in practice and about the proposed timeframes for implementing the service. Feedback on a proposed funding model was also received.

51. Since the Government consulted on the package of Death Certification Reforms, events have moved on. New information on how a medical examiner service could be introduced has been generated by the pilot sites, the Learning from Deaths initiative and a number of early adopters of the medical examiner service within the NHS across England.

52. As an alternative to a reform based on MEs, an option where the current system for cremations is extended to cover burials is also considered in this IA.

53. The policies set out in this IA cover England.

iii. The options assessed in the rest of the IA

Option 1

54. This is the do nothing option and is not explored separately. Options 2 and 3 are considered in relation to this Option.

Option 2

55. This option would extend the current system, including the fee, to cover burials as well.

Option 3

56. The DHSC response to the consultation sets out proposals for a unified system applying to all non-coronial deaths, either a burial or a cremation, that provides additional protection for the public against criminal activity of the sort exposed in the Shipman case as well as poor care leading to death.

Creation of role of ME

57. The post of ME and its supporting medical examiner officer (MEO) would be created under this option.

58. MEs will be medical practitioners with at least five years' full registration with the General Medical Council (GMC) and with a license to practise, who have received special training in the role. Appointments are expected to be on a part-time basis enabling some ongoing clinical practice. MEs will have additional functions including reporting concerns of a clinical governance nature by following local reporting procedures.

59. Each ME will be assisted in their role by MEOs who will have responsibility for gathering information from different sources and preparing cases for scrutiny. The detailed specification for this role has been developed and piloted alongside that of the ME.

60. The responsibilities of the ME will include:

- Independent scrutiny of MCCDs for cremations and burials and consideration of associated information provided by the bereaved and the certifying doctor;
- Certifying deaths referred by the coroner where no attending practitioner is available within a reasonable period;
- Confirmation of the cause of death stated by the certifying doctor in a timely manner to register the death and ensure urgent cremations and burials can take place;
- Ensuring information related to hazardous implants or medical devices or if the deceased person was suffering from a communicable infection, is verified, recorded and notified to the doctor. The information will then be given to the bereaved (with a confirmed MCCD) to pass on to the funeral director, or the appropriate authorities arranging a burial or cremation;
- Notification to a coroner of a death under s.18 regulations of the Coroners and Justice Act 2009 where the duty arises during the course of a ME's scrutiny; or refer a death where the ME is unable to confirm the cause of death stated by the doctor;
- Reporting any concerns of a clinical governance nature, or of interest for public health surveillance;
- Identifying the training needs of doctors in completion of MCCDs and provide feedback on accuracy of certification locally.

Links with Clinical Governance

61. It is anticipated that MEs with access to clinical and administrative information accompanying the MCCD will be well placed to identify adverse patterns of deaths. MEs are expected to follow an organisation's local procedures for reporting incidents of a clinical governance nature and expected to be kept informed of the outcome of their reporting of such matters.

Timeline of implementation and funding of ME system

62. There will be two stages to the funding of the ME system to enable its introduction whilst the legislation is in progress. The system will be set up in 2018/19 with the ME functions commencing in April 2019 for all deaths that are not referred to a coroner. The current cremation forms 4, 5 and 10 will continue to apply for the first 2 years of the ME system coming into effect

and the two systems will run alongside each other. The ME will complete cremation form 5 for all those being cremated as well as carrying out all the functions in the ME system for all non-coronial deaths. Once the ME system legislation has been enacted cremation forms 4, 5 and 10 will cease to be applied and the ME functions will be applied to all deaths that are not referred to the coroner.

63. During the interim period of both the cremation forms and the ME system running alongside the ME system will be funded through revenues from cremation form 5 and DHSC (for the interest of brevity for the remainder of this document this will be referred as the 'interim period'). The ME costs for those being cremated will be funded by cremation form fee revenues sourced from efficiencies found by MEs completing cremation form 5 and DHSC funding any deficit between the ME system costs for those being cremated and these cremation form fee revenues. DHSC will also fund the ME system cost of those being buried and for child deaths any other costs to the service not covered by the fee.
64. Once the ME system is underpinned by statute, it would be primarily funded through a fee for all adult non-coronial deaths that are certified by an ME. A fee is presented here to illustrate how this policy could be funded after the interim period. DHSC will fund ME costs related to child deaths and any other costs to the service not covered by the fee. DHSC will also fund the set-up costs of the system.

Table 3: Timeline of functions completed by staff and fees

Function	Present	Interim period: 2019/20 – 2020/21	Statutory ME system: 2021/22 onwards
Attending Doctor completes MCCD for all cases	Yes	Yes	Yes
Attending Doctor completes Cremation form 4	Yes	Yes	No
Medical referee completes cremation form 10	Yes	Yes	No
Independent doctor completes cremation form 5	Yes	No	No
ME completes cremation form 5	No	Yes	No
ME completes ME system process	No	Yes (non-statutory)	Yes (statutory)
Public pays a fee (adult non-coronial deaths):	Yes	Yes	Yes
- Those cremated	Yes (£184 medical cremation form fees)	Yes (£184 medical cremation form fees)	Yes (lower than medical cremation form fees)
- Those buried	No	No	Yes (lower than medical cremation form fees)

F. Impacts, Costs and Benefits of Option 2

i. The mechanism by which Option 2 is intended to work

65. Option 2 would extend to burials the additional scrutiny currently applied to cremations. In the current system there is no scrutiny on the quality of MCCDs or forms and checks similar to cremation forms for burials where the death is not thought to be suspicious beyond those checks performed by registrars. This option would potentially provide some increase in scrutiny and subsequently improved patient safety. There would be no introduction of an ME or an MEO in the option. Costs of this scrutiny for burials would be covered by a fee.

ii. The costs and benefits of Option 2 arising from the impacts

Costs

66. Extending the system that currently applies to cremations to cover burials will increase the costs of the current system. It will mean that those being buried, in non-coroner cases, will have some level of additional scrutiny and so the new system would have an annual average cost of £78.1m from 2019/20 (based on 18% of deaths with a fee of £20 and 82% with a fee of £184). This estimate accounts for the removal of duty for coroners to automatically conduct an inquest in all DoLs cases. The costs of completing the cremation form are assumed to be constant in real terms over the 10 year period.

67. Savings resulting from fewer exhumations are expected to be trivial and are not considered in this IA.

68. The additional cost of this option above the baseline costs of the current system would be £15.5m per year. This cost would be faced by bereaved families and paid through fees for forms akin to the existing cremation forms.

Benefits

69. Extending the system currently used for cremations to burials would increase the level of scrutiny for burials to that currently applied to cremations. This could have some positive impact on patient safety and offer some peace of mind for the bereaved however these elements are difficult to quantify. As a result, the benefits of resulting from Option 2 have been left unquantified.

1. Additional Scrutiny and Improved Patient Safety

70. The additional scrutiny of burial cases should increase detection rates of malpractice. Universal checks could also act as a deterrent to new cases of poor practice and malpractice. However, this deterrent effect may be limited in reality - if doctors are currently unaware of the posthumous wishes of their patients, they would expect the majority of cases to result in cremation, and as such be subject to further checks.

2. Improved level of assurance for the bereaved

71. There may also be a benefit for the bereaved in terms of their peace of mind, though this effect is likely to be minimal given the limitations of this scrutiny, as already outlined.

Net Present Value of Option 2

72. Under this option, there are several unquantified benefits, with quantified average annual costs of £15.5m per annum, for a 10 year period.

73. As compared with Option 1, over 10 years and using a discount of 3.5%, this would give an estimated Net Present Value (NPV) of £-117.7m. This assumes that real prices and the split of cremations and burials remains constant over the 10 year period, and takes into account varying death projections.

Table 4: NPV of Option 2

£millions	Discounted Costs	Discounted Benefits	NPV
Option 2 NPV (relative to Option 1)	117.7	<i>Unquantified</i>	-117.7

74. It should be noted that this NPV does not include any of the unquantified benefits to the health and well-being of the public that are described in the Benefits section. Therefore, it underestimates the NPV of the policy.

G. Impacts, Costs and Benefits of Option 3

i. Mechanism by which Option 3 is intended to work

75. As explained in Section A, the criticism of the current death certification system is that it does not provide sufficient independent scrutiny to ensure that the cause of death stated by doctors on MCCDs are accurately and correctly completed beyond the checks performed by registrars when registering a death in the local register service, who are not medically qualified.

76. Under Option 3, all MCCDs for non-coronial deaths resulting in either cremation or burials will be scrutinised by MEs, replacing the current system described in sections A and D. MEs will be independent and appropriately trained. This means that both the independence and the quality of the scrutiny should improve, allowing death certification to achieve its aims of deterring poor practice and crime, providing assurance to patients and generating data for epidemiological studies and public health policy.

Impact on different groups

Private and voluntary sector

77. The procedure would apply to doctors completing MCCDs regardless of whether they are employed in the NHS or the private sector. We are not proposing significant changes to the MCCD itself, so the impact for doctors completing the MCCDs is likely to be essentially the short-term need to understand the new procedures and establish key contacts with MEs.

78. After the interim period, Doctors currently completing Forms 4 and 5 and medical referees completing Form 10 will no longer need to carry out these functions. During the interim period the doctor will continue to complete Form 4, the Medical Examiner will complete form 5 and medical referee will continue to complete Form 10. The ME function will result in remunerated work and will be supported by a paid workforce.

79. The only businesses likely to be affected by the proposals will be funeral directors. Traditionally, funeral directors have collected cremation form fees on behalf of doctors from the bereaved as part of the bill for the funeral. No changes are proposed to the mechanism for the collection of cremation fees. Going forward it would be a preferred option for fees for the ME system (including burial cases) to be collected in the same way.

Public sector

NHS

80. The introduction of the ME system will have an impact on the NHS through:

- The requirement for the NHS to recruit and train MEs and MEOs;
- The requirement for the NHS to monitor and manage performance of MEs (whilst ensuring that MEs are independent in how they exercise their professional judgement as medical practitioner);

- The requirement for the NHS to provide office facilities, resources and access to information systems.
 - The appointment of a National Medical Examiner (NME)
81. Initial set-up costs for the service will be met by DHSC in line with the new burdens doctrine, whichever funding option is chosen. Thereafter the running costs will be funded as presented in paragraphs 63-65 above which will cover all the running costs incurred by the service. In financial terms then, the net financial impact on the NHS as a whole is expected to be zero. The costs presented in the cost section concern the costs of the system at national (average) level.
82. See the Costs section for quantification of the different costs discussed in this section.
83. MEs will be recruited medical practitioners that hold a General Medical Council license to practise in the UK and at least five years' experience (the candidate must have been registered as a medical practitioner throughout the previous five years as of the date of appointment). Taking into account the role and responsibilities of a ME described in a generic job description and person specification, it is expected that the role will be suited to senior, experienced doctors. MEs will be employed by the NHS.
84. The new system is expected to inform the work of local NHS clinical governance teams, where they exist, through an ME's closer scrutiny on MCCDs. The national medical examiner guidance will require MEs to report clinical governance matters in accordance with any relevant local reporting arrangements and obtain information about the outcome of any reporting.
85. Introduction of the ME service will also have an impact on the NHS through its contribution to and use of data related to clinical governance. For example, in addition to closer scrutiny of MCCDs, any systemic failures involving poor practice or unusual patterns of deaths are expected to be detected and acted upon by MEs.
86. The impact of this policy on NHS litigation costs is difficult to estimate with any certainty. The new system may detect a greater number of problematic deaths. Detecting and acknowledging a greater number of mistakes, and supporting the learning from deaths scheme in hospitals, should lead to an improvement in the quality of medical care. The MEs will act as an initial filter to identify cases in the acute sector for structured judgement reviews¹⁷ and avoidable deaths. This impact is left unquantified.

Registrars

87. The General Register Office for England and Wales (GRO) is part of the HM Passport Office. The death certification reforms will affect the data on death registration collected by GRO and processed by ONS, which will mean essential changes to the online registration (RON) system. DHSC will be meeting the cost of this work (described in more detail in the costs section below).
88. Following the interim period and the introductory of the statutory ME system, local registrars will need training on the new system which will be funded by DHSC, see paragraph 145 in set-up costs.
89. DHSC will continue to work with the GRO to ensure that the ME function links with registration procedures. The GRO is represented on the Strategic Programme Board in order to direct and support the development and implementation of these proposals.

Coroners

90. The over-arching principle governing the ME scrutiny will be the safety of the certification process. We anticipate that by exposing MCCDs to medical scrutiny at an early stage in the process, referrals to Coroners will be more appropriately targeted and therefore be more efficient use of Coroners' resources. DHSC will work with Coroners and MoJ to ensure that the interface between the ME and Coroner functions works smoothly.
91. Evidence from the death certification pilots suggests that the new system can lead to an increase of appropriate cases forwarded to Coroners but a decrease in the numbers of inappropriate cases. The impact on the costs of the Coroner service is discussed in the Costs

¹⁷ <https://www.england.nhs.uk/publication/national-guidance-on-learning-from-deaths/>

section below. DHSC and MoJ will continue to work together to assess the financial consequences for coroner services.

The public

92. As already explained, currently 80% of deaths result in cremation and, where these are not investigated by the coroner, require payment of certification fees totalling £184: these fees are paid to doctors for completion of cremation Forms 4 and 5 and to the medical referee for completion of Form 10. Cremations that follow investigation by the coroner only require Form 10 and therefore incur a fee of £20. Under Option 1, we estimated that the average annual expenditure on cremation fees would be about £62.6m. No similar fees are paid currently in cases of burial.
93. After the interim period a fee would continue to be paid by the informant for non-coronial cremations with the equivalent being introduced for non-coronial burials. This fee will be lower than the current cremation fees but it will represent a new cost for burial cases. This will have a disproportionate impact on those groups that use burials, as a requirement of religious or cultural practice. Given the anticipated level of the fee for burials (being lower than which is currently paid for cremation form fees), this would represent a small increase in costs only relative to the costs of the average burial funeral which is over £4,000¹⁸. The costs section below contains more information on how the anticipated public fee has been calculated.
94. The main benefits from the new system will be felt by the public in terms of deterrence of poor practice and of crime, and greater assurance for the bereaved that due process has been followed. The fact that MCCDs will be of better quality should also have a positive impact on epidemiological research and public health management, which would be expected to contribute to the health of the public in the future.

ii. Costs and benefits of Option 3 arising from the impacts listed in section F.i.

Overview

95. After the interim period, death certification is primarily financed by either payments from the informant in cremation and burial cases with DHSC funding the ME costs of child deaths (up to the age of 18) and any other costs to the service not covered by the fee. This would, cover the costs of the ME and the MEO duties. Any changes to the system will therefore have an impact on the costs. We assume that any changes to running costs will be passed on directly to DHSC and the informant, and so will not represent a net cost or saving to the NHS. Set-up costs will be financed by DHSC.
96. The costs of Option 3 have been calculated by estimating the number of MEs necessary to provide scrutiny and confirmation of cause of death stated by the certifying doctor, as well as the costs of recruiting, training and providing MEO staff and resources to them. These costs would initially be incurred by the NHS, who have responsibility for establishing the service and resourcing, although it is expected that they would be recovered by the fees charged to the informant and DHSC.
97. In Option 3 the person liable to pay, or make arrangements to pay the fee, will be the death registration informant (a person who goes to register a death).
98. A best estimate and a high cost scenario has been included in the analysis. The high cost scenario is based on a longer time spent per case by MEs; this is considered an uncertainty in the process once a national roll-out is carried out. A sensitivity analysis has also been carried out around the death projections and this is presented in Annex B.

¹⁸ National Funeral Cost Index Report 2017, Royal London: <https://www.royallondon.com/Documents/PDFs/2017/Royal-London-National-Funeral-Cost-Index-2017.pdf>

Cost of potential delays for burial cases

99. Under Option 3, there would be an improved death certification process for cremations that would be extended to burials. It would represent an increase in the scrutiny of burial cases. In the pilot sites there has been no delay to cremations or burials with the introduction of the medical examiner process.
100. As a requirement of some cultural and religious customs burials occur within 24 hours of death, so an inability of the ME system to facilitate this requirement could result in a significant community criticism. In the new process, we expect guidance and national exemplar forms will enable the ME's office to be alerted to the need for urgent scrutiny of the MCCD prepared by the doctor. NHS ME areas with large faith populations will need to ensure that the local ME service is configured to meet the needs of their community.

Running costs of Option 3

101. The running costs of Option 3 after the interim period will be financed through the continuation of a fee for cremation lower than present and an introduction of an equivalent fee for burials. The exceptions to this are the cost associated with those cases referred from an ME to a coroner, and those with child deaths which would be financed by DHSC. In the interim period the running costs will be funded by cremation form 5 fee revenues and DHSC, including the ME costs for burials, and any deficit that may result from the cremation form 5 fee revenue not being sufficient to cover the running costs of the system.
102. This section provides (and utilises) estimates of the *average* costs across England. Analysis is based upon 2016 death registrations and coroner statistics, ONS 2016 based population projections¹⁹ and uses the best available evidence as of April 2018.
103. The assumptions below are based on conversations with expert stakeholders and the teams that work on the DHSC pilots. They have been reviewed in light of evidence provided through consultation responses.

1: Number of Cases

104. The total number of deaths registered in England in 2016 was 490,791²⁰. Data from the Cremation Society of Great Britain show that 80% of deaths result in a cremation, with the remaining 20% resulting in a burial¹. Under Option 3, all 393,402 cremations and 97,389 burials would be scrutinised within the new system.
105. Evidence from the death certification pilots suggests that MEs would be involved in around 89% of scrutinised deaths corresponding to 436,804 cases (the remaining 11% would be forwarded to coroners directly and would not require the intervention of an ME). It also suggested that 13% (63,803 deaths) of all deaths would be forwarded to coroners by MEs²¹.
106. Therefore, MEs would scrutinise 76% of all deaths for which a fee would be charged to the informant. This equated to 373,001 deaths in 2016.
107. The other 13% of cases, representing 63,803 deaths in 2016, would require scrutiny by MEs but would ultimately be investigated and certified by coroners and therefore a fee would not be charged to an informant for these specific cases.

2: Number of Full Time Equivalent (FTE) and headcount

108. The new service would involve different types of staff:

¹⁹ <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationprojections>

²⁰ For those resident in England

²¹ The duty to automatically conduct an inquest for DoLs cases no longer applies. Assuming that only a minority of DoLs cases will require a coronial investigation for other reasons, this can be expected to lead to an increase in the percentage of cases seen by MEs relative to the current system. However, the estimate of 89% is informed by pilot evidence before 2014-15. Prior to this, there were significantly fewer DoLs issued (the number of active DoLs authorisations in England in the years 2009-10 to 2013-14 are approximately 2-4% of those observed in 2015-16). As such, the 89% should be representative of the percentage of cases seen in the scenario where DoLs cases are seen by MEs, rather than coroners. Source for DoLs order: NHS Digital (2016) Mental Capacity Act, Deprivation of Liberty Safeguards, England 2015-16

- Medical Examiners: MEs are doctors who will verify the information on MCCDs, providing independent scrutiny. There will be a lead ME responsible for managing the service within the local area.
- Medical Examiner Officers: MEOs are administrative personnel to support MEs. There will be a lead MEO working with the lead ME to manage the service within the local area.
- Non-doctors who undertake external examinations: These are non-medical personnel who will provide an external, non-forensic examination of the body in those cases that are deemed to require an external examination. The extension of the Sheffield pilot had tested, among other things, the use of local funeral directors and mortuary technicians to undertake the non-forensic examination of bodies. To run the system as efficiently as possible, the person carrying out the external examination will be a person who would otherwise be seeing the body and therefore this involves a negligible cost.

109. It is expected that MEs and MEOs will be involved in all cases that are not immediately referred to a coroner. However consultation responses have suggested that the necessity of an external examination should be left to the discretion of MEs and will therefore only be necessary for a subset of cases. Based on discussions with the pilot sites, we estimate that the vast majority of cases will not require external examination by the ME. For the purposes of this IA, we have assumed that 50% of cases that are not immediately referred to a coroner will require an external examination of which 47.5% will be carried out by non-doctors. (It should be noted that certifying doctors will continue to have the option to examine the body of the deceased in order to establish the cause of death and complete the MCCD). These non-doctors will have been trained for this purpose. Based on evidence from the pilots it is assumed that other people who carry out examinations will not require the presence of MEs.

110. Based on discussions with those involved with the Sheffield pilot, the split below can be derived.

Table 5: Proportion of ME cases requiring external examination

Staff Type	Proportion of ME cases requiring external examination
MEs	2.5%
Non-doctors that carry out external examinations	47.5%
Total	50%

111. Evidence from the pilots can be used to estimate the average time that each death or external examination takes for each type of employee. Scrutiny will involve several steps. It is anticipated that steps 1-6 will be carried out in the case of all deaths. Coronial deaths identified by the ME will only require some of the following steps:

1. Receipt of appropriate level of supporting medical records
2. Receipt of the proposed cause of death
3. Conversation with relatives (this will be undertaken by either the ME or MEO depending on the case)
4. May also involve the certifying doctor asking the ME for advice and in addition the ME could have a need to speak with the certifying doctor
5. Discussion with certifying doctor. Both the ME and MEO are likely to need to do this.
6. Review of any further medical records and test results
7. External Examination carried out by non-doctors or ME, where the ME deems it necessary

What is required for proportionate scrutiny will vary on a case by case basis and these estimates are simplifications. Below are the estimated numbers of minutes to carry out the different steps, high estimates are presented in brackets, as they are throughout the document.

Table 6: Time required per case

Minutes Needed	Steps	Time required (high)
Minutes per case - ME	1-6	15 (25)
Minutes per case – MEO	1-6	85
Minutes per examination – Non-doctor or ME	7	10

112. In cases where the ME refers the case to the coroner it has been assumed that the ME still needs 15 minutes per case, but that the workload would be less for the MEO in these cases and therefore an estimate of 65 minutes per case has been used.
113. In the interim period the ME will also have to complete cremation form 5. The cost of this is a transfer from the doctor completing cremation form 5 currently to the ME, the same function is taking place although it is expected that the ME will be specifically employed, trained and therefore have the expertise in the area to complete this function more accurately and efficiently. It is estimated from discussions with pilots that it would take 10 minutes to complete the form and 10 minutes to complete the external examination required for that form. These are not considered a cost of the new system as cremation form 5 is part of option 1. However, any resource savings from these forms being completed more efficiently is considered a cost saving resulting from this option when comparing it to option 1.
114. Moreover, an additional 12.5% FTE has been added to the ME and MEO staff requirements in order to cover non-case duties such as administrative tasks, collaborating with other MEs (e.g. peer review) and writing reports.
115. In addition, the lead ME and lead MEO in each office are expected to spend around 4 hours a week on management tasks, and ultimately report to the NME.
116. During the first year, when the new system is introduced it is likely that staff will need to put in extra time. It is therefore assumed that in the first year, the equivalent of 10% additional FTEs will be necessary.
117. See Annex A for details relating to the expected hours and weeks worked per year for each type of staff and the expected headcount to FTE ratios (most staff members are expected to work on a part-time basis). It has been assumed that the MEs will work for a larger proportion of their time in this role during the interim period to cover the cremation form 5 functions rather than training and employing more MEs. These timings, combined with the total number of cases, are used to calculate the expected total ME and MEO FTE and headcounts reported below (high estimate in brackets):

Table 7: Total staff required

Staff Requirements (Average annual figures)	Total Headcount (high)
Total number of MEs required	246 (408)
Total number of MEOs required	1086
Total headcount staff	1,332 (1,494)

3: Employment costs

118. This section summarises the assumptions about costs of employment relative to the number of FTEs for each type of staff. The employment costs for each staff type are included in Annex A under a central and high estimate (the latter in brackets).

Table 8: Total employment costs (excluding recruitment and training costs)

Staff Type (£millions) Average annual costs in 2018 prices	Employment cost per interim year (high)	Employment cost per Statutory ME year (high)
MEs	11.7 (17.7) ⁺	11.5 (17.5)
MEOs	20.5	20.5
Total	32.2 (38.2)⁺	32.0 (38.1)

⁺does not include the cost of the time taken to complete cremation form 5 functions as discussed in paragraph 114 as this is replacing work carried out at present and is expected to result in efficiency savings.

119. First year inefficiency costs as mentioned above in paragraph 117 are based on salary costs for each type of employee, and are included in the estimates in table 8. Since most staff are not expected to be full-time, this is assumed not to require overtime, but simply longer working hours in the first year, which will be paid at the usual rate for each member of staff. This is expected to cost £2.5m (£2.9m) in the first operating year.

120. The extra time taken by MEs in the interim period to complete the cremation form 5 functions, as detailed in paragraph 114 above has been costed in the same way as the inefficiency costs, being based on salary costs only. Due to the uncertainty around the estimates and implementation timings total employment cost estimates on the time taken to carry out this function have been included in the high cost estimate.

121. In addition, DHSC will appoint a National ME (NME), a senior doctor, who will provide leadership and advice on matters relevant to MEs. This will be funded directly by DHSC and does not contribute to the costs covered by the fee paid.

Table 9: Total cost of the National Medical Examiner

Element of Staff Cost (£)	Estimate
Average annual costs in 2018 prices	
Salary cost of the National ME	142,000
On-costs (at 30% of salary) of National ME	42,600
Proportion of NME time dedicated to NME duties	40%
Total cost of the NME	73,840

4: Recruitment costs

122. The set-up costs section covers the initial recruitment costs necessary in the first year. After that period, there will be an on-going cost of recruitment to cover staff turnover. An assumption of 11.5% is used for all staff types, based on overall NHS leavers rate in the year from September 2016²². Since this is a new service and the turnover is not known, this overall rate is used as an approximation. Recruitment costs including advertising and interviewing are estimated to be £750 per post. Therefore, in option 3, for an estimate total of 1,332 (1,494) staff

²² NHS Workforce Statistics, September 2017, Provisional Statistics

headcount, around 149 (167) new recruits are expected every year and the average annual costs of recruitment are expected to be around £115,000 (£129,000).

5: Training costs

123. Each year after set-up, new members of staff are estimated to receive four-day's on-the-job training as part of their induction. The cost of a day's work varies for different staff types but, based on the turnover rate of 11.5%, 28 (46) MEs and 121 MEOs will be recruited each year costing £70,000 (£115,000) and £105,000 respectively. The average annual cost is therefore expected to be around £175,000 (£220,000).

124. Additionally, training for MEs and MEOs will be available through e-Learning for Health. E-Learning for Health (e-LfH) will have the following costs:

- Running the Platform: The costs of running the e-LfH platform is approximately £2.5m/year and the ME module (91 sessions) as a proportion of the total e-LfH platform would be £66,000. This is part of the e-LfH budget and therefore will not require fresh spending from DHSC. However, it is included in this IA as an expression of the opportunity cost of using this portion of the online platform.
- Updating sessions: The material will need to be updated every year. The annual cost for this is estimated to be around £5,000 and includes clinical input.

125. Overall, this gives a cost of E-learning for Health of £71,000 per year. Additional costs incurred in the first year are reflected in Set-Up costs.

126. The time spent by employees on ongoing training is accounted for as part of their CPD. The assumptions used in the "Number of FTEs and Headcount" section account for this.

6. Office costs, fee collection and bad debt

127. There will be office costs to account for the administration needed for the ME service. These are estimated to be £1,300 per office per year, based on information from the Sheffield pilot. This results in a total annual average cost estimate of £198,000.

128. As explained in paragraph 64, during the interim years the collection of the cremation form fees will continue as at present and so there are no extra costs. The only difference is the funeral directors will pay the NHS rather than individual doctors and so this should be more straight forward. It is hoped that funeral directors will continue with this function once the ME system flat fee comes in for ease and continuity for the bereaved. Since this will be a straight-forward flat fee on all deaths and being paid to one place rather than multiple doctors the administration is expected to be easier. Therefore, it is estimated that there will be no addition costs from fee-collection.

129. The proportion of public fees that go unpaid ("bad debt") is difficult to estimate as there are few comparable fees. The Social Fund Funeral Expenses Payment scheme offers to make a significant contribution towards the cost of a simple, respectful funeral for claimants on certain benefits or tax credits. In 2014/15, there were 19,000 unsuccessful applications for this payment support. It is unclear how these individuals went on to pay these costs, though their application suggests they were concerned about their ability to pay for funeral expenses. In the absence of other information, we have estimated that 5% of fees go unpaid which approximately aligns with 19,000 individuals failing to pay the fee.

130. Based on these proportions, it is estimated that the annual average cost of "bad debt" will be £1.45m (£1.71m).

131. Department of Work and Pensions remains committed to supporting vulnerable people going through bereavement. This includes providing Funeral Expenses Payments to help people on qualifying benefits with the costs of arranging a funeral.

132. The un-paid debt costs are only applied to those cases where the death is certified by ME (as opposed to being referred onto the coroner) after the interim period and thus where a fee is payable.

7. Total Running Costs

Table 10: Total Running Costs of Option 3

£millions Average annual costs in 2018 prices	Interim period running costs (high)	Statutory ME system running costs (high)
Employment costs (including overheads, on-costs, etc. and NME not including the ME costs of completing cremation form 5 functions)	32.3 (38.3)	32.1 (38.1)
Recruitment and training costs for new staff and E-learning costs (see subsection 5)	0.4	0.4
Office costs	0.2	0.2
Bad Debt*	-	1.5 (1.7)
Total	32.8 (38.9)	34.1 (40.5)

Total may not sum due to rounding, *bad debt only applies after interim system

133. Table 10 shows the financial average annual running costs in 2018 prices, the interim period is averaged over 2 years and the statutory ME system period is averaged over 7 years and high estimates are presented in brackets. How these costs will be funded and the economic costs are presented below in the Total Costs section on page 29.

Set-up costs of Option 3

134. Overall set-up costs for England are estimated to be around £19.7m which will be funded by DHSC.

135. It has been assumed here that there will be 152 ME offices. For example, one based in (but not employed by) each NHS Acute Trust²³ (including both specialist and non-specialist trusts).

136. It is expected that set-up costs will be released for the required expenditure.

137. As before, analysis is based upon 2016 death registrations and coroner statistics, ONS 2016 population projections and uses the best available evidence as of April 2018. The assumptions and estimates below are informed by conversations with expert stakeholders and the teams that work on the different pilots and have been reviewed in light of evidence provided through consultation responses.

1. Cost of planning & preparation, including lead MEs, lead MEOs and contribution to national planning

138. The cost of planning and preparation by NHS staff: a lead ME and lead MEO per office for 6 months ahead of implementation is expected to cost around £88,000 per office, this would represent a total cost estimate of £13.4m.

139. It is expected that during this time the lead ME and lead MEO will set up the office in (but not employed by) the NHS Acute Trust and recruit the necessary staff for the office. They will also engage with others working in the system to inform them about changes the system and discuss how they will work together, these will include people such as coroners, registrars hospital doctors, hospital staff, GPs and Practice Managers, funeral directors and patient representatives.

140. It is also expected that the National Medical Examiner (NME) will be employed to work on planning and preparation for 6 months on a part time (0.4FTE) basis.

141. The employment of an implementation team is estimated to cost in the region of £0.2m.

²³ <http://www.nhsconfed.org/resources/key-statistics-on-the-nhs>

142. The pilots that are currently running in Sheffield and Gloucestershire will continue in 2018/19 and these will help inform the planning and preparation for national roll out, this is estimated to cost £300,000.

2. Cost of recruitment for set-up of service

143. The total number of headcount staff required for the system is estimated to be 1,332 (see the section on running costs for a derivation of this figure). Recruitment costs, including advertising and interviewing, are estimated to be £750 per post. Therefore the initial recruitment costs are estimated to be around £1.0m.

3. Cost of local training on changes to related procedures and systems

144. Local registrars will need to receive training to use the new procedures and systems. It is assumed here that around 11 people will need training per ME Area, with a total cost estimate of around £140,000.

145. The initial design of the ME e-learning module cost in the region of £500,000 and has already been incurred by DHSC.

146. DHSC has also commissioned the Royal College of Pathologists to run a full-day training session for all MEs that are recruited ahead of full roll out of the ME system and to refresh the existing e-learning module. The total combined cost is £125,000.

147. There will also be training courses in the NHS for staff interfacing with the new ME system with a total cost of £231,000.

4. Cost of staff providing “retrospective scrutiny” prior to implementation

148. This represents the cost of the system running in shadow form for 7 working days prior to implementation, allowing the new members of staff to acquaint themselves with their tasks by analysing retrospectively the MCCDs produced in the area. This will also provide time for MEs to complete the e-learning training modules

149. Based on the employment costs of the staff per year the costs can be calculated by assuming that around 3% (7 days over the number of weeks of work per year, as set out in Annex A) of annual FTEs are needed to participate in the shadow-run. The total cost is estimated to be around £1.2m.

5. Existing system changes and upgrades

150. The death certification reforms will affect the data on death registration collected by the General Register Office for England and Wales, which will mean essential changes to the Registration online (RON) system. The estimated cost from GRO for redevelopment of the RON system is approximately £1m.

151. Similarly, the ONS will need to update the Life Events Continuity (LEC) system (which acts as the interface between RON and ONS Life Events systems), the M204 systems and processes, and the SAS and SQL systems which generate mortality statistics to allow processing of the data received from GRO. The ONS estimates that this will have an overall cost of £240,000. DHSC will be meeting the cost of this work.

152. As the ONS case study showed that scrutiny of MCCDs is likely to impact on trends of cause of death statistics, ONS has asked DHSC to fund a study which would examine discontinuities in these trends when death certification reform is implemented. This will allow users to take account of these discontinuities when using mortality statistics for planning, resource allocation and epidemiological studies. DHSC has acknowledged that such a study is required but the design and cost has yet to be agreed with ONS.

153. The digital service for will be developed during the year and is estimated to cost £1.4m.

6. Total Set-Up Costs

Table 11: Total Set-up Costs of Option 3

£millions	Set-up Cost
National Preparation	13.6
Pilot continuation	0.3
Initial recruitment	1.0
Local training and related procedures and systems	1.0
Retrospective scrutiny	1.2
IT System changes (GRO, ONS and digital service)	2.6
Total	19.7

Total may not sum due to rounding

154. Table 11 shows the financial set up costs in 2018/19. How these costs will be funded and the economic costs are presented below in the Total Costs section on page 29.

Additional costs due to increased coroner workload

155. The introduction of MEs will contribute to a more robust determination of cause of death which, in turn, will result in fewer deaths being unnecessarily reported to the coroner. At the same time, the involvement of MEs is also likely to lead to the detection of deaths that meet the coroner's investigative duty but would otherwise have gone unreported. These effects will, of course, support the Ministry of Justice's reforms to the coroner services by focussing resources on deaths where the coroner duty applies.
156. Evidence from the Sheffield pilot supports this, demonstrating a fall in the proportion of registered deaths that are reported to the coroner while, at the same time, an increase in the proportion of registered deaths that result in an inquest.
157. Taken together, this is in line with anecdotal reports from the pilots that suggest that MEs are better able than the current system to determine whether or not cases meet the coroner's duty to investigate and, although fewer cases are reported, those that are will require an inquest more often than at present.
158. To estimate the net effect on coroners it is necessary to weigh the fewer referrals against an increased number that will require more thorough investigation. In principle, the resource saving from each referral that will no longer be made as a result of more robust death certification procedures would be less than the additional resources required for each of those investigations and inquests that would otherwise have been unreported (though the resources for such investigations can vary significantly).
159. Additionally, it may be that, through the involvement of MEs, those cases that are referred to coroners will take less time than those cases referred to coroners under the existing system. This may serve to dampen any resource pressure.
160. Given the uncertainties about this net effect, this impact will be reviewed as part of a burdens assessment that DHSC and MoJ have committed to undertaking after a period of approximately 18 months after implementation. Undertaking an assessment any earlier runs the risk of underestimating the full impact of these reforms given that preliminary evidence from the pilots suggest that changes in coroner activity materialised after approximately this amount of time.
161. This IA does not attempt to pre-empt the conclusions of the joint DHSC and MoJ assessment by estimating the net effect on coroners.

Total Costs of Option 3

162. The setup costs and running costs of the ME system are presented in the sections above with breakdowns of the costs in tables 10 and 11. In this section the total costs and how they will be funded are presented.

163. The timeline and funding of the policy is presented on page 15, paragraphs 63-65. As discussed DHSC will be funding the set-up costs of the ME system in 2018/19. Following this there will be an interim period of 2 years, 2019/20 and 2020/21, where both the current cremation forms (4, 5, and 10) will continue and apply and the new ME system will commence before moving forward to a statutory ME system in 2021/22.
164. During the interim period the ME will take-over completing cremation form 5 from other doctors at the same level who complete them at present. The fees from cremation form 5 will cover the MEs carrying out this cremation form function and fund costs of the ME system for those adults being cremated through efficiencies (see paragraph 114). Any deficit between the revenue found from efficiencies in completing cremation form 5 and the costs of the ME system for those adults being cremated will be funded by DHSC.
165. DHSC will also fund the ME system costs for those being buried, those cases where the ME refers the case to the coroner and the ME system costs for child deaths.
166. Once the statutory ME system commences, after the interim period, the costs for all adult deaths certified by an ME will be funded by a fee. DHSC will fund ME costs of scrutinising child deaths and any other costs to the service not covered by the fee.
167. The estimate of the total cost of the new system is therefore as follows (high estimates in brackets):

Table 12: Total Costs of Option 3

£millions Average annual costs in 2018 prices	Set-up costs 2018/19	Interim period costs 2019/20 – 2020/21 (high)	Statutory ME system costs 2021/22 – 2027/28 (high)
Set-up costs funded by DHSC	19.7		
Running costs funded by DHSC	0	14.5 (23.0)	4.0 (4.9)
Running costs funded by the public ⁺	0	18.3 (15.9)	30.1 (35.6)
Total costs	19.7	32.8 (38.9)	34.1 (40.5)

“+” In the interim period this is an estimated proportion of cremation form 5 fees that will go towards funding the ME system (after funding the cremation form 5 function that will now be carried out by MEs). In the subsequent years this will be in the form of a fee for all deaths certified by an ME.

168. Table 12 shows the quantified cost of the new certification system and how those costs will be funded. The total costs differ in the interim period and the subsequent years from an increase in the projected number of deaths and the assumptions on bad debt from unpaid fees that have been applied to the ME system costs.
169. The average annual total cost of running the new death certification system that can be attributed to the fee after the interim period will be £30.1m, with a high estimate of £35.6m. This is an illustrative figure only, and is subject to change over time as the underlying costs of the ME system change. Further analysis will be undertaken to inform the recommended fee upon implementation of a statutory ME system. This will incorporate new evidence, including updated statistical releases and projected deaths, and reflect any implementation decisions where these are known.
170. The running costs have been adjusted using 2016-based ONS Death Projections and real wage changes for a 9 year period.
171. The average annual cost to DHSC is expected to be around £14.5m (£23.0m) during the interim period and £4.0m (£4.9m) per annum during the statutory system and relates to the ME system costs for child deaths and any other costs to the service that is not covered by the fee.
172. It is important to consider the option with respect to option 1 (do nothing) to compare the option with the counterfactual of the existing system continuing over this period, as shown in table 13 below. During the interim period average annual resource savings are estimated £18.3m (£15.9m) compared to option 1 as the MEs are expected to complete cremation form 5 more efficiently.

173. After the interim period the statutory ME system will replace Cremation Forms 4, 5 and 10 (total resource cost of the three forms is assumed to be £184). This would imply an average annual resource saving of £63.1m in these years for the doctors and medical referees who currently complete these forms in comparison to option 1.

174. As shown in Table 13 below, as compared to Option 1 baseline, the total cost of the ME's service is expected to result in an average annual cost of £14.5m (£23.0m) during the interim period, and a £29.0 (£22.6m) average annual resource saving once the statutory ME system begins.

Table 13: Total Costs of Option 3 with respect to Option 1

£millions Average annual costs in 2018 prices	Set-up costs 2018/19	Interim period costs 2019/20 – 2020/21 (high)	Statutory ME system costs 2021/22 – 2027/28 (high)
Set-up costs funded by DHSC	19.7		
Running costs funded by DHSC	0	14.5 (23.0)	4.0 (4.9)
Running costs funded by the public ⁺	0	18.3 (15.9)	30.1 (35.6)
Resource saving from option 1	0	-18.3 (-15.9)	-63.1
Total costs	19.7	14.5 (23.0)	-29.0 (-22.6)

175. Although the above table includes the financial cost that DHSC will face, from an economic point of view it is also necessary to take into account the opportunity cost of these funds, that is, the health improvement in terms of quality-adjusted life years (QALYs) that these funds could have produced from alternative uses.

176. It is estimated that, at the margin, DHSC funds secure a QALY for every £15,000 spent. The value of these QALYs (reflecting what the public would on average pay to secure such an improvement in health status) is estimated at £60,000 per QALY. This opportunity cost is applied to all DHSC costs in the below tables:

Table 14: Total Economic Costs of Option 3 with respect to Option 1 (QALYs foregone and costs discounted)

£millions QALYs foregone and discounted costs	Set-up costs 2018/19	Interim period costs 2019/20 – 2020/21 (high)	Statutory ME system costs 2021/22 – 2027/28 (high)
Set-up costs funded by DHSC	78.7		
Running costs funded by DHSC	0	56.6 (90.0)	14.5 (17.9)
Running costs funded by the public ⁺	0	17.4 (15.1)	24.5 (29.0)
Resource saving from option 1	0	-17.4 (-15.1)	-51.4
Total costs	78.7	56.6 (90.0)	-12.4 (-4.5)

^{“+”}A 1.5% discount rate is applied to costs that have applied QALYs and 3.5% discount to all other costs

177. The QALY opportunity cost has been applied to set-up costs as these will be funded by DHSC. DHSC will also partially fund the running costs and so the QALY opportunity cost has been applied to this part of the running costs.

178. The QALY opportunity cost has not been applied to running costs attributable to the public because these funds would not necessarily be otherwise spent on health.

179. In the current system (option 1) the Cremation Forms 4, 5 and 10 are being paid for by the public through £82, £82 and £20 fees respectively. Discontinuing all three forms in the statutory ME system, and MEs taking over Cremation Form 5 in the interim period implies a proportional resource saving. However, once the statutory ME system commences, along with the resource savings, the funds for the Cremation Form system will discontinue. Therefore, the QALY

opportunity cost has not been applied to any resource savings as no new funds become available for spending on health.

180. Hence, the average annual net economic cost of option 3 is £56.6m (£90.0m) in the interim period and an economic cost saving of £12.4m (£4.5m) once the statutory ME system commences.

181. It must be noted that the resource saving only affects economic costs and not financial costs because the saving is not cash-releasing.

Benefits of Option 3 arising from the impacts listed in section F.i.

Overview

182. The Francis Inquiry recommendations concerning death certification in hospitals are largely consistent with the reforms as detailed in Option 3. The expected benefits of the changes include:

- Crime and malpractice deterred by the knowledge that the cause of death stated on MCCDs by doctors will be scrutinised by a ME;
- More coordinated and consistent use of evidence-based patterns and trends leading to earlier detection of criminal activity and poor practice and the prevention of future deaths;
- MCCDs provide more accurate information about the causes of death and this, in turn, could lead to better planning of local health services;
- Improved information for clinical governance and local health monitoring to support local learning and, in some instances, bring about change in clinical practice and procedures;
- A death certification process that is easier for bereaved families to understand, ensures they can raise any concerns with an independent individual about the standard of care leading up to a death and provides reassurance that the cause of death is correctly established by the doctor.

183. As was the case for Option 2, quantifying these benefits is extremely difficult. This is because the extent of the current problem the policy seeks to rectify is difficult to estimate and the malpractice-deterrence effect of MEs is largely unknown.

1. Improved scrutiny on death certification can help improve clinical governance as well as detect and deter crime and malpractice

184. Under Option 3, death certification of burial cases will be subject to independent scrutiny for the first time. A unified system of scrutiny of all deaths (excluding coroner cases) will be provided by an ME workforce that has undergone specific training on death certification and identifying and reporting anything untoward about a death.

185. This is likely to provide a better chance of detecting any anomalies in MCCDs that are signs of criminal activity or malpractice. This Option also entails a better link between death certification and clinical governance, which should help to ensure that once detected, these activities can be addressed and future crime or malpractice can be prevented.

186. As well as allowing better detection and remediation of crime and malpractice, improved scrutiny of MCCDs will also act as a deterrent of this behaviour, by increasing the likelihood it will be detected. This prevents any costs associated with such crime. This includes cases such as that of Harold Shipman.

187. There is evidence from the pilots that the improved quality of MCCDs has led to an increase in clinical governance matters being reported by MEs to the Clinical Governance Team. A qualitative improvement in openness and transparency has also been reported.

188. Moreover, a potential impact of MEs that has emerged from pilots is an increase in the number of Coronial investigations. Coronial investigations, especially inquests, provide a valuable service in determining natural causes deaths and in identifying the causes behind unnatural deaths, and evidence suggests that doctors are currently poor at determining which cases should be referred to coroners. The ME intervention results in increased reporting to coroners of

deaths relating to patient care issues and industrial diseases and help ensure any possible safety risks are brought to light.

189. Coroners help avoid future deaths by utilising 'Reports to Prevent Future Deaths'. These reports are directed at persons or organisations the coroner believes should take specified actions to prevent future deaths. The person to whom a report is directed must to respond to the coroner in writing explaining what actions they plan to take and when or why no action will be taken, 375 such reports were issued in 2016.
190. Data from the Sheffield pilot does indicate that MEs refer more cases to coroners that result in 'critical' conclusions. During the first 4 years of full rollout, 15 critical conclusions were issued for deaths occurring at Northern General Hospital (NGH). Expert opinion is that 2 of these cases would not have been referred to coroners under the current system, and a further case may not have been. If this change were representative of the country, and taking into account that under this proposed option all deaths would be scrutinised under the ME system, this would result in an additional 141 critical conclusions nationally per year (assuming the case that may have been referred under the current system constitutes half an additional critical conclusions).
191. With reporting otherwise unreported cases, there is a trade-off to be considered in terms of the psychological effect resulting from detecting previously undiscovered cases of malpractice. Whilst people who had previously unaddressed concerns over deaths will benefit from additional investigations, people who were unaware of wrongdoing may well experience greater anxiety as a result of an inquest. It is difficult to estimate which of these two effects will dominate. However, it could be argued that the overall effect will be positive, based on the fact that people who were unaware of any wrongdoing are likely to prefer being informed to not being informed. This is supported by evidence showing that, in general terms, patients prefer disclosure of medical errors²⁴. It is difficult to say whether this will also be the case for bereaved relatives in an inquest setting.
192. An additional point is that the involvement of MEs is expected to reduce the number of unnecessary autopsies, which should reduce the unnecessary suffering of families. Again, this impact is difficult to quantify.

2. Improved quality of MCCDs

193. The increased scrutiny of MCCDs by trained MEs is likely to improve the quality of MCCDs. This is expected to have a positive influence on those activities that use the information recorded in these documents. The legal system and insurance companies use MCCDs as "proof of legal death". Better quality information should help them work more effectively.
194. In addition, the statistics compiled from MCCDs are also used for epidemiological studies and for public health planning. Better quality MCCDs are likely to improve the effectiveness of these activities, which over time should impact positively on the health of the public.
195. The poor quality of certification is something that the Shipman Inquiry identified. Past audits of MCCDs showed that only 55 percent of certificates were completed to a minimally accepted standard, a figure consistent with the wider literature on death certification in the UK⁹. Many of these failed to provide relevant information to allow adequate coding of cause of death to the International Classification of Diseases 10th revision (ICD-10). Nearly 10 per cent were completed to a poor standard, being illogical or inappropriately completed. Although that audit is over ten years old, more recent studies have also found shortcomings in the quality of certification, despite its introduction into formal undergraduate training.
196. In 2012, ONS carried out a case study analysing just over 5,000 records supplied by the pilots, comparing the cause of death proposed by the certifier and the cause confirmed by a ME²⁵. This suggests that MEs' analysis of the information relating to the cause of death, obtained both from the medical notes and in discussion with relatives, results in better understanding of the sequence of conditions that led to death. If the conditions and sequence are recorded more fully, this may lead to a change in the underlying cause of death. The results of this case study

²⁴"Communication with patients in the context of medical error" (Lesley Fallowfield and Anne Fleissig), Cancer Research UK, Psychosocial Oncology Group, Brighton & Sussex Medical School, University of Sussex.

²⁵"Death Certification Reform: A Case Study on the Potential Impact on Mortality Statistics, England and Wales", ONS 2012

indicate that the ME scrutiny is likely to affect trends in causes of death reported in mortality statistics.

197. There is also the potential for MEs to identify trends in unexpected causes of death, for example, MEs in one of the pilot schemes triggered investigations that identified problems with post-operative infections²⁶.
198. Further supporting evidence was found in an independent review of death certification at Mid Staffordshire NHS Foundation Trust commissioned by the Trust's Mortality Group²⁷. This review found that, in 22% of just over 200 cases occurring between April and June 2008, there was a significant difference in the cause of death recorded in the MCCD and that recorded in corresponding medical records.
199. MEs will be experienced, registered medical practitioners capable of ensuring that the cause of death stated by the certifying doctor is accurate and corresponds with the medical records. Where the cause of death is unknown or unclear after reviewing the medical records, MEs will ensure the death is referred to the coroner for investigation.
200. In the aforementioned review of death certification at Mid Staffordshire NHS Foundation Trust, the Trust's Mortality Group attributed the poor completion of MCCDs in part to the lack of training of junior doctors who may have been wrongly delegated the task of completing the MCCDs by consultants without closer inspection.
201. In the new system, doctors will have access to advice from a ME that will assist them to propose a preliminary cause of death. Due to the frequency with which MEs will be handling MCCDs as part of their scrutiny and confirmation of cause of death MEs will be ideally placed to identify training needs of doctors as far as how to complete a MCCD fully and accurately.
202. Numerous studies have shown that experience is strongly correlated with an ability to complete MCCDs, so the special training received by MEs would in principle be expected to result in significantly more accurate certificates.
203. Preliminary results from the pilot sites indicate that ME scrutiny results in a substantial change in the number of deaths coded under each ICD-10 code. Although small numbers prevent thorough statistical analysis from being performed, some findings can be drawn from the data²⁵.
204. The ICD-10 chapter identified by the original certifying doctor was changed by the ME in 12% of deaths. An example of such a change is moving from a cause of death of cancer to respiratory disease. There is an even larger difference when looking at 3 digit ICD-10 codes (which identify specific conditions such as lung cancer or stroke): 20% of these codes were changed, along with 22% of precise 4-digit ICD-10 codes.
205. The numbers of deaths from respiratory diseases, cancer and cardiovascular diseases are deemed sufficiently large to present here. Under MEs, the following changes were observed:
 - 1.3% increase in deaths from neoplasms
 - 5.7% increase in deaths from circulatory diseases
 - 6.6% decrease in deaths from respiratory disease.
206. Whilst it is possible that these arose from MEs identifying incorrect causes, this is not likely to be the case in view of the available evidence. The pilots indicate a general increase in the level of detail provided by MEs, which when combined with the literature on doctors' abilities to complete MCCDs indicates that these results are likely to reflect the true underlying distribution of deaths.
207. This could allow a more efficient allocation of NHS resources and any epidemiological studies using mortality data will also be made more accurate, providing better information for commissioners and further refining expenditure decisions. Often research that provides insight into the cost-effectiveness of health care spending relies on data from MCCDs which is used to calculate the mortality rate for different health problems. However, these benefits have not been estimated due to the complexities and uncertainties involved.

²⁶ The Royal College of Pathologists 'Medical Examiners' May 2016. <https://www.rcpath.org/resourceLibrary/medical-examiners-.html>

²⁷ An independent review of death certification at Mid Staffordshire NHS Foundation Trust commissioned by the Trust's Mortality Group

3. Improved level of assurance for the bereaved

208. The proposed system is expected to be more transparent and understandable for the bereaved, while providing assurance that all due process has been followed. The ME and MEO will also provide an opportunity to discuss the case with the bereaved
209. For cremation cases, it is not certain that the greater level of scrutiny will be perceived directly by the bereaved since these deaths already require a secondary and independent medical certification before a cremation can proceed. However, the process should be more transparent and easier for the bereaved to understand, which is expected to provide them with better assurance that due process has been followed. The simplified structure should also make the logging of any concerns or complaints easier.
210. For burial cases, the fact that MCCDs will be scrutinised should lead to an increase in assurance and confidence in death certification from the bereaved. The ME system is expected to achieve this through two channels: firstly by providing the background knowledge that deaths have been scrutinised, and secondly by being able to provide any information to the bereaved during the course of their scrutiny. Whilst there is no documented evidence to confirm the first channel, studies have found that relatives of patients who have had stays in Intensive Care Units were more likely to display symptoms of Post-Traumatic Stress Disorder in cases where information was felt to be missing (48.4% of cases compared to 33.1%)²⁸. Whilst we know that sufficient information can help to mitigate depression post bereavement, this would probably be on the margins of emotions felt upon the death. Given the uncertainties relating to the magnitude, duration and dispersal of this benefit, it is left unquantified.

4. Addressing concerns from the consultation

211. The response to the consultation demonstrates that there is widespread support for the aims of the reforms and for the introduction of medical examiners but there were concerns about some aspects of the proposals. In particular, concerns were raised about how the proposed model, based in local authorities, would work in practice. Option 3 addresses this concern by running the ME system within the NHS. This also enables the system to work alongside the Learning from Deaths initiative and a number of early adopters of the ME service within the NHS across England. However, it is important that the MEs are independent from the NHS Provider and therefore the line of accountability needs to be at least one step removed. Where the line of accountability will be within the NHS is being developed.
212. Feedback on the proposed funding model was also received. Whilst this fee will be a new burden on those being buried, it represents a reduced burden on the majority of the bereaved who are cremated. Having a flat fee on all those adult deaths that are certified by an ME ensures all deaths are treated equally and scrutinised on a consistent basis. Whilst roll-out is being carried out in the interim period, all efficiencies will be sort to ensure that the flat fee represents the best value for money whilst ensuring that the level of scrutiny is delivered to realise the benefits presented above.
213. Concerns were also raised about the timeframes for implementing the service. There is an ambitious timeline with the policy to have the ME system operating by April 2019. As noted in paragraph 217 below, whilst it is the ambition to have a fully operating system at this start date, full roll-out covering all deaths may take longer until local areas are able to staff offices. The existing pilots based in hospitals have demonstrated that the ME system can be rolled out to primary care. We anticipate that this roll out would start in April 2019 and cover all deaths by the end of 2019.

Net Present Value of Option 3

214. Over 10 years, the central estimate of the net present value is -£105.5m for Option 3; along with unquantified benefits to the health and well-being of the public, as described in the preceding section. As such, the NPV will be underestimated. Any policy decision must therefore weigh up the estimated costs against these qualitative benefits.

²⁸ "Risk of post-traumatic stress symptoms in family members of Intensive Care Unit patients". (Azoulay et al, 2005) American Journal of Respiratory and Critical Care Medicine

215. The NPV does not include the potential additional burden on coroners.

Table 15: NPV of Option 3

£millions	Discounted Costs (high)	Discounted Benefits	NPV (high)
Option 3	105.5 (227.4)	<i>unquantified</i>	-105.5 (-227.4)

iii. Assumptions upon which projections for Option 3 have been based, and the risks to which they are subject

The following key risks have been identified:

Recruiting and retaining MEs and support officers

216. The current proposal makes a clear and plausible estimate of staff requirements. However, experience suggests that there is some risk attached to the recruitment and retention of MEs and support officers (both initially and over time). It has been assumed in this analysis that all MEs and MEOs will be recruited ready for the April 2019 roll-out so as to show the possible cost level in 2019/20. However, it is understood that roll-out may take longer and therefore the ME system may not be able to cover all deaths in all locations. Support will be in place to help local areas get their offices fully staffed and covering all deaths as soon as possible in 2019/20.

217. Consultation responses also highlighted the risk of “brain drain” from the coroner services as coroner’s officers take up MEO positions. While this is a risk, it is expected to be less likely with the offices now being based in the NHS.

Greater independence of MEs

218. The fact that scrutiny of cremation cases will be more independent under MEs than under the current system is a crucial assumption for the benefits of this Option to be realised. This is particular assumption is justified by the fact that MEs will be employed by the NHS for this specific role, and not any qualified doctor of their choosing. The certifying doctors will not be able to choose the ME that will scrutinise the cause of death stated on the MCCD. National examiner guidance will stipulate that MEs must be independent of the certifying doctor and the deceased.

219. As stated above in paragraph 212, it is important that the MEs are independent from the NHS Provider and therefore the line of accountability needs to be at least one step removed. Where the line of accountability will be within the NHS to being developed currently.

220. There may be a trade-off between ensuring sufficient local cover and ME independence. In rural communities, it is unlikely that GPs will not know their ME and vice versa. Bearing this in mind, ME offices will be encouraged to have reciprocal agreements with neighbouring offices to ensure that where the issue of independence arises, another ME can step in and fulfil the statutory function.

Impact on coroners

221. The impact that this option will have on the workload of coroners is an important area of uncertainty, and has the potential to increase or decrease the costs of the policy significantly. The evidence base for this assumption is at present relatively bare, consisting chiefly of expert opinion and evidence largely based on evidence from the Sheffield pilot. Moreover, the coroner service is undergoing reforms that increase this uncertainty.

222. Funding will be informed by a burdens assessment that DHSC and MoJ have committed to undertaking approximately 18 months after implementation.

Impact of changes within the policy term

223. This IA estimates the impact of the policy over a 10 year term. Therefore assumptions have to be made about how the policy will be taken forwards in advance of the parliamentary process. This IA by no means pre-empts what Parliament will decide on a flat fee, but in order to carry out analysis over a 10 year term this policy assumption has been presented. The policy is going to be reviewed for the impact on coroners (as discussed in paragraphs 222 and 223) 18 months after its implementation in April 2019 in relation to legislative requirements (as stated on the first page). In addition, a review will take place to compare the actual fee revenue against the forecast in this IA, 18 months after the statutory ME system fee comes into effect. If changes from this review result in any simplification of the policy and improve the efficiencies of the system, the costs presented here could decrease from the time of implementation.

H. SUMMARY AND WEIGHING OF OPTIONS

224. Option 1, representing the status quo, does not address the issue of lack of scrutiny in the death certification process, and so it does not reduce the current risks to patients and the bereaved. Moreover, it does not address the difference in the level of assurance provided to the bereaved depending on whether the body is cremated or buried.

Table 16: NPV of Options relative to option 1 (do nothing)

£million	Discounted Costs (high)	Discounted Benefits	NPV (high)
Option 2	117.7	<i>unquantified</i>	-117.7
Option 3	105.5 (227.4)	<i>unquantified</i>	-105.5 (-227.4)

225. Option 2 would improve the scrutiny level on burial cases somewhat and, as such, would be expected to lead to some improvements in patient safety. However, it does not address the issues raised about the current level of scrutiny on cremation cases.

226. Option 3 is expected to lead to both an increase in independent scrutiny for death certification for both cremations and burials, providing all cases with the same level of assurance.

227. Option 3 is the preferred option as it will improve the assurance and crime deterrence aspects of death certification and provide the same level of scrutiny for both burial and cremation cases. It will also provide an improved level of assurance for the bereaved. In addition, the improved quality of MCCDs results in improved information in the health system on deaths. Since this is a major consideration of where policy efforts and health spending should be focussed, any improvement to this information should help improve the nation's health in the future.

228. In terms of affordability, Option 3 will require some further public expenditure, particularly in the transition period. However, in the central cost estimate option 3 has a higher net present value than option 2, even without the important benefits of the ME system as presented above being quantified.

229. The response to the consultation suggested that there was widespread support for the aims of the reforms and for the introduction of medical examiners but there were concerns about some aspects of the proposals. In particular, concerns were raised about the introduction of a new public fee to cover the cost the medical examiner service and practical concerns about how the model proposed, of a medical examiner service based in local authorities, would work in practice.

230. Since the Government consulted on the package of Death Certification Reforms, events have moved on. New information on how a medical examiner service could be introduced have been generated by our pilot sites, the Learning from Deaths initiative and a number of early adopters of the medical examiner service within the NHS across England.

231. Option 3 addresses the concerns above by running the ME system in the NHS and being able to work alongside the Learning from Deaths initiative whilst ensuring independence. However, it

is assumed here that after the interim period there will be the introduction of a fee. This needs to be considered alongside the reduced burden for the majority of the bereaved who are cremated will no longer have to pay the higher cremation form fees.

232. Therefore Option 3 is the preferred option and the benefits of the option, although unquantified are believed to outweigh the costs.

Annex A: Further Cost Details – Staff

Relating to section 2: Number of FTEs and Headcount

233. All staff will be employed by the NHS and are therefore likely to adopt NHS terms and conditions which typically stipulate the following weeks and hours worked per year²⁹.

Table 17: NHS FTEs working time

	ME	MEO
FTE weeks worked per year	42.4	42.7
FTE hours worked per week	43.3	37.5

234. It is anticipated that the majority of staff will be part-time and thus the following Headcount – FTE ratios have been used. These will be different for MEs during the interim period where they are also completing the cremation form 5 functions as shown below in brackets.

Table 18: Assumed Headcount / FTE Ratios (interim period estimate in brackets)

Staff Type	Headcount / FTE ratio
MEs	3.5 (central:1.7, high 2.2)
MEOs	2.5

Relating to section 3: Employment Costs

Table 19: Medical Examiners

Element of Staff Cost: Medical Examiners (FTE)	£
Salary cost per FTE ³⁰	91,733
On Costs (30%)	27,520
Other attributable overheads (12%)	11,008
Travelling costs	700
Total cost per FTE	130,960

²⁹Unit Costs of Health and Social Care 2017, PSSRU: <https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2017/>

³⁰ [https://digital.nhs.uk/catalogue/PUB30252\(NHS Earnings December 2017 - provisional - basic pay, ME: Consultants \(including Directors of public health\): £89,925, MEO: Qualified nursing, midwifery & health visiting staff: £31,090 as proxy for Band 6 staff\) Used year to March 2017 to fit base year and then applied a 1% pay increase per year to reach a £2018/19 estimate.](https://digital.nhs.uk/catalogue/PUB30252(NHS+Earnings+December+2017+-+provisional+-+basic+pay,+ME:+Consultants+(including+Directors+of+public+health):+£89,925,+MEO:+Qualified+nursing,+midwifery+%26amp;+health+visiting+staff:+£31,090+as+proxy+for+Band+6+staff)+Used+year+to+March+2017+to+fit+base+year+and+then+applied+a+1%+pay+increase+per+year+to+reach+a+£2018/19+estimate.)

Table 20: Medical Examiner Officers

Element of Staff Cost: Medical Examiner Officers	£
Salary cost per FTE ²⁸	31,715
On Costs (30%)	9,514
Other attributable overheads (12%)	3,806
Travelling costs	
Total cost per FTE	45,035

Annex B: Sensitivity Analysis

235. This sensitivity analysis is based on variant 2016-based ONS death projections³¹. The principal projection has been used as the central death figure. For the high deaths figure, low population death projections have been used, whereas for the low death figure, high population death projections have been used.

Table 20: Central cost scenario (£millions)

Option	Death scenario	Total Transition (constant prices)	Average Annual (constant prices)	NPV
3	Low deaths	78.5	-0.3	-106.0
	Central deaths	78.7	-0.5	-105.5
	High deaths	78.9	-0.7	-104.4

Table 21: High cost scenario (£millions)

Option	Death scenario	Total Transition (constant prices)	Average Annual (constant prices)	NPV
3	Low deaths	78.5	14.2	-225.6
	Central deaths	78.7	14.3	-227.4
	High deaths	78.9	14.4	-229.1

³¹ <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationprojections>