Title: Consultation on Reforming the Death Certification Process in England and Wales **IA No:** **Lead department or agency:** Department of Health (DH) **Other departments or agencies:** Welsh Government	Impact Assessment (IA) **Date: 29/01/2016** **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary Legislation **Contact for enquiries**: Meena.Paterson@dh.gsi.gov.uk Thomas.Dillon@dh.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion:

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Three-Out?** Yes	**Measure qualifies as**

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. The death certification system for cremations is expensive but the independence and effectiveness of the scrutiny has been questioned. The system for burials does not include any scrutiny of the quality or accuracy of the MCCD. The Shipman Inquiry concluded that it was no longer sensible to have a different certification processes for cremation and burial, 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 MCCD and provides adequate scrutiny to identify and deter criminal activity or poor practice. This should be achieved without imposing undue delays on bereaved families 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.

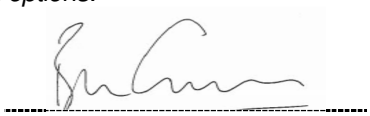
Option 2: Extend the current system for cremations to burials.

Option 3: (preferred): Reform the current system for cremations and burials by introducing a new universal check applicable to all deaths that are not subject to an investigation by the coroner, irrespective of whether a death is followed by a cremation or burial.

Will the policy be reviewed? It will be reviewed in 3 to 5 years

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** No	**Small** No	**Medium** No	**Large** No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	

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

Signed by the responsible Minister: 

Summary: Analysis & Evidence Policy Option 1

Description: Do Nothing

BASELINE

Price Base Year	PV Base Year 2014	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	0		0	**0**

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 **Discount rate (%)**

This option represents the baseline against which other options are compared

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs:	**Benefits:**	**Net:**	No	IN/OUT/Zero net cost

Summary: Analysis & Evidence Policy Option 2

Description: Extension of current death certification scrutiny to burials

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 10	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate: -163.2

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low		0		
High				
Best Estimate	0		19.0	189.6

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

Increased scrutiny for burials will lead to relatives of the deceased paying fees (in contrast to current system where there is no scrutiny for burials and the bereaved do not pay fees).

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		0		
High				
Best Estimate	0		0	0

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

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

- Scrutiny of MCCDs for burials could improve patient safety through deterrence of crime and malpractice.
- Improved level of assurance for bereaved families in burial cases
- Improved quality of MCCDs

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

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	No	Zero net cost

Summary: Analysis & Evidence Policy Option 3

Description: Implementation of Medical Examiner System

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 73.7	**High: 107.9**	**Best Estimate: 88.3**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	23.4	1	-12.8	-91.4
High	13.8		-16.0	-130.2
Best Estimate	**18.6**		**-14.1**	**-107.9**

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

- The public will fund the Medical Examiner system via fees – this represents a saving for families of those cremated but a new cost for families of those buried
- Costs of establishing the Medical Examiner system and of those cases referred from medical examiners to coroners, both of which will be funded by DH
- Additional burden on coroner services due to a greater number of complex cases (though fewer cases in total)

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

- The effect on NHS Litigation liability is uncertain

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'

- Improved scrutiny on death certification can help improve clinical governance as well as detect and deter crime and malpractice
- Improved quality of MCCDs
- Improved level of assurance for bereaved families

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

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	No	Zero net cost

Evidence Base – References

No.	Legislation or publication
1	The Shipman Inquiry. Third Report – Death Certification and the Investigation of Deaths by Coroners, 2003
2	Death Certification and the Coroner Services in England, Wales and Northern Ireland: The Report of the Fundamental Review, June 2003
3	Learning from Tragedy, Keeping Patients Safe, February 2007
4	The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Robert Francis QC, Feb 2013
5	The Report of the Morecombe Bay Investigation, Dr Bill Kirkup, March 2015
6	Coroner statistics 2014, ONS, 2015
7	Deaths registered in England and Wales 2014, ONS, 2015
8	Cremation Society of Great Britain, National Cremation Statistics (http://www.cremation.org.uk/ accessed on 29/01/2016)
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	*Review into death certification*. Home Office. London: HMSO, 2000 (add)
13	**"**The many faces of depression following spousal bereavement' Journal of Affective Disorders", Zisook et al, 1997.
14	"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
15	Chief Coroner's report 2014/15
16	"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.
17	"Death Certification Reform: A Case Study on the Potential Impact on Mortality Statistics, England and Wales", ONS 2012
18	an independent review of death certification at Mid Staffordshire NHS Foundation Trust commissioned by the Trust's Mortality Group
19	Sheffield Medical Examiner Pathfinder Pilot Report, August 2008
20	NHS Workforce Statistics August 2015, Provisional statistics
21	PSSRU Unit Costs of Health and Social Care 2014, Curtis 2014

Annual profile of financial costs (£m) constant prices – Option 3 with respect to Option 1 – Central Estimate

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs (DH)	18.6									
Annual recurring cost (public)		-26.5	-26.5	-26.5	-26.5	-26.5	-26.5	-26.5	-26.5	-26.5
Annual recurring cost (DH)		4.4	4.4	4.4	4.4	4.4	4.4	4.4	4.4	4.4
Annual recurring cost (DCLG)		8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0
Total annual costs	**18.6**	**-14.1**	**-14.1**	**-14.1**	**-14.1**	**-14.1**	**-14.1**	**-14.1**	**-14.1**	**-14.1**

Evidence Base

A. What is the problem under consideration?

i. Characterisation of the underlying problem

Background

1. The system for death certification in England and Wales 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 75% of deaths are followed by cremation.
2. There are however concerns that the death certification process does not provide enough independent scrutiny on the accuracy and completeness of the MCCD for those deaths which are treated as not suspicious 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, despite an onerous process that involves three separate doctors, 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 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 (1) , the Shipman Inquiry examined the process of death certification and the coroner system. 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)

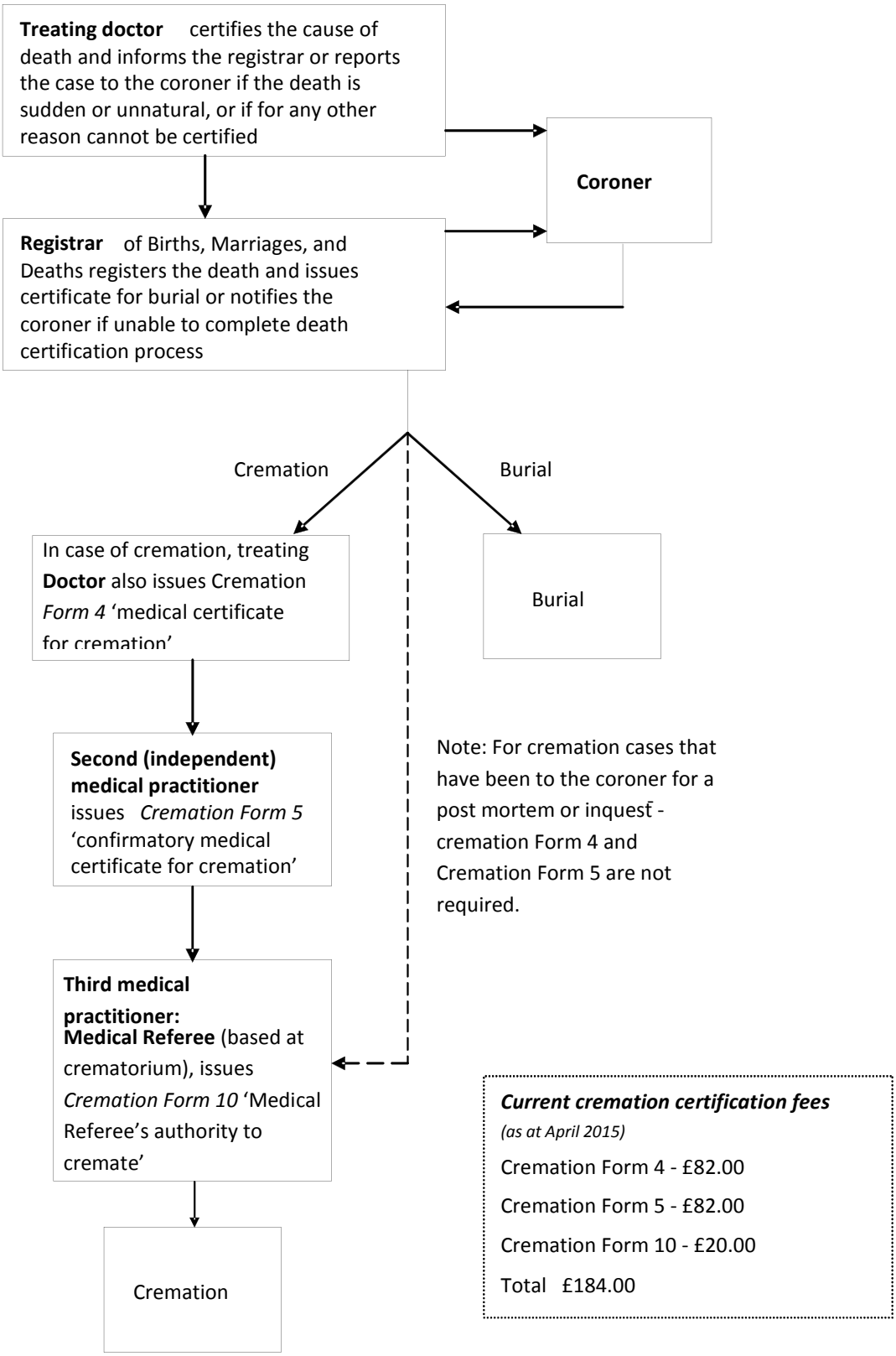
the doctor completing the Medical Certificate of Cause of Death (MCCD) was himself responsible for the patient's death.

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 arrangements (2).
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 England and Wales (3).
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 reforming the death certification process. Renewed calls for medical examiners were made by the Francis Inquiry into Mid Staffordshire (4) and Bill Kirkup's Inquiry into Morecambe Bay (5). 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.

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 aberrant doctor), and a lack of a suitable 'guardian' to detect the crime (an independent medical examiner).
10. This can be analysed as a principal-agent problem, with the NHS as the principal and the doctor signing the MCCD as the agent. Problems can arise if the principal and the agent have divergent objectives and there is "asymmetry of information", where the principal cannot directly observe the actions of the agent.
11. In the case of deaths which are not treated as suspicious or referred to a coroner, there is a clear "asymmetry of information" in that the NHS does not directly observe whether the MCCD is accurate. A divergence in objectives can occur if the doctor is, for instance, responsible for the death of the patient (whether intentionally or not) or is afraid the MCCD will reveal medical errors or irregularities and has the intent to misreport this. Under "asymmetry of information" it is difficult to detect these cases unless a suitable accountability mechanism is put in place to ensure independent scrutiny of Death Certification and therefore to reduce the asymmetry of information.
12. 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 compromised (1). These are listed below.
13. These weaknesses relate in particular to the registration of those deaths that are not investigated by coroners which, using 2014 Coroner Statistics figures and 2014 ONS Death Registrations, are 276,473 (6) (7). Figure 1 outlines the main features of the current system.

Figure 1


Treating doctor certifies the cause of death and informs the registrar or reports the case to the coroner if the death is sudden or unnatural, or if for any other reason cannot be certified
Coroner
Registrar of Births, Marriages, and Deaths registers the death and issues certificate for burial or notifies the coroner if unable to complete death certification process
Cremation
Burial
In case of cremation, treating **Doctor** also issues Cremation *Form 4* 'medical certificate for cremation'
Burial
Second (independent) medical practitioner issues *Cremation Form 5* 'confirmatory medical certificate for cremation'
Note: For cremation cases that have been to the coroner for a post mortem or inquest - cremation Form 4 and Cremation Form 5 are not required.
Third medical practitioner:
Medical Referee (based at crematorium), issues *Cremation Form 10* 'Medical Referee's authority to cremate'
Cremation
Current cremation certification fees
(as at April 2015)
Cremation Form 4 - £82.00
Cremation Form 5 - £82.00
Cremation Form 10 - £20.00
Total £184.00

Burial cases: Lack of scrutiny

14. There is no additional medical scrutiny for burial cases (25% of the total in 2014, according to the Cremation Society of Great Britain) once the Medical Certificate of Cause of Death (MCCD) has been completed (8). 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.
15. 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.
16. According to the Shipman Inquiry (Third Report, page 11, 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)." (1)
17. The risk to patient safety involved 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.
18. It is difficult to quantify to what extent any such abuses are prevalent, given the lack of data. The benefits section below describes the existing evidence.

Cremation cases: Scrutiny may not be independent despite onerous system

19. In contrast to burial cases, cremation cases are subject to a series of checks involving three different doctors (completing Forms 4, 5 and 10).
20. However, before the additional safeguards added by the Cremation (England and Wales) Regulations 2008 and Ministry of Justice 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" (2).
21. This lack of independence played an important role in the failure to detect Harold Shipman's crimes, as it is noted in the Shipman Inquiry (Third Report, Summary, Paragraph 64) that "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" (1). The lack of independence can be compounded by the fact that the doctors may not be experts in examining MCCDs.
22. There is a third certifying doctor, the crematorium referee, who is attached to the crematorium. While this doctor 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 effective (2). 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

23. Despite the requirement for Form 10 to be completed by a doctor, the Shipman Inquiry found that (at least for those people involved in this case) the exercise was viewed as nothing more than a clerical duty.
24. Therefore the system, despite being resource-intensive and involving three different doctors, may fail to provide effective independent scrutiny and is liable to the risks outlined in the preceding section. The available evidence is described below in the benefits section.

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

25. 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.
26. The study "Death certification: an audit of practice entering the 21st century" (9) looks at a sample of 1000 completed certificate counterfoils. 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 Medical Examiner system in Finland, where 71.4% of MCCDs were validated as giving the correct ICD-9 code (10).
27. 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
28. It can further be argued that current 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.
29. Inaccurate MCCDs can have a negative effect on health outcomes and the provision of health care. MCCDs are the source of mortality statistics and these statistics inform medical research, public health and healthcare policy as well as in some cases the financing of health systems. Therefore, inaccuracies in MCCDs can 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" (11), which looks at the potential misallocation of health care-related resources due to such inaccuracies.

ii. Summary and context of the analytical narrative.

30. To a large extent, the problem to be tackled stems from the principal/agent and asymmetrical information characteristics set out above. Improving the independent scrutiny of MCCDs would help tackle both those problems.

B. Policy objectives and intended effects

31. To ensure that the system for certifying (non-coronial) deaths provides adequate scrutiny to identify and deter criminal activity or poor practice.
32. To rationalise the existing system to ensure that the level of scrutiny is proportionate and does not impose undue delays on bereaved families or undue burdens on medical practitioners and others involved in the process.
33. To provide a common death certification procedure that ensures the same level of scrutiny and assurance, irrespective of their choice of burial or cremation.

34. 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. Therefore, an improvement to patient safety should be expected.

35. Similarly, the confidence of bereaved families 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. The reduction in cases and a more transparent system should both contribute to increase confidence that all due process has been followed.

36. 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.

C. Underlying causes of the problem

37. 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 can provide the necessary incentives for better performance.

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

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

38. The current process and its drawbacks are set out above.

39. According to the "*Review into death certification*. Home Office. London: HMSO, 2000", "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 areas. (12)

Cost of current system

40. In order to compare different options against the current system, it is necessary to quantify the costs of the latter. This can be done 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 (for example, making inquiries of the family and examination of the body). Cremation Form 10 is authorisation of cremation of deceased by a medical referee.

41. In April 2015, the fees for Forms 4 and 5 were £82 each. The average fee for cremation form 10 is £20. 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.

42. According to data from the Ministry Of Justice and ONS, in 2014 there were 500,314 registered deaths for those usually residing in England and Wales, of which 96,195 were scrutinised by coroners and 404,279 were either returned or did not feature any involvement by coroners (6)(7). Provision figures from the Cremation Society of Great Britain show that in 2014 for the UK the

proportion of registered deaths that resulted in cremations was 75% (8). Assuming that this ratio applies across England and Wales, this gives us 72,290 cremation cases investigated by coroners and 303,695 cremation cases not investigated by coroners. Therefore the total annual cost of the current system in 2014 was approximately £57.3m (based on 303,695 deaths with a fee of £184 and 72,290 deaths with a fee of £20).

43. This calculation assumes that the current system is funded fully and precisely through the fees paid by the bereaved relatives. That is, the fees do not provide a transfer rent for those who provide scrutiny (in which case the costs of the system would be over-estimated by this calculation), nor, on the other hand, does the system currently need to be cross-subsidised by the salary of those who provide scrutiny (in which case the costs of the system would be underestimated by this calculation). However, given that the forms are largely seen as a clerical duty, it may be that the existing fees do provide a transfer to doctors.

ii. Derivation of the short-listed options

44. 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.

45. Membership includes 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. Membership of the Steering Group was extended in 2012 to include representation from the Department for Communities and Local Government to reflect the fact that the Health and Social Care Act 2012 transferred responsibility for the medical examiner service from primary care trusts to upper-tier Local Authorities. From February 2013, an Implementation Board comprising of delivery partners is advising on matters relating to implementation. The Steering Group is now a Reference Group of all stakeholders and delivery partners advising on wider issues.

46. The main proposal that has been considered is to establish a new system based on medical examiners, specially trained doctors that scrutinise MCCDs. The proposed new local medical examiner service 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 medical examiner in scrutinising MCCDs in hospitals. The report of the first three months of the pilot concluded by saying –

"Including a Medical Examiner 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" (19)

47. 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

48. Having demonstrated that the new system can work in a range of settings, in hospital 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 a city and countywide basis to test the new medical examiner service at a scale that will be required for implementation by Local Authorities. The two sites now act as implementation resource for local authorities and local health boards to observe a fully operational medical examiner service.

49. 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 report (1). The new medical examiner process and its associated policies has 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.

50. 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, it was considered 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 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-medic and there is a generally held view that a person with suitable expertise and appropriate training is far better equipped to carry out a non-forensic examination than a doctor. The policy on examination has evolved as shown by the draft Death Certification Regulations and the consultation document. The consultation invites wider views on whether the examination could be carried out by non-medics, (an observation made in the Third Report), who already have the expertise, for example funeral directors and mortuary technicians. In addition, DH will recommend that non-medics complete the medical examiner e-learning session on 'Examination of the body', developed by a forensic consultant.

51. A possible variation of this option would be to allow external examinations to be performed by trained non-doctors under the current system. However, under the current system there is no figure equivalent to the Medical Examiner who, as a trained and experienced professional in charge of validating MCCDs could scrutinise the quality of the external examination and provide support to those who undertake it (it is proposed that Medical Examiners themselves would still undertake 10% of external examinations themselves). Therefore this option was rejected.

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

53. The regulations set out in this Impact Assessment cover both England and Wales. At present there is no information as to how the Welsh devolved administration intends to implement the reforms. For the purposes of this Impact Assessment it is assumed that their implementation will be in line with that planned by DH for England. This is just done for simplicity and should not pre-empt the Welsh devolved administrations future decisions of how they wish to appoint medical examiners and fund the service.

iv. 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 for cremations to cover burials as well.

Option 3

56. The consultation published along this Impact Assessment titled "Improving the Process of Death Certification in England and Wales: consultation on Policy and Draft Regulations" sets out proposals for a unified system applying to both burials and cremations that provides additional protection for the public against criminal activity of the sort exposed in the Shipman case. The main features of these proposals are summarised in **Figure 2**.

Creation of role of Medical Examiner

57. The post of Medical Examiner and its supporting officers would be created under this option.
58. Medical Examiners 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. Medical Examiners will be appointed by Local Authorities (or Local Health Boards in Wales) which have responsibility for the health of populations. Appointments are expected to be on a part-time basis enabling some on-going clinical practice. Medical Examiners will have additional functions including reporting concerns of a clinical governance nature by following local reporting procedures.
59. Each Medical Examiner will be assisted in their role by a Medical Examiner Support Officer 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 Medical Examiner.
60. The responsibilities of the Medical Examiner will include:
    - Independent scrutiny of MCCDs for cremations and burials and consideration of associated information provided by the family and the certifying doctor, including results from any external examination of the body;
    - Certifying deaths referred by the coroner where no attending practitioner is available within a reasonable period, as defined by the Death Certification Regulations;
    - Confirmation of the cause of death stated by the certifying doctor and notification to registrar to enable the bereaved to register a death and/or to arrange 'urgent' burial or cremation;
    - 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 family (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 where the duty arises during the course of a medical examiner's scrutiny; or refer a death where the medical examiner 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.
61. The current proposal is to introduce this new system for all cremations and burials, improving and streamlining the current system. This would be financed through a single fee paid by the

bereaved families, which is estimated to be significantly lower than current cremation form fees (£184) – see 'Running Costs of Option 3'. This is considered to introduce improved scrutiny that will help tackle the principal-agent problem described above.

Simplification: Removal of three cremation forms and role of medical referees

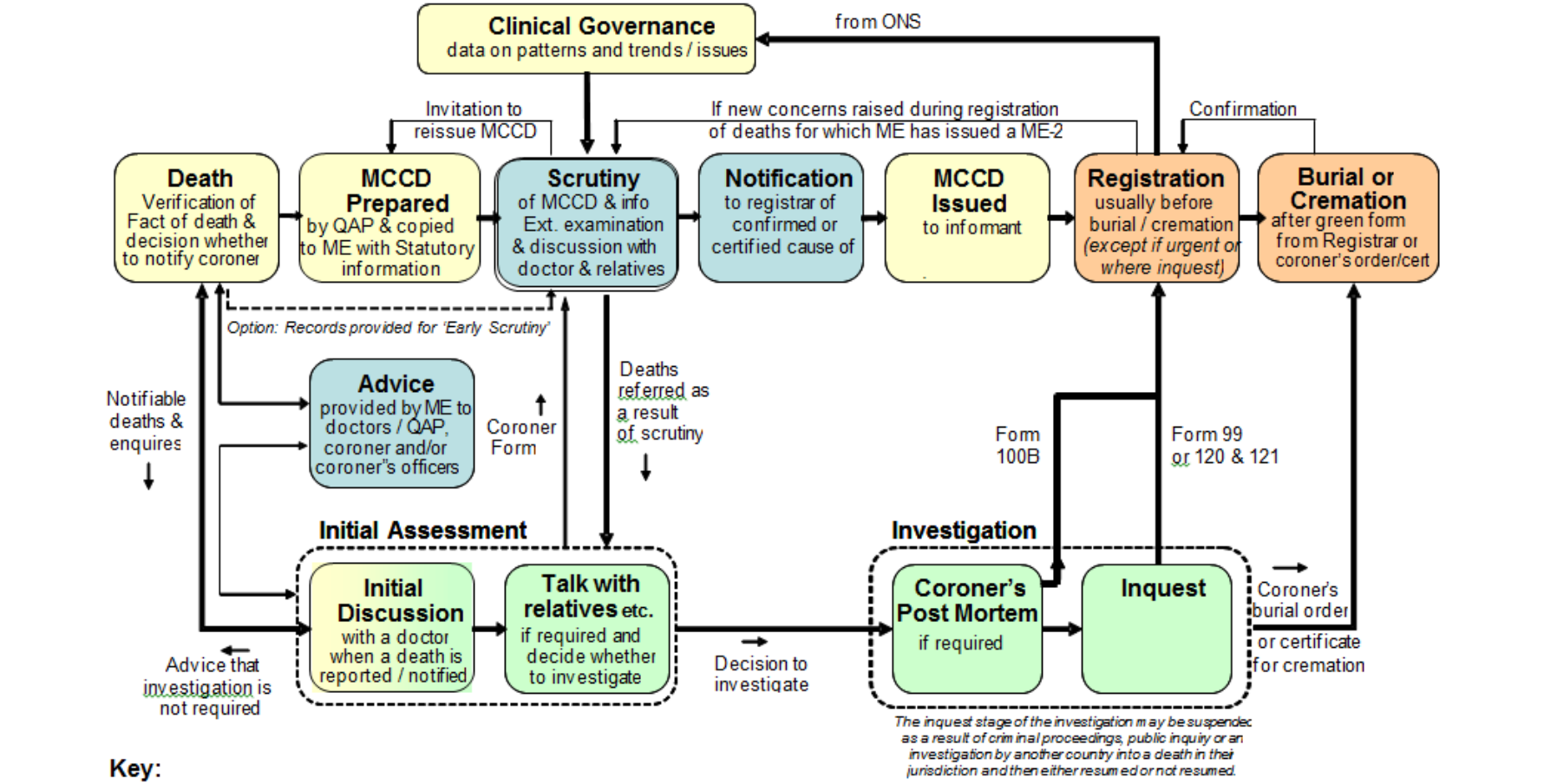
62. If the Medical Examiner is satisfied that all is in order, he or she will issue a notification by e-mail or fax to the registrar in order for the family of the deceased to register the death and proceed with burial or cremation. The medical examiner and his/her scrutiny described above will replace the role of medical referees, who are based in crematoria and check the cremation application and certificates.

63. Payments made by the bereaved to doctors for completion of Cremation Forms 4 and 5 known as "ash cash" (and for Form 10 to medical referees) will not be required. The BMA who are represented on the Death Certification National Steering Group are aware of the changes that the reforms will brings about.

Links with Clinical Governance

64. It is anticipated that medical examiners with access to clinical and administrative information accompanying the MCCD will be well placed to identify adverse patterns of deaths. They will also make observations from external examinations of the bodies, such as bed sores not recorded in notes, which might suggest poor care. Medical examiners 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.

Figure 2:



Abbreviations & Notes: QAP = Qualified attending practitioner. ME = Medical examiner. Statutory information required with the copy of the MCCD may be documented in records. External examination may be delegated in certain conditions. The Coroner Form is issued by a coroner for deaths that have been reported, notified or referred, but do not need to be investigated.

E. 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 therefore increase the level of scrutiny and would be likely to improve patient safety somewhat.

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 an additional 25% of deaths will have some level of scrutiny and so the new system would cost £76.3m (based on 96,195 deaths with a fee of £20 and 404,119 deaths with a fee of £184). The cremation form fees are assumed to be constant over the 10 year period.
67. Savings resulting from fewer exhumations are expected to be trivial and so are not considered in this IA.
68. The additional cost of this option above the £57.3m baseline costs of the current system would therefore be £19.0m 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 that the deaths of people who are buried are subject to. This could have a positive impact on patient safety, the quality of death certification data and the peace of mind of bereaved families.

1. Additional Scrutiny and Improved Patient Safety

70. The additional scrutiny of burial cases should increase detection rates of malpractice. Universal checks will 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. The proportion of cremations cases may be high enough, at 75%, to raise the expected level of scrutiny above the threshold at which people are willing to take risks. This benefit is inherently difficult to estimate and so is left unquantified in this IA.

2. Improved Quality of MCCDs

71. Extending the current system is likely to improve the quality of MCCDs through two channels. Firstly, the additional checks on MCCDs for burial cases should have a direct impact on their quality. A second indirect route may also arise due to the increase in volume of checks being performed. If this results in doctors completing more Forms 4 & 5, their ability to do so should improve through the increased experience. This is left as an unquantified benefit.

72. Furthermore, rolling out the current cremations certification process to all deaths would create a unified system and a single pathway for all patients. This allows for the creation of simplified guidance. This is left is also left as an unquantified benefit.

3. Improved level of assurance for bereaved families

73. There may also be a benefit for bereaved families in terms of their peace of mind. Numerous studies have shown that bereaved relatives often suffer from depression, ranging from minor short-term depression to major depression up to 25 months post bereavement (13). The Medical Examiner system is expected to alleviate 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 families 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 PTSD in cases where information was felt to be missing (48.4% of cases compared to 33.1%) (14). 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 of a loved one. Given the uncertainties relating to the magnitude, duration and dispersal of this benefit, it is left unquantified.

Net Benefits of Option 2

74. Under this option there are several unquantified benefits and quantified costs of £19.0m per annum.

75. 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 £-163.2m.

£ million	Discounted Costs	Discounted Benefits	NPV
Option 2 NPV (relative to Option 1)	163.2	*unquantified*	-163.2

76. 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.

F. Impacts, Costs and Benefits of Option 3

i. Mechanism by which Option 3 is intended to work

77. As explained in Section A, the current death certification system does not provide sufficient independent scrutiny to ensure MCCDs are accurately and correctly completed beyond the checks performed by registrars.

78. Under Option 3, all MCCDs for cremation cases and burials will be scrutinised by Medical Examiners, replacing the current system described in section D. Medical examiners 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

79. 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 get to know the new procedures and establish key contacts with Medical Examiners.
80. Under the proposed system, doctors currently completing Forms 4 and 5 and medical referees completing Form 10 will not carry out these functions and therefore no longer receive fees for this activity. The Medical Examiner function will result in remunerated work of a similar nature but a public fee will be collected by Local Authorities to cover the costs of the local medical examiner service, including for a paid workforce.
81. 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 bereaved families as part of the bill for the funeral. The decision on whether funeral directors will continue to be involved and collect the new medical examiner fee will be entirely a local matter between individual funeral directors and Local Authorities. In the interest of the bereaved, the general preference is to continue with the familiar practice of making the new fee part of the Funeral Director's bill. DH will facilitate the drawing up of a framework on the voluntary agreement between local authority and a local funeral service to collect the fee.

Public sector

NHS

82. The new system is expected to provide support for clinical governance NHS teams, through closer scrutiny on MCCDs. The medical examiner regulations, when introduced, will require medical examiners to report clinical governance matters in accordance with any relevant local reporting arrangements and obtaining information about the outcome of any reporting.
83. Introduction of the medical examiner's service will also have an impact on the NHS through its contribution to and use of data related to clinical governance.
84. The impact of this policy on NHS litigation costs is difficult to estimate with any certainty. On the one hand, the new system is likely to detect a greater number of problematic deaths and therefore may give grounds for bereaved families to sue the NHS. On the other hand, detecting and acknowledging a greater number of mistakes should lead to an improvement in the quality of medical care and fewer mistakes taking place, which would result in a reduction in litigation. This impact is left unquantified.

Local Authorities

85. Introduction of the medical examiner's service will have an impact on the Local Authorities through:
    - the requirement for Local Authorities to recruit and train medical examiners and their support officers;
    - the requirement for Local Authorities to monitor and manage performance of medical examiners (whilst ensuring that medical examiners are independent in how they exercise their professional judgement as medical practitioner);
    - the requirement for Local Authorities to provide office facilities, resources and access to information systems.
86. Initial set up costs for the service will be met by DH as part of the additional burden but thereafter a flat fee will be paid per case by the public to cover all the running costs incurred by the service.

In financial terms then, the net financial impact on LAs as a whole is expected to be zero. The costs presented in the cost section are about the costs of the system at national level.

87. Since Option 3 proposes a single national fee to fund the Medical Examiner service, a potential issue is that differences in costs across LAs will lead some of them (those with lower costs) to be funded beyond their costs and others (those with higher costs) to be underfunded. These variations are most likely to pertain to non-salary employment costs. Under option 3, travelling (one of the possible sources of variation) will be minimised by mainly using local staff to perform external examinations. During the consultation period, feedback will be sought on how to adjust for variations in costs across different LAs, in order to prevent or minimise any systematic under or over payment.

88. The calculation of the running costs that LAs will face is based on the assumption that LAs will provide the Medical Examiner service. Alternatively, it is possible that some LAs will commission local NHS organisations to provide this service for them. In principle, the overall costs should be similar to the ones that have been calculated below, including all salary, capital and other overhead costs. Therefore, whether LAs provide or commission the service is not expected to affect the overall cost of the service.

89. See the costs section for quantification of the different costs discussed in this section.

Registrars

90. 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 Registration online (RON) system. DH will be meeting the cost of this work (which is described in more detail in the costs section below).

91. Registrars will be required to obtain the signature of the informant to confirm that an opportunity to raise any matters related to the death has been offered by the medical examiner's office, if the signature was not obtained in Part B of the ME-2 form medical examiner's notification to registrar before it is transmitted to the registrar. This represents a new burden because this form does not exist in the current in system, and it would include contacting the informant and obtaining their signature whenever the medical examiner's office has failed to do so. However, it is anticipated that this burden on the registrars will be small and will be outweighed by them not needing to query poorly completed MCCDs which will be quality-assured by medical examiners.

92. DH is working with the GRO to ensure that the Medical Examiner function dovetails smoothly with registration procedures. The GRO is represented on the Implementation Board and Reference Group directing and supporting the development and implementation of these proposals.

Coroners

93. The over-arching principle governing the Medical Examiner scrutiny will be the safety of the certification process – i.e. safeguarding against certifying deaths that should be investigated by the coroner. The initial assessment by the Medical Examiner of the stated cause of death will be to determine whether or not the death should be referred to the coroner. We anticipate that by exposing MCCDs to medical scrutiny at an early stage in the process, referrals to Coroners will be better targeted and will therefore make more efficient use of Coroners' resources. DH is working with Coroners and the Ministry of Justice (MoJ) to ensure that the interface between the Medical Examiner and Coroner functions works smoothly. The Coroners' Society, Coroner's Officers Association and the MoJ are represented on the Implementation Board and Reference Group directing and supporting the development and implementation of these proposals.

94. 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 section below. The Department of Health, the Department for Communities and Local

Government and the Ministry of Justice will continue to work together to assess the financial consequences for coroner services.

The public

95. As already explained, currently 75% of deaths result in cremation and, where these are not investigated by the coroner, require payment of certification fees totalling around £180: 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. We estimate that the total annual expenditure on cremation fees is about £57.3m. No similar fees are paid currently in cases of burial.
96. In the proposed system, a fee would be paid by the public in cremation and burial cases. We estimate that the fee should be less than the current fee for cremation, at around £81. The costs section below contains more information on how this has been calculated.
97. 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 to bereaved families 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. The benefits section below contains more information on how these benefits.

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

Costs

98. Under this option, Death Certification is ultimately financed by payments from bereaved families in cremation and burial cases, which should cover the costs of examining the body and completing the relevant forms. Any changes to the system will therefore have an impact on these payments. We assume that any changes to running costs will be passed on directly to families and DH and so will not represent a net cost or saving to Local Authorities. Set-up costs will be financed by the DH.
99. The costs of Option 3 have been calculated by estimating the number of Medical Examiners that would be 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 resource to them. These costs would initially be incurred by Local Authorities, who have responsibility for establishing the service and resourcing, although it is expected that they would be recovered by the fees charged to bereaved families.

Cost of potential delays for burial cases

100. Under Option 3, there would be an improved death certification process for cremations that would be extended to burials. While this would entail a simplification of the current process for cremation cases, it would also represent an increase in the scrutiny of burial cases. This is likely to increase the time between the moment of death and the burial in those cases. This increased delay can be problematic, as many families would prefer, for personal as well as religious or cultural reasons, for it to be as short as possible.
101. In order to mitigate this potential negative effect, the new Death Certification process has been designed to be as quick as possible while ensuring that MCCDs for burial cases can be scrutinised adequately.
102. Islamic and Jewish burials customarily occur within 24 hours of death, so an inability to meet this target could result in a significant religious response. Our pilot in Leicester, which has large Islamic and Jewish communities, demonstrated that the requests for an urgent release of

the body for cremation (and burial) can be dealt with significantly quicker than the existing processes, which can take up to two days. This was because the Medical Examiner could complete all the requirements for cremation with the medical examiner processes as opposed to seeking an independent doctor to complete existing cremation paperwork. Where urgent burials are required, the families make their needs known to the certifying doctor. In the new process, we expect a similar process and guidance and national exemplar forms will enable the medical examiner's office to be alerted to the need for urgent scrutiny of the MCCD prepared by the doctor. Local Authorities with large faith populations will need to ensure that the local medical examiner service is configured to meet the needs of their community.

Running costs of Option 3

103. The running costs of Option 3 will be financed by a public fee charged by LAs, with the exception of E-learning for healthcare training costs and the cost of medical examiner time for those cases subsequently referred to a coroner, which will be financed by DH.

1: Number of Cases

104. The total number of deaths registered in England and Wales in 2014 was 500,314. Data from the Cremation Society of Great Britain show that 75% of deaths result in a cremation, with the remainder 25% resulting in a burial (8). Under the Option 3, all 375,986 cremations and 124,328 burials would be scrutinised within the new system.

105. Evidence from the Death Certification pilots suggests that medical examiners would be involved in around 89% of scrutinised deaths corresponding to 445,279 cases (the remaining 11% would be forwarded to coroners directly and would not require the intervention of a medical examiner). It also suggested that 13% (65,041 deaths) of the deaths that Medical Examiners are involved in would be forwarded to coroners, who would complete the Form 100B to certify the cause of death for those cases.

106. Therefore, Medical Examiners would scrutinise 76% of deaths for which a fee would be issued. This equated to 380,239 deaths in 2014. See subsections 2-6 for an investigation of these costs.

107. The other 13% of cases, representing 65,041 deaths in 2014, would require scrutiny by Medical Examiners but would ultimately be investigated and certified by coroners (they would not result in a fee). The associated costs for the medical examiner scrutiny in these cases will be financed by DH – see subsection 7.

2: Number of FTEs and headcount

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

- Medical Examiners: Medical Examiners are doctors who will verify and check MCCDs, providing independent scrutiny.
- Medical Examiner Officers: These are administrative personnel to support Medical Examiners.
- Non-doctors in charge of external examinations: These are non-medical personnel who will be trained and paid to provide an external, non-forensic examination of the body in most cases. 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.

109. It is expected that Medical Examiners and Medical Examiner Officers will be involved in every case. However, the majority of external examinations 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 Medical Examiners (beyond the transition period, where it has been assumed that additional involvement by Medical Examiners will be necessary).

110. Based on evidence from the pilots, the following split can be derived:

External examinations per group of staff

Medical examiners	10%
Other people who carry out external examinations	90%
Total	100%

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 all of these steps will be carried out in the case of both cremations and burials:

1. Receipt of modified ME-1a and appropriate level of supporting medical records
2. Receipt of the proposed cause of death (on the modified ME1a)
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 further medical records and test results
7. External Examination carried out by non-Doctors.

What is required for proportionate scrutiny will vary on a case by case basis and these estimates are simplifications. Below are estimated numbers of minutes to carry out all 7 steps:

Minutes needed	Steps 1-7
Min per case - Medical Examiner	28
Min per case - Medical Examiner Officer	60
Min per examination - Other	10

112. 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). These are used to calculate the expected total FTE and headcounts reported below:

	Total FTE	Total Headcount
Total number of MEs required including NME	110	385
Total number of MEOs required	234	586
Total number of Other carrying out external examinations needed per death	32	192
Total headcount staff		**1163**

3: Employment costs

113. This section summarises the assumptions about costs of employment relative to the number of FTEs for each type of staff. National scales are used for employment costs of those working within the Medical Examiner system to reflect the fact that employees will be performing the same role across the country. The employment costs for each staff type are included in Annex A.

Total employment costs (excluding recruitment and training costs)

Staff type	Employment cost per year (£m)
Medical Examiners	14.9
Medical Examiner Officers	10.1
Non-Doctors (external examinations)	1.3
Total	**26.2**

114. Additionally to this, DH will appoint a National Medical Examiner, a senior doctor who will provide leadership and advice on matters relative to Medical Examiners. This will be funded directly by the DH and not contribute to the fee paid by the public.

National Medical Examiner FTE	
Salary cost per National Medical Examiner	£142,000
On-costs (at 30% of salary) of National Medical Examiner	£42,600
Proportion of NME dedicated to NME duties	60%
Total cost per NME	**£110,760**

4: Recruitment costs

115. The set-up costs section covers the initial recruitment costs necessary in the first year. After that year, there will be an on-going cost of recruitment to cover staff turnover. An assumption of 8.9% is used for all staff types, based on overall NHS turnover rate in the year up to August 2015 (reference 10). 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 £500 per post. Therefore, for an estimate total of 991 staff headcount, around 89 new recruits are expected every year and the costs of recruitment are expected to be around £50,000. This cost will be incorporated into the fee.

5: Training costs

116. Each year after start-up, new members of staff will receive one-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 8.9%, 30, 42 and 18 ME, MEOs and Other (non-clinical) staff members will be recruited each year. This corresponds to a total cost of £20,000, £10,000 and £5,000 for the aforementioned respective staff types. The total cost is therefore expected to be around £35,000 per annum.

117. Additionally, training for Medical Examiners and Medical Examiner Officers will be available through e-Learning for Health. E-Learning for Health will have the following costs:

- Running the Platform: The costs of running the e-LfH platform is approximately £2.5m/year and the Medical Examiner 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 DH. 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. In the first year this is expected to be £15,000, higher than usual because of the likely significant changes as a result of legislation. The annual cost for Year 2 onwards it is expected to be around £10,000.
- Additional clinical costs: It would also be necessary to have a subject matter expert who would lead on the review of the content and agree the final changes. This is costed as £500/day. In the first year it is likely that this would require up to 25 days of the clinicians time and in subsequent years up to 10 days. Therefore £12,500 in the first year and £5,000 in subsequent years.
- The time spent by employees on training is accounted for as part of their CPD. The assumptions used above in the "Number of FTEs and Headcount" section to calculate the amount of time that Medical Examiners and other staff members will be able to spend on their duties include an assumption that they will take a set number of days per year for training. This cost has therefore already taken account of.

118. Overall, this gives us a financial cost of E-learning for Health of £93,500 for the first year and £81,000 in subsequent years, to be financed by DH. These costs are reflected in Start-Up costs and in subsection 7 of Running Costs.

6. Non-Staff costs, fee collection costs and bad debt

Printing and distributing documents and forms

119. Checking MCCDs will require the printing and distribution of forms as well as scanning or transporting paper-based health records. These costs, summing to around £0.5m, are detailed in Annex A.

120. The cost of collecting the fees will depend on the method used to do so. It is difficult to predict what methods will be used, however it is believed that payment via funeral directors will be a cost effective and feasible form of payment as such we intend the majority of payments will take place via this method (80%), with the remainder of payments divided among other payment methods. The Programme team are aware of the sensitivities about how individuals are asked to pay the fee with a general preference to continue with the familiar practice of making the new fee part of the Funeral Director's bill. It is envisaged that DH will facilitate the drawing up of a framework on the voluntary agreement between a local authority and a local funeral service to collect the fee.

121. The make-up of the collection costs, which total £3.1m, is detailed in Annex A.

122. Based on discussions with local authority representatives, an assumption has been made that 2.5% of debts will go unpaid. This equates to around £750,000 per annum. As a result, the costs associated to payment by post / phone, via funeral directors or through existing on-line facilities do not incur charges for these cases. Costs associated to invoices sent requesting payment are still incurred for the relevant proportion of cases because it is assumed that these costs will be incurred regardless of whether the fee is actually collected.

8. Payment from DH to cover the costs of Medical Examiners scrutinising cases that are forwarded to coroners

123. Cases scrutinised by Medical Examiners but that are then forwarded to coroners and certified by coroners will not be subject to a fee (in line with current practice, coroner services will not have a cost to relatives). However, these are still real cases that require the work of Medical examiners and have costs to LAs as providers of the service. DH will finance this cost.

124. Based on information from the pilots, 15% of the cases that Medical Examiners deal with are certified by Coroners. The scrutiny provided for these cases that are ultimately forwarded to coroner will represent a per annum cost. This is calculated in exactly the same way as above

(though excluding fee collection payments). The Table below shows the components of this recurring cost which reveals around £4.3m will be financed by DH.

8. Total Running Costs

Total costs not chargeable to fee:

Employment costs (including overheads, on-costs, etc.)	£4.3m
Recruitment and training costs for new staff and E-learning costs (see subsection 5)	£0.1m
Other costs (printing and transporting forms)	£0.1m
TOTAL	£4.4m

Total costs chargeable to fee.

Employment costs (including overheads, on-costs, etc. but excluding cases forwarded to coroners)	£26.4m
Recruitment and training costs for new staff	£0.2m
Fee collection costs	£3.1m
Other costs (printing and transporting forms)	£0.5m
The costs associated to uncollectable debt ("bad debt")	£0.8m
TOTAL	£30.9m

125. Based on the above elements, the total cost of running the new Death Certification system that can be attributed to the fee will be £30.9m. When divided by the number of relevant deaths each year (i.e. excluding those investigated by a coroner), this gives an estimated fee of around £81. This figure is subject to change over time as the underlying costs of the Medical Examiner service change (e.g. if the salaries of those working within the Medical Examiner service were to increase by 1-2%, the fee would need to increase by a similar amount to ensure that it reflects the full cost of the Medical Examiner service). For the purpose of this IA, the fee is assumed to be constant over the 10 year period (as is assumed for the counterfactual, the cost of the existing cremation fees).

126. The recurring cost to DH is expected to be £4.4m per annum.

Additional costs due to increased coroner workload

127. The introduction of medical examiners will ensure unnecessary deaths are not reported to the coroner but that appropriate deaths are referred for investigation, which would otherwise go undetected. This will, of course, support the Ministry of Justice's reforms to the coroner services in making it more efficient. However, it does mean that coroners could potentially see an increase in their workload which might need additional resourcing.

128. Evidence from the Sheffield pilot shows that a decrease of around 10 percentage points in the proportion of registered deaths that are reported to coroners can be attributed to the new system.

129. Evidence from this pilot also shows that the proportion of registered deaths that require a Coroner to perform a post-mortem and/or an inquest increased by around 4 percentage points due to the pilot.

130. Taken together, this is in line with anecdotal reports from the pilots that suggest that Medical Examiners are better able than regular doctors to identify cases that should be

investigated by Coroners and, although they report fewer cases, those they report tend to lead to inquests and/or post-mortems more often than at present.

131. Applying these percentages to the number of deaths that would be scrutinised by the Medical Examiner system, this gives us a reduction of deaths reported to coroners of 50,364 and an increase of 20,378 coroner post-mortems/inquests.

132. To calculate the impact this will have on the workload of coroners requires identifying the cost for a coroner of dealing with a case that should not have been forwarded to them, as well as that of an average post-mortem/inquest. These costs should include the time that coroners and their staff dedicate to each case as well as the costs of hearings, and other activities.

133. For the purposes of this IA, a range of costs are considered for the different types of coronial investigations. Based on these estimated costs, the average costs per inquest/examination is £772, based on £700 costs for an inquest (excluding post-mortem costs), £600 for a post-mortem and £1,300 for cases where both a post-mortem and an inquest are performed are assumed. These figures are based on expert advice.

2014 Coroner Statistics	Number	Proportion	Cost
Inquests without PM	6,320	6.6%	£700
PM with Inquest	22,767	23.7%	£1,300
PMs without Inquest	67,108	69.8%	£600
Weighted Average post mortem and/or Inquest	**96,195**	**100%**	**£772**

134. The cost to a coroner of dealing with a case that should not have been forwarded to them is more difficult to calculate. In principle such a case should require less of the coroner's time and therefore its cost should be lower. In the absence of evidence on this, the assumption that this represents 1/5 of the cost of an average post-mortem and/or inquest is used as the central estimate. This assumption was based on advice from coroners in the pilot site areas but, because of the uncertainty, High and Low Scenarios are set out below at 1/4 and 1/6 of the cost. The High Scenario is the one that has a positive effect on the NPV (and hence lowers the cost of the Medical Examiner service) and vice versa for the Low Scenario. These Scenarios are depicted below, in 'Total Costs of Option 3' and in 'Net Benefit of Option 3'.

Scenario	Proportion of time spent on inappropriate coroner referral	Associated Cost (£)
Low	1/6	129
Central	1/5	154
High	1/4	193

135. Bringing these estimates together allows us to calculate the total additional burden for coroner services:

	% of registered deaths	% of registered deaths	**Total Cost Increase**
	Deaths reported to a coroner	Coroner's post-mortems/inquest	
Current process (% of registered deaths)	45%	19%	
New process (% of registered deaths)	35%	23%	
Change in number of cases based on registered deaths in 2014	-50,364	20,378	
Additional cost – Low Scenario	-£9.7m	£15.7m	**£6.0m**
Additional cost – Central Estimate	**-£7.8m**	**£15.7m**	**£8.0m**
Additional cost – High Scenario	-£6.5m	£15.7m	**£9.3m**

136. As can be seen above, these assumptions can have a large bearing on the costs of the policy. There are also other factors, including the modernisation of the Coroner Service, which are likely to affect individual coroners' workload. During the consultation period, DH will work with MoJ, DCLG and the Chief Coroner's Office to gather evidence that will allow for a better assessment of costs.

137. It may be that, through the involvement of Medical Examiners, the extra cases referred to coroners take less time than those cases referred to coroners immediately. This has not been considered in this IA but may serve to dampen this cost pressure.

138. It should be noted that the expected change in the workload of coroners resulting from the introduction of a Medical Examiner service is relatively small compared to changes from other causes, such as changes in local staff and local practices, which differ considerably between different coronial jurisdictions.

139. DCLG, who allocate funding to local authorities for coroner services, have advised that DH should work with them and the Ministry of Justice to gather evidence for a further additional burdens assessment after a period of approximately 18 months after implementation. This should allow the medical examiner service to become properly embedded. DCLG Ministers will then consider the assessment, and the need for additional funding, if any, for coroner services.

Set-up costs of Option 3

140. Setting up the service will require up-front costs, particularly in the first year of operation. The overall set-up costs are estimated to be around £18.6m for the country as a whole and will be funded by DH.

141. Although Local Authorities are responsible for providing the Medical Examiner service, it is likely that several of them may join forces to provide the service and benefit from economies of scale. Based on DH discussions with the LGA, it is estimated that Local Authorities will organise themselves into 80-120 areas to provide Medical Examiner service ('ME Areas'). Upon advice from the LGA, we have used a central estimate of 120 in this IA. This could be considered conservative as it is hoped that ME Areas will align with coroner areas; in the Chief Coroners 2014/15 annual report, the chief coroner expressed an ambition that there would be 75 coroner areas in the future (15). Because this assumption is subject to such uncertainty, High and Low Scenarios are set at 80 and 160 ME Areas. As before, the High and Low Scenarios are determined with respect to their effect on the NPV (High denoting a positive effect). These scenarios are reflected in '9.Total Start-Up Costs', 'Total Costs of Option 3' and 'Net Benefits of Option 3'. In Sections 1 – 8, only the central estimate is given.

142. The assumptions and estimates below are based on conversations with LGA representatives and the teams that work on the different pilots. They will be reviewed to take account of consultation responses.

1. Cost of planning & preparation, including local authority lead, lead medical examiner, contribution to national planning

143. The cost of planning and preparation by Local Authority staff to establish the service ahead of implementation is expected to be around £93,500 for each area. For the whole of England and Wales, this would represent £11.2m.

2. Cost of recruitment for start-up of service

144. The total number of headcount staff required for the system is estimated to be 972 (see the section on running costs for a derivation of this figure, ME and MEO only). Recruitment costs

including advertising and interviewing are estimated to be £500 per post. Therefore, the initial recruitment costs are estimated to be around £485,000.

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

145. Local registrars will need to receive training to use the new procedures and systems. If we assume a total of 25 people need training per area (for 120 areas) and the cost of a training course is assumed to be £81, this gives a total cost of around £240,000.

146. There are also additional E-learning costs that fall in the first year which relate to additional updates and associated clinical time. These are estimated to cost around £12,500

4. Cost of local briefings and communication materials

147. As part of their preparation, Local Authorities would hold local briefing sessions for hospital doctors, hospital staff, GPs and Practice Managers, Funeral Directors and Patient Representatives. They would also print supporting materials such as leaflets. It is estimated there would be 10 briefings per area and that the cost per area would be around £1,000, leading to a total cost of £1.2m.

5. Cost of establishing medical examiner's offices and facilities

148. Local Authorities will face the costs of establishing offices and facilities for their new staff. This will include alterations and extensions to provide accommodation for new medical examiner's offices, installation of new networking / telecommunications, procurement and implementation of new computers and printers and, finally, procurement and implementation of basic standalone database. Recognised set-up costs exclude any electronic interface or integration with existing systems.

149. This is estimated to cost around £14,000 per Medical Examiner Area, around £1,680,000 in total.

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

150. 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.

151. 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 FTEs are needed to participate in the shadow-run. The total cost is therefore £0.8m.

	Additional FTEs required	Cost per FTE	Additional cost
MEs	3.6	£135,000	**£0.5m**
MEOs	7.4	£43,000	**£0.3m**
Non-Clinical	1.0	£41,000	**£0.05m**
Total			**£0.8m**

7. Cost of lower process efficiency during first year of operation

152. 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, 10% additional FTEs will be necessary.

153. The additional cost of this is based on salary costs for each type of employee. 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 two years, which will be paid at the usual rate for each member of staff. The costs are shown in the table below.

	Total	10%	Salary costs	Cost
Total number of FTE MEs required	110	11.0	£89,010	£1m
Total number of FTE MEOs required	234	23.4	£26,333	£0.6m
Total number of FTE Other carrying out external examinations required	32	3.2	£30,384	£0.1m
Total				£1.7m

8. Existing system changes and upgrades

154. Additionally to these set-up costs for Local Authorities, the death certification reforms will affect the data on death registration collected by the General Register Office for England and Wales and processed by ONS, 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. 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) and to the M204 systems and processes, and to 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. DH will be meeting the cost of this work and will be refining these cost estimates during the consultation.

As the ONS case study showed that scrutiny of MCCDs is likely to impact on trends of cause of death statistics, ONS has asked DH 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. DH has acknowledged that such a study is required but the design and cost has yet to be agreed with ONS.

9. Total Start-Up Costs

£ millions	High Scenario	Central Estimate	Low Scenario
LA and National Preparation	7.5	11.2	15.0
Recruitment and training costs	0.7	0.7	0.8
Other costs (briefings, communications and establishing ME Offices)	1.9	2.9	3.8
Retrospective scrutiny	-	0.8	-
Initial inefficiency	-	1.7	-
IT System changes	-	1.2	-
TOTAL	13.8	18.6	23.4

Note: "-" reflects the fact that we only present a central estimate for this cost, and thus the high and low scenario values are equal to the central estimate.

Total Costs of Option 3

155. The central estimate of the cost of the new system is therefore as follows:

Total cost of new system under Option 3 under Central Estimate

£ million	Transition year			Subsequent years		
	High	**Central**	Low	High	**Central**	Low
Running costs paid by the public through fee	-	**0**	-	-	**30.9**	-
Running costs paid by DH	-	**0**	-	-	**4.4**	-
Costs from impact on Coroners	-	**0**	-	6.0	**8.0**	9.3
Set-up costs paid by DH	13.8	**18.6**	23.4	-	**0**	-
Total costs	13.8	**18.6**	23.4	40.8	**43.3**	44.1

Note: "-" reflects the fact that we only present a central estimate for this cost, and thus the high and low scenario values are equal to the central estimate.

156. The tables above show the quantified cost of the new certification system. This is estimated at around £43.3m per year. However, in order to obtain the net cost of moving from the current system to this system it is necessary to take into account the cost of the current system. Therefore the net cost of moving to the Option 3 Death Certification system would be as follows:

Total cost of Option 3 as compared to Option 1 baseline under Central Estimate

£ million	Transition year			Subsequent years		
	High	**Central**	Low	High	**Central**	Low
Running costs paid by the public through fee	-	**0**	-	-	**-26.5**	-
Running costs paid by DH	-	**0**	-	-	**4.4**	-
Costs from impact on Coroners	-	**0**	-	6.0	**8.0**	9.3
Set-up costs paid by DH	13.8	**18.6**	23.4	-	**0**	-
Total costs	13.8	**18.6**	23.4	-15.5	**-14.1**	-12.2

Note: "-" reflects the fact that we only present a central estimate for this cost, and thus the high and low scenario values are equal to the central estimate.

157. As shown above, as compared to Option 1 baseline, the total cost (financial) of the medical examiner's service is expected to result in a £14.1m saving after the transition year.

Benefits

158. 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 state on MCCDs by doctors will be scrutinised by a medical examiner.
- 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 that they can raise and concerns with an independent individuals about the standard of care leading up to a death and provides reassurance that the cause of death is correctly established by the doctor and confirmed by and independent medical examiner.

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

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

160. Under this Option, 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 independent medical examiner workforce that has undergone specific training on death certification and identifying and reporting anything untoward about a death.

161. 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.

162. 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 includes cases such as that of Harold Shipman.

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

164. Moreover, a potential impact of Medical Examiners that has emerged from pilots is an increase in the number of Coronial Investigations. The increase due specifically to MEs has been estimated in the “Additional costs due to increased coroner workload” section at around 20,378 investigations. Coronial Investigations, especially Inquests, provide a valuable service 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 increased reporting of deaths relating to hospital issues and industrial diseases should help any possible safety risks to be brought to light.

165. Coroners can also help avoid future deaths by using ‘Reports to Prevent Future Deaths’. This requires organisations to respond to a coroner’s concerns about medical safety arising from an inquest. Around 400 such reports were issued between Nov 2014 and Nov 2015.

166. Data from the Sheffield pilot does indicate that Medical Examiners refer more cases to coroners that result in ‘critical’ verdicts. During the first 4 years of full rollout, 15 critical verdicts 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 Medical Examiner system, this would result in an additional 141 critical verdicts nationally per year (assuming the case that may have been referred under the current system constitutes half an additional critical verdict).

167. With both inquests and critical verdicts, there is a trade-off to be considered in terms of the psychological effect of detecting previously undiscovered cases of malpractice. Whilst people who had previously unaddressed concerns over deaths will certainly benefit from these 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, so this

impact is not quantified. 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 errors (16). It is difficult to say whether this will also be the case for bereaved relatives in an inquest setting.

168. An additional point is that the involvement of Medical Examiners is expected, based on the evidence presented in the "Additional costs due to increased coroner workload" section, 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

169. 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.

170. 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.

171. The poor quality of certification is something that the Shipman Inquiry identified. Past audits (9) of MCCDs showed that only 55 per cent of certificates were completed to a minimally accepted standard, a figure consistent with the wider literature on death certification in the UK. 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.

172. The Office for National Statistics carried out a case study analysing just over 5000 records supplied by the pilots, comparing the cause of death proposed by the certifier and the cause confirmed by a medical examiner (17). This suggests that medical examiners' 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 the 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 indicate that the medical examiner scrutiny is likely to affect trends in causes of death reported in mortality statistics.

173. Further supporting evidence was found in an independent review of death certification at Mid Staffordshire NHS Foundation Trust commissioned by the Trust's Mortality Group (18). 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.

174. Medical Examiners 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, medical examiners will ensure the death is referred to the coroner for investigation.

175. 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

176. In the new system, doctors will have access to advice from a medical examiner that will assist them to propose a preliminary cause of death. Due to the frequency with which Medical Examiners will be handling MCCDs as part of their scrutiny and confirmation of cause of death Medical Examiners will be ideally placed to identify training needs of doctors as far as how to complete a MCCD fully and accurately. This requirement will be formalised in additional statutory duties conferred on medical examiners.

177. 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.

178. Preliminary results from the pilot sites indicate that Medical Examiner 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 data (17).

179. The ICD-10 chapter identified by the original certifying doctor was changed by the Medical Examiner 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.

180. The numbers of deaths from respiratory diseases, cancer and cardiovascular diseases are deemed sufficiently large to present here. Under Medical Examiners, 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.

181. Whilst it is possible that these changes 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.

182. 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. For example research which provides insight on which health care spending is most cost effective relies on data from MCCDs which is used to calculate the mortality rate for different health problems (11). However, these benefits have not been estimated due to the complexities and uncertainties involved.

3. Improved level of assurance for bereaved families

183. The proposed system is expected to be more transparent and understandable for bereaved families, while providing assurance that all due process has been followed.

184. For cremation cases, it is not certain that the greater level of scrutiny will be perceived directly by families. However, the fact that the process has been simplified and the number of forms reduced is likely to make the process more transparent and easier to understand for families, 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.

185. For burial cases, the fact that MCCDs will be at all scrutinised should lead to an increase in assurance and confidence in death certification from bereaved families. This benefit is described in more detail in the Option 2 benefits section.

Net Benefits of Option 3

186. The Net Benefits of this Option are shown below. Over 10 years and using a discount rate of 3.5%, this would give a range from £107.9m to £73.7m, with a central estimate of £88.3m. The upper and lower bounds are calculated using variable assumptions relating to the number of ME Areas and the cost of inappropriate referrals to coroners.

£ million	Discounted Costs	Discounted Benefits	NPV
High NPV scenario	-107.9	unquantified	107.9
Central scenario	-88.3	unquantified	88.3
Low NPV scenario	-73.7	unquantified	73.7

187. 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 significantly underestimates the NPV of the policy.

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 Medical Examiners and support officers

188. 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 Medical Examiners and support officers (both initially and over time).

Greater independence of Medical Examiners

189. The fact that scrutiny on cremation cases will be more independent under Medical Examiners 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 Medical Examiners will be employed by Local Authorities and Health Boards. The certifying doctors will not be able to choose the medical examiner that will scrutinise the cause of death stated on the MCCD. In fact, the Death Certification Regulations stipulate that medical examiners must be independent of the certifying doctor and the deceased.

190. There may be a trade-off between ensuring sufficient local cover and Medical Examiner independence. In rural communities, it is unlikely that GPs will not know their Medical Examiner and vice versa. Bearing this in mind, where Local Authorities have not joined to provide a ME Area, they will be encouraged to have reciprocal agreements with neighbouring LAs to ensure that where the issue of independence arises, another medical examiner can step in and fulfil the statutory function.

Impact on coroners

191. The impact that Option 3 will have on the workload of coroners is a very important assumption, as it can increase or reduce the costs of the policy significantly. Moreover, the evidence base for this assumption is at present relatively bare, consisting chiefly of expert opinion and assumptions based on evidence from the Sheffield pilot. Moreover, the Coroner Service is undergoing reforms that increase the uncertainty.

192. Because of this, assessing this Option fully will require collecting additional evidence on the impact on the workload of coroners and the costs that this will have.

193. Benefits arising from an increased referral of appropriate cases to coroners are at risk if this additional workload is not funded. Therefore Option 3's status as the preferred Option depends to large extent on whether this funding can be secured. DH will be discussing this issue with DCLG, MoJ and the Chief Coroner's Office over the consultation period.

I. SUMMARY AND WEIGHING OF OPTIONS

194. 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 bereaved families. It does not address either the difference in the level of assurance provided to bereaved families depending on whether the body is cremated or buried.

195. Option 2 would improve the scrutiny level on burial cases 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.

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

197. Option 3 is the preferred Option, since it allows for policy objectives of improving the assurance and crime deterrence aspects of death certification and ending the unjustified difference in treatment to burial and cremation cases to be met while producing net savings for the public in the form of lower death certification fees for cremation cases.

198. However, further evidence on the costs and benefits associated with this Option, in particular those deriving from the impact on coroners, is desirable. DH will work with its counterparts during the consultation period to acquire this additional evidence.

199. In terms of affordability, Option 2 does not impose any further cost on public expenditure. Option 3 will require some further public expenditure, particularly in the transition period.

Annexes

Annex A: Further Cost Details

Running costs of Option 3

2: Number of FTEs and Headcount

Weeks and Hours worked per year for each staff type. This takes account of time spent on training, annual leave and sick leave (based on PSSRU assumptions of annual leave, sick leave and time spent on Continuous Professional Development including any training) as well as travelling to inspect bodies, desk work, peer-review and other duties:

FTE ME weeks worked per year	42.4	PSSRU Unit Costs of Health and Social Care 2014. Consultant
FTE ME hours worked per week	43.3	PSSRU Unit Costs of Health and Social Care 2014. Consultant

FTE MEO weeks worked per year	44.6	Assumption based on 27 days of annual leave + 10 bank holidays
FTE MEO hours worked per week	40	Assumption

FTE Other weeks worked per year	44.6	Assumption based on 27 days of annual leave + 10 bank holidays
FTE Other hours worked per week	40	Assumption

The ratio of headcount to FTE for each staff type is shown below. It is expected that most of the staff involved will provide work on a part-time basis. The expected headcount to FTE ratios are shown below, based on evidence from the pilots:

Headcount/FTE ratio

	Headcount/FTE ratio
MEs	3.5
MEOs	2.5
Non-doctors	6

3. Employment Costs

Medical Examiners

Salary cost per ME FTE	£89,010	Source: Health and Social Care Information Centre NHS Staff Earnings Estimates, 12 month period ending August 2015. Mean Basic Pay per Full Time Equivalent for Consultant (20)
Adjustment for overtime (at 2.5% of salary)	£2,225	Overtime is modelled as a 2.5% increase in the salary.
On-costs (at 30% of salary) per ME	£26,703	Based on super-annuation and National Insurance on-costs

Other attributable overheads (at 12% of salary)	£10,681	Based on PSSRU overhead assumptions for Consultants, excluding those elements that have been accounted for elsewhere or which are not relevant to Medical examiners. Takes account of overheads such as Establishment costs including printing & stationery, postage, telephone, advertising and travel and subsistence as well as Education & training which is additional to the separate PSSRU provision for 'on-going training' (21)
Travelling costs (per year per FTE)	£700	Includes only travelling costs to perform external examinations. Assumption validated by discussion with pilots.
Accommodation cost per FTE	£5,600	Based on 7 sqm per FTE and £800 per sqm in accommodation costs and associated overheads. The 7 sqm is based on discussions with the pilot leads and has been validated by representatives from Local Authorities. . The £800 per square metre is an assumption based on figures provided and validated by NHS stakeholders.
Total cost per ME	**£134,919**	

Medical Examiner Officers

Salary cost per FTE ME Officer	£26,333	Based on discussions with experts. Weighted average salary consisting of: 1 senior MEO, 1 MNEO and 1 admin MEO (respective salaries £32k, £27k, £20k)
On-costs (at 30% of salary) per ME Officer	£7,900	Based on super-annuation and National Insurance on-costs
Other attributable overheads (at 12% of salary)	£3,160	Based on PSSRU overhead assumptions, excluding those elements that have been accounted for elsewhere or which are not relevant to Medical examiners. Takes account of overheads such as Establishment costs including printing & stationery, postage, telephone, advertising and travel and subsistence as well as Education & training which is additional to the separate PSSRU provision for 'on-going training' (21)
Accommodation cost per FTE	£5,600	Based on 7 sqm per FTE and £800 per sqm in accommodation costs and associated overheads. The 7 sqm is based on discussions with the pilot leads and has been validated by representatives from Local Authorities. The £800 per square metre is an assumption based on figures provided and validated by NHS stakeholders
Total cost per FTE MEO	£42,993	

Non-doctors performing medical examinations

Salary cost per FTE Other carrying out external examinations needed	£30,834	Source: Health and Social Care Information Centre NHS Staff Earnings Estimates, 12 month period ending August 2015. Mean Basic Pay per Full Time Equivalent for qualified Nurses, Midwives and Health Visiting Staff. (20)
Adjustment for overtime (at 0.9% of salary)	£273	Overtime is modelled as a 0.9% increase in the salary perceived.
On-costs (at 30% of salary) per Other carrying out external examinations needed	£9,115	Based on super-annuation and National Insurance on-costs
Travelling costs (per year per FTE)	£1,200	Assumption validated through discussion with pilots. This assumption lower than for examining doctors to take account of the fact that almost all of the examinations they perform will be in their usual place work.
Total cost per FTE Other carrying out external examinations	**£40,972**	

6. Non-Staff costs, fee collection costs and bad debt

Printing/distribution of forms	£310,000	Based on 60% of cases requiring printing forms for completion by hand (6 sides) at £0.54 as well as printing forms received electronically (9 sides) at £0.81
Cost of scanning or transporting paper-based health records	£140,000	Based on 10% of cases requiring scanning (at £3.75 per case) and 0.5% of cases requiring transporting (at £0.5 per case).

Proportion of payments by method	
Payment by post / phone following issue of MCCD	6%
Payment using existing on-line facility	7%
Payment via funeral director	80%
Invoice sent requesting payment	7%
Total	100%

Cost of each payment method per each death where the fee can be charged	
Payment by post / phone following issue of MCCD	£4
Payment using existing on-line facility	£2
Payment via funeral director	£7
Invoice sent requesting payment	£35

Total cost of payment and collection for 369,088 MCCD p.a.	
Payment by post / phone following issue of MCCD	£90,000
Payment using existing on-line facility	£50,000
Payment via funeral director	£**2,080,000**
Invoice sent requesting payment	£930,000
Total	**£3,150,000**

Annex B: Post Implementation Review (PIR) Plan

Basis of the review: Commitment to review and to monitor results.
Review objective: The reforms introduce additional steps to certification and registration of deaths and on that basis we would review whether the regulations are operating as expected and delivering the benefits anticipated.
Review approach and rationale: The review would look at an analysis of data that is collected and consider feedback from stakeholders including coroners, registrars, funeral directors, the medical profession and the public via local bereavement services.
Baseline: Comparison to current pre-implementation performance.
Success criteria: • appropriate deaths are referred to coroners; • deaths continue to be registered within the 5-day rule (unless extension to 14 days agreed by a Registrar);
Monitoring information arrangements: There are existing arrangements in place for obtaining data on deaths published by the Office for National Statistics and the Ministry of Justice, which will support any future policy review. In addition, the National Medical Examiner (Additional Functions) Regulations [xxxx] require that the NME provide the Secretary of State for Health with reports relating to death certification and the medical examiner process. In order for the NME to write such reports, information will need to be collected from local medical examiner services and mechanisms put in place for it.
Reasons for not planning a review: N/A