Rapid evaluation of the 2024 death certification reforms and statutory medical examiner system

Study protocol (Version 5; October 13 2025)

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Protocol summary

Introduction

On 9th September 2024, significant changes to the way that deaths are certified and registered came into force in England and Wales. The death certification reforms (DCRs) established a statutory medical examiner system to scrutinise all deaths that are not accepted for investigation by a coroner, in both acute and community settings. The system is intended to identify clinical concerns and future learning opportunities, thereby improving patient safety and deterring against criminal activity and poor practice. The DCRs also made changes to the eligibility of doctors to complete the Medical Certificate of the Cause of Death (MCCD); introduced a new MCCD with additional data fields relating to ethnicity, pregnancy and medical devices, and a further field to report cause of death, bringing the MCCD in line with international standards of death registration; and permits medical examiners to certify deaths in exceptional circumstances. The reforms also include a requirement for the medical examiner system to engage with bereaved people, giving them the opportunity ask questions and raise concerns about the death of their family member or friend.

Aims

The overall aim of this study is to evaluate the implementation, delivery and early outcomes of the death certification reforms and statutory medical examiner system. The study research questions are shown in the box below.

Study research questions

1. What are stakeholders' experiences of implementing the death certification reforms (DCRs)? Our focus will be on those working in medical examiner offices, and the other key stakeholders in the death certification process with whom they interact including bereaved people, attending practitioners, coroners and coroner officer staff, registrars, and clinical governance teams to whom concerns about patient care would be referred.
2. How are medical examiner teams/offices delivering the core elements of the scrutiny process; what is working well, what challenges have arisen? Are there any unmet workforce training, development or support needs?
3. How well is the post-September 2024 death certification system operating from the perspective of those who deliver and use the system?
4. Are the death certification reforms achieving their intended benefits (see below); what factors are influencing whether, and to what extent, these benefits are being achieved?
    a. Improved accuracy in recording of cause of death and, therefore, more accurate mortality data at local and national level.
    b. Improvement in the detection and deterrence of malpractice, poor care, and patient safety concerns, and providing opportunities for learning.
    c. Improved engagement with bereaved people, offering them the opportunity to ask questions and raise concerns about the care their family member or friend received before death.
    d. More consistent and appropriate referrals to coroners for further investigation.
5. Are the DCRs producing any unintended consequences and, if yes, how might any negative consequences be avoided or mitigated?

This protocol has been informed by a programme of scoping activities that included: interviews with key system and institutional stakeholders; consultation with groups representing bereaved people and the general public; engagement with NHS England, Department of Health and Social Care, NHS Wales Shared Services Partnership and the Office for National Statistics (ONS) to map routine and administrative data relevant to the evaluation; and a rapid scoping of relevant literature. The draft protocol was reviewed by the study advisory group (see p. 27 for details of group membership); by other key contacts at the Department of Health and Social Care and Welsh Government; and by the regional medical examiners and medical examiner officers' network.

Study design and methods

This is a 15 month, mixed-methods evaluation combining survey research with all medical examiner offices and coroner areas in England and Wales, in-depth qualitative fieldwork with diverse stakeholders (including bereaved people) in four case study sites, supplemented by routine data analysis. Each of the three main elements of the study is described in turn below.

1. Routine data analysis

We are working with stakeholders to gain access to monitoring data that are regularly collected by NHS England and NHS Wales Shared Services Partnership on the activity of medical examiner offices across England and Wales. Examples where routine data is collected and will be used by the evaluation include the number of deaths scrutinised by a medical examiner, time taken from death/referral to a medical examiner officer to registration, and the number of bereaved people who have accepted the offer of a discussion with a member of the medical examiner's office. Working with stakeholders, we will seek to understand quality and variation within and across datasets, and use them accordingly. Further data mapping with stakeholders may identify additional data sets that could be used for the evaluation.

2. In-depth qualitative research

In-depth qualitative research will be carried out in four purposively selected case study sites. The sites will be selected to provide a snapshot of how the DCRs are working in diverse locations at a specific time point (early 2026). They will not be selected to be representative of the DCR experience for the whole of Wales or England and will not be interpreted as such in the analysis. Limiting the study to four sites means that the team can conduct in-depth qualitative analyses with a wide range of participants, with flexibility to adapt fieldwork to the unique experiences and needs of each case study site.

In England, a case study will be defined as a local medical examiner office, and in Wales it will be defined as an acute hospital. There will be at least one case study site in both England and Wales. At each case study site, we will conduct a programme of in-depth qualitative fieldwork, undertaking up to 15 one-to-one and/or small group interviews with a range of participants including bereaved people, staff and professionals working in medical examiner offices and the stakeholders with whom they interact. At least four interviews per site will be with a bereaved person.

In each case study area, we will work with the medical examiner office to recruit bereaved people to share their views and experiences in a one-to-one interview. Recruitment methods will be developed and agreed with each local office. We will also consider using other methods for recruiting bereaved people if these can enhance access to groups that might overwise be under-represented in the research. This might involve, for example, working with trusted faith-specific funeral directors with close links to local community groups. In all case studies we will seek to include as diverse a range of bereaved families as possible, aiming to ensure we have

engaged with a variety of views and experiences. We will aim to make contact with bereaved people between three and six months after the death of their family member or friend. All recruitment materials will be developed in consultation with the BRACE Patient and Public Involvement and Engagement (PPIE) group, seeking further advice and input where necessary from bereavement charities with whom we have developed links during the study scoping and development phase. We will also, once case study sites have been identified and access negotiated, ensure that advice from relevant faith communities and organisations specific to the case study location are sought. The primary focus of the interviews will be to hear about people's expectations and experiences of interacting with medical examiners or medical examiner officers (MEOs). Interviews will be semi-structured and carried out face-to-face, by telephone or via an online platform.

The second component of the case study research will be interviews with a range of professionals, teams and services involved in the death certification process. Interview samples will be purposively selected in each site, but we would expect the overall sample to include those working in the medical examiner system, coroners and coroner officer staff, registrars, attending practitioners with recent experience of completing a MCCD under the new system, and clinical governance teams to whom concerns about patient care would be referred. In undertaking fieldwork, we will be mindful of the impact of winter pressures on those working in the NHS and the death certification system and will be sensitive to workloads when requesting staff time.

3. National surveys of the medical examiner system workforce and coroner areas

We will carry out two national surveys across England and Wales: i) of the medical examiner system workforce (125 offices in England, four regional hubs in Wales); and ii) of coroner areas (n=77). The surveys will provide a picture of the DCRs and how the post-September 2024 death certification process – including the statutory medical examiner system – is operating, their positive impacts and any concerns or challenges. They will also provide data to explore differences in views and experiences (e.g. between different roles/groups within the medical examiner office workforce; between different geographical areas). The surveys will be online and hosted on the Thiscovery platform (https://www.thiscovery.org/). As with the qualitative fieldwork, we will be mindful of NHS staff workloads when designing and distributing surveys.

To maximise participation, the surveys will be administered through trusted networks. Following preliminary discussions during our scoping work, we plan to administer the medical examiner workforce survey through Regional Medical Examiner Offices in England and NHS Wales Shared Services Partnership in Wales, and the coroner area survey through the Office of the Chief Coroner. The first survey will be administered to lead medical examiners, medical examiners and medical examiner officers, combining a core question set and tailored items for each group. The second survey will be sent to the Senior Coroner in each area, with instructions that questionnaire completion can be delegated to a representative (e.g. an assistant coroner or team leader) if appropriate.

Timescale

The project timetable below assumes that the protocol will be signed off by NIHR Health and Social Care Delivery Programme (HSDR) in October 2025, and that this will be a 15-month study. The timetable does not include the scheduling of secondary data analysis, as this will depend on the time taken to secure access to these datasets.

	2025			2026											
Activity	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Submit application for ethical review															

Finalise and submit data requests															
Identify and secure access to case study sites															
Case study interviews															
Qualitative analysis															
Design ME/MEO and coroner surveys															
Administer ME/MEO and coroner surveys															
Survey analysis															
Data synthesis and stakeholder workshops															
Preparation of outputs															

Outputs and dissemination

The findings of the evaluation will be written up in a threaded series of research outputs, complemented by an overall synopsis report, that will be made available through the NIHR website. They will also be shared widely in a number of different ways, including:

1. A short-written summary report of the key findings, accompanied by an infographic.
2. An animated video summarising the key findings; we envisage that this output would be suitable for all audiences but would be particularly tailored to bereaved people and the public.
3. Web-based resources including blogs and short-read pieces, tailored for different audiences.
4. Papers published in high-quality, peer-reviewed, academic journals.
5. Presentations to key stakeholder groups – including national/policy leads for DCR, the medical examiner workforce and bereavement services/charities.
6. Oral and/or poster presentations at academic and practitioner conferences.
7. Disseminating findings through BRACE/institutional networks, the National Voices network of health and social care charities, and the contacts we have established in the communities involved in the death certification process.
8. Use of social media, such as LinkedIn and Bluesky.

Funding

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Background and rationale

Background

On 9th September 2024, significant changes to the way that deaths are certified and registered came into force in England and Wales (see Box 1 for an overview of the reforms). The case for reforming the death certification process – which had remained largely unchanged for over 80 years – had been made in numerous high-profile reviews and reports since the early 2000s, most notably those relating to the Shipman and Francis (Mid Staffordshire) enquiries and the Morecombe Bay investigation (Smith 2003; Francis 2013; Kirkup 2015). In her third report from the Shipman enquiry, Dame Janet Smith described how "*existing arrangements for death certification were confusing and provided inadequate safeguards for the public*" (Hansard 2009). As a result, the UK Government determined that a system for scrutinising all deaths, either by a coroner or medical examiner, would help identify clinical concerns and future learning opportunities, thereby improving patient safety and deterring against criminal activity and poor practice (Department of Health and Social Care 2018).

Box 1. Summary of the September 2024 Death Certification Reforms

The main changes introduced by the death certification reforms are as follows:

- **Statutory medical examiner system.** For all deaths not referred to a coroner, a medical examiner will independently scrutinise the cause of death proposed by an attending practitioner before the Medical Certificate of Cause of Death is completed and submitted to a registrar.
- **Attending practitioners**. Any medical practitioner who has attended the deceased during their lifetime is eligible to be the 'attending practitioner' and complete the Medical Certificate of Cause of Death. Before September 9th 2024, the attending practitioner was required to have attended the patient within 28 days before death.
- **Medical Certificate of Cause of Death (MCCD).** More information is required on the MCCD, including new fields for ethnicity, maternal deaths, the presence of a medical device or implant, and an additional line for cause of death (bringing the MCCD in line with international standards of death registration).
- **Medical examiner certification.** In exceptional circumstances, where no attending practitioner can be identified within a reasonable timeframe, a medical examiner may now certify a death. This is intended to reduce the number of uncertified deaths.

The 2024 reforms aim to bring about greater efficiency in the death certification system, and have been designed to improve:

1. Accuracy in recording of cause of death and, therefore, more accurate mortality data at local and national level.
2. The detection and deterrence of malpractice, poor care, and patient safety concerns, and providing opportunities for learning.
3. Engagement with bereaved people, offering them the opportunity to ask questions and raise concerns about the care their family member or friend received before death.
4. The consistency and appropriateness of referrals to coroners for further investigation.

The organisation of the medical examiner system differs in England and Wales (see Box 2 below for more detail), but in each nation medical examiners are required to carry out independent scrutiny to answer the following three questions (NHS England 2025b):

1. What did the person die from? (ensuring accuracy of the Medical Certificate of Cause of Death)
2. Does the death need to be reported to a coroner? (ensuring timely and accurate notification in line with statutory requirements and guidance)
3. Are there any clinical governance concerns? (ensuring the relevant referral is made where appropriate)

The independent scrutiny process has three elements:

1. A proportionate review of medical records
2. Interacting with the medical practitioner who completed the Medical Certificate Cause of Death (MCCD)
3. Interacting with a bereaved person, providing them with an opportunity to ask questions and to raise concerns.

If issues or concerns are identified during the scrutiny process, medical examiners are required to refer these cases for further review, either to a coroner or through the appropriate clinical governance process; they do not investigate concerns in-depth (Fletcher 2023). It is intended that the benefits of the reforms will be achieved without imposing undue delays on bereaved people or undue burdens on medical practitioners and others involved in the death certification process. Figure 1 provides an overview of the process for death certification since September 9th, 2024.

Box 2. How does the medical examiner system in England and Wales differ?

In England, there are 125 medical examiner offices located in NHS trusts. In each office, a lead medical examiner provides leadership to the office. There is a regional medical examiner and regional medical examiner officer, employed by NHS England, serving each of the seven NHS regions, who provide regional leadership, advice and guidance.

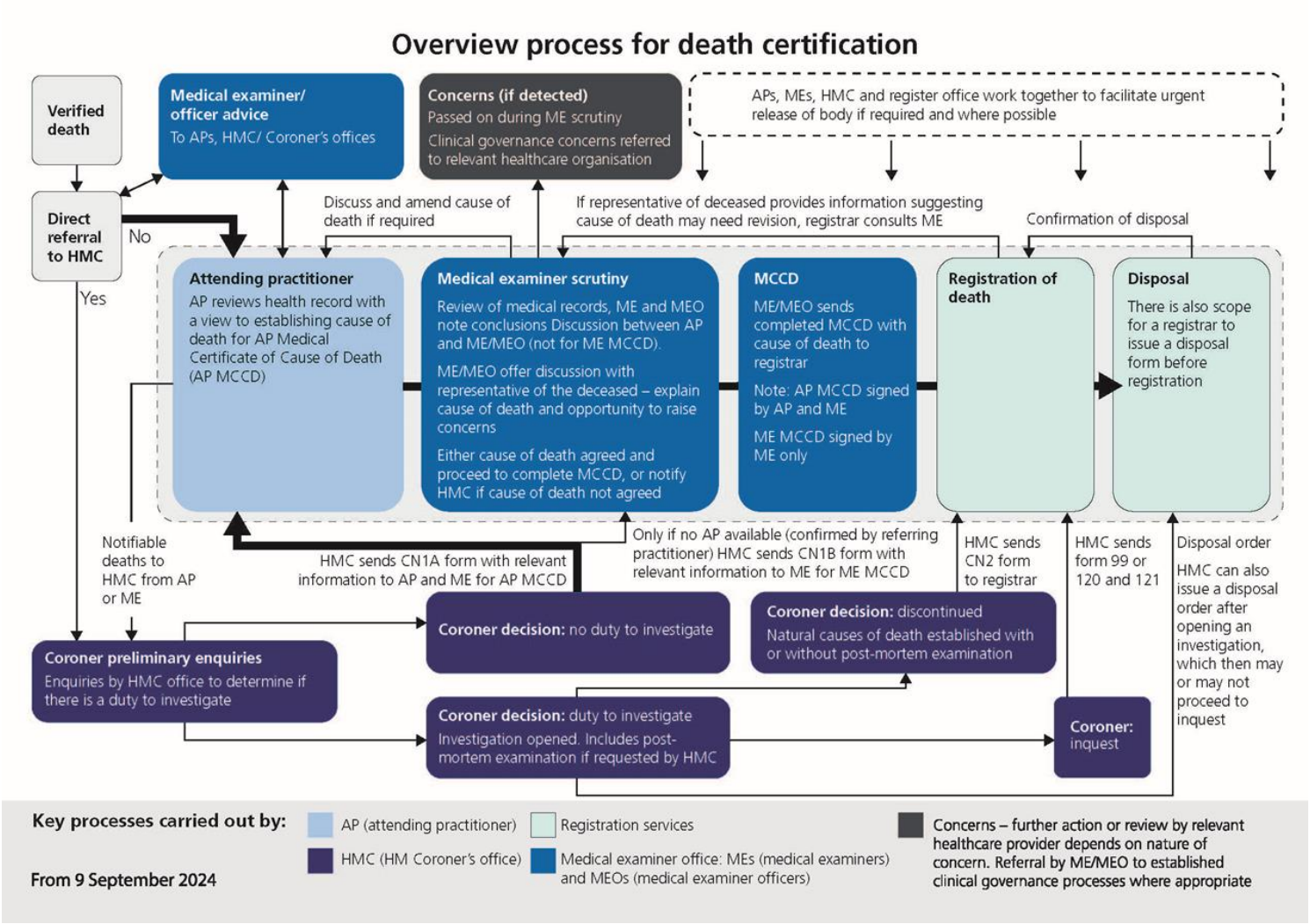
In Wales, the medical examiner system is provided by NHS Wales Shared Services Partnership, an independent mutual organisation, owned and directed by NHS Wales and hosted by Velindre University NHS Trust. It is organised into four hub sites, which are located separately from local NHS facilities:

- **North Wales:** covers the Betsi Cadwaladr health board area.
- **Mid and West Wales:** covers the Hywel Dda and Swansea Bay health board areas.
- **South Wales Central:** covers the Cwm Taf Morgannwg and Powys health board areas.
- **South Wales East:** covers the Cardiff & Vale and Aneurin Bevan health board areas.

In England, medical examiners officers have a line manager within the NHS body that employs them. In Wales, medical examiner officers are accountable to the Lead Medical Examiner Officer for Wales.

There is a national medical examiner for England and Wales, whose role is to provide professional and strategic leadership to regional and trust-based medical examiners.

Figure 1: Summary of the process for death certification post September 9th 2024



Source: NHS England, 2025a

Medical examiners are doctors with a minimum of five years' experience who are contracted to provide independent scrutiny for a number of sessions each week, outside of their usual clinical duties. Before undertaking the role, they must complete training in the legal and clinical aspects of the death certification process, provided by the Royal College of Pathologists and comprising e-learning modules and a face-to-face training day. Their work is supported by a wider team including medical examiner officers (MEOs), who manage the scrutiny process, obtain and carry out a preliminary review of relevant medical records, and can undertake some elements of the scrutiny process described above through delegation (although final scrutiny and sign off must be undertaken by a medical examiner).

The national medical examiner system was originally introduced in 2019 on a non-statutory basis, with acute trusts in England and NWSSP in Wales asked to set up medical examiner offices to focus initially on hospital deaths (Payne-James et al 2023). During the first year of the non-statutory medical examiner system, the COVID-19 pandemic disrupted implementation as medical professionals shifted focus to acute care or transitioned to full-time death certification roles (NHS England and Improvement 2021). However, since 2021 the number of deaths scrutinised in England and Wales steadily increased and, as of June 2024, more than 900,000 deaths had been scrutinised by a medical examiner (NHS England 2023). It is estimated that around 500,000 deaths will be scrutinised each year by medical examiners under the statutory system.

Research exploring the impact of the non-statutory medical examiner system has broadly reported positive results. These include:

- Reductions in referrals to coroners, with cases that were referred more likely to result in post-mortem investigations and inquests (indicating greater appropriateness of referrals) (Coster et al 2021; Payne-James et al 2024).
- Bereaved people mostly given the opportunity to raise concerns regarding the care their loved one received and reporting that their concerns were acknowledged (Carpenter et al 2025).
- Medical examiners reporting that engagement with bereaved people was a valuable part of their role and an important source for identifying issues around poor care and patient safety (Coster et al 2021; Dorman et al 2025).
- Perceived improvement in recording cause of death and a decrease in the proportion of MCCDs rejected by registrars (Coster et al 2021).

Studies have also identified areas where the system may not yet be working effectively; for example, on the basis of the findings from their qualitative investigation of the medical examiner role in eleven acute trusts, O'Hara and colleagues (2021) concluded that:

> *"The way in which ME services were organised appeared to restrict opportunities for formal team communication, although some had developed approaches to facilitate more direct communication (eg, team meetings, social messaging platform). Feedback and learning were considered particular areas of weakness in most of the ME services. Specifically, the lack of structures for providing meaningful feedback to 'close the loop' on problems in care and clinical governance issues identified by MEs, and for sharing learning."*

This raises a question as to whether these early challenges identified by O'Hara and colleagues have endured or improved as the medical examiner system has evolved over time and, since September 2024, been put on a statutory footing.

It is important to consider these insights when evaluating the statutory system to determine whether these experiences are consistent across all contexts, and to understand whether the feedback mechanism is being strained by increased workloads associated with the demand to scrutinise all non-coronial deaths.

The evaluation brief

In December 2024, the BRACE Rapid Evaluation Centre received a request from the NIHR Health and Social Care Delivery Research Programme to undertake a rapid evaluation of the death certification reforms, including the statutory medical examiner system. An evaluation brief had been prepared by the Department of Health and Social Care, highlighting that "*the changes need to be evaluated to determine whether they are delivering the reform objectives (benefits) and ensure that the system is operating as intended without negative impact*." The brief, in particular, emphasised the importance of qualitatively investigating how those who deliver and use the death certification system view and have experienced the reforms, to complement and provide contextual insights to inform quantitative data analysis being carried out by the Office for National Statistics (ONS) and others. The overall purpose of the evaluation, the brief noted, was to generate learning for understanding and improvement. In so doing, it would provide the Department of Health and Social Care and other key stakeholders with insights to "*improve the administration of the Death Certification process, [and] ensure the impact is felt positively across all those stakeholders who either use or deliver the system*."

Preliminary scoping work to inform the study design and methods

What did the scoping work comprise?

Between April and July 2025, we carried out a programme of scoping work to inform the study focus, design and methods, and enable the evaluation team to gain a deeper understanding of the death certification reforms (DCRs) and medical examiner system. While scoping had to be undertaken rapidly, we were keen to engage widely to ensure that the evaluation design was informed by a variety of perspectives and experiences.

The scoping activities comprised:

1. Interviews with key system and institutional stakeholders, including:
    1. Department of Health and Social Care
    2. Welsh Government
    3. NHS Wales Shared Services Partnership
    4. NHS England
    5. The National Medical Examiner
    6. Ministry of Justice
    7. Royal College of Pathologists Medical Examiners Committee
    8. General Register Office
    9. Office of the Chief Coroner
    10. Home Office
    11. National Association of Funeral Directors
    12. An attending practitioner working in the Welsh health system
    13. Two researchers who had undertaken prior research on the non-statutory medical examiner system, one in England and the other in Wales.

We also presented and discussed preliminary ideas for the study design at a meeting of regional medical examiners and officers, chaired by the National Medical Examiner.

2. Consulting with groups representing bereaved people and the general public, to understand views of the reforms and the medical examiner scrutiny process from a 'user' perspective. Several of these meetings were organised and facilitated by National Voices, BRACE co-production partner. In total, we met with:
    1. The BRACE PPIE (Patient and Public Involvement and Engagement) Panel
    2. National Bereavement Alliance
    3. CRUSE
    4. Marie Curie
    5. Taraki (Mental Health in Punjabi Communities)
    6. Compassion in Dying
    7. Caribbean and African Health Network
    8. Noah's Ark Children's Hospice
    9. OUTpatients (The UK's LGBTIQ+ Cancer Charity)

3. Meetings with NHS England, Department of Health and Social Care, NHS Wales Shared Services Partnership and the Office for National Statistics (ONS) to understand what data are being routinely gathered that are relevant to and could be used in the evaluation. See 'Mapping existing data sources' below for more details.

4. Rapid scoping of recent literature to identify relevant learning, in particular from research on the non-statutory medical examiner system and related issues (including bereaved people's experiences of the death certification process).

What we learned from the scoping work and implications for the evaluation

The scoping work generated rich and valuable insights, which have informed the design and will guide the delivery of this study:

- A recurring theme throughout the scoping interviews was that death certification is delivered by *a system* comprised of several – intersecting and interdependent – parties and processes. As has also been highlighted in previous research (Coster at al 2222), good working relationships between the different parties involved in this system is crucial to success. Thus, the evaluation must look at how medical examiner offices operate in the wider systemic context and inter-relationships in which their work takes place, paying attention to how that context influences both the medical examiner scrutiny process specifically and the death certification pathway more generally.

- The time taken to register a death – which has received some media attention – was another prominent theme in the interviews, and the potential for impact on bereaved people was widely acknowledged. Though it is not an explicit purpose of this evaluation to assess trends in the time taken to register deaths pre and post the DCRs, it was proposed that the study could usefully explore the reasons for any unnecessary or avoidable delays. This would provide insights to complement the Office for National Statistics' (ONS) analysis of trends in time taken from death to registration (see 'Mapping existing data sources' below, for more details).

- It was also suggested that time taken to register deaths might be one criterion that could be used to select case study sites for the in-depth qualitative research, but interviewees felt that this should not be privileged over other important considerations. For example, several interviewees suggested that it would be useful to compare experiences in a

large, demographically diverse urban area which includes specialist and tertiary care, and in a rural area served by a smaller district general hospital.

- The scale of the changes brought about by the reforms is likely to be greatest in community settings, as many acute trusts in England and local health boards in Wales had already established a medical examiner office to scrutinise deaths within their organisations prior to September 9th, 2024. Several interviewees described challenges in primary care, including technical difficulties sharing GP patient records with medical examiner offices and the lack of clear mechanisms for sharing clinical governance concerns with GP practices. We were encouraged to pay particular attention to the experiences and challenges for those working in primary care, both in terms of the 'cultural' adaption to a new system for certifying deaths and how the requirements of the scrutiny process align with primary care systems and processes.

- Another dominant theme in the scoping work was that many of the challenges being reported in relation to the DCRs were existing issues in the death certification process that have been exacerbated or brought into the spotlight by the reforms. There were, for example, marked geographical variations in the time taken to register deaths long pre-dating the DCRs, and analysis of timepoint data by NHS England shows that the median time to register a death has been rising over the past 20 years. This highlights the need for the evaluation to untangle existing issues from reform-related impacts, which qualitative research is especially well suited to.

- Through the scoping work, we were able to understand clearly the key differences between England and Wales in terms of how the medical examiner system is organised and delivered. The centralised model in Wales, operating from four regional hubs, contrasts with the decentralised network in England, consisting of 125 local medical examiner offices. This results in some variability in governance, resource allocation and service delivery. Consequently, it is important that this evaluation examines medical examiner offices from both England and Wales, understanding the strengths and limitations of both models.

- Interviewees emphasised the importance of looking at the entire medical examiner office team, and not just medical examiners themselves. Much of the day-to-day work in the scrutiny process is carried out by MEOs, although there is variation in local practice and what MEOs are doing. The MEO role is a crucial one for the efficient and effective operation of the scrutiny process, as they are responsible for liaising with other key stakeholders including registrars, coroner's offices, legal services, funeral directors and bereavement services, as well as obtaining medical records for review.

- Interviewees were unanimous in their view that the experiences of bereaved people must be a core focus of the evaluation. The proportion of bereaved people taking up the opportunity to speak to a medical examiner or MEO is very high (around 97%, according to NHS England monitoring data), but stakeholders were in agreement that assessing whether this aspect of the scrutiny process is successful requires more in-depth research. They were keen for us to explore people's experiences of these interactions, whether they met their expectations (and, indeed, what those expectations were) and whether the experience was a constructive one (e.g. did it help with the grieving process and/or enable people to raise concerns about the cause of death or care provided). The importance of recruiting diverse participants, enabling us to explore whether and how bereaved people's experiences differ, was also emphasised. The scoping work also produced valuable learning about how to approach the research with bereaved people; see 'Sensitivities of interviewing bereaved people' below for more details.

- A further issue emerging in relation to bereaved people was about who is approached to speak with the medical examiner or MEO. Our understanding is that contact is made with the person who is formally identified as the next of kin. But our PPIE consultees questioned this approach, suggesting that the focus on biological (rather than chosen) family might exclude significant others who were closer to the deceased and had a better understanding of their health and care. This was an issue that, it was felt, the evaluation could usefully explore.
- There is currently a reliance on manual workflows, such as scanning and sharing medical records, and the completion of the MCCD in a paper-based format, which hampers efficiency and coordination. Plans to introduce an electronic MCCD are currently paused, and the lack of an electronic system for managing death certification was widely felt to be impacting on system efficiency and effectiveness, including the ability to identify trends and patterns in deaths that could inform learning and improvement. It might also be contributing to the time taken in registering deaths. These technical aspects of the death certification process should be included in the evaluation focus.

Sensitivities of interviewing bereaved people

Our scoping work foregrounded the sensitivities that must be considered when engaging with bereaved people, particularly around communication and timing. Regarding interview timing, there is no 'ideal' time for contacting bereaved people after a death, however, consideration will be given to not contacting people too early so as to not risk further distress, and to not delay communication as this may reduce recall accuracy.

Furthermore, conversations with bereaved people will require a trauma-informed approach to navigate the emotional vulnerability of participants and balance the aims of the evaluation with questions that are compassionate. This should include developing a participant information sheet that explains the purpose of the evaluation, which we will design in consultation with the BRACE PPIE panel, in addition to considering appropriate support mechanisms and signposting individuals to available services and charities. By focusing on dignity and reducing re-traumatisation, the evaluation should aim to understand bereaved people's experiences of interacting with the medical examiner system, identify factors that can improve the outcomes of these interactions for the people involved, and provide practical learning to further shape and inform practice.

Our engagement with organisations representing marginalised and faith-based communities provided further insights into how best to recruit participants. Some faith-based communities have time-pressured needs, including the emphasis on prompt burial (ideally within 24 hours) for families of Jewish, Muslim and other faiths. We also heard of communities that find it especially difficult to navigate the death certification process due, for example, to language barriers, the absence of family or wider support networks and/or distrust of state-aligned institutions. These include, but are not limited to, recent migrants, refugees and asylum seekers. Where necessary, we will seek specialist advice to ensure that our recruitment methods are culturally sensitive and appropriate and consider how barriers to participation for minoritised and marginalised people can be mitigated or overcome.

Mapping existing data sources

A key task for the scoping work was to begin mapping existing data sources and sets that could potentially be used in the evaluation. So far, we have identified three data sets of particular

relevance, described in turn below. We are continuing to work with stakeholders, including the Department of Health and Social Care's Data Strategy Group, to identify any further sources of routine data that could be used in the evaluation.

1. Monitoring data collected from medical examiner offices in England and Wales

Medical Examiner Offices report information to the National Medical Examiner on a quarterly basis, for the purposes of service monitoring. The fields in the reporting template used in England are shown in Box 3 below. The management form used in Wales includes a number of similar fields; we have not included it in this document as it is a much longer form which captures a wider range of information from medical examiner offices. We understand that consistency of reporting is variable and that the data are not currently subject to quality checks. Therefore, we are tentative about what we can learn from these data, and the extent to which we might be able to reliably explore differences between medical examiner offices in terms of service operation and activity. Notwithstanding, we are currently negotiating with NHS England and NHS Wales Shared Service Partnership to access the data. Depending on the time taken to secure access, we may also be able to use them to inform the selection of case study sites, alongside other considerations and information sources.

Box 3. Quarterly monitoring template completed by medical examiner officers in England and reported to NHS England

Activity Summary

- Total number of deaths scrutinised by medical examiners
- Total number of deaths notified to coroner after scrutiny by a medical examiner

Workforce

- Total medical examiner/medical examiner officer FTEs

Completion of AP MCCDs

- Mean/median number of calendar days from death to sending AP MCCD to register office
- Number of AP MCCDs where a registrar consults a medical examiner about potential revision to cause of death

Medical Examiner MCCDs

- Number of Medical Examiner MCCDS completed because there is an AP but they are not available within a reasonable time
- Number of Medical Examiner MCCDs completed for other reasons (e.g. deceased did not have an attending practitioner)

Urgent Medical Scrutiny

- Does the medical examiner office operate at weekends and bank holidays?
- Is weekend/bank holiday cover provided in partnership with another NHS trust?
- Number of cases where urgent medical examiner scrutiny is requested and achieved within requested time
- Number of cases where urgent medical examiner scrutiny is requested but not achieved within requested time (and reason)

Giving bereaved people opportunities to ask questions and raise concerns

- Number of deaths where interaction between medical examiner office and bereaved families did not take place (and reason)

Clinical governance issues detected at host NHS trust

- Deaths where a significant concern about the quality of care has been raised by bereaved families/carers or medical examiners/staff
- Deaths in a service speciality, particular diagnosis or treatment group where an 'alarm' has been raised with the provider
- Deaths in areas where people are not expected to die
- Deaths where learning will inform the provider's existing or planned improvement work
- Number of deaths where medical examiners recommend a case record review
- Deaths referred by the medical examiner office to other clinical governance processes for review not covered above
- Number of Patient Safety Incidents notified by medical examiner office as a result of scrutiny
- Number of cases signposted to Patient Advice and Liaison Service or equivalent by medical examiner office

Feedback and complaints

- Feedback/complaints received by the medical examiner office

2. Office for National Statistics (ONS) data

Information from MCCDs and other details that are gathered when a death is registered are, by law, reported by registrars to ONS to compile mortality statistics and for other analyses. ONS publishes weekly statistics on the median time for a death to be registered by certification type, place of death, country and region as part of its weekly death registrations release. It is also conducting more in-depth analysis of these data, which is exploring longitudinal trends in registration timescales and will focus on deaths certified by a doctor that undergo medical examiner scrutiny. The first publication of findings from this work was published in October 2025 (ONS 2025). This reported that there had been a statistically significant increase in the overall median time taken to register a death in England and Wales of 1.91 days (from around six to eight days), when comparing registration timescales post-DCR with the same weeks in 2023 and 2024. There was substantial regional variation in these trends though; by the end of June 2025, median times for death registration were highest in Wales (ten days) and the South East of England (nine days), and lower in London, North East, North West, and West Midlands (all six days).

ONS is also assessing trends in cause of death reporting pre/post the DCRs. Each given cause of death reported on an MCCD is translated by ONS into a recognised medical code to create national and comparable mortality statistics, using the internationally accepted classification system ICD-10. Their current analysis is examining changes in the number and type of ICD-10 codes used over time, as an indicator of reporting quality.

This study has been designed to complement existing analytical and evaluative activities. To achieve this, we will use in-depth case study and survey research to explore stakeholders' views and experiences of cause of death reporting and registration timescales. This will provide rich qualitative insights to contextualise and support the interpretation of any trends identified

through the ONS analyses, as well as potentially identifying where system changes may be needed to improve the effective functioning of the death certification process.

One of the anticipated impacts of the statutory medical examiner system across England and Wales was that it should eliminate any recording of uncertified deaths. This should be a result of medical examiners being able to complete a MCCD in exceptional cases, where an attending practitioner cannot be identified. ONS gathers and reports data on uncertified deaths, and this data presents a potential indicator to measure how thoroughly the ME system has embedded in local contexts.

3. Coroner statistics

When an attending practitioner/medical examiner refers a death to the coroner, in all cases the coroner will open a preliminary investigation. The coroner can then take one of three routes outlined below:

1. After the preliminary investigation, the coroner decides that the death is a natural death and sends it back for the attending practitioner/medical examiner certification route to proceed.
2. After the preliminary investigation, the coroner opens a full investigation, decides the death is a natural death and the investigation is discontinued. A form (CN2) is sent to the registrar, and the death is registered.
3. The coroner decides that an inquest should be held.

During scoping interviews, it was suggested that if the DCRs are working well, then the proportion of coroner referrals that take route one above should decrease as the changes embed. Conversely an increase in proportion of referrals following routes two or three could be interpreted as an indicator that coronial time is being used appropriately. Data on these referral processes and outcomes are held by the Ministry of Justice and will be accessed and analysed as part of the evaluation. They offer one means by which the study can measure whether a key intended benefit of the reforms – more efficient use of coronial time – is being achieved.

Why is this research needed now?

One year after the mandatory introduction of the medical examiner system presents an opportunity to assess impact and consequences on those involved in delivering the service, as well as those receiving it. It is hoped that any initial teething problems will have largely been resolved and that our evaluation will be able to assess the system once it has embedded and is operating on a 'business-as-usual' basis. The evaluation will generate learning about how the system is delivering intended benefits and where it might be experiencing obstacles that are affecting achievement of the reform objectives. Importantly, it will also identify any unintended outcomes, positive or negative.

Evaluation plan

Aims and objectives

The overall aim of this study is to evaluate the implementation, delivery and early outcomes of the death certification reforms and statutory medical examiner system. The study research questions are set out in Box 4.

Box 4. Study research questions

1. What are stakeholders' experiences of implementing the death certification reforms (DCRs)? Our focus will be on those working in medical examiner offices, and the other key stakeholders in the death certification process with whom they interact including bereaved people, attending practitioners, coroners and coroner officer staff, registrars, and clinical governance teams to whom concerns about patient care would be referred.
2. How are medical examiner teams/offices delivering the core elements of the scrutiny process; what is working well, what challenges have arisen? Are there any unmet workforce training, development or support needs?
3. How well is the post-September 2024 death certification system operating from the perspective of those who deliver and use the system?
4. Are the death certification reforms achieving their intended benefits (see below); what factors are influencing whether, and to what extent, these benefits are being achieved?
    a) Improved accuracy in recording of cause of death and, therefore, more accurate mortality data at local and national level.
    b) Improvement in the detection and deterrence of malpractice, poor care, and patient safety concerns, and providing opportunities for learning.
    c) Improved engagement with bereaved people, offering them the opportunity to ask questions and raise concerns about the care their family member received before death.
    d) More consistent and appropriate referrals to coroners for further investigation.
5. Are the DCRs producing any unintended consequences and, if yes, how might any negative consequences be avoided or mitigated?

The specific impact of the DCRs on the Child Death Review process is outside of the scope of this evaluation.

Study design

This is a mixed-methods evaluation combining survey research with all medical examiner offices and coroner areas in England and Wales, in-depth qualitative fieldwork with diverse stakeholders (including bereaved people) in four case study sites, supplemented by routine data analysis. This design will enable a rich understanding of what is working well and any challenges faced in the implementation of the DCRs and how the post-September 2024 death certification system is operating. The qualitative work will follow a case study design. This will allow multi-site analysis to capture different clinical settings (primary, community, secondary, tertiary care) and analysis across different geographies (urban and rural) and demographic contexts.

The study design is underpinned by the following key principles:

- **Breadth and depth elements**: we have designed the study to include breadth and depth elements, generating insights into the how the system is working overall and in-depth learning from more detailed investigation in purposively selected case study sites.

Perspectives will be sought from the death certification workforce and bereaved people, allowing a broad range of views and experiences to be included.

- **Understanding the DCRs and statutory medical examiner system in context**: the study will approach death certification as a system, and we are interested in how the different people/processes involved in this system intersect and interact. While the evaluation is centred on medical examiner offices, we remain aware that medical examiners are one part of a longer pathway to death registration and burial/cremation for bereaved people.
- **Theory-based approach**: the study will employ a theory-based approach, and the development of a preliminary theory of change for the DCRs is already being developed, based on the information and insights gathered during the scoping phase. The theory of change will specify the DCRs' intended benefits, describe the activities and mechanisms by which these benefits are expected to be achieved and the contextual conditions which may be integral to success. The evaluation will explore whether the assumptions and causal logic on which the theory of change is based hold true.
- **Consideration of timescale**: while conducting the evaluation one year after the reforms were introduced allows the evaluation to bypass the teething problems of early implementation, we are also aware that one year may not be long enough to assess whether some of the intended benefits of the new system have been realised. Some of the aims of the reforms may take longer to be fully achieved, especially those that require cultural changes in attitudes and practices. For these benefits, we will need to look for evidence that there is progress towards key aims, rather than asking the binary question of whether impacts have or have not been achieved.
- **Complementarity with other analytical and evaluative activities**: the evaluation has been designed to be complementary to and build on existing work/data, including the ONS analyses of trends in the quality of cause of death reporting and time taken to register deaths, described in 'Mapping existing data sources' above. The evaluation will add qualitative perspectives to support the interpretation of any patterns and trends found in the ONS data.
- **Flexibility and adaptiveness to context**: the death certification reforms operate at many different levels, in varied settings and with a complex array of stakeholders. The evaluation will pay particular attention to the influence of context and has been designed to be flexible and iterative. Case study fieldwork will be adapted to suit local contexts, sensitivities and needs.
- **Gathering formative learning to support ongoing implementation**: this is a formative and learning-oriented study with the primary goal to provide stakeholders with evidence to understand how the death certification system is operating and guide improvement. To this end, the evaluation will seek not only to describe the impact of the DCRs but also identify the reasons behind successful implementation and, if found, where intended benefits are not being achieved or progress is slower than anticipated.

Methods

The study is comprised of three main elements: i) routine data analysis; ii) in-depth qualitative research; and iii) national surveys of the medical examiner system workforce and coroner areas. Each of these is described in turn below, and in Table 1 we map our methods against the evaluation questions to summarise where the main sources of data to answer each research question will come from.

Table 1. Mapping methods to the evaluation questions

	NHS England and Wales monitoring data	Coroner statistics	Interviews with bereaved people	Interviews with system stakeholders	Survey of medical examiner system workforce	Survey of coroner areas
1. What are stakeholders' experiences of implementing the death certification reforms (DCRs)?				■	■	■
2. How are medical examiner teams/offices delivering the core elements of the scrutiny process; what is working well, what challenges have arisen? Are there any unmet workforce training, development or support needs?	■			■	■	
3. How well is the post-September 2024 death certification system operating from the perspective of those who deliver and use the system?			■	■	■	■
4. Are the death certification reforms achieving their intended benefits (see below); what factors are influencing whether, and to what extent, these benefits are being achieved?	☒	☒	☒	☒	☒	☒
a) Improved accuracy in recording of cause of death and, therefore, more accurate mortality data at local and national level.				■	■	
b) Improvement in the detection and deterrence of malpractice, poor care, and patient safety concerns, and providing opportunities for learning.	■		■	■	■	
c) Improved engagement with bereaved people, offering them the opportunity to ask questions and raise concerns about the care their family member or friend received before death.			■			
d) More consistent and appropriate referrals to coroners for further investigation.		■		■		■
5. Are the DCRs producing any unintended consequences and, if yes, how might any negative consequences be avoided or mitigated?			■	■	■	■

Routine data analysis

The team has mapped and consulted with key stakeholders and data owners on the relevant routine data assets that capture the Medical Examiner service. Decisions will be made to ensure routine data assets are analysed in a way that does not replicate the existing reporting of national statistics in England and Wales. The team will also assess the feasibility of analysing data assets depending on data access approvals and timelines. Stakeholders will be informed on the progress of analyses and be invited to shape the analytical approach where appropriate.

The structure, meta data, quality and consistency of the data assets will be assessed and reported once received. Any necessary data wrangling and linking will be completed to ensure that the data are complete, missingness and quality is understood, as well as the potential for linking other external geographical data (e.g. Indices of Multiple Deprivation). This will enable the team to potentially create longitudinal data linked to geographical context to understand trends and variations over time and place.

At the time of writing, the two main sources of data that the team will most likely use are the NHS England and Wales datasets. Box 3 (above) outlines the data fields and variables captured in the English data that can be explored to inform the evaluation. Some key variables include: the numbers of deaths scrutinised by a medical examiner, time taken from death to registration, and the number of bereaved people who have accepted the offer of an appointment with a member of the medical examiner's office.

In the first instance, we will provide univariate statistical summaries of key evaluation variables over time and place to summarise trends and pattens, before exploring bivariate and multivariate relationships and patterns to further understand trends and variations in the medical examiner service.

In-depth qualitative research

In-depth qualitative research will be carried out in four purposively selected case study sites; there will be at least one case study site in both England and Wales. We have chosen a case study approach to ensure the study captures detailed and on-the-ground experiences of the DCRs in diverse settings and from multiple perspectives. This approach is also well suited to the goal of understanding how death certification operates in, and is influenced by, the broader interactional and institutional contexts in which it takes place.

At each case study site, we will conduct a programme of in-depth qualitative fieldwork, undertaking up to 15 one-to-one and/or small group interviews with a range of participants including bereaved people, staff and professionals working in medical examiner offices and the stakeholders with whom they interact. This makes a maximum total of 60 potential interviews. At least four interviews per site will be with a bereaved person. Interviewees will be purposively sampled to represent a range of perspectives and to enable the research to focus on the key issues specific to each area; therefore, the composition of samples may differ from site to site.

Defining and identifying case study sites

In England, a case study will be defined as a local medical examiner office, and in Wales it will be defined as an acute hospital. Case study sites will be selected to include variation in the type of work that medical examiners and their offices carry out, and variation in the local contexts in which this work takes place. They will not be selected to be representative of the DCR experience for the whole of Wales or England and will not be interpreted as such in the analysis.

The selection criteria will be finalised in discussion with our advisory group (see 'Stakeholder Involvement' below for more details about the advisory group); based on insights from the scoping work, the final sample of sites might include:

- A large, urban centre with a local healthcare system that includes specialist and tertiary services providing care to the most complex medical cases.
- A semi-rural/rural location, served by a smaller district general hospital, to understand the implementation and impact of the DCRs in a contrasting health system.
- An area with a comparatively high number of requests for urgent scrutiny (for example, to address the specific needs of certain faith-based communities) where a high proportion of those requests are met within the requested time, to explore how the certification process prioritises cases that require urgent attention and operates in time-sensitive situations.
- An area where the death certification process and system are considered to be working particularly well, to capture learning and best practice from a 'positive outlier'. This might include, for example, an area recognised for having strong partnership working between the different teams and professionals involved in death certification; or for having effective systems and processes in place for identifying, referring and learning from patient care concerns through the scrutiny process; or for good practice in communicating and interacting with bereaved people.

We will work with key stakeholders, including regional medical examiners and regional medical examiner officers (RMEOs), to identify areas that meet our criteria. The final selection of case study sites will be made by the evaluation team.

Interviews with bereaved people

In each case study area, we will work with the medical examiner office to recruit bereaved people to share their views and experiences in a one-to-one interview. Recruitment methods will be developed and agreed with each local office, but we will aim to ensure that the opportunity to take part in the research is offered to all bereaved people who have had contact with the medical examiner office within a defined period. We will also consider using other methods for recruiting bereaved people if these can enhance access to groups that might overwise be under-represented in the research. This might involve, for example, working with trusted faith-specific funeral directors with close links to local community groups. A key consideration is when to approach a bereaved person to take part in the research. This must balance the need for sensitivity with the aim to speak to somebody within a timeframe when they are still able to recall the details of their contact with the medical examiner office. The advice we received during the scoping phase, coupled with insights from published literature (Bentley and O'Connor 2015), suggest that making contact between three and six months after the death is most appropriate. All recruitment materials will be developed in consultation with the BRACE PPIE group, seeking further advice and input where necessary from the bereavement charities with whom we developed links with during the scoping work.

It is important that the evaluation seeks to engage with a diverse range of bereaved people. Dying, death and bereavement are not experienced in a homogenous way, and the evaluation will aim to capture the expectations, preferences and needs of different communities (for example, where there are differences in mourning and funerary rites). To this end, we have consulted with a range of organisations representing marginalised and faith-based communities to understand how best to recruit participants into the study (see 'Sensitivities of interviewing bereaved people' above). While recruitment will be through medical examiner offices, the communication inviting bereaved people to take part in the research will emphasise that this is an independent study and that all information shared will be treated as confidential and

reported anonymously to protect participants' identities. It will also explain that a key purpose of the research is to identify ways in which the current system could be improved for bereaved people. These, we hope, will encourage participation and open and honest responses.

The primary focus of the interviews will be to hear about people's expectations and experiences of interacting with medical examiners or MEOs. We will be mindful that, for bereaved people, this interaction forms only one part of their grief and bereavement journey and our research will seek to understand people's experiences of contact with the medical examiner system in that broader context. Interviews will be semi-structured and carried out face-to-face, by telephone or via an online platform. Key themes they will explore will include:

- Relationship with the deceased person
- General awareness/understanding of the medical examiner system and its purpose
- Expectations before the call/meeting with the medical examiner office
- Overall experience of the interaction
    - Did the interaction meet their expectations?
    - Was the interaction sensitive to specific needs (e.g. language, culture, relationship to the deceased)?
    - Was the timing of interaction helpful?
- Was the interaction constructive – for example, did it help the grieving process?
- Was there an opportunity to ask questions and raise concerns and how did the medical examiner/MEO respond to these?
- How could the experience be improved?

Interviews with stakeholders involved in the death certification process

The second component of the case study research will be interviews with a range of professionals, teams and services involved in the death certification process. Interview samples will be purposively selected in each site, but we would expect the overall sample to include lead medical examiners and medical examiners, MEOs, regional medical examiners and RMEOs, coroners and coroner officer staff, attending practitioners with recent experience of completing a MCCD under the new system, registrars and clinical governance teams to whom concerns about patient care would be referred. As far as possible, we will select interviewees to represent the full range of healthcare settings in which deaths can occur.

We will make contact with the medical examiner office in the case study area and will propose an initial meeting to engage key staff, gather any relevant local documentation and start to build an understanding of the local context. An initial list of potential participants will be developed from this meeting, but we also remain open to suggestions from interview participants regarding additional contacts. Interviews will be semi-structured and carried out by telephone or via an online platform. Key themes to be explored will include:

- Medical examiners'/MEOs' experiences of their roles and carrying out the scrutiny process
- Skill-mix, team-working and allocation of work within medical examiner offices
- Different stakeholders' experiences of interacting and collaborating in the death certification process
- Medical examiners'/MEOs' experiences of, and learning from, engaging with bereaved people
- Processes for and experiences of reporting clinical governance concerns and how these are handled
- Experiences of handling complex cases and skill/workload implications

- Processes for identifying trends and patterns in deaths, who these are shared with and if/how they inform learning and improvement
- Issues or challenges in the death certification process
- Perceptions of the impact of the DCRs and the statutory medical examiner system.

National surveys of the medical examiner system workforce and coroner areas

We will carry out two national surveys across England and Wales: i) of the medical examiner system workforce (125 offices in England, four regional hubs in Wales); and ii) of coroner areas (n=77). The surveys will provide a picture of the DCRs and how the post-September 2024 death certification process – including the statutory medical examiner system – is operating, their positive impacts and any concerns or challenges. They will also provide data to explore differences in views and experiences (e.g. between different roles/groups within the medical examiner office workforce; between different geographical areas).

The surveys will be online and hosted on the Thiscovery platform (https://www.thiscovery.org/). Questionnaire design will be informed by and build on emerging findings from the case study research. The process will also include involvement of target participants – for example, testing draft questions for content and tone using the Think-Aloud technique. The questionnaires will be principally comprised of fixed-response questions, with a small number of free-text questions to capture qualitative insights. Our aim will be to minimise respondent burden, with the medical examiner system workforce survey taking no longer than 15 minutes to complete, and the coroner area survey no longer than 5-10 minutes.

To maximise participation, the surveys will be administered through trusted networks. Following preliminary discussions during our scoping work, we plan to administer the medical examiner workforce survey through Regional Medical Examiner Offices in England and NHS Wales Shared Services Partnership in Wales, and the coroner area survey through the Office of the Chief Coroner. The first survey will be administered to lead medical examiners, medical examiners and MEOs, combining a core question set and tailored items for each group. The second survey will be sent to the Senior Coroner in each area, with instructions that questionnaire completion can be delegated to a representative (e.g. an assistant coroner or team leader) if appropriate. Surveys will be sent out with a short covering email explaining the purpose of the research and how the findings will be used, with a guarantee that responses will be anonymous and cannot be traced back to individual participants.

Data synthesis and analysis

Each data set will first be analysed separately, before synthesis and interpretation. Qualitative data from the case study sites will be analysed thematically and comparatively, guided by the principles of the Framework Method (Ritchie and Spencer 1994) and managed by NVivo software. We will draw out both context-specific and general themes to support within and cross-case study comparisons. Comparative analysis will examine similarities, differences and patterns in the case study data, focusing in particular on the identification of explanatory factors – i.e. factors that account for observed differences in death certification processes and experiences, and the functioning of the medical examiner service, across the four areas. Survey data will be analysed using descriptive statistics, with thematic analysis of free text responses. An analysis plan for the routine data will be developed once the relevant data sets have been accessed and reviewed.

The research team will then draw together the findings from across the study in a final synthesis. This will be undertaken, principally, through a series of in-person data analysis workshops. The primary focus of these workshops will be to identify key themes, explore commonalities and differences (e.g. between different participants, different data sets) and incorporate insights from the wider theoretical, empirical and policy literature. This will also inform further iteration of the preliminary theory of change for the DCRs.

The findings will then be shared, tested and refined in two online workshops with wider stakeholders: the first with members of the study advisory group and key policy and practice stakeholders; the second with groups representing bereaved people and the general public, including members of the BRACE PPIE Panel. A key purpose of these workshops will to be draw out lessons for ongoing delivery of the death certification process and identify if and how this process can be improved, from both a system and family/public perspective. We will also offer to present to each case study site, to sense-check emerging findings and ensure that any identified improvements are grounded in the day-to-day realities of the death certification process, as it is experienced by those who deliver and engage with it.

Project timetable

The project timetable below assumes that the protocol will be signed off by NIHR Health and Social Care Delivery Programme (HS&DR) in October 2025, and that this will be a 15-month study. The timetable does not include the scheduling of secondary data analysis, as this will depend on the time taken to secure access to these datasets.

	2025			2026											
Activity	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Submit application for ethical review	■														
Finalise and submit data requests	■														
Identify and secure access to case study sites	■	■	■												
Case study interviews				■	■	■	■	■							
Qualitative analysis						■	■	■	■	■					
Design ME/MEO and coroner surveys						■	■	■							
Administer ME/MEO and coroner surveys									■	■					
Survey analysis											■	■			
Data synthesis and stakeholder workshops												■	■		
Preparation of outputs													■	■	■

Research team and study delivery

Project management, governance and quality assurance

The study principal investigator, Professor Jo Ellins, will be responsible for the overall delivery and quality assurance of this project. The project manager and lead researcher, Dr Alisi Mekatoa, will be responsible for day-to-day management and coordination of inputs from evaluation team members, supported by BRACE Project Officer Helen Dent. All evaluation team members will be involved in data collection, analysis and dissemination of the research.

We will apply the following project management principles and processes: ensuring clarity of team members' roles, and the delegation of tasks and reporting duties; internal team meetings and catch-ups; and use of project planning tools (Gantt chart, timesheets, internal monitoring reports). We will hold fortnightly team meetings to review progress and promptly address any

issues arising. The project will formally report to the BRACE executive team and steering group – including monthly progress reports and prompt sharing of any concerns or identified risks for resolution.

Research team

Team member	Role and contribution in research team	Relevant expertise
Jo Ellins, Professor of Health Services Research, University of Birmingham	Principal investigator, responsible for the overall management of the research and team, and delivery of study outcomes.	Over 25 years' experience of leading mixed-methods health service and policy evaluations, including as BRACE Deputy Director (2018-2022). Specific expertise in qualitative research with patients and the public.
Alisi Mekatoa, Research Fellow, University of Birmingham	Project management and team coordination. Project conception and scoping, data collection and analysis, and writing and dissemination of reports and other outputs.	Over 20 years' experience working in the NHS, central government and academia in the health policy area, including leading several health service evaluations.
Kayleigh Sharp, Analyst, RAND Europe	Supporting project conception and scoping, data collection, analysis, and writing/dissemination of reports and other outputs.	Experienced researcher with specific expertise in qualitative data collection and analysis.
Jenni Burt, Chief Scientific and Innovation Officer, Thiscovery	Thiscovery lead for the medical examiner system workforce and coroner area surveys, including survey design, administration and analysis.	Over 25 years' experience of leading health services research projects (including end-of-life and bereavement research) with particular expertise in accessible online survey design.
Helen Dent, BRACE Project Officer	Research management and administration support across all aspects of the project, including coordination of the study advisory group.	Highly experienced research administrator, with varied experience across clinical and non-clinical research.
Jon Sussex, Chief Economist, RAND Europe	Oversight support for RAND Europe.	Health economist and health services researcher with over 30 years' experience of NHS research and consultancy using both qualitative and quantitative methodologies.

In relation to stakeholder involvement (see below for more details), the research team will work closely with Dr Jenny Newbould and Tina Coldham (BRACE PPIE Leads) and Sharon Brennan (Director of Policy and External Affairs at National Voices).

Stakeholder involvement

There has been extensive and diverse stakeholder involvement in shaping the development of this protocol. In addition to the activities described in 'Preliminary scoping work' above, this protocol was reviewed by one of the BRACE PPIE co-leads; the study advisory group (see below for membership); other key contacts at the Department of Health and Social Care and Welsh Government; and the regional medical examiners and medical examiner officers' network.

We will continue to seek input from key stakeholder groups as the evaluation progresses, which will include:

- Establishing a study advisory group to provide advice and support to the evaluation team throughout the delivery and reporting of the study. Confirmed members include Simon Hawkins, Policy Lead for the Death Certification Reforms, Department of Health and Social Care; Daisy Shale, Lead Medical Examiner Officer for Wales; Lucy Brant, Senior Policy Manager, Marie Curie; Bronwen Moss, Senior Policy Advisor, Department of Health and Social Care; Alison Penny, Coordinator, National Bereavement Alliance; Laura Mitzel, Principal Researcher, and Robyn O'Connor, Deputy Head, NHS Quality, Safety and Investigations Analytical Team, Department of Health and Social Care (shared membership); and Nick Day, Policy and Programme Lead, National Medical Examiner System, NHS England. The group will also include a representative from the Welsh Government, and we will invite the new National Medical Examiner to join, once they have been appointed (expected in autumn 2025).

- Specialist advisory input from bereavement organisations, including Cruse Bereavement Support and The National Bereavement Alliance, to seek advice on proposed methods for the research with bereaved people. We will also, once case study sites have been identified and access negotiated, ensure that advice from relevant faith communities and organisations specific to the case study location are sought.
- Regular meetings with the BRACE PPIE group throughout the evaluation to support data collection, analysis, interpretation and reporting. This will include a PPIE review of draft recruitment and research tools for use in the interviews with bereaved people.
- Through two online workshops, we will involve professional/policy and public stakeholders in data analysis and the identification of learning and key themes for reporting. This will ensure that our findings are grounded in and relevant to stakeholder perspectives and priorities (see 'Data synthesis and analysis' above for more details).
- Seeking wider opportunities to present and sense-check emerging findings and reflect on their implications, for example through presentations to the regional medical examiners/officers network and to policy colleagues in the relevant government departments (Department of Health and Social Care, Ministry of Justice, Welsh Government).
- Working closely with National Voices (BRACE co-production partner) on study outputs and dissemination for public audiences, including the creation of an animated video summarising key findings (see 'Outputs and dissemination' below).

Research inclusion

This study has been designed with research inclusion considerations as paramount:

- The study is underpinned by a firm and inclusive commitment to stakeholder engagement, with an equal commitment to involving policy, professional and public audiences in shaping the design and delivery of the study and interpreting the research findings.
- Our approach is underpinned by an understanding that death certification is a complex and often difficult process for those who have been bereaved, and – for many different cultural, social and religious reasons – some people may find understanding and/or navigating the interactions and tasks involved particularly difficult. The research will be attentive to the variation in how bereaved people experience death certification and interactions with medical examiner offices and will seek to identify groups for whom the current system works less well.
- Linked to the above point, case study areas will be purposively selected so that the final sample includes socio-economically and demographically diverse areas, thereby enabling the study to explore how death certification works in different local contexts and for different population groups.
- We will work closely with the BRACE PPIE panel, and the voluntary sector organisations with whom we have developed links through our scoping work, to develop inclusive approaches to participant recruitment and, wherever possible, anticipate and address barriers to participation.

Potential risks and mitigation strategies

Risk	Impact	Likelihood	Mitigation
Identifying and gaining access to case study sites	High	Medium-Low	We have already established relationships with key stakeholders (including the network of Regional Medical Examiners in England and Lead Medical Examiner Officer for Wales) who have offered their support in securing access to case study sites. Our experience so far suggests that there is widespread support for the evaluation and a desire to understand how the DCRs are working in practice. We will provide potential sites with a summary of the aims and purpose of the evaluation, emphasising that the primary purpose is to generate understanding and learning for improvement. We will have back-up options for all sites, in the event that our initial approaches are not successful.
Non-engagement from participants within case study sites	High	Medium	Team members will work with key contacts in each site to discuss the contribution required during the evaluation and the best way of approaching potential participants. We will also work with the BRACE PPIE Panel and seek the advice of the specialist organisations with whom we have already developed links (e.g. National Bereavement Alliance, Cruse, Marie Curie) to design our strategies and materials for recruiting bereaved people, paying particular attention to potential barriers to participation and how these can be mitigated or overcome. In our experience of research with members of the public, the way in which people are approached to take part is crucial, and we will tailor our approaches in each site to ensure that they are engaging and appropriate.
Low survey response rates	Medium	Medium	We plan to administer surveys through known and trusted networks/contacts and will ask other key stakeholders to encourage participation. The surveys will be designed to be brief, and the purpose of the surveys will be prominent in correspondence with potential participants. We will use up to two reminders to prompt non-responders to complete. We will consider offering group meetings or information webinars to build relationships, trust and buy-in from the populations of interest.
Lack of clarity about the policy 'customer' for the evaluation given the abolishment of NHS England	Medium	Low	With a learning-oriented evaluation of this kind, it is crucial that national leads have clear ownership of and engage with study findings, so that these can guide ongoing implementation and inform improvement. Given this, the abolishment of NHS England, which hosts the National Medical Examiner for England and Wales and leads/commissions the national medical examiner service in England, may present challenges to the evaluation. We have already raised this potential risk with policy colleagues

			and have asked to be kept updated about plans for transferring national leadership of the service (once these are known).
Unable to access data and/or poor data quality	Medium	Medium	We are already discussing data needs for the evaluation with the relevant organisations (NHS England, NHS Wales Shared Services Partnership and ONS) and will proceed with data requests at the earliest possible opportunity. Our mixed-method approach means that evaluation questions could still be explored even in the event that we cannot access these datasets in the lifetime of the evaluation, or that the datasets are of poor or inconsistent quality.
Loss of key staff	Medium	Low	The BRACE staffing model provides a pool of experienced researchers across three organisations who can be brought into teams as and when required, even at short notice.

Ethical issues and approvals required

The project will be undertaken in compliance with the Data Protection Act/GDPR and University of Birmingham policies relating to the conduct and integrity of research. The study sponsor (University of Birmingham's Research Ethics, Governance and Integrity Team) has confirmed that the study meets the Health Research Authority (HRA) criteria for a service evaluation, and therefore HRA/NHS Ethics approvals are not required. The study will require ethical approval by the University of Birmingham Humanities and Social Sciences Research Ethics Committee, and this will be sought at the earliest possible opportunity. The team has significant experience of securing ethical approval, including for projects on sensitive topics and involving public participants and vulnerable groups.

Recognising that research on the topic of death certification may involve sensitive and potentially upsetting topics, the study PI will meet regularly with the researchers undertaking qualitative interviews throughout the fieldwork to provide an opportunity to debrief and discuss any issues arising in the interviews.

Participant consent

Research processes will be designed to ensure that participation is informed and voluntary. All potential participants will receive information about the study before deciding whether to take part. This will detail the evaluation aims and purpose, what taking part would involve, any risks involved, how participants' data will be stored and used, and who they should contact if they have further questions about the study or wish to make a complaint. For the qualitative research, the information sheet will also make clear that participants can withdraw from the study, without giving a reason, at any time up to two weeks after taking part in an interview. Should they withdraw, their data will be destroyed. For the survey research, the information sheet will make clear that withdrawal after survey completion is not possible, as responses will be submitted anonymously.

Consent will be taken prior to participation through an electronic or paper consent form. In the event that a consent form has not been returned before the scheduled time for an interview, verbal consent will be taken instead. Once the researcher has been through the consent process, the voice recorder will be turned on, and the participant will be asked to confirm on the recording that they have given their consent to take part.

All information materials and the surveys will be translated into Welsh for the data collection in Wales, and we will make arrangements for a translator to be present in any interviews that are conducted in Welsh.

Outputs and dissemination

The findings of this evaluation will be written up in a threaded series of research outputs, complemented by an overall synopsis report, that will be made available through the NIHR website. They will also be shared widely in a number of different ways, including:

1. A short-written summary report of the key findings, accompanied by an infographic.
2. An animated video summarising the key findings; we envisage that this output would be suitable for all audiences but would be particularly tailored to bereaved people and the public.
3. Web-based resources including blogs and short-read pieces, tailored for different audiences.

4. Papers published in high-quality, peer-reviewed, academic journals.
5. Presentations to key stakeholder groups – including national/policy leads for DCR, the medical examiner workforce and bereavement services/charities.
6. Oral and/or poster presentations at academic and practitioner conferences.
7. Disseminating findings through BRACE/institutional networks, the National Voices network of health and social care charities, and the contacts we have established with the communities involved in the death certification process.
8. Use of social media, such as LinkedIn and Bluesky.

Indemnity and insurance

The University of Birmingham holds the relevant insurance cover for this study, as confirmed via our BRACE contract with NIHR.

Sponsor

The University of Birmingham will act as the main sponsor and guarantor for this study.

Data storage

Data will be stored securely and managed in accordance with the UK Data Protection Act (2018) and General Data Protection Regulation (GDPR) 2018 and in accordance with the University of Birmingham's policies for data storage and management. Identifiable data (names and contact details) may be stored at either the University of Birmingham, RAND Europe or Thiscovery. Data processing and sharing agreements will be in place for any data securely transferred between researchers from the different organisations involved. All data will be stored on password-protected computers and servers and will only be accessible to members of the research team. Data will be stored for a period of 10 years in line with the University of Birmingham's Research Data Management Policy, after which it will be destroyed. All data will be reported anonymously and consent for this data plan will be obtained from all respondents prior to their participation in the study.

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