Llywodraeth Cymru
Welsh Government

IMPACT ASSESSMENT, DOCUMENT

# Medical Examiners (Wales) Regulations 2024: integrated impact assessment

An assessment of the impact of the Medical Examiners (Wales) Regulations 2024.

**First published:** 11 April 2024

**Last updated:** 11 April 2024

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# Section 1. What action is the Welsh Government considering and why?

## Background

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).

In its third report, the Shipman Inquiry examined the process of death certification and the coroner system. It concluded that the current system was confusing and provided inadequate safeguards, particularly against the possibility that the doctor completing the MCCD was himself responsible for the patient's death.

Renewed calls for Medical Examiners (MEs) were made by the Francis Inquiry into Mid Staffordshire and Bill Kirkup's Inquiry into Morecambe Bay. These reports imply that the reforms will help identify poor care and protect patients.

The Coroners and Justice Act 2009 form the basis of these reforms.

Relevant sections of the Coroners and Justice Act 2009 will be commenced in April 2024 along with required consequential amendments and regulations for the wider death certification reforms and the introduction of the statutory medical examiner role.

Death certification is a reserved area so the wider death certification reform will be introduced through regulations being made by Department of Health and Social Care (DHSC) namely:

- The MCCD (England and Wales) Regulations 2024
- The Medical Examiners (England) Regulations 2024
- The National Medical Examiner (England and Wales) (Additional functions) Regulations 2024

Further regulatory changes will be introduced by the Ministry of Justice and General Registration Office.

Welsh Ministers have powers to make The Medical Examiner (Wales) Regulations 2024 to which this Integrated Impact Assessment (IIA) relates. These set out the terms and conditions of employment for MEs and some additional functions. This IIA considers the impact of the Medical Examiner (Wales) Regulations 2024 (not all the regulation being introduced) but does touch on the impact of the wider death certification reforms where appropriate.

A full detailed consideration of the characteristics of the underlying problems to be addressed can be found within DHSC's Impact Assessment for England and Wales.

### Introduction of medical examiners and death certification reform in England: impact assessment (publishing.service.gov.uk)

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

The aims of the policy for the wider death certification reforms and the introduction of the statutory role of medical examiners by means of the Medical Examiner (Wales) Regulations 2024 and associated legislation are:

- to ensure that the system for certifying all non-coronial deaths provides

adequate scrutiny to identify and deter criminal activity or poor practice
- to rationalise the existing system to ensure that the level of scrutiny is proportionate and does not impose undue delays on the bereaved or undue burdens on medical practitioners and others involved in the process
- to provide a common death certification procedure that ensures the same level of scrutiny and assurance, irrespective of the choice of burial or cremation

## Long term

These regulations will establish the legal framework for a statutory, unified system of scrutiny by independent medical examiners for all deaths in England and Wales not investigated by a coroner.

The UK and Welsh governments in 2019, began introducing MEs on a non-statutory basis. In Wales, MEs and Medical Examiner Officers (MEOs) are employed by NHS Wales Shared Services Partnership (NWSSP) and have access to cases as assigned to them usually deaths from outside of the NHS organisation where they work as medical practitioners. The Lead Medical Examiner provides professional leadership, and the Lead Medical Examiner Officer for Wales provides support to medical examiner offices across Wales. The National Medical Examiner (NME) for England and Wales provides strategic leadership.

The ME's review of the cause of death provides additional safeguards to representatives of the deceased and provides them with the opportunity to ask questions about the death and to raise concerns. Medical Examiners as part of their scrutiny will also speak to the attending practitioner completing the MCCD and review the patient record. These three elements of scrutiny are recorded within the ME's scrutiny notes. This allows the ME to understand if there are any factors, in relation to the cause of death, that should be fed back to the

organisation/s who provided care to the deceased. Training is available (provided by the Royal College of Pathologists) for all aspects of the MEs role and to support MEs in discussing the cause of death with the representatives of the deceased.

## Prevention

The Shipman Inquiry third report (2003) concluded that it was no longer suitable to have different certification processes for cremations and burials, and that all MCCDs should be subject to independent medical scrutiny.

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

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

The responsibilities of the ME will include:

- independent scrutiny of MCCDs for cremations and burials and consideration of associated information provided by the bereaved and the certifying doctor
- certifying deaths referred by the coroner where no attending practitioner is available within a reasonable period
- confirmation of the cause of death stated by the certifying doctor in a timely manner to register the death and ensure urgent cremations and burials can

take place
- ensuring information related to hazardous implants or medical devices or if the deceased person was suffering from a communicable infection, is recorded
- notification to a coroner of a death under s.18 regulations of the Coroners and Justice Act 2009 where the duty arises during the course of a ME's scrutiny; or refer a death where the ME is unable to confirm the cause of death stated by the doctor
- reporting any concerns of a clinical governance nature, or of interest for public health surveillance
- identifying the training needs of doctors in completion of MCCDs and provide feedback on accuracy of certification locally

The all-Wales non-statutory service already developed provides an additional level of independence to that set out in the regulations. In Wales, MEs will not scrutinise deaths within the NHS organisation in which they work as doctors. Deaths will be allocated across the regional offices in Wales.

DHSC will be introducing ME certification for the exceptional circumstances where either there is no attending practitioner, or an attending practitioner is not available within a reasonable time to complete the Medical Certificate of Cause of Death (MCCD). The introduction of the ME MCCD will greatly reduce the number of uncertified deaths.

## Integration

The five ways of working in the Well-being of Future Generations (Wales) Act 2015 has been applied to the proposed action and will be throughout the policy and delivery cycle.

The well-being objectives in Programme for Government 2021 to 2026 have been considered. The proposal meets the objective to 'provide effective, high

quality and sustainable healthcare’.

The proposal fits with the wellbeing goal of ‘A Healthier Wales’ by improving the quality of mortality statistics and the use of this data in planning, resource allocation and epidemiological studies. MEs will also contribute to the processes of learning and improvement within health services.

## Collaboration and involvement

Key partners from the UK and Welsh Government departments have been engaged throughout the development of the proposal via a programme board facilitated by the UK government along with various working groups focussed on the development of policy proposals, digital systems, finance, communication, legislation and guidance over many years. These groups in collaboration have developed policy proposals that are able to be practically delivered.

In Wales, partners have been engaged in programme boards, implementation boards, working groups and advisory groups. The Lead ME and MEO for Wales have engaged with registrars, coroners, funeral directors medical practitioner associations and bereavement services in developing and agreeing local working arrangements.

## Impact

The Department of Health and Social Care (DHSC) conducted a full cost/benefit impact assessment of the options available for both England and Wales in 2018 following pilots of the service in England and Wales.

The regulations will positively improve the safety of the death certification process for the bereaved and result in better mortality data to be used for research and health planning purposes and appropriate referrals to the coroner.

The regulations have the potential to impact on members of faith communities who require an early release of the body for burial or cremation. There has been continuous engagement by both UK and Welsh Governments and latterly the Lead ME and MEO for Wales with faith communities. An out-of-hours on call arrangement is in place to facilitate the immediate scrutiny of deaths requiring an early release of the body.

## Costs and savings

The UK government has committed to fund the ME service in England and Wales ‘subject to the standard annual review of budgets and to the upholding of the decision not to introduce a new public fee in England’.

The updated costs of the statutory system in Wales for 2024 to 2025, based on the latest costs of providing the service for 2023 to 2024 is £4.3 million.

No proposals for savings have been identified.

## Mechanism

Legislation is proposed and a regulatory impact assessment has been completed.

# Section 8. Conclusion

## 8.1 How have people most likely to be affected by the proposal been involved in developing it?

The proposals have been developed with key stakeholders such as attending medical practitioners, medical examiners, medical examiner officers, registrars, coroners and funeral directors and bereavement services in the course of pilots, consultations and at UK Government's Strategic Programme Board, the Royal College of Pathologists stakeholder events, Welsh Government implementation boards, working groups and latterly by NWSSPs Programme Board and Advisory Group.

The ME system has been piloted in a number of different locations in England and Wales. An initial pathfinder pilot was established in March 2008 at the Sheffield Teaching Hospitals NHS Foundation Trust in collaboration with HM Coroner for South Yorkshire (West) to test and evaluate the proposed role of the ME in scrutinising MCCDs in hospitals. Further pilots were chosen to represent a true cross-section of society representing all religions and beliefs including in Powys for primary care. The pilots demonstrated that the medical examiner system could work in a range of settings, in hospital and in the community, in urban and in rural areas.

A public consultation was held by both UK and Welsh Government in 2016 to 2017 and responses put forward have shaped the development of the service in Wales. The response to the consultation demonstrates that there is widespread support for the aims of the reforms and for the introduction of medical examiners.

The responses received to the public consultations held by both the UK and Welsh Governments in 2016 to 2017 have shaped the development of the

reforms. They demonstrated widespread support for the aims of the reforms and for the introduction of medical examiners. For example, responses to the consultation in Wales highlighted the preference for an All-Wales service, highlighted the importance of medical examiner independence and for the service to be mindful of the Welsh language.

On 14 December 2023, DHSC and Welsh Government's draft regulations were published with an opportunity for stakeholders to comment. However, no changes were required to be made to the regulations as a result of comments received.

## 8.2 What are the most significant impacts, positive and negative?

Whilst the wider death certification reform legislation is a reserved matter its impact in Wales has been considered in this integrated impact assessment where appropriate.

The system will allow for the scrutiny of all deaths not referred to a coroner.

The wider medical examiner system will bring positive impact and benefits to the Welsh health system by providing assurance on the death certification process and improving overall safety for the people of Wales using health services. The ME service will also promote learning and improvement in the health system by the sharing of concerns information identified by medical examiners in their scrutiny with health care providers and through the identification of any patterns or trends in causes of death.

The reforms will impact positively on many of the Health and Care Quality Standards 2023 as part of the duty of quality. For example, the positive impact on the 'information' standard will feed valuable information into learning systems and positively impact on the 'learning, improvement and research' standard.

The introduction of the Medical Examiner (Wales) Regulations 2024 as part of the wider death certification reforms will have a significant positive impact on the people and health services of Wales. The expected benefits of the medical examiner service as provided for in the Medical Examiner (Wales) Regulations 2024 are:

- crime and malpractice deterred by the knowledge that the cause of death stated on MCCDs by doctors will be scrutinised by a ME and the identification of patterns and trends leading to earlier detection of criminal activity and poor practice
- MCCDs provide more accurate information about the causes of death leading to better planning of health services
- improved information for clinical governance and health monitoring to support learning and improvement, making health services safer for patients
- a death certification process that is easier, for bereaved families to understand, open and transparent, with the opportunity to raise any concerns with an independent individual about the standard of care leading up to a death and providing reassurance that the cause of death is correctly established by the doctor
- appropriate referrals to the coroner service

The medical examiner scrutiny is expected to be more transparent and understandable for the bereaved, while providing assurance that all due process has been followed. The ME and MEO will also provide an opportunity to discuss the case with the bereaved. There is also the potential for MEs to identify trends in unexpected causes of death.

For burial cases, the fact that MCCDs will be scrutinised should lead to an increase in assurance and confidence in death certification from the bereaved. This may not be directly perceived directly by the bereaved in cremation cases since these deaths already require a secondary and independent medical certification before a cremation can proceed.

Central funding of all deaths that are certified by an ME ensures all deaths are treated equally and scrutinised on a consistent basis.

There were concerns about some aspects of the proposals. Some religious groups require prompt disposal of the body and there were concerns that the introduction of the role of MEs could cause delay. This issue is of particular concern to Jewish, Muslim, Hindu and Roman Catholic communities whose religious practice favours burial or cremation to take place as soon as possible after death. These concerns have been mitigated by engagement with faith communities at a local and national level and by the ME service in Wales having in place an out of hours on call service.

The themes that have emerged from involving people in Wales are the preference for an all-Wales service, that the independence of medical examiners should be preserved and that in developing the ME service the requirements of the Welsh language standards should be taken into account.

## 8.3 In light of the impacts identified, how will the proposal:

- Maximise contribution to our well-being objectives and the seven well-being goals.
- Avoid, reduce or mitigate any negative impacts?

The Medical Examiners (Wales) Regulations 2024 will support the goal of ‘a healthier Wales’ as set out in the Wellbeing of Future Generations Act. They also support the first Programme for Government well-being objective (2021 to 2026) to ‘provide effective, high quality and sustainable healthcare’.

The poor quality of certification is something that the Shipman Inquiry identified. Past audits and more recent studies of MCCDs showed that only 55 percent of certificates were completed to a minimally accepted standard. 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.

MEs will be experienced, registered medical practitioners capable of ensuring that the cause of death stated by the certifying doctor is accurate and corresponds with the medical records. Where the cause of death is unknown or unclear after reviewing the medical records, MEs will ensure the death is referred to the coroner for investigation.

Specialist training received by MEs would in principle be expected to result in significantly more accurate MCCD certificates. The pilot sites demonstrated that ME scrutiny led to the ability to adequately code a greater number of deaths. The ICD-10 chapter identified by the original certifying doctor was changed by the ME in 12% of deaths. Greater accuracy and better coding have the potential for the more efficient allocation of NHS resources, public health planning and any epidemiological studies using mortality data will be more accurate. Over time should impact positively on the health of the public.

The wider medical examiner system will bring positive impact and benefits to the Welsh health system by providing assurance on the death certification process and improving overall safety for the people of Wales using health services. The ME service will also promote learning and improvement in the health system by the sharing of concerns information identified by medical examiners in their scrutiny with healthcare providers and through the identification of any patterns or trends in causes of death.

The death certification reforms will affect the data on death registration collected by the General Register Office (GRO) for England and Wales, which will mean essential changes to the Registration Online (RON) system. Similarly, the Office for National Statistics (ONS) will need to update the Life Events Continuity (LEC)

system (which acts as the interface between RON and ONS Life Events systems), the M204 systems and processes, and the SAS and Structured Query Language (SQL) systems which generate mortality statistics to allow processing of the data received from GRO.

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Engagement with stakeholders, including faith groups, will continue to mitigate against any negative impacts.

The Welsh Language Standards (No 7) Regulations already apply to the medical examiner and medical examiner officer's interaction with the bereaved by telephone and written correspondence such when providing a summary report of their conversation with the medical examiner. The regulations also apply to the medical examiner webpages and on-line services on NWSSP's webpages, and the availability of Welsh services will be promoted. The Medical Examiners (Wales) Regulations 2024 when laid will therefore have a positive impact on opportunities for the use of Welsh as these moves to a new statutory service.

## 8.4 How will the impact of the proposal be monitored and evaluated as it progresses and when it concludes?

DHSC have indicated that the impact of these regulations and the wider death certification reforms on coroners will be reviewed 18 months after implementation.

The NME will be required by regulations to provide a report to the Secretary of State for Health and Social Care and Welsh Ministers on the operation of the medical examiner system.