



## The Medical Examiner and patient safety

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## The Medical Examiner and patient safety

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## The Medical Examiner and patient safety

*The Medical Examiner system ensures that acute hospital Trusts are able to say something about every death and, alongside case record review, has the potential to create a world-leading mortality review system.*

### Introduction

The Government recently announced its intention to introduce a system of Medical Examiners in England and Wales that from April 2019 will deliver a more comprehensive system of assurances for all non-coronial deaths<sup>1</sup>. This important initiative provides an opportunity to develop a system that addresses concerns about avoidable hospital deaths and the need to identify deaths due to problems in care. ~~The role of the Medical Examiner has been developing in the United Kingdom (UK) over the last ten years. It has attracted recent interest in response to concerns about avoidable hospital deaths and the need to identify deaths due to problems in care.~~ In this article we draw upon our experience and ongoing research to describe the role of the Medical Examiner and ~~consider~~ how this role could be used to improve patient safety.

### What is the current system for examining deaths in England and Wales?

The current death certification system has not changed in over 50 years. A registered medical practitioner who has attended the deceased must complete a Medical Certificate of Cause of Death (MCCD) to the best of his/her knowledge and belief. If the cause of death is unknown or the death is in any way thought to be unnatural, the death must be investigated by a coroner, who is an independent judicial officer with legislated powers. There is no second check of the cause or circumstances of death unless the deceased is to be cremated.

### What is a Medical Examiner?

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3 The role of the Medical Examiners (of the documents and cause of death) was developed  
4 from recommendations in the 2003 Home Office Fundamental Review of Death Certification  
5 and Investigation<sup>2</sup> and in response to concerns raised ~~were recommended in 2003~~ by Dame  
6 Janet Smith in the third report of her investigation into the murders committed by Harold  
7 Shipman ~~in Hyde, UK<sup>34</sup>~~. This recommendation was endorsed by Sir Robert Francis in his  
8 investigation into deaths at the Mid Staffordshire NHS Foundation Trust<sup>42</sup> and Sir Bill Kirkup  
9 in the review of deaths at Morecombe Bay Hospitals.<sup>53</sup>

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16 A Medical Examiner is an independent senior doctor who will be accountable to the  
17 National Medical Examiner<sup>64</sup>. The role is to manage three issues, taking the views of the  
18 bereaved into consideration:  
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21 • Where a ~~medical certificate of cause of death (MCCD)~~ is completed, the content  
22 should be as accurate as possible
- 23 • Where a case needs to be notified to a coroner, that is undertaken in as timely and  
24 accurate manner as possible
- 25 • To enable the detection and notification of clinical governance concerns early on  
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31 This is different to the North American Medical Examiner, who investigates deaths occurring  
32 under unusual or suspicious circumstances, performs post-mortem examinations and may  
33 initiate inquests.  
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#### 40 **What does a Medical Examiner do?**

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42 Medical Examiners undertake their duties supported by Medical Examiner Officers at the  
43 beginning of the processes following a death. There are mandatory components of the  
44 work on each case, some of which may be delegated to an appropriately qualified Medical  
45 Examiner Officer. In all cases not investigated by a coroner, there must be a proportionate  
46 review of medical records, interaction with the qualified attending practitioner completing a  
47 MCCD, an interaction with the bereaved to clarify if there are any concerns or questions  
48 regarding the cause or circumstances of death, and a finally a review of the original or copy  
49 of the MCCD. All of these steps must be completed prior to registration of the death and the  
50 target standard is to achieve this within 24 hours of notification of a death. Standards for  
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3 the delivery of the Medical Examiner Service have been published by the Medical Examiners  
4 Committee of the Royal College of Pathologists<sup>75</sup>.

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7 The legislation of the Coroners and Justice Act 2009<sup>8</sup> provides for Medical Examiners but  
8 this has not yet been enacted. The planned implementation of the initial non-statutory  
9 Medical Examiner system will be focused on acute hospitals from April 2019 but there will  
10 be places where primary care deaths are considered. The full statutory system is planned to  
11 be implemented within 18-24 months to include all deaths not investigated by a coroner,  
12 including primary care.  
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### 20 21 **What is the impact of Medical Examiner assessment?**

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23 ~~The legislation of the Coroners and Justice Act 2009<sup>6</sup> provides for Medical Examiners but~~  
24 ~~this has not yet been enacted.~~ Medical Examiners have been established in a number of  
25 pilot sites across the UK to help the Department of Health and Social Care refine their policy  
26 plans and establish the key functions of a medical examiner system. In 2016 the Department  
27 reported data from over 23,000 Medical Examiner reviews of deaths at pilot sites in  
28 Sheffield and Gloucester showing that the referrals to the coroner were more consistent  
29 and appropriate, rejection of the MCCD by the Registrar was eliminated and input from  
30 relatives was assured<sup>97</sup>.  
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38 A parallel study by the Office for National Statistics to examine the effect of Medical  
39 Examiners on the confirmed cause of death found that the International Classification of  
40 Disease coding was changed in 12% and less fundamental changes were made in a further  
41 10% underlying cause of death changed in 22%<sup>108</sup>. This arose because MCCDs have  
42 historically been shown to contain inaccuracies and incomplete information<sup>9-11-13</sup>, which was  
43 corrected by Medical Examiners.  
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49 The 2016 review also found that independent scrutiny of medical records, supplemented by  
50 discussions with the bereaved, proved to be a consistent source of high-quality information  
51 about the quality of care, irrespective of the nature of the problem and irrespective of the  
52 type of organisation involved. This suggests that Medical Examiner review of deaths could  
53 have a role in improving patient safety.  
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### What role could Medical Examiners play in improving patient safety?

In December 2016 the Care Quality Commission (CQC) reported that learning from deaths was not being given sufficient priority in some NHS organisations and valuable opportunities for improvements were being missed<sup>1442</sup>. It identified the need to engage families and carers and to recognise their insights as a vital source of information. The CQC now requires all acute hospital Trusts to be able to “say something about every death”. In March 2017 NHS England launched the Learning from Deaths initiative<sup>1543</sup>, which required acute hospitals to undertake case record reviews on selected cases based on criteria most likely to yield opportunities for learning, reflection and improvement. No one case record review method was stipulated by NHS England, although structured judgement review<sup>1644</sup> was recommended.

Medical Examiners could help to address these requirements. The role, as developed in the pilot sites, involves proportionate review of all cases not referred to the Coroner, interaction with bereaved relatives and early notification of clinical governance concerns. This process could be used to ensure that every death is examined and that families and carers are engaged, while allowing structured judgement review to focus on cases with clinical governance concerns.

### What are the potential challenges to implementing the Medical Examiner system?

The timescale for implementing the Medical Examiner system is tight. Medical Examiners and officers will come from a limited pool of clinicians who already face substantial demands, but it is essential that Medical Examiners and officers with the correct skills and attributes are appointed. New Medical Examiners will need training and existing Medical Examiners will need ongoing updates to ensure consistent quality of assessments. Data collection systems also need to be developed that can be linked to existing systems.

The Medical Examiner system will require funding, with plans to initially use cremation form fees for this purpose facing logistical challenges. Furthermore, the introduction of the

Medical Examiner system may produce knock-on increases in workload for clinical governance and coroner services. The Medical Examiner pilot sites were mainly based in hospital care so extending the system to primary care is likely to involve addressing additional and potentially unforeseen problems.

It is clearly essential for the Medical Examiner to be independent and able to make potentially critical assessments of NHS care but ensuring independence alongside the need for accountability, and practical issues such as resources and data protection, will be challenging. Ensuring the many different stakeholders understand the changes resulting from the Medical Examiner system represents a communications challenge.

### **Could Medical Examiner review be used to estimate preventable death rates?**

Structured review of hospital deaths can be used to make a judgement about whether death was potentially preventable. Studies using structured judgement review estimated that up to 5.2% of deaths were probably avoidable<sup>45-17-19</sup>. However, judgements regarding levels of preventability vary between observers<sup>1745</sup> so each case would require agreement between independent reviewers for a reliable judgement to be made. Medical Examiner review is intended to identify cause for concern requiring further investigation. It is not intended to determine preventability. Subsequent structured review could be used to inform a judgement process about preventability in selected cases but uncertainty around this sometimes very difficult judgement has led many to conclude that review is better used to identify themes in causes for concern.

### **Does Medical Examiner assessment appropriately identify threats to patient safety?**

Unpublished data from the ~~Sheffield~~ Medical Examiner pilot ~~site~~ (Fletcher, personal communication, see appendix) showed that out of 3875 consecutive deaths, the Medical Examiner identified 153 cases with clinical governance concerns where attending doctors were unaware of the issues. This suggests that Medical Examiner screening prior to structured judgement review could substantially reduce the number of reviews required.

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3 However, valuable lessons from structured judgement review could be missed if Medical  
4 Examiner assessment is too limited or the threshold for clinical governance notification too  
5 high. To date we have no data to determine how appropriately Medical Examiner  
6 assessment identifies threats to patient safety, although serves the requirement to know  
7 something about every death.  
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12 The National Institute for Health Research Policy Research Programme has funded a  
13 study<sup>2018</sup> involving Medical Examiner Pilot sites that will compare the findings of Medical  
14 Examiner assessment and structured judgement review as used in the National Mortality  
15 Case Record Review Programme<sup>2119</sup>. These two processes are different and intended to be  
16 complementary, so inconsistencies are expected and neither should be considered the gold  
17 standard. However, the study will provide valuable insights into how these two processes  
18 work alongside each other and determine how Medical Examiner screening influences the  
19 workload and yield of information from structured judgement review.  
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### 29 **Should Medical Examiner assessment be used to screen cases for structured judgement** 30 **review?** 31

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33 Hospital trusts facing the need to implement the requirements of learning from deaths may  
34 be tempted to use Medical Examiner screening to select cases for structured judgement  
35 review. Trusts need to recognise the current lack of data to support this approach and, until  
36 findings from the research in progress are available, should at least augment structured  
37 judgement review based on Medical Examiner screening with additional reviews selected  
38 using an alternative process.  
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44 Medical Examiner assessment and structured judgement review have different origins,  
45 purposes and methods, so we should expect different results. However, the opportunity to  
46 align these two important policy measures to give a robust independent system that is  
47 protected by statute has the potential to make the mortality review system in England and  
48 Wales the best in the world.  
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**Key Messages**

Medical Examiners provide independent scrutiny of medical records, supplemented by discussions with the bereaved, for all hospital deaths

This assessment can improve recording of the cause of death, address the need to say something about every death and identify threats to patient safety

Medical Examiner assessment is not intended to make a judgement about preventability of death but to highlight causes for concern

Research is in progress to determine how Medical Examiner assessment can work alongside case record review to provide a robust mortality review system

**Contributors and sources**

AF is chair of the Medical Examiners committee of the Royal College of Pathologists and used this role and his position as a Medical Examiner to write the first draft of the paper and provide key content. JC is project manager for the Safety for Patients through Quality Review study (Evaluation of medical examiners' review to identify potentially avoidable deaths due to problems in care) and was project manager for research developing structured judgement review. She used her involvement on these projects to contribute to drafting the paper. SG is Chief Investigator for the Safety for Patients through Quality Review study. He used his involvement in this project and expertise as a National Institute for Health Research Senior Investigator to contribute to drafting the paper. All authors approved the final draft. SG is guarantor for the paper.

**Conflicts of interest**

AF is chair of the Medical Examiners committee of the Royal College of Pathologists and Medical Examiner at Sheffield Teaching Hospitals NHS Foundation Trust. All three authors are investigators on the Safety for Patients through Quality Review study. SG is chair of the NIHR Health Technology Assessment Clinical Evaluation & Trials Board.

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**Appendix: Unpublished data from the Medical Examiner pilot**

Total deaths 1 October 2013 to 16 February 2015	3875
Cases reported to the coroner for consideration of further investigation*	1360
Cases taken by the coroner for further investigation	698
Of all deaths, cases where clinical governance concerns were detected†	405
Cases with clinical governance concerns where the attending doctor was unaware of the concerns at the time of medical certificate completion, i.e. would not have been highlighted early for coroner referral and/or clinical governance investigation but for the Medical Examiner office involvement	153
Cases where bereaved concerns about clinical governance concerns were detected (in records or in Medical Examiner office discussion)	86
Cases where bereaved concerns about potentially avoidable harm were not recorded in medical notes	26

\* Includes deaths where the cause may include trauma, poisoning, neglect, or due to a medical/surgical treatment, in state detention, under an anaesthetic, or where the cause is unknown. Cases reported after Medical Examiner review.

† Including e.g. diagnosis or treatment errors, falls in hospital or care relating to death, delay in diagnosis, pressure sore development or progression, surgical intra-operative complications, post op infections, failure to escalate, failure to follow up in outpatients, or as inpatient (e.g. bloods, X-ray/scans) and family concerns about treatment or care