Witness Name: Alan Keith Fletcher

Statement No.: 1

Exhibits: Index of exhibits

Dated: [8 March 2024]

THIRLWALL INQUIRY

WITNESS STATEMENT OF DR ALAN KEITH FLETCHER

I, Dr Alan Keith Fletcher, will say as follows: -

Background

1. I, Dr Alan Keith Fletcher (GMC No I&S), Consultant in Emergency Medicine, qualified with B. Med. Sci, (Hons) 2:1 Anaesthesia in 1991 and Bachelor of Surgery and Medicine (MB. ChB) in 1992. I am a Fellow of the Royal Colleges of Physicians of Edinburgh and London and the Royal College of Emergency Medicine. I hold qualifications in medical leadership and management. I have been a Consultant in Emergency Medicine and Acute General (Internal Medicine) at Northern General Hospital, Sheffield Teaching Hospitals NHS Foundation Trust since 1 July 2004.

2. Since 1 March 2019, I have been the National Medical Examiner for England and Wales. I submitted an application in response to a public advertisement for the role and I was then interviewed with three other shortlisted candidates by a panel comprising of Dr Aidan Fowler (NHS National Director of Patient Safety NHS England), a Deputy Director at the Department of Health and Social Care, the Deputy Chief Medical Officer for Wales, and the Chief Coroner at the time. I was formally appointed by NHS England and my team sits within NHS England's National Patient Safety Team. I report to Dr Aidan Fowler. Dr Fowler, in turn reports to Professor Sir Stephen Powis, National Medical Director of NHS England. I perform this role in addition to my clinical role described above, and 60% of my time is apportioned to the National Medical Examiner role.

3. In brief, the role of the National Medical Examiner is to provide professional and strategic leadership to regional and Trust-based medical examiners whose objective is to scrutinise all deaths in England and Wales that are not reported to a coroner. The role supports medical examiners in providing better safeguards for the public, patient safety monitoring and improvement, and informs wider learning from deaths.

4. Prior to this appointment, I was Lead Medical Examiner (of the documents and cause of death) in Sheffield, following on from a pilot scheme there (covered in further detail below) from March 2008 to 2019. I was also the Chair of the Royal College of Pathologists' Medical Examiners Committee from 2015 to 2019.

5. In addition to the above two posts, my other current responsibilities are:

   a. National Clinical Lead for e-Learning for Health (Medical Examiners) since 2009. At that time, e-Learning for Health was part of Health Education England, which has since merged with NHS England.

   b. Member of the Death Certification Reforms Strategic Board, Department of Health and Social Care, since 2016.

   c. Member of the Editorial Board, Emergency Medicine Journal since 2015.

   d. Appraiser, Sheffield Teaching Hospitals NHS Foundation Trust since 2004. In this role, I undertake annual appraisals for medical staff (usually consultants) as part of their appraisal and revalidation process.

   e. Visiting Professor at the Centre for Contemporary Coronial Law, University of Bolton since 2023.

6. I exhibit my full CV, showing my qualifications, certificates, previous posts, research interests and publications **[Exhibit AF/0001 [INQ0012380]]**.

Definitions

The following definitions are not intended to be a comprehensive explanation, but merely to assist the reader in their understanding of some of the terms used in this witness statement. I understand that further detail in relation to most these areas will be provided by other colleagues at NHS England.

   a. **Department of Health / Department of Health and Social Care**: is the Government department responsible for setting policies that deliver the

Government's strategic health objectives; and in turn for making sure the legislative, financial, and administrative frameworks are in place to deliver those policies. The Department of Health became the Department of Health and Social Care in 2018.

b. **NHS England**: leads the National Health Service (NHS) in England. It is an Executive Non-Departmental Public Body sponsored by the Department of Health and Social Care. It is called an Arm's Length Body as it is a public body established with autonomy from the Secretary of State. It was established on 1 October 2012 and is operationally distinct from the Department of Health and Social Care. It is responsible for determining how to operationalise the Department of Health and Social Care's policies to ensure effective delivery and also for evaluation of their impact.

c. **Health Education England**: supported the delivery of healthcare and health improvement to patients in England by ensuring that the NHS workforce had the right numbers, skills, values and behaviours. It did this by planning, recruiting, educating and training the healthcare workforce. It merged with NHS England on 1 April 2023 and NHS England assumed responsibility for the activities previously undertaken by Health Education England.

d. **NHS Improvement**: was created in 2016 and included the National Patient Safety Team and was one of the organisations responsible for regulation of Foundation Trusts and performance management of NHS Trusts. It was abolished in 2022 and its functions were transferred to NHS England.

e. **NHS Business Services Authority**: is responsible for providing platforms and delivering services which support the priorities of the NHS, government and local health economies. It is an Arm's Length Body of the Department of Health and Social Care.

f. **Trusts**: patients in England receive their services from "providers" who have an arrangement to deliver these services. Providers employ their own staff, procure their own supplies and oversee the day to day running of the services at the point of patient care and are responsible for the day-to-day care and management of patients. NHS Trusts and NHS Foundation Trusts are the two types of providers of NHS secondary care, i.e., in a hospital setting in England. As many Trusts cover more services than purely hospital based, and some

Trusts do not run an acute hospital, where the term "acute Trust" is used in this witness statement, it refers to NHS Trusts which manage hospitals providing acute care.

g. **Section 251**: refers to Section 251 of the National Health Service Act 2006 (originally section 60 of the Health and Social Care Act 2001) and associated regulations: the Health Service (Control of Patient Information) Regulations 2002. Where section 251 support is obtained under the regulations, it operates to set aside the common law duty of confidence for defined purposes. This means for example that the person responsible for the information can disclose confidential patient information without consent to an applicant with section 251 support, without being in breach of the common law duty of confidence, if the requirements of the regulations are met.

The Medical Examiner System

7. Medical examiners are senior doctors in England and Wales who, in the period before a death is registered (five days), provide independent scrutiny of deaths not taken for investigation by a coroner. Normally they work in this role for one or two sessions a week to scrutinise deaths referred to them, in addition to their normal clinical duties. They come from all specialties, including GPs, and are trained in the legal and clinical elements of the death certification processes. Medical examiners, and the officers working with them, will not have been involved in providing care for the deceased people whose deaths they review.

8. The purpose of the medical examiner system is to:

   a. provide greater safeguards for the public by ensuring independent scrutiny of all non-coronial deaths;

   b. ensure the appropriate direction of deaths to the coroner;

   c. provide a better service for the bereaved and an opportunity for them to raise any concerns to a doctor not involved in the care of the deceased;

   d. improve the quality of death certification; and

   e. improve the quality of mortality data.

9. As will hopefully be clear from this statement, I believe that a correctly functioning medical examiner system would detect issues like Harold Shipman, Beverley Allitt and LL. This is because I consider that the system not only adds an extra, independent, layer of scrutiny for deaths not taken for investigation by a coroner, but it provides various junctures where a medical examiner would have the opportunity to consider a death (or series of deaths) alarming either from a review of records where the death was unexpected and unexplained, from noting patterns and trends such as an unusual frequency and a change in frequency, or crucially the 'Shipman question' asked of relatives as to whether they had any concerns. This is discussed further at paragraphs 105 and 123, and also in in the sections on Relationship with the Coroners and Register Offices (paragraphs 107-109); Relationship with bereaved families (paragraphs 110 – 115); and Escalation of concerns (paragraphs 116 - 123), as each of these are opportunities for issues to be flagged within the medical examiner system.

10. However, as will also be apparent through this statement, the medical examiner system has been developing incrementally on a non-statutory basis. It could not immediately review every death not taken for investigation by a coroner, which is the overall goal. It started with pilot schemes, grew to more acute Trusts, which were where the medical examiner offices were hosted, then care under other providers and community settings. Therefore, it is important to note at the outset that child and neonatal deaths have only more recently been encompassed by the system. Whilst the same principles, questions, and practical steps should be universal for all deaths scrutinised by a medical examiner, the nuances of scrutinising a child or neonatal death, particularly in the context of an existing statutory scheme for the review of such deaths, are covered in more detail at paragraphs 140 – 146, below.

Establishment and History – National and Legislative Picture

11. I set out below the national and legislative changes in the development of a medical examiner system. It will be appreciated that I have not had personal involvement in most of these developments, and they are included within this statement to provide background and context for the current system. It is not intended to be a full history and any further detail on those areas would be best addressed with the relevant department or organisation to which I refer. I specify below any personal involvement I have had in these developments.

12. In short, I would say that the medical examiner system in England and Wales was introduced as a result of the Government's response to the recommendations following Dame Janet Smith's recommendations in her third report from the inquiry into the murders committed by Harold Shipman. The importance of bereaved people at the centre of the medical examiner system has been paramount from the outset and will always continue. The system provides them with a voice regarding the cause of death and listens to any concerns they may have about the death of their loved ones. I believe that the system is important in ensuring consistent and accurate cause of death recording, coroner notification, and detection of clinical governance concerns.

2004 – 2007: early development

13. In March 2004, the Home Office published a position paper "Reforming the Coroner and Death Certification Service" **[Exhibit AF/0002 [INQ0012339]]** which drew on the consultation and recommendations of:

    a. a government-commissioned independent Fundamental Review of Death Certification and Investigation in England, Wales and Northern Ireland, chaired by Tom Luce CB, former Head of Social Care Policy at the Department of Health **[Exhibit AF/0003 [INQ0012393]]**; and

    b. the third report of the Shipman Inquiry chaired by Dame Janet Smith, a High Court and then an Appeal Court judge **[Exhibit AF/0004 [INQ0012341]]**.

14. This Home Office position paper proposed that all deaths be referred to a second certifier, who would be a medical examiner: a qualified doctor employed by the new coroner service.

15. In 2007, the Department of Health published a consultation paper "Improving the Process of Death Certification", seeking views on proposals to address the weaknesses identified by the Shipman Inquiry in the process of death certification in England and Wales. This included proposals that for deaths that had not been directly referred to a coroner, all Medical Certificates of Cause of Death would be subject to scrutiny by an independent medical examiner.

16. The summary of responses to the consultation was published in May 2008 **[Exhibit AF/0005 [INQ0012340]]**. The Department of Health then established a Stakeholder Working Group to direct and support the implementation of the proposed

improvements by developing guidance and advising on plans for medical examiners, and for pilots for the proposed improvements to take place. It noted that the proposals would require significant legislative change, and the intended timetable for implementation would broadly mirror that for introducing reforms to the coroner service.

Pilot Scheme

17. On 1 March 2008, a pilot scheme for a medical examiner system started in Sheffield. I cover my personal involvement with the pilot scheme in more detail below. In 2009, Mrs. Daisy Shale was appointed as medical examiner officer to support the pilot medical examiner scheme. In 2008 to 2009 the pilot in Sheffield was joined by pilots in other areas, including Gloucestershire, mid-Essex, Powys (Wales), inner north London (briefly), and Brighton.

18. The Coroners and Justice Act 2009 included a power to establish an independent medical examiners system to review the recording of deaths[1]. I believe that the Department of Health led on this as they supported the pilot scheme and relied on its findings to inform the Coroners and Justice Act 2009, in liaison with the Ministry of Justice.

19. In 2012, the Office for National Statistics published a statistical bulletin on "Death certification reform: a case study on the potential impact on mortality statistics" based on the pilot schemes in operation **[Exhibit AF/0007 [INQ0012400]]**. This showed how medical examiners improved accuracy of recording of cause of death. This was one aspect of the medical examiner system's intended benefits.

20. In between pilots commencing, other Trusts in England became early adopters of the system, including the University Hospitals Leicester in or around 2016. The pilots in Gloucester, mid-Essex and Brighton continued but the pilot in Powys (Wales) and inner North London were time limited. To my knowledge, the Countess of Chester Hospital did not have a pilot scheme and were not one of the early adopters.

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[1]The Coroners and Justice Act 2009, Chapter 2: Notification, Certification and Registration of Deaths: **[Exhibit AF/0006 [INQ0012391]]**

Consultations 2016 - 2018

21. In 2016, the Department of Health issued a further consultation on Death Certification Reforms **[Exhibit AF/0008 [INQ0012345];**[2] **Exhibit AF/0009 [INQ0012346]]**[3], seeking views on proposed changes to the death certification process and accompanying draft regulations. The consultation made clear that it was not asking whether or not there should be a unified system of independent medical examiners, as that had been covered in the 2007 consultation. Instead, it was consulting on the details of the operation of such a system. The consultation also acknowledged that the death certification system in England and Wales was overdue for reform, and it had remained largely unchanged for over fifty years, despite repeated criticism in consultations and reports.

22. In June 2018, the Department of Health and Social Care published its response to the 2016 consultation in which the Government announced its intention to introduce a new death certification process and a statutory medical examiner system, nationally from April 2019 **[Exhibit AF/0010 [INQ0012348]]**. A statement made by the Minister of State for Care on 11 June 2018 set out that medical examiners would be "a key element of the death certification reforms, which, once in place, will deliver a more comprehensive system of assurances for all non-coronial deaths [...] Medical examiners will be employed in the NHS system, ensuring lines of accountability are separate from NHS acute Trusts but allowing for access to information in the sensitive and urgent timescales to register a death" **[Exhibit AF/0011 [INQ0012376]]**.

23. Although changes would be required through primary legislation before the medical examiner system could commence on a statutory basis, the NHS started introducing medical examiners on a non-statutory basis. I believe that this was a decision taken by Department of Health and Social Care's Death Certification Reform Strategic Board, to be implemented by NHS England and in Wales. Hospital Trusts in England (and local health boards in Wales) were asked to set up medical examiner offices. I believe that this was agreed between Department of Health and Social Care, NHS England, and the Welsh Government, as a pragmatic way to establish a medical examiner system, pending statutory footing. It recognised the desirability of

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[2] Introduction Of Medical Examiners and Reforms to Death Certification in England and Wales - Policy and Draft Regulations - Consultation March 2016
[3] Reforming Death Certification: Introducing Scrutiny by Medical Examiners Lessons from The Pilots of The Reforms Set Out in The Coroners and Justice Act 2009, May 2016

implementing the medical examiner arrangements, in light of the ministerial statement of June 2018.

2019 onwards: setting up a national non-statutory system

24. In early 2019, NHS England appointed me as National Medical Examiner for England and Wales, following the open recruitment process that I have described in the background section above.

25. In 2019/2020, the National Medical Examiner's national and regional teams were appointed. The Department of Health and Social Care and NHS England agreed funding arrangements for the medical examiner offices in England, with details communicated by myself, Dr Aidan Fowler, and Professor Sir Stephen Powis to NHS Trusts in September 2019 **[Exhibit AF/0012 [INQ0012395]; Exhibit AF/0013 [INQ0012351]]**. Acute NHS Trusts in England started setting up medical examiner offices, initially scrutinising non-coronial deaths that occurred within that Trust, as the principal requirement was for acute Trusts to set up offices. The system could not immediately review every death (which was the long-term goal) therefore it had to grow incrementally, starting with deaths in acute Trusts, which were where the medical examiner offices were hosted.

26. In February 2021, the Department of Health and Social Care published a white paper setting out legislative proposals for a Health and Care Bill, called "Working together to improve health and social care for all" **[Exhibit AF/0014 [INQ0012355]]**. This contained the legislative changes required for the statutory medical examiner system. Until the statutory framework is implemented, the medical examiner offices which had been set up have continued on a non-statutory basis.

27. In May 2021, the Confidentiality Advisory Group notified NHS England of "s251 support" which was granted for all healthcare providers to share records of deceased patients with medical examiners during the non-statutory period[4].

28. In June 2021, all acute NHS Trusts reported that they had established medical examiner offices. NHS England (myself, Dr Aidan Fowler, Professor Sir Stephen Powis, and Dr Nikita Kanani the Medical Director of Primary Care for NHS England) then wrote to NHS organisations (NHS Trusts, GP practices, clinical commissioning groups, and integrated care systems) setting out the need to prepare for medical

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[4] See s251 CAG Register, tab A1016, **[Exhibit AF/0015 [INQ0012384]]**

examiners to review all non-coronial deaths across all non-acute sectors by the end of March 2022 **[Exhibit AF/0016 [INQ0009257]]**. As a non-statutory function however, this was not mandatory as the Health and Care Bill was still progressing through parliament, and Trusts were continuing to struggle with the effects of the Covid-19 pandemic.

29. In April 2022, the Health and Care Act received royal assent, but some provisions were subject to later implementation, including the medical examiner system[5].

30. In June 2022, the Government announced its intention to commence the statutory medical examiner system from April 2023 **[Exhibit AF/0018 [INQ0012377]]**, using the relevant provisions from the Coroners and Justice Act 2009 (as amended by the Health and Care Act 2022).

31. In July 2022, NHS England (myself, Dr Aidan Fowler and Professor Sir Stephen Powis) wrote to NHS organisations (NHS Trusts, GP practices, integrated care boards, and primary care networks) **[Exhibit AF/0019 [INQ0012364]]** setting out steps required locally to prepare for the statutory medical examiner system, working to the anticipated timeframe of implementation of April 2023, as per the announcement in June 2022. Acute Trusts were asked to ensure that medical examiner offices based at their Trusts had adequate workforce and support in processing patient records from other healthcare providers.

2023: Commencement of Primary Legislation and draft regulations

32. In April 2023, the Government announced **[Exhibit AF/0020 [INQ0012378]]** its intention to defer commencement of the statutory medical examiner system from April 2023 to April 2024. The announcement noted that the medical examiner system is part of a broader death certification, registration and coronial process, requiring work across Government on legislative and operational preparations.

33. In October 2023, the following Commencement Orders brought the following sections of primary legislation into force:

    a. The Coroners and Justice Act 2009 (Commencement No.21) Order 2023 **[Exhibit AF/0021 [INQ0012392]]**, which stated that from 1 October 2023, section 19 (Medical examiners: supplementary) and section 20 (medical

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[5] Section 169 of the Health and Care Act 2022 relates to Medical Examiners: **[Exhibit AF/0017 [INQ0012394]]**

certificate cause of death) of the Coroners and Justice Act 2009 came into force.

b. The Health and Care Act 2022 (Commencement No. 7) Regulations 2023 **[Exhibit AF/0022 [INQ0012403]]**, which stated that from 1 October 2023, section 169 (medical examiners) except subsection (5) of the Health and Care Act 2022 came into force.

34. In December 2023, the Department for Health and Social Care announced what they described as new measures to help protect the public and support bereaved families in relation to how deaths are certified, noting that medical examiners would strengthen safeguards by scrutinising how people have died **[Exhibit AF/0023 [INQ0012379]]**. It confirmed the intention that death certification reforms would come into force from April 2024 (including medical examiners). It also published draft regulations relating to:

    a. Medical examiners in England **[Exhibit AF/0024 [INQ0012371]]**

    b. Medical Certificate of Cause of Death **[Exhibit AF/0025 [INQ0012373]]**

    c. Additional functions of the National Medical Examiner **[Exhibit AF/0026 [INQ0012372]]**

35. Therefore, the medical examiner system in England and Wales continues to function on a non-statutory basis, pending statutory implementation.

Establishment and History – My personal Involvement

36. As a senior trainee doctor, I had visited HM Coroner's Court to understand the inquest process, which stimulated a personal interest in accurate coroner referrals and accurate causes of death.

37. In 2007, following a chance conversation in the hospital car park with the then HM Coroner for South Yorkshire (West), Mr Christopher Dorries, we discussed the potential to improve the accuracy of notification of deaths to the coroner locally by use of a medical examiner system. At the time, Mr Dorries was the Coroner's Society representative to a primary working group convened by the Department of Health considering the recommendations from Dame Janet Smith's third report following the Inquiry that followed the murders committed by Dr. Harold Shipman. He agreed that

a medical examiner system was worth trialling in Sheffield, so he would approach the Department of Health and Social Care with my idea.

38. Following meetings I had with the Department of Health at the end of 2007, the first medical examiner system pilot began in Sheffield from 1 March 2008. The initial pilot established two sessions from a consultant geriatrician (now retired Dr. David Da Costa). The examiner would focus on the accuracy of medical certificates of cause of death, proportionate review of relevant medical records, and accuracy of notification to HM Coroner. In the early stages, interaction with bereaved family members was not routine. Further details of the pilot can be found in the paper "Improving the Death Certification Process: The Sheffield Medical Examiner Pathfinder Pilot" **[Exhibit AF/0027 [INQ0012381]]**.

39. The Department of Health convened regular steering group meetings (now Department of Health and Social Care's Death Certification Reforms Strategic Board), which I attended. I remained involved in those monthly meetings from 2007 to the present day. The group is attended by representatives from NHS England (including myself and Dr Aidan Fowler), the Ministry of Justice, the Office for National Statistics, the General Register Office, the Home Office, the Chief Coroner's Office, National Panel for Registration, and Royal College of Pathologists. Latterly, the NHS Business Service Authority has attended because they are the Department of Health and Social Care's sponsored developers of the case management system for medical examiners and digital Medical Certificates of Cause of Death (covered elsewhere in this statement).

40. In 2009, I was appointed by Health Education England (now part of NHS England) as the first National Clinical Lead for e-Learning for Health (medical examiners). E-Learning for Health already had established programmes for other clinical specialties and the Department of Health commissioned it to support training for medical examiners. In this role, I worked as lead editor in developing the e-learning training for medical examiners and medical examiner officers. Mr Dorries, Dr. George Fernie, and Dr. Emyr Benbow were my module editors. The e-learning was complete and published by e-Learning for Health under Health Education England (now part of NHS England) from 2010 to 2011.

41. In addition to my clinical responsibilities, I continued to work as lead medical examiner in Sheffield for ten years. I have scrutinised the deaths of over 21,000 people.

42. When the Government decided to proceed with implementing the medical examiner system, I was appointed as National Medical Examiner for England and Wales on 1 March 2019.

43. As time went by and policy evolved, the wider benefits to bereaved people were appreciated. Based on this, I developed the fundamental principles of medical examiner work, involving three questions and three steps set out in the National Medical Examiner's Good Practice guidelines of January 2020 **[Exhibit AF/0028 [INQ0012353]**:

44. Questions

    a. What did the patient die from? (Accurate Medical Certificate of Cause of Death completion)

    b. Does the death need reporting to the coroner? (Timely and accurate referral to the coroner)

    c. Are there any clinical governance concerns? (Early detection and notification.)

45. Steps

    a. Proportionate review of relevant medical records

    b. Interaction with the attending doctor

    c. Interaction with the bereaved

46. Medical examiner work is focused on individual cases, and I emphasise that each death is unique, representing unique patient characteristics and a life with experiences that are individual. However, in every case, regardless of specialism or complexity, the medical examiner's responsibility remains to consider the same three questions and undertake the same three steps. I set out at paragraphs 110-115 below the relationship between medical examiners and bereaved families, and at paragraphs 141 - 142 the additional considerations for medical examiners speaking to bereaved parents of children. I believe that medical examiners should in every case try to obtain the views of the bereaved family, but of course families are not obliged to engage with the medical examiner and I would expect a medical examiner to be respectful of the family's wishes.

47. Since my involvement with the pilot system schemes and the formal implementation that commenced after my appointment, the implementation of the statutory system has been complex. Although the benefits of the system are obvious to me and my colleague enthusiasts, including from initial pilots, it is a big change to the process of death certification. I understand that there are some clinicians and departments who do not see why an external review of their cases is needed. Some of the GP community have had reservations about the system and some organisations challenge the need for medical examiner involvement in what could be seen as an already crowded space of regulated deaths. For example, this view has been expressed by the Paediatric Critical Care Society, as there are already Child Death Reviews, the Child Death Overview Panel, and the National Perinatal Mortality Review Tool. Mid-way through the timeline set out above, perhaps around 2012, I realised that a statutory footing was necessary to achieve consistency and universal uptake. I referred to Government activity relating to this when I gave evidence to Sir Robert Francis KC's Mid-Staffordshire Inquiry **[Exhibit AF/0052 [INQ0012648] and Exhibit AF/0053 [INQ0012635]]**, and I note that Sir Robert made recommendations regarding the medical examiner system **[Exhibit AF/0029 [INQ0012382]]**. The advent of the statutory system reflects the implementation of his recommendations regarding medical examiners.

48. I also learned, very early on in the development of the medical examiner system, around 2008, that death certification reform involves cross-government working and many stakeholders such as the National Panel for Registration, the Chief Coroner's Office, the Coroners Society, funeral sector representatives, faith leaders, and most importantly, bereaved people and those representing them.

49. Over the 15 years of my involvement with this programme, there have been several changes of government, changes of ministers, and in later years, opportunities to reflect, adapt and learn from implementation progress. For example, the value of identifying clinical governance concerns became clear early on which enabled us to refine the mechanisms for successful stakeholder engagement, especially from coroners. There were previously frustrations that Registrars sometimes seemed to reject medical certificate cause of death wording without informed medical knowledge, and the requirement for a crematorium second doctor created delays and distress when their involvement was not informed with complete medical information. These two points have been developed to inform policy for the statutory system and make it work better for bereaved people.

50. Although the Medical Examiner system has been 15 years in the making, it could of course only become a statutory system when the necessary legislation had been passed and commenced by Parliament. Even now the legislation is commenced, secondary legislation is required for the existing death certification and medical examiner practices to change on the ground.

51. Naturally, questions arise as to the length of time that it has taken to implement the system, even though the issues were discussed following the inquiry into the murders carried out by Harold Shipman, and I note that the murders committed by Beverly Allitt is an earlier example where, if there had been more scrutiny of deaths, those murders would have been detectable. I have hopefully made clear in the chronology above that I have worked to progress the implementation of the medical examiner system, but it has not been within my power to effect change any quicker, whilst we await statutory implementation, and the Covid-19 pandemic also impacted the speed at which Trusts could establish and develop medical examiner offices.

<u>Evolution and Expansion of the system</u>

52. Since my appointment in 2019, there has been no change to the principles or the expectations of the medical examiner system. I have been explicit that throughout the development of the system, bereaved people remain at its centre, and that the system provides independent scrutiny and facilitating accurate death certification, coroner notification where needed, and the detection of clinical governance concerns.

53. We are however on an implementation journey, so there have been natural changes to how we work, and the development of the system. The policy objective of the Department of Health and Social Care is to establish a statutory system in which medical examiners scrutinise all deaths that are not investigated by a coroner. The non-statutory system has been working towards that. It has taken time for medical examiners to be recruited and trained, and for medical examiner offices to be set up. Once established, they cannot immediately scrutinise every death in their region. Therefore, the non-statutory period has been used to grow the system incrementally.

54. In June 2021 NHS England asked that medical examiner offices start reviewing cases where the deceased was in the care of other providers – e.g., deaths in the community, at home or independent hospices. This was part of the continued expansion of the system. As set out above, I, along with my colleagues at NHS England wrote in June 2021 to all Trusts, GP practices, Clinical Commissioning

Groups and Integrated Care Systems setting out this change **[Exhibit AF/0016 [INQ0009257]]**. We followed this up by the letter in July 2022, setting out what was required of local health systems in order to prepare for the statutory system **[Exhibit AF/0019 [INQ0012364]]**.

55. As I have said, when the system started, it focused on adult deaths in acute Trusts. Medical examiner offices started adding in other local units and children's hospitals as the function and capability of the medical examiner office grew, probably from early 2022, prompted by the June 2021 letter.

56. The engagement of acute hospital Trusts since implementation began from 2019 has been excellent. Extending the medical examiner system to the non-acute sector has been inevitably more complex, requiring engagement locally by all 126 medical examiner offices and nationally, with primary care providers, the independent sector, private hospices and the establishment of a statutory basis for records to be shared with medical examiner officers.

Roles within the Medical Examiner System

Medical Examiners

57. Medical examiners provide independent scrutiny in three principal ways, which I have explained above at paragraph 45: they offer bereaved people the opportunity to ask questions and raise concerns; there is contact with the doctor completing the Medical Certificate of Cause of Death; and they carry out a proportionate review of medical records. If they detect issues or concerns, medical examiners refer their concerns to coroners for a coronial decision as to whether to conduct an investigation via the inquest process, and they refer cases back to the provider concerned for further review through established clinical governance processes specific to that provider, such as Structured Judgment Reviews. Medical examiners do not themselves investigate cases, as their scrutiny must be completed before the death is registered: their role is to "detect and pass on". I cover the escalation process in more detail below.

58. The role of medical examiners is set out in the National Medical Examiner's Good Practice Guidelines of January 2020 **[Exhibit AF/0028 [INQ0012353]]**. There will be additional requirements in the statutory system as set out in the draft regulation published on 14 December 2023. These include:

a. Extending the pool of doctors eligible to complete a Medical Certificate of Cause of Death;

b. Removal of the Registrar's route to notify the coroner (instead directing queries about cause of death to the medical examiner);

c. Removal of the Form 100A from coroners;

d. Establishing a medical examiner Medical Certificate of Cause of Death at the invitation of HM Senior Coroner if there is no attending practitioner available within a reasonable timeframe; and

e. Removal of Medical Certificate (Cremation 4), which is completed by registered medical practitioners to release a body for cremation.

59. Medical examiners are employed by NHS Trusts. The responsibility for appointment is for the individual employing Trusts in England and for NHS Wales Shared Services Partnership in Wales.

Medical Examiner Officers

60. Medical examiner officers help to run an efficient and effective medical examiner service. They obtain medical records and other tasks delegated to them by medical examiners, to allow the medical examiners to focus on their scrutiny. As medical examiners tend to be part-time, medical examiner officers provide a consistent point of contact within the office. After thorough training, and experience, they can provide expertise in death certification processes, advising attending practitioners, and liaising with registrars and coroners' officers.

Medical Examiner Offices

61. Medical examiners and their officers are based in medical examiner offices. Each medical examiner office tends to have a lead medical examiner, together with a team of medical examiners and medical examiner officers.

62. There are 126 medical examiner offices in England in total, all based within Trusts. 122 of these are based in acute NHS Trusts, and four are based in non-acute specialist Trusts. I do not have visibility of which of these Trusts have neonatal units and as discussed elsewhere in this statement, a medical examiner will scrutinise deaths from any specialism. Each Trust does not require its own dedicated medical

examiner office, as medical examiners are part of the wider healthcare system, albeit offices happen to be based mainly in acute NHS Trusts. For example, Alder Hey Children's NHS Foundation Trust does not have a medical examiner office based at its site but is instead part of a wider Liverpool medical examiner service.

63. The four non-acute specialist Trusts which host medical examiner offices are:

a. Liverpool Heart and Chest Hospital NHS Foundation Trust;

b. Royal Papworth Hospital NHS Foundation Trust;

c. The Christie NHS Foundation Trust; and

d. The Royal Marsden NHS Foundation Trust.

64. In Wales, NHS Wales Shared Services Partnership set up medical examiner offices in four hubs.

65. As I have explained above, once the full statutory system is in force, medical examiner offices will be scrutinising every death that is not investigated by a coroner, not solely deaths which occur in the Trust where their office is based. All adult acute Trusts had established medical examiner offices by June 2021. However, this does not mean that by this stage each office scrutinised all adult deaths within that Trust, but instead that that the office had started operating, and would expand its remit as it became established, and its function developed.

66. Recruitment to posts within medical examiner offices is at 94% across England and Wales.

67. I understand that the medical examiner office at the Countess of Chester Hospital NHS Foundation Trust started to develop and began recruitment in 2020. A lead medical examiner was appointed, but in 2021 there were some local personnel issues which were taken to the Regional Medical Examiner, who asked me to assist with escalating the issues at the Trusts concerned, which then dealt with it through their internal Trust HR processes, as one would expect in relation to an employee of the Trust. An interim lead medical examiner was appointed during this time, and I understand that Chester is 100% recruited now, i.e., it is fully staffed for medical examiners and medical examiner officers as a whole, and I understand that the Trust has recently appointed someone to the position of lead medical examiner.

Regional Medical Examiners and Regional Medical Examiner Officers

68. The 126 medical examiner offices in England are split across seven Regional Medical Examiners (one for each NHS England region team). Each region has a Regional Medical Examiner and a Regional Medical Examiner Officer. Regional Medical Examiners oversee the provision of services and provide an independent line of advice for medical examiners at offices in their region. They were appointed in 2019, commencing work between October 2019 and February 2020.

69. The role of Regional Medical Examiners was set out in the Programme Definition Document **[Exhibit AF/0030 [INQ0012396]]** (drafted by my office to set out how the implementation of the system would work on a practical level in England) as follows:

    a. Provide professional leadership and guidance to medical examiners within the specified region.

    b. Represent the National Medical Examiner within the region, including formally deputising where required.

    c. Advise the National Medical Examiner on progress with implementation of the medical examiner system within the region and to highlight any issues that require national attention.

    d. Provide support and guidance where necessary to resolve local issues.

    e. Ensure all medical examiners and medical examiner officers within the region comply with the legal and procedural requirements.

70. Regional Medical Examiners and Regional Medical Examiner Officers are employed by NHS England.

71. The system in Wales is hosted by NHS Wales Shared Services Partnership, which has essentially one large medical examiner office, with four regionally based hubs throughout Wales, with medical examiners distributed from those hubs, to cover the whole of Wales. Instead of a Regional Medical Examiner, Wales has the Lead Medical Examiner for Wales, the Lead Medical Examiner Officer for Wales, and a National Programme Manager. The principles of the system are the same as in England.

72. Regional Medical Examiners and Regional Medical Examiner Officers engage with medical examiner offices in their region through a range of activities: meetings, visits, regional fora and also through review of medical examiner offices' quarterly submissions to the NHS England data portal (see paragraph 128). However, in the non-statutory system there is no direct line of accountability between medical examiners and Regional Medical Examiners and Regional Medical Examiner Officers, as medical examiners are employed by different organisations. In the statutory system, it is expected that medical examiners will continue to be employed directly by NHS Trusts, but given the draft regulations published in December 2023, revised guidelines will be issued in due course, and we will consider the lines of medical examiner accountability and seek advice on this area.

73. Regional Medical Examiners and Regional Medical Examiner Officers work with other regional teams at NHS England, and with my team to support medical examiner offices in preparing for the statutory system. Where required, they liaise with other NHS England regional teams to use their influence with NHS Trusts and other NHS healthcare providers.

<u>Funding</u>

74. One of the main issues in establishing the statutory system was the initial intention to levy a fee on bereaved people at the completion of medical examiner scrutiny. The decision to charge a fee was outside of my influence or control and proved to be controversial, ultimately leading to the Government deciding not to charge a fee, instead funding the service centrally, latterly through the NHS England mandate. The initial primary legislation in the Coroners and Justice Act 2009 provided for medical examiner services to sit within local authorities. The practical challenges of this (employment, pensions, accommodation) meant this was logistically extremely challenging. The decision to amend the primary legislation through the Health and Care Act 2022 enabled medical examiner offices to sit within the NHS. This unlocked many of these difficulties, pragmatically facilitating employment, pensions and resources to be deployed.

75. NHS England obtained bespoke death certification data from Office of National Statistics, setting out deaths according to where the death had occurred. This was used to estimate the number of deaths each year that each medical examiner office would need to review.

76. The Department of Health and Social Care's impact assessment in 2018 set out a model based on a staffing requirement that for every 3,000 deaths not investigated by a coroner, there would be one full-time equivalent medical examiner and three full-time equivalent medical examiner officers **[Exhibit AF/0031 [INQ0012349]]**. By apportioning this ratio to the number of deaths for each medical examiner office, a staffing requirement and cost is determined. Each year NHS England sends a letter to medical examiner offices setting out the maximum available financial envelope for the financial year.

77. The NHS Trusts hosting medical examiner offices submit quarterly invoices for actual expenditure occurred. The reimbursement process was set out in an annexe to a letter dated 11 September 2019 to all NHS medical directors regarding the medical examiner system **[Exhibit AF/0013 [INQ0012351]].**

78. There were two changes to funding during the Covid-19 pandemic. Initially, the financial arrangement expected medical examiner offices to receive income from completion of a Cremation Form 5 for relevant deaths. The Cremation Form 5 was suspended during the pandemic and has not been reintroduced. Since this point, reimbursement by NHS England has been for the full costs without any deduction for income. Secondly, there was a brief period during the pandemic when all NHS funding arrangements changed to facilitate focus on pandemic response. There was no invoicing during this time.

Jurisdictional Differences

79. As National Medical Examiner for England and Wales, Wales falls within my remit and is part of the national medical examiner system, although it is outside of NHS England's usual remit.

80. I have no responsibility for examination of deaths in Northern Ireland or Scotland.

81. It is my understanding that in Scotland, there is a medical reviewer system. The medical reviewer system samples approximately 10% of all medical certificates of cause of death, reviewing the content and interacting with the certifying doctor. These are considered level 1 reviews. It is my understanding there is no review of medical records or interaction with bereaved people. There is an opportunity to undertake a level 2 review, including at bereaved people's request. I understand these are done in a small proportion of level 1 reviewed cases, but as I am not involved in this, I am unable to provide further information.

82. The Northern Ireland government have been included in the Department of Health and Social Care steering and strategic board meetings. I have visited Northern Ireland to discuss their approaches as they were deciding which avenue to take. It is my understanding that having initially favoured the Scottish approach, they have instead established an independent medical examiner system similar to that in England and Wales.

83. I have liaised with the Gibraltar health authority to support their establishment of a medical examiner system, which I believe is fully operational.

84. I am the medical examiner for St. Helena and Ascension Island in the South Atlantic. I review approximately 50 deaths per annum remotely from the UK, undertaking the medical examiner function as it exists in England and Wales.

Medical Examiner Resources

Training

85. The original curriculum for medical examiners was devised in 2008/2009 under Department of Health supervision and with involvement of medical Royal Colleges. The Department of Health decided to make the Royal College of Pathologists the lead medical college for medical examiners. I attest to the unflinching support of the Royal College of Pathologists. I have experienced this initially as National Clinical Lead for e-learning, then as Chair of the Royal College of Pathologists Medical Examiner Committee, and latterly attending the Medical Examiner Committee in an *ex officio* capacity.

86. The Royal College of Pathologists leads the two main components of medical examiner and medical examiner officer training: the e-learning and face-to-face training. The Royal College of Pathologists and its training is independent, and not commissioned by NHS England.

87. It is my expectation that all medical examiners must have completed 26 e-learning core mandatory core models (amounting to approximately 24 hours) before commencing work, with attendance at a face-to-face training event undertaken as soon as practicable before or within six months of appointment. These expectations are set out in the Good Practice Guidelines, as set out below.

88. The e-learning modules cover a range of topics, including the medical examiner system, death certification and registration, the role of the coroner, clinical

governance matters, faith considerations, and interacting with bereaved people. They are supported by case scenarios.

89. The face-to-face training has been largely held virtually via Zoom in a highly successful way since the pandemic. The Royal College of Pathologists administers this. It comprises a series of short lectures, interspersed with breakout groups and discussion. Faith and patient representatives have had a prominent place in this face-to-face training on every occasion. Their support is most welcome.

90. Once appointed, medical examiners should undertake continuing professional development (CPD) activities relevant to their role. Examples include completing further e-learning modules, attending regional and national update meetings or further training sessions such as with local coroners. Reflective practice is also encouraged.

91. The Royal College of Pathologists is currently developing systems to support the medical examiner and medical examiner officer community through professional discussion fora and continuing professional development opportunities. The Royal College of Pathologists has organised an annual conference for the last two years, providing a platform for the launch of my annual reports (see below).

92. Like all doctors, medical examiners are subject to medical appraisal and revalidation requirements. The Royal College of Pathologists provides guidance about appraisal and revalidation for medical examiners **[Exhibit AF/0032 [INQ0012350]]**.

93. There is also formal guidance directed at the attending practitioners who are reporting deaths. I am aware of guidance for doctors completing medical certificates of cause of death in England and Wales, published by the Office for National Statistics and the General Register Office (HM Passport Office) **[Exhibit AF/0033 [INQ0012362]]**, but I was not involved in its drafting or publication. There is also the "Cause of Death List", which was published in June 2020 by the Royal College of Pathologists, providing guidance for those completing death certificates and registering deaths **[Exhibit AF/0034 [INQ0012354]]**. I was consulted and provided a foreword for this publication.

94. Through their training, plus their experience in the role, medical examiners in turn train attending practitioners. It is my experience that the discussion between a medical examiner or medical examiner officer and attending practitioner reporting the death provides informal but practical education and training in the completion of

Medical Certificates of Cause of Death, leading to a cycle of continued improvement. I believe that this is far superior to a one-off lecture to attending practitioners, because the case is 'real' and personal to the attending practitioner.

The National Medical Examiner's Good Practice Guidelines

95. The National Medical Examiner's Good Practice Guidelines of January 2020 were published on behalf of my office by NHS England and NHS Improvement **[Exhibit AF/0028 [INQ0012353]]**. They are an overview for all medical examiners in their day-to-day work and touch on many aspects of the practice of medical examiners, such as independence and escalation. As such, they are referred to below, where relevant to the topics discussed. The Good Practice Guidelines will be refreshed to reflect the new statutory system when it commences.

The Good Practice Series

96. The Good Practice Series of papers is a topical collection of focused summary documents, designed to be read by front-line staff, with links to further reading, guidance and support. In most cases, these papers are created by a process that starts with a group of subject-matter experts being invited to a roundtable discussion. They therefore provide an opportunity to gather input from a wide range of subject matter experts specific to the topics concerned. There is a standing core group of representatives including Welsh government, Chief Coroner's Office, Ministry of Justice, GRO Home Office, Office for National Statistics, Royal College of Pathologists.

97. I decide the subject matter and topics for each meeting, after discussion with my team, and informed by asking Regional Medical Examiners and Officer and Welsh colleagues for suggestions, plus suggestions from the Royal College of Pathologists training faculty members. An interested Regional Medical Examiner will produce a draft discussion paper with input from subject matter experts, then a document providing context and suggested questions for discussion is prepared by my team, drawing on existing published material and other information available on the internet. This is then circulated to the group, who often share with their respective organisations for comment in advance of our discussion. After a round table discussion amongst the subject matter experts, a good practice paper for medical examiners is drafted and circulated to the group for comment. It is then finalised and

published. My office usually leads on drafting, occasionally with support from a Regional Medical Examiner with particular interest or expertise in the subject area.

98. The Good Practice Series is published through the Royal College of Pathologists and there are currently 13 documents in the series. They will all be considered for revision in due course, likely following statutory commencement of the system. The findings and any learning from this Inquiry will also be considered and the papers updated with any aspects that can improve the work of medical examiners. I expect that the papers most relevant to the Inquiry will be the following, which are covered in further detail below:

   a. No. 6: Child deaths, March 2022 **[Exhibit AF/0035 [INQ0012363]]** (covered in further detail at paragraphs 142-143, below); and

   b. No. 12: Escalating thematic issues **[Exhibit AF/0036 [INQ0009270]]** (covered in further detail at paragraph 117 below).

<u>Medical Records</u>

99. Medical examiners have responsibility to undertake a proportionate review of relevant medical records. This may be on paper or increasingly in an electronic format. Section 251 approval enabled records-sharing between primary care, other non-NHS organisations and medical examiner officers that would not have otherwise been possible in the non-statutory phase[6]. In the non-statutory phase, medical examiner officers have kept their own records, adhering to information governance principles. There is no sharing of person-identifiable information outside of the medical examiner office, except for the statutory requirement to inform HM Senior Coroner when necessary.

100. As the medical examiner system continues to develop, work is still required around information governance and sharing of patient records. I believe that the certainty of statute will assist with this by setting out the legal basis on which a healthcare provider shares patient records with a medical examiner. Whilst we currently have s.251 support for healthcare providers to share patient records of deceased patients with medical examiners, we often have issues with access to electronic patient record systems, as most data sharing agreements are predicated on the basis of direct care.

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[6] Organisational Assurance Statement for medical examiners: **Exhibit AF/0037 [INQ0012401]**; and medical examiner Programme Data Sharing Statement: **Exhibit AF/0038 [INQ0012385]**

I understand that in the statutory system, medical examiners will have a right to access records, underpinned by an amendment to the Access to Healthcare Records Act 1990.

101. NHS England's e-Referral System, which is used by GPs to make referrals to secondary care, and to make requests for advice from secondary care, now includes a section for medical examiners. This can be used by GP practices to refer deaths to medical examiners and to attach patient record summaries. This has been taken up by around 15 Trusts, but others are using other methods. It has the ability to share summary records, but not full patient records. The position, both now and following the statutory system (as the statutory system does not alter the fundamental challenges of sharing records across NHS IT systems) is subject to the extremely varied nature of NHS electronic patient records and varying levels of digital maturity across the NHS. Local providers have different electronic patient record systems, so medical examiner systems cannot require each provider to use a particular system. I am aware of the Federated Data Platform software, which in due course will sit across NHS Trusts and Integrated Care Systems, will allow them to connect data that they hold. However, this has not been directly discussed with me, so I do not know what, if any, difference this would make to the medical examiner system. That said, I would not expect it to be sufficient to cover the full ambit of records required by the work of medical examiners, because we consider events which are broader than the NHS. The medical examiner system considers the entire patient journey and so involves pre-hospital events in primary care, local authority or private care homes, private and independent hospice care, ambulance services and acute/community/mental health Trusts.

Case Management Systems

102. The medical examiner system does not currently have its own case management system. The Department of Health and Social Care are leading in relation to the introduction of such a system and I understand that they started working towards one in 2017, before my appointment. I understand that they have commissioned the NHS Business Services Authority to develop a case management system for medical examiners. I understand that this is still in development, and it may not be ready in time for the implementation of the statutory system. Regional Medical Examiners and Officers have been involved in a key user group so that they could have some influence in its design, but any further information about the system would need to be sought from the Department of Health and Social Care as my office has not been

involved with commissioning, or the specification for the system and its intended outcomes. My understanding is that when such a system comes into place, the medical examiner offices within the individual Trusts will be the data processors and Department of Health and Social Care will be the data controller, and this will be outside of the remit of my office and NHS England.

103. In the meantime, most medical examiner offices have developed their own local database systems: some have adapted their local NHS Trust systems, and some use the developing NHS Business Services Authority case management system. Given the varied capabilities of local NHS IT systems, we would not be able to mandate the use of particular systems, but we have provided exemplar forms to illustrate how a medical examiner scrutiny may be recorded **[Exhibit AF/0039 [INQ0012343]; Exhibit AF/0040 [INQ0012344]; Exhibit AF/0041 [INQ0012342]]**.

104. Any national case management system would need to be very sophisticated if it was intended to spot patterns in mortality. For example, if looking at deaths per GP practice, one GP might stand out as having a high number of deaths, but if they were the lead GP for various local care homes, one would expect the numbers to be higher. Similarly, with child deaths, one would expect Alder Hey Hospital to have more child deaths because it takes on the more complex cases. A system may be able to flag deviations against the baseline for that specific care provider, but it would be more difficult to compare between different care providers. A system may be able to provide more national data on trends and wider issues, such as noting an increase in sepsis cases over the long term. Such a system would likely have its own limitations, as I expect that it would flag many deviations from a baseline that had benign causes but would be useful alongside the more "human" element of judgment from fully functioning medical examiner system.

105. In my view, a fully functioning medical examiner system will have the ability to detect more local issues with a specific care provider as set out at paragraphs 9 above, and 123, below. For example, in neonatal deaths, if a medical examiner noted that a baby's death was unexpected, it would attract concern and probably lead to notification to the coroner. There would also be interaction with the attending practitioner, and they would have the conversation as to whether they were expecting the death. Then, there would be conversation with the family, and if they said that the baby had seemed to be fine or improving and they did not understand what had happened, this would be a third way that a concern may be flagged. Medical examiners would discuss cases like this within the office, as they are unusual, and

between them would likely spot a pattern of this happening a few times. In such a case, I would expect the lead medical examiner from that office to escalate it to the organisation responsible for the care given, and to their Regional Medical Examiner, as per the escalation process (discussed elsewhere in this statement). The independence of the medical examiner system also provides clinicians with another route of escalation outside of the setting where care has been provided, so during the conversation between the medical examiner and attending practitioner, they can raise concerns that they might have. Through the above means, I believe that the "human element" and independent clinical judgment provides a means for spotting local issues, that even a sophisticated system may not be able to recognise.

106. I would therefore say that it is my view that the absence of a national IT system or database for medical examiners does not hamper the work that they have been doing and continue to perform.

Relationship with the Coroners and Register Offices

107. Locally, medical examiner offices are responsible for relationships and operational work with their local coroner's office(s) and register office(s). More detail on this can be found in the National Medical Examiner's Good Practice Guidelines January 2020, which includes a section on local work **[Exhibit AF/0028 [INQ0012353]]**. The Notification of Deaths Regulations 2019 also sets out requirements for notifying coroners **[Exhibit AF/0042 [INQ0012399]]**.

108. From the outset of my role, I have emphasised the importance of medical examiner offices building strong working relationships with registration services and coroners. Over time, I have been impressed at the success of coroner engagement. Relationships in many places with coroners are so strong that coroners have asked medical examiners for their medical advice on many matters. However, I have been clear that the remit of medical examiners is not to provide expert medical opinion for coroners' investigations. As set out below, at paragraphs 116-118, it is the medical examiner's role to detect issues and pass them on, including to a coroner. This can assist the coroner in identifying issues that they may wish to consider by way of further investigation, but coroners make independent judicial decisions and therefore it is therefore their decision whether to conduct a coronial investigation into the death.

109. At a national level, I meet regularly with the Chief Coroner. I have continued to have strong working relationships with successive chief coroners, including regular

meetings every six weeks. I have also met the Coroner's Society on several occasions, attended and supported the Chief Coroner's annual conferences with coroners and area coroners and local authorities, and supported joint training between coroners and medical examiners that ran through 2022 in collaboration with the Royal College of Pathologists. I have attended the Local Area Registration and Coroner Services Association conferences and have met the National Panel for Registration on several occasions. This pattern of engagement is replicated at regional level, including attendance at regional registration services and regional coroner meetings.

Relationship with bereaved families

110. Listening to bereaved people is one of three steps that a medical examiner must take in scrutinising any death, and it is a core thread of medical examiner work. Medical examiners draw on their many years of experience of constructive patient interaction. These conversations provide an opportunity to explain medical terminology and cause of death, and crucially, ask if the bereaved have any concerns regarding the care or treatment that their loved one received. I am pleased to say that we receive feedback that medical examiner and medical examiner officer interaction is compassionate, helpful and reassuring.

111. In very many cases, families explain that they have no concerns about the care or treatment their loved one received, usually praising elements of care or individuals (the medical examiners then pass on this praise).

112. In some cases, family members find it helpful to talk through their concerns with an independent medical examiner or medical examiner officer providing explanations and interpretations. Often, this allays their worries and doubts at a time that is critical in their bereavement. It is an important step in the process and feedback has shown that some cases would have resulted in unnecessary complaints had there not been the opportunity provided by the medical examiner to raise questions and explore the issues with the family, and to provide the family with the information they needed to understand what had happened.

113. Occasionally, the family may have steadfast opinions about responsibility, which are respected and passed on to the relevant authorities. Where there are serious allegations, it is always appropriate to refer the death to HM Senior Coroner, who will make an independent judicial decision on the case.

114. If the medical examiner finds evidence in their scrutiny which is similar to the family's concerns, or the medical examiner detects other concerns that had not been raised by the family, they will also pass this information to the coroner's office and the care provider. In a small minority of cases, bereaved people raise concerns that had not been detectable in medical records or from the medical examiner's interaction with the attending practitioner. That will also be passed on to the coroner's office and care provider.

115. I am confident that the process gives patients a voice where the bereaved can express their concerns, but it is worth noting that a medical examiner is not the family's advocate.

Escalation of concerns

116. Medical examiners detect issues and pass them up through local processes where necessary in two ways. First, where medical examiners detect concerns, they refer these to established clinical governance processes at the care provider for further review. Medical examiner offices in England report that they refer around 10% of cases for clinical governance review. Secondly, during scrutiny of a Medical Certificate of Cause of Death, if a medical examiner determines that the death is reportable then they will refer it to a coroner.

117. "Good Practice Series No. 12: Escalating thematic issues and maximising the impact of medical examiner scrutiny" confirms that a medical examiner should also consider whether there is a need to notify the coroner of certain deaths that form part of a wider concern identified, such as trends, themes and systemic issues to existing clinical and quality governance processes **[Exhibit AF/0036 [INQ0009270]]**.

118. Medical examiners' responsibility is to "detect and pass on" not inform judgement or investigate. For this reason, a medical examiner's scrutiny will not be couched in definitive or conclusive terms, and it will instead use phrases such as "it appears there was....". While there is inevitably an element of judgment in deciding if there is a concern which needs to be raised, beyond that, it is not a medical examiner's role to judge a likely outcome, such as a coroner's conclusion or result of a Trust's internal investigation. This is because a medical examiner's scrutiny is based on a snapshot and relatively brief review, considering some evidence, but not necessarily all subsequent available evidence. It is the role of others, such as coroners' offices and Trust investigations to make conclusions with the benefit of further evidence and

investigation. The medical examiner's function is the first step in that process, of flagging concerns that may need to be looked into further. I consider that the same principles of "detect and pass on" apply to all deaths that are scrutinised, including child, neonatal and maternal deaths.

119. The National Medical Examiner's Good Practice Guidelines of January 2020 considered options for medical examiners where their referral of cases did not appear to be leading to appropriate action, and how this could be addressed in a non-statutory medical examiner system **[Exhibit AF/0028 [INQ0012353]]**. The guidelines noted that if this situation arises, medical examiners should inform their Regional Medical Examiner, who would be able to provide support and work with the medical director at the relevant NHS organisation and NHS England's Regional Medical Director as required.

120. While I do not consider that it is the responsibility of my office or medical examiners locally to insist on accountability of acute Trusts or senior managers, I consider that where medical examiners have concerns regarding persistent or emerging patterns, they should raise this locally, including informing the Regional Medical Examiner, who in turn would inform me. I have no reservations about raising concerns I may have regarding care in the wider NHS or individual organisations with HM Senior Coroners or the Secretary of State should they come to light. So far, I have not had to raise systemic or serious concerns with the Secretary of State.

121. I consider that the same escalation process should occur in cases of neonatal death concerns, as with any other death, and medical examiners have additional guidance relating to child deaths to assist in this respect (set out in more detail below).

122. If there is any reservation I have about the system, it is that medical examiners and medical examiner officers cannot guarantee that the concerns they relay lead to an action that is helpful to bereaved people. However, in my opinion, the medical examiner system is one component of a properly functioning concern detection system. Patient safety improvements that flow from it are outside of my office's remit and medical examiners cannot dictate what patient safety improvements should occur. There has been some debate as to whether medical examiners should receive feedback following any concerns they have raised. An advantage of this would be to help accuracy and learning, but there is also a risk that it would lead to the medical examiner system being perceived as "policing", thus risking suspicion and losing the

openness of the peer-to-peer conversation that medical examiners have with attending practitioners.

123. As set out at the beginning of this statement, at paragraph 9, I believe that a correctly functioning medical examiner system would detect issues like Harold Shipman, Beverley Allitt and LL. This is because I consider that if the necessary three questions set out at paragraph 44, above have been asked, and the three steps set out at paragraph 45, above have been carried out, a medical examiner would likely consider deaths alarming at any one of these junctures, such as from a review of records where the death was unexpected and unexplained, or from noting patterns and trends such as an unusual frequency and a change in frequency, or asking relatives as to whether they had any concerns.

Oversight and Reporting

124. Approximately every six weeks, I meet with Regional Medical Examiners, Regional Medical Examiner Officers and with colleagues from Wales to review implementation progress. This is not a formal meeting. Further, as health is a devolved function in Wales, NHS England does not have a remit for delivery of health objectives in Wales.

125. I also have quarterly supervision meetings with Regional Medical Examiners and the Lead Medical Examiner for Wales. These are structured conversations, following a set template **[Exhibit AF/0043 [INQ0012402]].** This covers: current objectives and progress made; an update on their personal development plan; reciprocal feedback; career development; and any other areas. If required, I can liaise with other Directors at NHS England.

126. The Medical Examiner Implementation and Oversight Group is an NHS England governance group, which meets quarterly **[Exhibit AF/0044 [INQ0012398]]**. It has had a focus on implementation of the non-statutory medical examiner system in England as the programme was developed but is now developing a focus on oversight as the system becomes more established and embedded. It tracks and monitors progress, reviews operational reporting by medical examiner offices, and provides a forum for decisions and for escalation where required. I wished to have patient and public involvement representation in this group and am delighted to have the benefit of two wise and challenging representatives for the whole of the group's existence.

Quarterly Reports

127. Each medical examiner office is required to provide regular submissions to the National Medical Examiner. This includes important information for quality assurance of the medical examiner office, such as the number of cases referred for clinical governance review due to concerns, including deaths in hospitals of people with learning disabilities or severe mental illness; and the number of cases notified to coroners.

128. In 2020/2021, NHS England introduced a quarterly reporting template for medical examiners **[Exhibit AF/0045 [INQ0012369]]**, which is completed manually by the medical examiner offices and added to the NHS England data portal. This includes the following free text questions for response:

a. Summary of activity – "Provide a summary of noteworthy activity, findings, milestones and achievements. Please include any operational or implementation issues we should be aware of".

b. Concerns – "The lead medical examiner, or equivalent, should use this section to confirm they have considered whether scrutiny by medical examiners has indicated any potential themes, trends, or any areas of particular concern. This includes but is not restricted to: specific service locations; particular specialties; and specific healthcare providers".

c. "Has any medical examiner requested support, or does any medical examiner require support, from the Regional Medical Examiner, Regional Medical Director and/or National Medical Examiner in addressing issues detected during scrutiny?"

d. "Any further comments you would like to add regarding detection of issues and actions."

129. This process is not automated and requires manual counting and reporting of each figure by the medical examiner officers. The submission provides quantitative information covering activity and staffing. It also provides an opportunity for narrative regarding issues and themes. Key headlines from Q2 2023/24 are that:

a) The staffing levels for MEs reached 93% and 94% for MEOs at Q2.

b) Medical examiners were providing independent scrutiny of almost all deaths in acute Trusts, and the equivalent proportion for deaths in non-acute settings had risen to an estimated 34%.

c) Of 66,235 deaths they had scrutinised medical examiner offices reported:

i. 5,948 (9%) were notified to coroners and taken for investigation.

ii. 5,488 (8.3%) were referred to case record review or similar clinical governance processes.

130. Individual office returns are reviewed by Regional Medical Examiners, and a summary is reviewed by NHS England's Medical Examiner Implementation and Oversight Group. Regional summaries are also shared with NHS England's Patient Safety Strategy Implementation Group and with NHS England's regional teams, although practice may vary by region.

131. Since the medical examiner offices started submitting quarterly data and information, we have introduced a template report which Regional Medical Examiners use to present the latest position in their region each quarter **[Exhibit AF/0046 [INQ0012390]]**.

Annual Reports

132. I have published three annual reports, to show progress with implementing the medical examiner system, milestones achieved, examples of the impact medical examiners are having, and details of key activity during the period covered by each report. The latest was in May 2023, reporting on 2022 **[Exhibit AF/0047 [INQ0012368]]** We also publish around six update bulletins per year, primarily aimed at medical examiners but with a wider circulation list. The latest was in December 2023 **[Exhibit AF/0048 [INQ0012386]]**.

133. The learning that has so far been achieved has almost exclusively been in relation to adult deaths. Neonate and child deaths have been a later addition due to the gradual expansion of the system from acute adult deaths. Even if medical examiners were considering every neonatal case (as they are moving towards and will be the position in the statutory system), the case would still go through the more comprehensive statutory child death processes (see paragraph 140 below).

Learning from trends in Medical Examiner reports

134. How organisations disseminate their learning is outside of my remit. In 2017, The National Quality Board[7] published National Guidance on Learning from Deaths: A Framework for NHS Trusts and NHS Foundation Trusts on Identifying, reporting, investigating and learning from deaths in Care **[Exhibit AF/0049 [INQ0012347]]**. I have no responsibility for the learning from deaths framework. However, I do engage in work on how to ensure that concerns raised by medical examiners are consolidated and reported, so that wider trends can be picked up by relevant organisations.

135. At a local level, there is no formal published local report of medical examiner office concerns. Publishing information regarding the deceased people, or healthcare practitioners attending them carries unacceptable data confidentiality risks in my opinion, because they will be easily identifiable. Nevertheless, it is important that learning is not lost.

136. At a regional level, NHS England Regional Medical Directors and those with patient safety responsibility have an established contact line with Regional Medical Examiners. I encourage quarterly reports to be shared at a regional level.

137. From a national learning perspective, it is my view that there is a gap when considering all the information available regarding mortality in health and care systems. I consider that whilst mortality is just one aspect of patient safety, there is a uniqueness of importance of mortality information that deserves ongoing review in the form of dashboard and opportunity to consider synthesising the information and learning from the myriad reports (mine included) that refer to mortality.

138. Therefore, in June 2023, my office provided a paper on "Medical Examiners – progress and themes" **[Exhibit AF/0050 [INQ0012397]]** to the Executive Quality Group of NHS England (a group jointly run by the Nursing Directorate and the Medical Directorate of NHS England). This set out themes identified across medical examiner offices. We noted that whilst many issues detected can be specific local matters, others may be appropriate for ICB/regional consideration. We wished to ensure that intelligence gathered by medical examiners is made available to existing quality governance processes. We therefore set out a diagram with a proposal that this

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[7] The National Quality Board was established in 2009 to bring about greater alignment in respect of quality, between the national bodies responsible for the overall health system. The aim of the National Quality Board is to consider the risks and opportunities for quality and safety across the while system, through bringing together the Department of Health and Social Care, Care Quality Commission, NHS England, NICE and others.

should occur at local, ICB, regional and national levels. I would not propose the creation of another group, board or body, but I think that we need to work towards a coherent report to look at everything to do with mortality. This would consolidate intelligence from all mortality reviews. My office has spoken with the medical directorate quality team and they are considering whether regional reports should be sent as a matter of course to regional quality groups, and the NME's annual report brought to the Executive Quality Group.

Medical Examiner Role in Neonatal Deaths

National Medical Examiner's Good Practice Series No. 6: Medical examiners and child deaths

139. As set out above, the evolution and expansion of the medical examiner system meant that it started out by scrutinising adult deaths in acute Trusts, and has developed into other areas, working towards the goal of scrutinising all deaths that are not investigated by a coroner. Therefore, child and neonatal deaths have only more recently been encompassed by the system.

140. In England, there was already a statutory process for reviewing the deaths of children in detail, set out in the "Child Death Review Statutory and Operational Guidance (England)" **[Exhibit AF/0051 [INQ0012367]]**. Therefore, my team and I have considered carefully how medical examiners should interact with existing statutory processes for reviewing the deaths of children and neonates.

141. From around 2020, my office received frequent questions about the interaction between medical examiners and the statutory process for reviewing deaths of children. In particular, there were questions about interactions with the bereaved family, and a concern about the potential for duplication or causing additional distress if families bereaved after the death of a child received calls from an NHS employee working as a medical examiner, in addition to their allocated key worker, especially as the medical examiner system had no statutory basis. However, a campaigner for bereaved families made a strong case that medical examiners/officers should offer families bereaved after the death of a child exactly the same opportunity as they do for other bereaved people – i.e., the opportunity to ask questions and raise concerns with someone not connected with the care of the deceased and queried why they should have fewer routes to voice their concerns. The point was made that key workers may be too closely linked with the team providing care and were not clearly

“independent” of the team. It was therefore decided that a good practice paper should set this out in guidance.

142. “Good Practice Series No.6: Medical examiners and child deaths, March 2022” was widely consulted upon, incorporating the views of representative organisations in the care of children and neonates, as set out in its appendix **[Exhibit AF/0035 [INQ0012363]]**. It sets out principles for medical examiners to interact and engage with the statutory child death review process. This recommends that after the death of a child, medical examiners (or medical examiner officers with delegated authority) should make contact with bereaved families to offer the opportunity of discussion with an independent person in the usual way. However, this recommendation has no statutory basis at present and there may be areas where key workers continue to lead on liaison with the family after the death of a child. After the statutory medical examiner system commences, it is expected that the National Medical Examiner’s Good Practice Guidelines will continue to require that medical examiners or officers provide a direct opportunity for families bereaved after the death of a child the opportunity to ask them questions and raise concerns. The draft regulations published in December 2023 seem to support such an approach.

143. The Good Practice paper also explains to medical examiners that NHS England is implementing a new perinatal quality surveillance model and provides a link to its full details. The paper notes that Trusts have been asked to report concerns with perinatal care to the regional chief midwife and regional lead obstetrician, who will be members of a regional-level quality oversight committee. The paper recommends that medical examiners should use this escalation route where appropriate.

144. Medical examiners are aware of the statutory requirement for child death review and child death overview panel work. I do not expect medical examiners to attend every child death overview panel meeting, but the outcome of their scrutiny may be made available to the panel and their attendance agreed if necessary.

145. Trusts are required to tell the Maternity and Newborn Safety Investigations (MNSI) programme about certain incidents that happen in maternity care, so that MNSI can carry out an independent investigation and where necessary make safety recommendations. MNSI was originally part of the Healthcare Safety Investigation Branch, but is now hosted by the Care Quality Commission. Medical examiners have no role in relation to the MNSI programme except to be able to share concerns detected during their scrutiny if they wish.

146. The fact that scrutiny by medical examiners has more recently extended into child and neonatal deaths has meant that the system had time to become more established, for medical examiners to be trained and develop experience, and for us to formulate specific guidance on child and neonatal deaths to support medical examiners. Some medical examiners and medical examiner officers had expressed anxieties about scrutinising child and neonatal deaths because of: sensitivities; lack of familiarity; understandable concerns about interacting with an existing statutory process; and a desire to ensure interactions with bereaved parents were fully appropriate. However, I believe that appropriate guidance is now in place, and I am not aware of medical examiners continuing to have those initial concerns.

Effectiveness of the Medical Examiner System

147. In due course the Office for National Statistics will, through comprehensive analysis of death certification, look at the statistical impact of medical examiners: whether it ensures that death certificates are more accurate, how many cases are referred to coroners and how many go to inquest.

148. My own view is that the medical examiner system provides important benefits in ensuring high quality scrutiny of deaths. In particular, I believe that the medical examiner system is unique in removing the siloed elements of healthcare governance. A medical examiner will consider the whole of the patient's journey from pre-hospital, ambulance journey, initial treatment, social care, and local authority or independent healthcare provision depending on the case. It is possible that concerns are raised in respect of each or all of these components.

149. The independence of the medical examiner system is important to its role in scrutinising any death, and I would make the following comments on this:

  a. The motivation for senior doctors to undertake medical examiner work is to make a difference to the lives of bereaved people. The role relies on their independent clinical judgement, to provide a force for good and a voice that they can raise (on behalf of others) in a healthcare system that can at times feel difficult for bereaved families to make one's voice heard. In my experience, medical examiners are fiercely independent minded and highly professional. The recent draft regulations for medical examiners set out the procedure for the independence of medical examiners and requirements for the terms of appointment to their roles.

b. Independence is promoted by the independence of the coronial system to which the medical examiner system is closely aligned.

c. Medical examiners have earned the confidence of attending practitioners, coroners, and bereaved people as they have undertaken their work.

d. Medical examiners have been assured by me (and Regional Medical Examiners) that I fully support their independence in their work, and we would support them if they encountered any pressure to act in a particular way.

e. Medical examiners are always independent of the case they scrutinise as per the Good Practice Guidelines.

f. Over 640,000 deaths have been scrutinised in the medical examiner system so far and I have not encountered any concerns raised about medical examiner independence from the Trusts that host their offices.

g. As work extends outside acute Trust cases, respect for independence has grown.

h. I have never felt anything other than independent in my role leading this system.

150. I therefore consider that the Medical Examiner System is so far successful at providing independent scrutiny of deaths and I am proud to provide leadership and independence for this system. I am content that the imminent statutory legislation set out in the draft regulations provides an essential scaffold for medical examiner independence.

151. The effectiveness of the medical examiner system cannot really be judged per medical specialism, as the goal is to cover all deaths in the statutory system. However, the nature of child and neonatal deaths means that there are some limitations on medical examiner involvement. Even now that medical examiner offices have started to provide independent scrutiny of child and neonatal deaths, my experience is that a higher proportion of child and neonatal deaths are taken for coronial investigation than adult notifications, meaning that they are not referred to medical examiners. There are approximately 3,200 child and neonatal deaths each year in England and Wales, at least 50% of which are notified to coroners, which is a higher proportion than in adult deaths (in 2022, 36% of all deaths were reported to coroners). I understand higher coronial reporting to arise from historic and practical

reasons. When a Medical Certificate of Cause of Death is completed, deaths of children and neonates are usually certified by a consultant. Despite their years of experience, consultants may not necessarily appreciate all the legal niceties of death certification, cause of death formulation, and coroner notification. As a result, even now, each individual medical examiner office still will only have an average of approximately 12 child or neonatal deaths per annum to scrutinise. In practice, most offices will have fewer than this because many deaths occur in the specialist children's hospitals, and some medical examiner offices will not have a specialist children's hospital in their area.

152. Despite the relative rarity of medical examiner scrutiny of child and neonatal deaths, there are already excellent examples of medical examiner liaison with maternity and neonatal services for training and supporting the processes. I would make the following comments on this:

a. The immediate past president of the Royal College of Paediatrics and Child Health is a neonatologist at the Evelina children's hospital Guy's and St Thomas' NHS Foundation Trust. When I met her for an informal discussion about extending the medical examiner system to include children and neonates in 2021, she expressed how positive the system was at the Evelina.

b. A number of lead medical examiners are themselves neonatologists or paediatric specialists. The lead medical examiner at St George's University Hospitals NHS Foundation Trust is a neonatologist. The lead medical examiner at Cambridge University Hospitals NHS Foundation Trust is a paediatric pathologist and has provided training updates to national and regional lead medical examiner fora.

c. There was an excellent development and training session at Sherwood Forest Hospitals NHS Foundation Trust including obstetricians and neonatologists.

153. I hope to see this good practice continuing, as scrutiny of child and neonatal death develops within the medical examiner system. I also hope to develop the process to ensure that medical examiner scrutiny is complementary to existing processes, sensitive to bereaved parents' wishes, and avoids a queue of people asking bereaved parents whether they have any concerns or not. I am confident this can be achieved.

154. In time, I consider that the medical examiner system will enable bereaved parents to express any concerns they have regarding the care their child received to an

independent person, consistent with the expectation of a statutory system that includes all deaths including deaths of children and neonates.

155. It has been queried by the neonatal community whether there should be specific neonatal medical examiners. This has not been raised formally with me or my office, so I cannot speak to a definitive policy position. I have considered this option in detail, and I would be happy to discuss the advantages and disadvantages. At this stage my personal view is that medical examiners from various specialties look at deaths from various other specialties, so any medical examiner can scrutinise neonatal deaths in the same way that they would a cardiology or neurology case: reviewing medical records to detect unusual events; conversing with the clinicians involved and asking difficult questions where needed; and liaising empathetically with family members to listen to any concerns. Any medical examiner scrutiny is not intended to be a specialist review and medical examiners can, and do, call colleagues in other specialties to discuss their views. However, I do not believe that each medical specialism should have dedicated medical examiners. Further, I would be concerned about potential conflicts of interests with a specialist neonatology medical examiner in each area because it is a relatively narrow specialty, and the specialist medical examiner would be likely to know the clinicians involved. They would therefore not provide the independent view which is the aim of the medical examiner system. I believe that the benefits of the generic approach outweigh benefits of specific medical examiners per specialty.

Improvements

156. As the medical examiner system continues to develop, we are constantly considering improvements to the system, which has been one benefit of developing the system on a non-statutory basis. We will continue this practice especially in the light of the recent draft regulations. There will therefore very likely be changes and improvements to the system as it continues to develop towards full implementation in a full statutory system.

157. As I have set out above, in the section regarding Escalation of Concerns, it is not the role of the medical examiner system to make specific proposals or recommendations to improve the quality of care and safety of patients in any specialty or care provider, therefore I cannot comment specifically on any proposals or recommendations in relation to neonatal care. I consider that the role of the medical examiner system is to pick up concerns and report them appropriately, but for others to then make

recommendations for improvement, after having the opportunity of more thorough consideration of the details and evidence than the medical examiner system is intended to provide.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

PD

Signed: ________________

Dated: _8 March 2024_______________________________