

Consultation on coronial investigations of stillbirths

March 2019

CP 16



Consultation on coronial investigations of stillbirths

Presented to Parliament by the Lord Chancellor and Secretary of State for Justice by Command of Her Majesty

March 2019

CP 16



© Crown copyright 2019

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit <u>nationalarchives.gov.uk/doc/open-government-licence/version/3</u>

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

This publication is available at https://www.gov.uk/government/publications

Any enquiries regarding this publication should be sent to us at:

Coroners, Burial, Cremation and Inquiries Policy Team Ministry of Justice 102 Petty France London SW1H 9AJ

Tel: 020 3334 3555

Fax: 020 3334 2233

Email: CoronerReview@justice.gov.uk

ISBN 978-1-5286-1057-5

CCS0219686644 03/19

Printed on paper containing 75% recycled fibre content minimum

Printed in the UK by the APS Group on behalf of the Controller of Her Majesty's Stationery Office

About this consultation

То:	Anyone with an interest but particularly people who have lost a baby to stillbirth or experienced any type of pregnancy loss; organisations supporting bereaved parents, or conducting or funding research on baby loss, and all organisations providing care, support or advice to pregnant women and their partners and families; organisations and individuals involved in clinical care reviews and investigations of stillbirths; coroners, coroner's officers and others working for coronial services; and any health professionals interested in the question, especially obstetricians, neonatologists, midwives, nurses and perinatal pathologists, as well as members and representatives of clinical professional organisations, the NHS and private maternity service providers.
	Whilst the proposals only extend to England and Wales, we also welcome views from people and organisations living, working or operating outside England and Wales.
Duration:	From 26/03/2019 to 18/06/2019
Enquiries (including requests for the paper in an alternative format) to:	Coroners, Burial, Cremation and Inquiries Policy Team Ministry of Justice 102 Petty France London SW1H 9AJ
	Tel: 020 3334 3555
	Fax: 020 3334 2233
	Email: CoronerReview@justice.gov.uk
How to respond:	Please respond by 18/06/2019 using the Ministry of Justice's online consultation hub at https://consult.justice.gov.uk/digital-communications/coronial-investigations-of-stillbirths
	You may also send your response via email to CoronerReview@justice.gov.uk or in hard copy using the "Enquiries" contact details above.
	Responses will be received and processed by officials in both the Ministry of Justice and Department of Health and Social Care.
Additional ways to feed in your views:	A series of stakeholder meetings is also taking place. For further information please use the "Enquiries" contact details above.
Response paper:	A response to this consultation exercise is due to be published by 10/09/2019 at: <u>https://consult.justice.gov.uk/digital-</u> communications/coronial-investigations-of-stillbirths

Contents

Foreword	3
Executive summary	5
Introduction	7
Background	8
The proposals	14
About you	34
Contact details/How to respond	35
Consultation principles	37
Annex A – List of consultees (A–Z)	38
Annex B – Useful links (A–Z)	40
Annex C – Glossary (A–Z)	41
Annex D – References	49
Annex E – Questionnaire	52

Consultation on coronial investigations of stillbirths

Foreword

A stillbirth is a tragedy which has a profound effect upon bereaved families. We are committed to ensuring that, wherever possible we do all we can to ensure that when such a tragedy occurs, lessons are learnt and changes made to prevent avoidable stillbirths in the future.

Our rates of stillbirth are the lowest on record but they are still higher than some other comparable countries, which have succeeded in bringing rates down even further. There is much to be proud of in the year on year falls in the proportion of pregnancies that end in a stillbirth, demonstrating an almost constant decline since the 1980s. Nevertheless, we believe that there is still more that can be done.

Whilst we have robust and comprehensive systems for establishing the possible causes of a stillbirth and reviewing the care that had been provided, there is room to further strengthen these processes. Although many parents are satisfied with the results of these reviews, others feel they have not always been listened to, or that they have not had access to all the facts. Still other parents are concerned that the lessons revealed in these reviews are not always put into practice.

Over the years there have been calls from bereaved parents, charities and others for a more transparent and independent process for determining the causes of, and learning from, stillbirths. It is time we considered this important and sensitive issue in detail.

Some of those calling for change have identified coronial investigations as the way to deliver an improved process, while the Chief Coroner for England and Wales has repeated his call for proper consideration of the question whether or not to give coroners powers to investigate stillbirths.

We are therefore very pleased to publish this consultation document, which seeks views on proposals for introducing coronial investigations of stillbirth cases in England and Wales. This consultation has been prepared jointly by the Ministry of Justice and the Department of Health and Social Care and is an important step towards delivering the Government's commitment to reduce the rate of stillbirths.

In addition to introducing greater transparency to the way in which stillbirths are investigated, the Government's proposals would ensure that bereaved parents are involved at all stages of the investigation, and that any learning that can be taken from such investigations is disseminated across the health system to help prevent future avoidable stillbirths.

At the same time as the Government has been developing its proposals, a Private Member's Bill, Tim Loughton MP's Civil Partnerships, Marriages and Deaths (Registration Etc) Bill, has been making its way through Parliament. The Bill, if enacted, would place a duty on the Secretary of State to make arrangements for the preparation and publication of a report on whether, and if so how, coroners should investigate stillbirths. The Bill would also provide a power for the Lord Chancellor to make provision, through secondary legislation, for stillbirth investigations by coroners if, following publication of that report, this is considered appropriate.

We would encourage a wide range of people and organisations will respond to this consultation because it is important that we hear and consider all points of view. We are particularly keen to hear from bereaved parents, the organisations that support them or that provide advice to pregnant women, researchers, health professionals and healthcare providers, as well as from those working for coronial services.

We will consider all responses carefully and will publish the Government's response to the consultation later this year.





Edward Argar Parliamentary Under Secretary of State for Justice

up i per

Jackie Doyle-Price

Parliamentary Under-Secretary of State for Mental Health, Inequalities and Suicide Prevention

Executive summary

This consultation follows from a commitment made by what is now the Department of Health and Social Care in November 2017 that it would work with the Ministry of Justice to develop proposals for coroners to investigate stillbirths.

The Government is consulting on a number of proposals which aim to:

- bring greater independence to the way stillbirths are investigated;
- ensure transparency and enhance the involvement of bereaved parents in stillbirth investigation processes, including in the development of recommendations aimed at improving maternity care; and
- effectively disseminate learning from investigations across the health system to help prevent future avoidable stillbirths.

There are currently several well-established processes in place for investigating the causes of stillbirths, which are set out in the background to this consultation. It is within this context that coroners would undertake investigation of stillbirths. However, we are not seeking to replace the important role the NHS plays. Rather, coronial investigations will supplement and support those investigations and ensure that coroners can contribute to the learning and play a role in reducing the stillbirth rate.

Chapter 1 of this document considers the need for coronial investigation of stillbirths. In recent years, the Department of Health and Social Care and the NHS have taken steps to improve the quality and transparency of reviews and investigations into deaths but not all of these initiatives include stillbirths. Concerns remain that most reviews and investigations are conducted within the local service in which the stillbirth occurred, with inadequate or no independent scrutiny. In some cases, parents do not receive a full explanation about the circumstances of their baby's death and what the service is doing to ensure that avoidable stillbirths with similar causes do not happen again. Some bereaved parents, charities and other interested parties have proposed that coroners' inquests that are conducted outside of the NHS in open court would ensure the quality and transparency of investigations and also provide a mechanism to hold providers to account for system improvements.

Chapter 2 explores coroners' duties and the potential outcomes from their investigations into stillbirths. We envisage that any determinations made by a coroner will largely reflect coroners' current duties when investigating a death. We propose that coroners should consider whether any lessons can be learned from how it was that a particular baby did not survive which could help prevent future stillbirths or otherwise improve the safety of, and care provided to, pregnant women. If the coroner concludes there are no lessons to be learned following the inquest, this should also be declared.

Chapter 3 considers the procedural aspects of a coroner's investigation, including the sequencing between coronial and non-coronial investigations. We propose that the principles underpinning coronial investigations of stillbirths should reflect those which currently form the basis of coronial investigations of deaths. Where non-coronial investigations of stillbirths (other than a criminal investigation or a public inquiry) are underway, we propose that coroners have the power to schedule the inquest so that, where appropriate, other investigations can first be concluded. We also propose that,

where a person is charged with the offence of child destruction or any offence associated with it or with the stillbirth, or where there is a public inquiry into matters relating to the stillbirth being investigated by the coroner, the coronial investigation should be suspended until the criminal proceedings or the public inquiry have concluded. We envisage that coroners' investigations could draw heavily on the reports and findings of non-coronial investigations.

Chapter 4 looks at the powers that are exercised by coroners in investigating a stillbirth. We propose that coroners should have the same powers in relation to evidence, documentation and witnesses, as well as in ordering medical examinations, as they do for death investigations now.

In Chapter 5, we explore which stillbirths should be in scope of a coroner's investigation. We propose that coronial investigations should be limited to term (also referred to as 'full-term') as well as post-term stillbirths, that is all stillbirths from 37 weeks and 0 days of gestation. We believe this subset of stillbirths would provide the richest source of learning to establish the causes of stillbirth, whether different care could have produced a different outcome, and to recommend changes to clinical practice that could minimise the risk of similar stillbirths.

Chapter 6 looks at the process for registering a stillbirth when it is reported to the coroner. We propose that term and post-term stillbirths should be registered only after the investigation has been concluded.

Chapter 7 sets out a series of specific questions on the impact of the proposals introduced in chapters 1 to 6.

Chapter 8 concludes the consultation, seeking views on our proposals in light of the Public Sector Equality Duty.

Introduction

This consultation seeks views on proposals for introducing coronial investigations of stillbirth cases in England and Wales.

A Welsh language consultation paper is available at <u>https://consult.justice.gov.uk/digital-communications/coronial-investigations-of-stillbirths</u>.

An Impact Assessment published in parallel with this consultation indicates that the following are likely to be particularly affected by the policy being consulted upon: parents of stillborn babies; coroners, their officers and staff; the Chief Coroner; local authorities; the General Register Office (GRO) and registrars; the Office for National Statistics (ONS); NHS pathology services; providers of maternity services and staff; NHS Improvement; the Healthcare Safety Investigation Branch (HSIB); NHS Resolution (England) and NHS Wales Shared Services Partnership (NWSSP) Legal & Risk Services.

The proposals are also likely to lead to additional costs and/or savings for the public sector.

The Impact Assessment is available at: <u>https://consult.justice.gov.uk/digital-</u>communications/coronial-investigations-of-stillbirths.

We would welcome comments on the Impact Assessment. Specific questions on the Impact Assessment can be found at chapters 7 and 8 (p. 30 and 33 respectively).

Copies of the consultation paper and Impact Assessment are being sent to the consultees listed at <u>Annex A</u>. This list is not meant to be exhaustive or exclusive and responses are welcomed from anyone with an interest in or views on the contents of this paper.

Background

- 1. A glossary of terms used in this document is available at <u>Annex C</u>. Words included in the glossary are <u>highlighted</u>. Clicking on a highlighted word will redirect you to its definition in the glossary.
- 2. This section summarises key background information about coronial investigations, the National Maternity Safety Ambition and current processes for investigating the causes of stillbirths. Should you need further information, a list of useful links is provided at Annex B.

Stillbirths and the National Maternity Safety Ambition

- 3. The <u>stillbirth</u> of a <u>baby</u> is a distressing experience for parents and families. Bereaved parents will want to know why their baby was not born alive.
- 4. A stillbirth is the loss of a baby before or during birth. Both miscarriage and stillbirth describe pregnancy loss, but are distinguished from each other by when the loss occurs. The Births and Deaths Registration Act 1953 provides a precise definition of stillbirth which specifies that the pregnancy must have concluded after the twenty-fourth week of pregnancy (that is from 24⁺⁰ weeks of gestation, i.e. 24 weeks + 0 days).¹

Babies born or stillborn from **37⁺⁰ weeks of gestation** are considered to be at <u>'term</u>' or at <u>'full term</u>'.² They are said to be stillborn <u>'post term</u>' from **42⁺⁰ weeks**.

5. In 2016, there were 3,112 stillbirths in England and Wales – a rate of 4.4 per 1,000 total births, 936 of which occurred at or post term.³ Whilst the stillbirth rate has been decreasing since the 1980s and is at historically low levels, England and Wales currently lag behind some other comparable countries whose stillbirth rates are lower and have been falling faster.⁴

The latest Office for National Statistics (ONS) statistical bulletin on birth characteristics in England and Wales reports that there were **2,830** babies stillborn in 2017, with **808** stillborn at or post term,⁵ which is a decrease from the 2016 figure above. These are preliminary figures and final statistics are expected to be published in spring 2019 as part of the ONS child mortality statistical bulletin for 2017.

¹ For the sake of clarity, gestational age is expressed in weeks and days throughout this document. Any reference to (for example) 24⁺⁰ weeks should be read as 24 weeks + 0 days.

² For the purposes of this document, 'term' and 'full term' are taken to be equivalent and interchangeable.

³ Source: See reference 3 at Annex D, p. 49.

⁴ Source: See reference 11 at <u>Annex D</u>, p. 50.

⁵ Source: See reference 2 at <u>Annex D</u>, p. 49.

- 6. In October 2015, the then Secretary of State for Health set a national ambition to halve, by 2030, the rates of stillbirths, neonatal and maternal deaths and brain injuries that occur during or soon after birth. In November 2017, he published Safer Maternity Care Progress and Next Steps, the Government's refreshed Maternity Safety Strategy, and brought forward the target date to achieve the National Maternity Safety Ambition from 2030 to 2025.
- 7. As part of this announcement, the Department of Health and Social Care (DHSC) committed to work with the Ministry of Justice (MoJ) to develop proposals for coroners to investigate stillbirths:

As part of the work to improve the investigation of and learning from stillbirths and neonatal deaths, the Government will consider with interested parties how coroners could carry out an investigation into those babies who are stillborn at term, i.e. at 37 weeks gestation and over. In doing so, we will engage with Welsh colleagues on how this would impact the Devolved Administration in Wales.

Safer Maternity Care – Progress and Next Steps, November 2017⁶

8. This consultation flows from this commitment and seeks views on proposals for the introduction of coronial investigations into stillbirth cases.

Current processes for investigating the causes of stillbirths

- 9. The NHS <u>National Quality Board</u>'s Guidance on Learning from Deaths⁷ sets out that each NHS Trust or Foundation Trust in England should have a published policy on how it reviews (or investigates) and learns from the deaths of patients who die under its management and care, including stillbirths.
- 10. Case note reviews and in-depth investigations enable NHS organisations and clinicians to understand how and why a death or stillbirth occurred, so that lessons can be learned and changes made to prevent avoidable deaths or stillbirths from similar causes from happening again.
- 11. NHS Improvement encourages healthcare staff and the general public to report all <u>patient safety incidents</u> (unintended or unexpected incidents which could have, or did, lead to harm for one or more patients) to the <u>National Reporting and Learning System</u> (NRLS). NHS organisations in Wales are required to report all patient safety incidents into the NRLS and manage these incidents locally under <u>Putting Things</u> <u>Right</u>,⁸ the NHS Wales procedure for the management of concerns raised by patients.
- 12. Where an event has particularly significant consequences, or presents great potential for learning, it should be addressed as a <u>Serious Incident</u>. To that end, NHS England has established a <u>Serious Incident Framework</u> (SIF)⁹ which describes the process and procedures that should be followed to help ensure that Serious Incidents are reviewed or investigated thoroughly and learned from to prevent the likelihood of

⁶ Source: See reference 4 at Annex D, p. 49.

⁷ Source: See reference 13 at Annex D, p. 50.

⁸ Source: See reference 15 at Annex D, p. 50.

⁹ Source: See reference 14 at Annex D, p. 50.

similar incidents happening again. NHS organisations in Wales also use the SIF, although adapted for the Wales context.

- 13. Under the SIF, in most cases, reviews and investigations are undertaken by the care provider where the incident occurred (i.e. the NHS Trust or Foundation Trust). Independent investigations (undertaken by investigators that do not work for the care provider) should be commissioned by the <u>commissioner of care</u> (for a provider-focused investigation looking into the specific care given to a patient or patients by one or more providers) or by <u>NHS England Regional Teams</u> or <u>NHS Wales Local Health Boards</u> (where a wider independent investigation of the role of the commissioning system or the configuration of services is needed such investigations will usually require a regionally or centrally led response).
- 14. The SIF sets out that an investigation team must hold an early meeting with the affected family to explain what action is being taken, how they can be informed, what support processes have been put in place and what they can expect from the investigation. The family must also:
 - have access to the necessary information and should have the opportunity to express any concerns and questions;
 - have the opportunity to inform the terms of reference for investigations and be provided with the terms of reference to ensure their questions are reflected;
 - be given the opportunity to contribute to the process of investigation (e.g. by giving evidence);
 - have access to the findings of any investigation, including interim findings; and
 - respond/comment on the findings and recommendations outlined in the final report, and be assured that this will be considered as part of the quality assurance and closure process undertaken by the commissioner.
- 15. To support NHS providers and commissioners in their investigations into Serious Incidents involving stillbirths or neonatal deaths, the DHSC in England and the Welsh and Scottish Governments jointly funded <u>MBRRACE-UK</u>¹⁰ to develop a standardised <u>Perinatal Mortality Review Tool</u> (PMRT). The PMRT was launched in February 2018 and is now being used by every NHS Trust in England and Health Board in Wales with maternity and neonatal services to undertake systematic, multidisciplinary, high quality reviews of the circumstances and the care leading up to and surrounding each stillbirth and neonatal death.
- 16. In November 2017, the Government provided funding for the <u>Healthcare Safety</u> <u>Investigation Branch</u> (HSIB) to develop investigation standards and conduct independent investigations into all maternity outcomes in England that meet the criteria for notification to the Royal College of Obstetricians and Gynaecologists' <u>Each Baby Counts</u> Programme and maternal deaths. These include term <u>intrapartum</u> stillbirths when the baby was known to be alive at the start of labour but was born with no <u>signs of life</u> due to potentially avoidable incidents occurring during labour or birth. Other stillbirths that occur from 37⁺⁰ weeks of gestation but before the

¹⁰ Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK. See definition in the glossary (Annex C), at p. 45.

start of labour are not independently investigated by the HSIB. The HSIB has no remit in Wales.

- 17. In April 2018, the HSIB began a phased roll out of individual maternity investigations with national coverage across England anticipated by March 2019. HSIB maternity investigations are focused on learning and provide patients and families with a full account of what happened in the individual case. They replace NHS England Trusts' internal Serious Incident investigations, but Trusts will still carry out case reviews of stillbirths using the PMRT. In Wales, Serious Incident investigations continue following any stillbirth.
- 18. The HSIB will involve families throughout the investigation and are in the process of developing an effective family engagement service. An HSIB maternity investigation report will include the terms of reference, the process of investigation, the evidence and recommendations for improvement both at an organisational and national level. Reports concerning individual cases will only be shared with the family, the organisation, and clinicians who were involved in the incident.
- 19. Funded by the DHSC and hosted by NHS Improvement, the HSIB is operationally independent of NHS England and other NHS organisations. It is also independent from all the regulatory bodies like the <u>Care Quality Commission</u> (CQC).
- 20. The Government has published draft legislation to establish a new statutorily independent body to take forward the work of the current HSIB. The draft legislation has been subject to pre-legislative scrutiny, and the Joint Committee tasked with this review recommended that the conduct of maternity investigations should be recognised as the responsibility of NHS Improvement.¹¹ In response, the Government set out its intentions to allow the current maternity investigations programme to complete its rollout to all healthcare regions in England and continue for a limited period so that the learning and benefit can be gained from these investigations, whether or not the new body has been established in the meantime.¹²
- 21. It also proposed to include provision in a revised Bill to allow the new body to undertake the maternity investigations, and that there should be flexibility in how long the maternity investigations should continue under the new body's remit to allow appropriate lessons to be learnt and to determine where these investigations might best sit in the future. This will ensure that the establishment of the new body does not, in itself, bring the programme to a premature end and should allow the benefits of the programme to be fully realised.

More information on existing processes for investigating the causes of stillbirths can be found using the **useful links** at <u>Annex B</u>, p. 40.

22. Over the years, there have been calls from some bereaved parents, charities and other interested parties for a more independent and transparent process for determining the cause of stillbirths, which ensures that lessons are learnt from past experiences. Some of those calling for change have identified coronial inquests that are conducted in open court by independent judicial officers as an option for

¹¹ Source: See reference 10 at Annex D, p. 50.

¹² Source: See reference 5 at Annex D, p. 49.

delivering an improved process, while the <u>Chief Coroner for England and Wales</u> has included the question of whether stillbirths should be reportable cases in his 2018-2019 development plan. Under separate legislation, coroners in Northern Ireland have powers to investigate stillbirths.

23. It is in this context that the Government has been considering the role, if any, that coroners in England and Wales should have in investigating and determining the cause of stillbirths.

Coroners and coronial investigations

- 24. <u>Coroners</u> are independent judicial office-holders who investigate deaths in certain defined circumstances to establish who the deceased was and how, when and where they died.
- 25. Coroners conduct <u>inquests</u>, which are investigations held in public that very occasionally involve a jury. They produce a <u>conclusion</u> (in the past referred to as a verdict) following an inquest. Where a coroner calls a jury, it is the jury that determines the conclusion.
- 26. Coroners do not conduct inquests into deaths where a qualified <u>attending doctor</u> is able to confirm the cause of death and that the death was natural, except where the deceased died whilst in <u>custody</u> or otherwise in <u>state detention</u>. However, even where the doctor is able to determine the precise natural cause of death and issues a <u>Medical Certificate of Cause of Death</u> (MCCD) to the family, a coroner may still become involved if any person is concerned that the death was suspicious.

In 2017, 43% of all deaths in England and Wales were reported to a coroner while 14% of reported deaths (6% of all registered deaths) had an inquest.¹³

- 27. In determining whether a death requires an inquest, coroners can make <u>preliminary</u> inquiries and may start an investigation. If at any point the coroner determines that the death was from natural causes (and did not occur in custody or state detention), the investigation will cease and a report may be sent to the <u>registrar</u>. Where a postmortem examination has been held (see below), the registrar will register the death without an MCCD. Otherwise, the coroner will give the doctor permission to issue an MCCD.
- 28. During their investigation, or even during preliminary inquiries, coroners may request a medical <u>post-mortem examination</u> of the body.¹⁴ Coroners will commission the medical tests which are the most likely to produce relevant information on the cause of death.

¹³ Source: See reference 1 at Annex D, p. 49.

¹⁴ For the purpose of the proposals in this document, this will be referred to as a 'medical examination' where in relation to a stillborn baby.

In 2017, a post-mortem examination was requested for 37% of all deaths reported to coroners in England and Wales.

- 29. Similarly, coroners can order access to various types of information during the course of an investigation. They may require any person to provide a written statement, produce any document relevant to the investigation or, for inspection, examination or testing purposes, produce anything else which is relevant to the investigation. Coroners have a duty to copy documents to an <u>interested person</u> upon request, subject to certain specified restrictions. This may include the deceased's medical records.
- 30. A conclusion may be issued in '<u>short form</u>' if the cause of death can be ascertained. Where there is insufficient evidence, an <u>'open' conclusion</u> is given. Sometimes the coroner or jury may record a more detailed <u>'narrative' conclusion</u> about the death.
- 31. A coroner or jury is prevented in law from apportioning blame or determining either criminal or civil liability. However, the facts presented at an inquest or the conclusion made by the coroner or jury may be used as evidence in separate criminal or civil proceedings.
- 32. A coroner must suspend their investigation if requested by a prosecuting authority where someone may be charged with an offence involving the death which the coroner is investigating. The same applies if the coroner becomes aware that someone charged with a homicide offence has appeared before a magistrates' court or has been charged on an indictment (i.e. accused of an offence to be tried in the Crown Court, generally an offence regarded as particularly serious). In such cases any inquest must be adjourned.
- 33. Similarly, a coroner must adjourn an inquest and notify the Director of Public Prosecutions if it appears to them that the death is likely to have been due to a homicide and that a person may be charged in relation to the offence.
- 34. Where anything that is revealed by the coroner's investigation or at the inquest poses a risk that other deaths may occur under similar circumstances, the coroner will issue a **report to Prevent Future Deaths** (PFD) (sometimes referred to as a 'Regulation 28 report') to those who may be able to mitigate that risk. Anyone issued with a PFD report is required by law to respond in writing setting out what action they have taken or will take in response to the report.
- 35. Under current legislation coroners cannot investigate deaths when it is known that the baby was not born alive. If there is doubt whether a baby was born alive or not, a coroner can investigate (which could include holding an inquest), but must halt that investigation if they conclude that the baby was stillborn.

In about a dozen or fewer cases each year, an investigation of a deceased new born baby leads to an inquest that concludes that the baby was in fact stillborn.

 Further information on the role of coroners is available in both English and Welsh at: https://www.gov.uk/government/publications/guide-to-coroner-services-and-coronerinvestigations-a-short-guide.

The proposals

37. The following chapters set out the case for introducing coronial investigations of stillbirths and proposals as to how these could be conducted. Specific consultation questions can be found at the end of each chapter, and are also compiled in a questionnaire at <u>Annex D</u>.

Chapter 1 – The need for coronial investigations of stillbirths

- 38. This chapter considers the gaps in current processes for investigating unexpected stillbirths that could potentially be filled by coroners.
- 39. National review programmes such as the MBRRACE-UK <u>Perinatal Mortality and</u> <u>Morbidity Confidential Enquiries</u>¹⁵ and the Royal College of Obstetricians and Gynaecologists' <u>Each Baby Counts</u> programme¹⁶ have identified that there is scope to improve the quality of investigations into the circumstances that have led to avoidable stillbirths occurring.
- 40. Parents and charities that we have spoken to have emphasised the need for a greater guarantee of independence and a transparent investigatory process that gives parents an opportunity to hear all the evidence of the facts that led to the unexpected stillbirth of their baby. They have also called for a system which ensures that lessons are being learnt and disseminated from past experiences.
- 41. The policy objectives underpinning the proposals in this consultation are, therefore:
 - to provide an independent assessment of the facts and causes of the stillbirth being investigated;
 - to provide for transparent investigations which give parents an opportunity to express their views on the circumstances leading to the stillbirth of their baby and keep them engaged and informed throughout the process; and
 - to contribute to system-wide learning about the causes of stillbirths and the circumstances leading to them, with a view to contributing to the wider health-system efforts being made to improve maternity outcomes.
- 42. In recent years, investigations undertaken by local health services into deaths and stillbirths have become increasingly transparent and supported by an ever-stronger range of procedural safeguards. *National Guidance on Learning from Deaths* published in March 2017 set out a national framework for NHS Trusts and Foundation Trusts on identifying, reporting, investigating and learning from deaths in care.¹⁷ It is complemented by guidance on conducting child death reviews in England released in

¹⁵ Source: See reference 7 at Annex D, p. 49.

¹⁶ Source: See reference 18 at Annex D, p. 51.

¹⁷ Source: See reference 14 at Annex D, p. 50.

October 2018 and designed to standardise practice nationally and enable thematic learning to prevent future deaths.¹⁸

- 43. Also, from April 2019, <u>medical examiners</u> will be introduced in the NHS to scrutinise the cause of death recorded on the MCCD. The ambition is that, in time, all non-coronial deaths will be reviewed by a medical examiner. The new system will provide a service to the bereaved, increasing transparency and offering them the opportunity to raise concerns.
- 44. Such independent scrutiny however, as currently proposed, will not encompass stillbirths. Medical examiners will be involved in the certification of natural deaths only.¹⁹ In relation to stillbirths, we believe that such a distinction between natural and unnatural cases would be impracticable. This is discussed further in Chapter 5.
- 45. Whilst the primary role of medical examiners will be to scrutinise the causes of natural deaths, medical examiners will also ensure compliance with the legal and procedural requirements associated with the current and proposed reformed processes of certification, investigation by coroners and registration of deaths. Medical examiners will have the knowledge of local and national clinical governance systems and an understanding of how medical examiners can work collaboratively to improve patient safety by identifying sub-optimal clinical and organisational performance.

More information on medical examiners can be found using the **useful links** at <u>Annex B</u>, p. 40.

- 46. As judicial office-holders, coroners provide an independent scrutiny of every death they are required to investigate, ascertaining the facts leading up to and the circumstances surrounding that death. Their duty is supported by a number of powers and safeguards set out in statute, which support an unbiased and transparent process.
- 47. We propose that, in line with their current role and duties in relation to the death of a living person, coroners should provide independent judicial scrutiny of a stillbirth. We believe they could give parents an authoritative and transparent account of what happened to their baby that will deliver wider public confidence.
- 48. Furthermore, whilst significant progress has been made in systematising and streamlining learning about the causes of all stillbirths, further work is required to improve the learning that can be made from each stillbirth so that, where changes to maternity care can be made to prevent similar avoidable stillbirths, these are disseminated and adopted by all maternity service providers.
- 49. It is our view that coroners possess the skills and experience from their existing statutory functions that make them ideally qualified to take forward a revised approach to investigating stillbirths. We believe this approach would deliver

¹⁸ Source: See reference 9 at Annex D, p. 50.

¹⁹ Except where the deceased died whilst in custody or under state detention.

independence and transparency, and add value to both local and national maternity system quality improvement processes.

50. If coroners investigate cases of stillbirth, we propose that these investigations should reflect the rules and principles that currently underpin the coronial process. These include the rules relating to the conduct of an inquest and the coroner's powers to access evidence.

Questions 1 – 2

Q1. Do you think coroners should have a role in investigating stillbirths? Please provide reasons.

Q2. Do you consider that coronial investigations of stillbirths would achieve the policy objectives set out in paragraph 41? Are there any other policy objectives that we should consider in improving the systems for determining the causes of stillbirths and delivering better services?

Chapter 2 – Duties of the coroner and investigation outcomes

- 51. This chapter explores the duties and potential outcomes from coroners' investigations into stillbirths. It considers the questions of what coroners could be asked to determine and how coroners could disseminate any learning points and recommendations.
- 52. Under section 5 of the Coroners and Justice Act 2009, a coroner is responsible for investigating certain unexpected deaths to ascertain, **who** died and **how**, **when** and **where** they died. Under Schedule 5 to the Act a coroner is responsible for reporting to any person who is able to take action to prevent future deaths whenever their investigation raises concerns that circumstances exist that put other lives at risk. The person who receives such a <u>report to Prevent Future Deaths</u> (PFD) (explained in paragraph 34 above) has a duty to respond in writing confirming what action they have taken.
- 53. We propose that, where a new duty is placed on the coroner to investigate a stillbirth, equivalent responsibilities are provided for but are adapted to reflect the policy objectives set out earlier in Chapter 1.
- 54. We think the coroner's determinations should provide a thorough account of the circumstances leading to the stillbirth of a baby, and identify any lessons that could be applied in any future pregnancies (for the mother concerned), to maternity service provision more generally (for maternity service providers and commissioners locally and nationally) and to any other relevant service provision (e.g. for social services or the police where applicable). The determinations could be as follows:
 - Who The coroner would seek to ascertain who the mother of the stillborn baby is and the baby's name where they have been given one. This would ensure that the baby can always be identified, either directly or indirectly.
 - **How** The coroner would seek to ascertain how it was that the baby came to be stillborn and, in doing so, aim to identify learning points for maternity care providers and future mothers.
 - When The coroner would seek to ascertain when <u>fetal death</u> occurred. Evidence demonstrates that it is often difficult to pinpoint the time of a fetal death so the duty would permit the coroner to give a conclusion in terms of a period within which it was likely that fetal death occurred. The coroner would additionally ascertain when the baby was <u>delivered</u> stillborn.
 - Where The coroner would seek to ascertain where the mother was at the time fetal death occurred or during the period when it was likely to have occurred and where she was when the stillborn baby was delivered.
- 55. Further to these determinations, which reflect the current duty of the coroner when investigating a death, we think coroners should consider whether any lessons can be learned which could prevent a future stillbirth or otherwise improve the safety of, and care provided to, pregnant women. If the coroner judges that there are no lessons to be learned following the inquest, this should be stated in their conclusions.

- 56. If the coroner concludes that there are lessons to be learned, we believe they should make appropriate recommendations to any person or organisation (including those not involved in the case) that would benefit from those recommendations (e.g. doctors, clinical professional organisations, academics etc.) and to anyone the coroner has identified as having power or authority to implement them (e.g. NHS Trust or Health Board Chief Executives).
- 57. At present, where something revealed at an investigation indicates a risk that other deaths may occur under similar circumstances, the coroner can report their concerns to any organisation or individual that the coroner believes is in a position to reduce or eliminate that risk, through a PFD report (see paragraphs 34 and 52 above). A PFD may not make formal recommendations to the organisations or persons it is addressed to.

Questions 3 – 9

Q3. Do you agree with the proposal about ascertaining who the mother of the stillborn baby is and the baby's name if they have been given one? Do you think there is anything else that should be considered?

Q4. Do you agree with the proposal about ascertaining how it was that the baby was not born alive? Do you think there is anything else that should be considered?

Q5. Do you agree with the proposal about ascertaining when fetal death occurred or was likely to have occurred and when the baby was delivered stillborn? Do you think there is anything else that should be considered?

Q6. Do you agree with the proposal about ascertaining where fetal death occurred or was likely to have occurred and where the stillborn baby was delivered? Do you think there is anything else that should be considered?

Q7. Do you agree that, as part of their findings, coroners should identify learning points and issue recommendations to the persons and bodies they consider relevant? If not, how do you think coroners should disseminate learning points?

Q8. Beyond identifying learning points in individual cases, do you think coroners should have a role in promoting best practice in antenatal care?

Q9. Is there anything else you would like to see come out of a coroner's investigation into a stillbirth? What other determinations should be made?

Chapter 3 – Procedures and links with non-coronial investigations

58. This chapter considers the procedural aspects of a coroner's investigation, including the sequencing between coronial and non-coronial investigations. The powers of the coroner are covered in Chapter 4.

Procedural arrangements for a coronial investigation into a case of stillbirth

- 59. We propose that the principles underpinning coronial investigations of stillbirths should reflect the fundamentals which currently form the basis of coronial investigations of deaths. The rules that would govern the opening and running of an investigation into the stillbirth of a baby would, therefore, be similar to the existing rules governing investigations into deaths.
- 60. Coronial jurisdiction is established in statute which sets out the circumstances in which an investigation must be undertaken. The coroner does not have discretion as to whether or not to investigate a death. <u>Interested persons</u>, such as the family of the deceased, are not required to consent or approve whether the coroner investigates a death.
- 61. We have considered whether the parents of a stillborn baby should be able to exercise a choice over whether or not a coronial investigation and inquest should take place. Our view is that there is no difference in principle between an inquest into the death of a recently born baby and that of a stillborn baby. Where the duty to investigate applies, an inquest should take place. Likewise, the suspension of any inquest can only take place as prescribed by statute.
- 62. We recognise that, where an inquest is held, it would take place at a particularly sensitive time for families. Coroners, together with their officers and staff, would ensure that parents are properly informed and listened to throughout the process. Organisations such as the <u>Coroners' Courts Support Service</u> (CCSS), as well as specialist organisations, may also be available to provide support to parents.

Links between coronial and non-coronial investigations

- 63. Following the death of a person there may be a range of different investigations that address some or all of the statutory determinations that coroners are required to make. These might be undertaken by agencies that were involved with the deceased person prior to death, or their regulators or inspectorates, such as social services and health providers, or those with statutory duties to investigate accidents or criminality, such as the police. These investigations operate separately from the coronial investigation and their findings often form part of the evidence that a coroner will draw on in their investigation and at the inquest.
- 64. We propose that, once coroners establish that their duty to investigate applies, they should open an inquest. However, we propose that coroners will have the power to determine the timetable for the conduct of the inquest so that, where appropriate, NHS and/or HSIB maternity investigations may first be concluded. In practice, coroners' investigations could draw heavily on the reports and findings of those done by the NHS and HSIB.

- 65. The coroner has powers and duties to suspend (and resume) an investigation into a death in certain circumstances related to criminal investigations and prosecutions²⁰ and to public inquires under the Inquiries Act 2005. These are provided for in Schedule 1 to the 2009 Act.
- 66. Whilst our purpose in considering coronial investigations into stillbirths is to provide parents with an independent and transparent investigation that contributes to the ongoing improvement of maternity services, we recognise that, in a small number of cases, a stillbirth may have come about by criminal actions or inactions.
- 67. We propose that a coroner will have the duty to suspend their investigation where a person is charged with the offence of <u>child destruction</u> or any offence associated with it or with the stillbirth, including any offence that relates to the conception of the stillborn baby. The coronial investigation should not be resumed until criminal proceedings have concluded or unless the relevant prosecuting authority does not object to the resumption.
- 68. In a small number of instances, a public inquiry may be investigating matters related to a stillbirth. As is currently the case for coronial investigations into deaths, we propose that, pending the outcome of such a public inquiry, a coroner should suspend any investigation into a stillbirth to which it relates.

Questions 10 – 12

Q10. Do you agree that no consent or permission from the bereaved parents, or anyone else, should be required for a coronial investigation into a stillbirth to be opened? Please give your reasons.

Q11. Do you agree that the coroner's duty to hold an inquest should apply to investigations of stillbirths? Please give your reasons.

Q12. Do you agree with the proposals for the links and sequencing between coronial and non-coronial investigations? Please give your reasons.

²⁰ See paragraphs 32 and 33 in the Background section, at p. 13.

Chapter 4 – The powers of the coroner

- 69. This chapter looks at the powers that would be exercised by coroners in investigating stillbirths.
- 70. Coroners' existing powers are detailed in Schedule 5 to the Coroners and Justice Act 2009. These powers allow a coroner to assume legal custody of the body and to order medical tests including a post-mortem examination. They also give coroners the power to order the disclosure of documents and any other evidence they consider relevant to their investigation.
- 71. Coroners may also call witnesses to give evidence at an inquest. Any person called by the coroner to give evidence is under an obligation to comply with that request, except under certain limited circumstances set out in the 2009 Act. The coroner has a duty to allow any interested person²¹ to examine any witness but they must disallow any question put to the witness that the coroner considers irrelevant. No witness at an inquest is obliged to answer any question tending to self-incrimination.
- 72. These powers support coroners to fulfil their statutory duty to investigate certain deaths (i.e. those that are violent, unnatural or where the cause of death is unknown) and help to provide the most comprehensive picture of how a person came by their death.
- 73. With regard to stillbirths, we believe that coroners should have an equivalent set of powers and propose that coroners should have a right to legal custody of the stillborn baby and placenta. Placental pathology plays an important role in identifying the causes of stillbirths and provides invaluable information about how future stillbirths might be prevented. The proportion of stillbirths attributed to a placental cause in 2016 was 28.8%.²²
- 74. We propose that coroners have powers to order a medical examination and testing of the stillborn baby and/or the placenta for the purposes of making the statutory determinations described at Chapter 3.
- 75. We understand that some parents may be concerned that decisions on conducting an inquest include the undertaking of medical examinations of their stillborn baby. We have considered this issue carefully and it is our view that this is central to guaranteeing the independence of a coronial investigation and making sure that coroners have access to the information and evidence that is necessary for them to fulfil their statutory duty, just as they do for investigations into the death of a newborn.
- 76. We also understand that some clinicians may be concerned that introducing coronial investigations could lead to delays in receiving the results of medical examinations which could increase the distress the family experience and prevent clinicians from providing meaningful support for the affected families, especially for women who have become pregnant again.

²¹ Within the meaning of section 47 of the Coroners and Justice Act 2009. See '<u>interested person</u>' in the glossary (<u>Annex C</u>), at p. 44.

²² Source: See reference 6 at Annex D, p. 49.

77. As interested persons,²³ both parents and clinicians would have the right to request copies of a report of any medical examination held as part of the investigation, and copies of any documents relevant to the investigation, even during that investigation and before conclusions have been made.

Questions 13 – 16

Q13. Do you think coroners should have the same powers in relation to evidence, documentation and witnesses in stillbirth investigations, as well as in ordering medical examinations, as they do for death investigations now? Please give your reasons.

Q14. What, if any, other powers should coroners exercise to aid in their investigations into stillbirths?

Q15. Do you think it is appropriate for coroners to assume legal custody of the placenta? If not, why?

Q16. Do you agree that coroners should not have to obtain consent or permission from any third party in exercising their powers, except where existing rules already provide for such a requirement? Please give your reasons.

²³ Within the meaning of section 47 of the Coroners and Justice Act 2009. See 'interested person' in the glossary (Annex C), at p. 44.

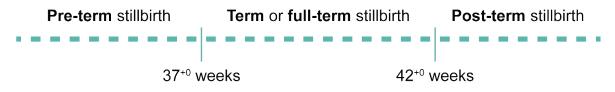
Chapter 5 – The extent of coronial jurisdiction in cases of stillbirth

78. This chapter considers which stillbirths should be in scope of a coroner's investigation. The key concepts used in this chapter are briefly explained below.

Key concepts

Pre-term, term and post-term stillbirth

- 79. <u>Gestational age</u> (age from the first day of the last menstrual period) is expressed in weeks and days throughout this document. Any reference to (for example) 24⁺⁰ weeks should be read as 24 weeks + 0 days.
- 80. Babies born or stillborn from 37⁺⁰ weeks of gestation are considered to be at '<u>term</u>' or at '<u>full term</u>'. They are said to be stillborn '<u>post term</u>' from 42⁺⁰ weeks. For the purposes of this document, 'term' and 'full term' are taken to be equivalent and interchangeable.



Antepartum and intrapartum stillbirth

81. A baby is said to be stillborn <u>antepartum</u> when fetal death is known to have occurred before the onset of care in labour. A baby is said to be stillborn <u>intrapartum</u> when the baby was known to be alive at the onset of care in labour.

Antepartum stillbirth	Intrapartum stillbirth	Live birth
Start of car	re in labour De	elivery

Stillbirth cases to be in scope of a coronial investigation

- 82. We believe that coroners could be tasked with focusing on those stillbirths whose investigation meets all the objectives set out in Chapter 1, which are:
 - to provide an independent assessment of the facts and causes of the stillbirth being investigated;
 - to provide for transparent investigations which give parents an opportunity to express their views on the circumstances leading to the stillbirth of their baby and keep them engaged and informed throughout the process; and
 - to contribute to system-wide learning about the causes of stillbirths and the circumstances leading to them, with a view to contributing to the wider health-system efforts being made to improve maternity outcomes.
- 83. In order to fulfil these objectives, and in particular to draw valuable lessons from the cases they investigate, coroners should investigate those stillbirths which are most likely to be deemed to be <u>amenable to care</u>. A stillbirth is amenable to care if, in the

light of the medical knowledge and technology available at the time of the stillbirth, all or most stillbirths from that cause could be avoided through good quality healthcare.²⁴ With this in mind, we have carefully considered the merits of coroners investigating all stillbirths or limiting their investigations to a defined subset of stillbirths such as those occurring in babies born at term or post term.

- 84. The *Lancet Stillbirth Series* found that in high-income countries, 90% of stillbirths occur in the <u>antepartum</u> period, often associated with lifestyle factors such as maternal age, obesity and smoking, and also with suboptimal <u>antenatal care</u>, including the failure to identify babies at risk.²⁵ In the UK, in 2016, almost two-thirds of stillbirths occurred in babies born before 37 weeks of gestation, indicating that <u>pre-term</u> delivery is a significant risk factor for stillbirth in this country.²⁶ A separate large multi-country analysis found that in two-thirds of pre-term <u>deliveries</u> the cause is unknown, even in high-income countries.²⁷ Such cases are not likely to be amenable to care and in our view may not warrant the involvement of a coroner.
- 85. The *Lancet Stillbirth Series* also found that stillbirths occurring during labour mostly happen at term and to infants who would have been expected to survive.²⁸ In the UK, a confidential enquiry conducted by MBRRACE-UK in 2015 concluded that in 78% of the <u>term intrapartum</u> stillbirths under study, improvements in care were identified which may have made a difference to the outcome for the baby²⁹. This may represent a single issue at one point in the care pathway with all remaining care being considered appropriate or multiple issues at one or more points on the care pathway.
- 86. Similarly, the Royal College of Obstetricians and Gynaecologists' Each Baby Counts 2018 progress report shows that while there was rarely one single cause of a term intrapartum stillbirth, or an early <u>neonatal death</u> or brain injury occurring in term births in the UK in 2016, 71% of the 955 cases considered (the majority of which were brain injuries) might have had a different outcome with different care.³⁰
- 87. Therefore, we propose that coronial investigations should be limited to 'term' or 'full-term', as well as 'post-term' stillbirths. This cohort of cases offers the best potential to identify the cause or causes of the stillbirth, whether different care could have produced a different outcome, and to recommend changes to clinical practice that could reduce the risk of similar stillbirths.
- 88. The Office for National Statistics (ONS) reports that term and post-term stillbirths constituted just under a third of all stillbirths in England and Wales in 2016: 936 (30%) out of a total of 3,112 stillbirths.

²⁵ Source: See reference 19 at Annex D, p. 51.

²⁴ Source: See reference 16 at Annex D, p. 50.

²⁶ Source: See reference 6 at Annex D, p. 49.

²⁷ Source: See reference 8 at Annex D, p. 50.

²⁸ Source: See reference 11 at Annex D, p. 50.

²⁹ Source: See reference 7 at Annex D, p. 49.

³⁰ Source: See reference 17 at Annex D, p. 51.

Determining gestational age

- 89. All pregnant women in England are offered an ultrasound scan, often referred to as the 'pregnancy dating scan', at around 8 to 14 weeks of pregnancy. Its purpose is to estimate gestational age and check the baby's development. The most accurate measurement for dating is the <u>crown-rump length</u> of the fetus, which can be done between 7 and 13 weeks of gestation.³¹ This method can assess gestational age ± 5 days with a 95% confidence limit, although it is acknowledged that ultrasound calculation of pregnancy duration can have a measurement error, due to inaccuracies in making the measurement, and because not all fetuses grow at exactly the same rate.³²
- 90. We recognise that there may be doubt or contention as to whether a stillborn baby was delivered before or after 37⁺⁰ weeks of gestation. In such a scenario, the coroner should conduct a **preliminary inquiry** and treat the question of whether the baby was stillborn at or before term as a priority. This is not unlike the current situation where there is doubt that a stillbirth occurred and it was possible that the baby was born alive before its death.
- 91. In some cases however, the coroner may open an inquest and only later discover that the baby was stillborn. Each year, in around a dozen inquests into the deaths of new born babies in England and Wales, the coroner concludes that the baby was in fact stillborn. In these cases, even though the coroner cannot issue any conclusion as to the cause of death, they should still issue a certificate to the registrar setting out the facts of the death as known. This avoids the need for a doctor to issue a Medical Certificate of Cause of Death (MCCD).
- 92. We propose that the same system applies where there is any doubt as to whether a stillborn baby was delivered before or after 37⁺⁰ weeks of gestation, and where an inquest is held and the coroner then discovers that the baby was delivered before term. We also propose that, where the inquest of a stillborn baby concludes that delivery took place before 37⁺⁰ weeks, the duty to identify lessons learnt and make recommendations will not apply.
- 93. We have considered whether some term stillbirths should not be subject to a coronial investigation, in the way that most natural deaths are not subject to the current coronial duty. We believe this approach may not be appropriate, as drawing a distinction between natural and unnatural term stillbirths would likely be impracticable and create a risk that some cases of term stillbirth where lessons could be learned would be missed.
- 94. Coroners would act in accordance with their duty to ascertain, by all means appropriate, the matters set out in Chapter 2, as they currently do when making their determinations about a death. However, where the cause of an unavoidable stillbirth is undisputed and well-documented, we would expect the investigatory process to be less demanding and often more concise than for other cases.

³¹ Source: See reference 18 at Annex D, p. 51.

³² Source: See reference 12 at Annex D, p. 50.

Questions 17 – 19

Q17. Do you agree with the proposal to investigate only full-term stillbirths, or do you think the obligation to investigate should encompass all stillbirths?

Q18. If you answered 'no' to both parts of the question above, which group of stillbirths do you think should be investigated?

Q19. Do you agree that coroners should investigate all full-term stillbirths (i.e. all stillbirths in scope)? Or do you think a further distinction should be made within this category?

Chapter 6 – Registration of a stillbirth where the coroner is involved

- 95. This chapter looks at the process for registering a stillbirth when it is reported to the coroner. A flow chart is provided at pages 28 and 29.
- 96. <u>Registrars</u> are required by law to report a death to the coroner in certain defined circumstances, such as where they have been unable to obtain a duly completed certificate of cause of death, where the cause of death appears to be unknown or otherwise where they have a reason to believe that the death was unnatural or of violent cause.
- 97. We do not propose that a duty be extended to the registrar to report stillbirths that happen on or after 37⁺⁰ weeks of gestation. However, just as for deaths, anyone could refer a stillbirth that takes place at or after 37⁺⁰ weeks of gestation to the coroner, including any member of the medical staff involved in the mother's care, the trust or unit manager, or the parents of the stillborn baby.
- 98. As part of the 2016 consultation on reforms to death certification, the Government consulted on draft Notification of Deaths Regulations which set out the circumstances under which medical practitioners will have a statutory duty to report a death to the coroner. In the Government's consultation response, published in June 2018, we confirmed our policy and that we would introduce regulations. Where such regulations are made we would amend them to include a duty to report a stillbirth for which the coroner had a duty to investigate.
- 99. Where a stillbirth has been reported to the coroner, as is the case for a death, we propose that it should not be registered until:
 - a) the registrar has received a coroner's certificate or a notification that the coroner does not intend to hold an inquest because the stillborn baby was delivered before term

or, where the coroner's duty to investigate applies;

- b) the inquest has been concluded and the coroner has ascertained the particulars of stillbirth required to be registered.
- 100. If a coroner notifies the registrar of his intention not to proceed further with the investigation (because they have found that the stillbirth occurred before 37⁺⁰ weeks of gestation) and no medical examination of the baby has been made, the attending medical practitioner would need to issue a <u>Medical Certificate of Stillbirth</u> for the stillbirth to be registered. A Medical Certificate of Stillbirth would not be required, however, where a medical examination had been made upon the coroner's request and the coroner subsequently discontinues his investigation.
- 101. Where an investigation is taking place and the coroner is under a duty to hold an inquest, we propose that the coroner issue a Certificate of the Fact of Stillbirth which would serve as a provisional certificate to facilitate the completion of administrative procedures related to the stillbirth. This would include procedures to claim the rights and benefits parents of a stillborn baby are entitled to.

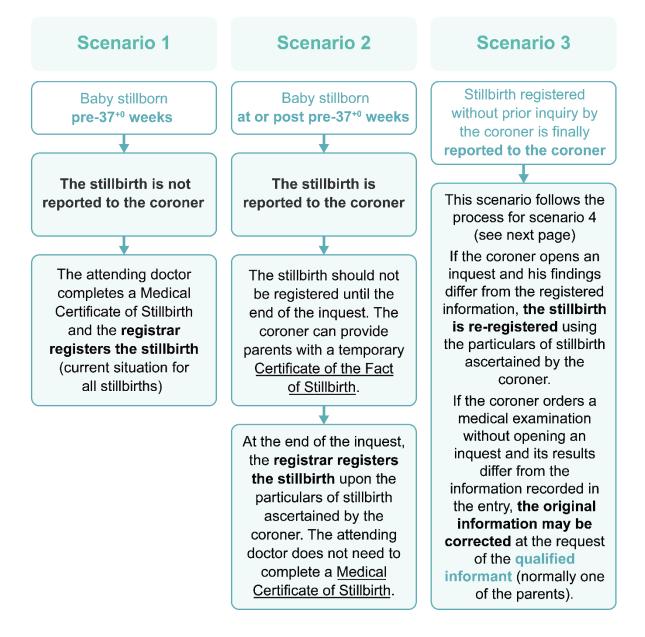
Question 20

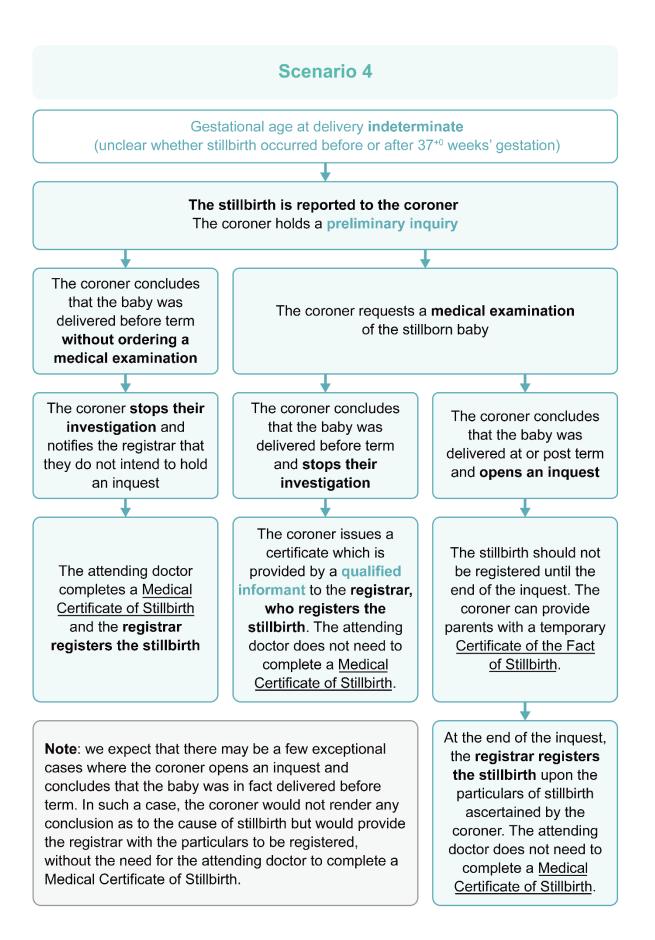
Q20. Do you agree with the above proposal as to how a stillbirth should be registered when a coronial investigation has taken place?

Registration of a stillbirth where the coroner is involved - flow chart

This flow chart describes the four possible scenarios for the process of registering a stillbirth under our proposals. This chart should be considered alongside paragraphs 95 to 101. Our four scenarios rest on the following premises:

- In scenario 1, there is no doubt that the baby was stillborn before 37⁺⁰ weeks' gestation.
- In **scenario 2**, there is no doubt that the baby was stillborn at or after 37⁺⁰ weeks' gestation.
- In **scenario 3**, a stillbirth that has been registered with a Medical Certificate of Stillbirth without any prior inquiry by the coroner is finally reported to the coroner.
- In scenario 4, it is unclear whether the baby was born before or from 37⁺⁰ weeks' gestation.





Chapter 7 – Impact Assessment

- 102. This chapter sets out a series of specific questions on the impact of the proposals introduced in chapters 1 to 6. The impact of these proposals on groups who share a relevant protected characteristic under the Equality Act 2010 is considered in chapter 8.
- 103. Our assessments of the potential impact of the proposals set out in Chapters 1 to 6 have been published alongside this consultation document as an Impact Assessment (IA). The IA is available at: <u>https://consult.justice.gov.uk/digital-</u> communications/coronial-investigations-of-stillbirths.
- 104. The IA indicates that the following are likely to be particularly affected by the policy being consulted upon: parents of stillborn babies; coroners, their officers and staff; the Chief Coroner; local authorities; the General Register Office (GRO) and registrars; the Office for National Statistics (ONS); NHS pathology services; providers of maternity services and staff; NHS Improvement; the Healthcare Safety Investigation Branch (HSIB); NHS Resolution (England) and NHS Wales Shared Services Partnership (NWSSP) Legal & Risk Services.
- 105. The proposals are likely to lead to additional costs and/or savings for the public sector.

Additional Impact Assessment Questions

- 106. In the IA, we acknowledge that there are gaps in the research and statistical evidence available to help us understand the potential impact of our proposals. We would welcome any further information, evidence and comment which may help to address these gaps in any further assessment.
- 107. The main assumptions made are detailed in the **Key Assumptions** section of the IA. While we would value views and further evidence on all of the assumptions, we have highlighted below those in particular that we would appreciate more detailed data or feedback on.
- 108. The following questions relate to, and should be cross-referenced with, the Impact Assessment published alongside this consultation document.

Questions 21 - 28 (IA)

Proportion of investigations requiring a post-mortem examination and the cost of a post-mortem examination

Question 21.1 (IA): Do you agree with the assumption that the majority of stillbirth investigations would require a post-mortem examination (in the IA we have used an upper bound estimate of 100%)? If not, please explain why, preferably with supporting evidence.

Question 21.2 (IA): We have also assumed that an upper bound estimate of the cost³³ of a post-mortem examination for a stillbirth is £2,000. We recognise that this varies by region and so would appreciate views on this, and particularly any evidence on the average cost of a stillbirth post-mortem examination in your region.

Documentary inquest and inquest requiring witnesses to attend and give oral evidence

Question 22 (IA): Do you agree with the assumption that the inquest in approximately 20% of stillbirth investigations could be conducted solely on the basis of written evidence (this is sometimes referred to as a documentary inquest) and approximately 80% would require witnesses to attend and give oral evidence? If not, please explain why, preferably with supporting evidence.

Average time needed by coroners to complete a stillbirth case

Question 23 (IA): Do you agree with our assumption that a stillbirth case is complex in nature and would require around 4 hours of coroner's time and around 15 hours of coroner's officer time to review the case (excluding time spent at the inquest)? If not, please explain why, preferably with supporting evidence.

Question 24 (IA): Do you agree with our assumptions that:

- the investigation of stillbirth cases is likely to be undertaken by a senior or area coroner and would be resourced by increasing the number of assistant coroners to deal with the less complex cases currently undertaken by senior or area coroners; and
- (ii) assistant coroners would take the same number of hours on these cases that have been redistributed as Senior/Area coroners?

Average cost of inquest

Question 25 (IA): We would welcome views on the assumption in the IA that the average cost of a documentary inquest is $\pounds400$ and the average cost of a full inquest is $\pounds3,000$ (including coroner costs, investigating officer costs, witness costs and court building costs).

³³ Please note that this is the average cost of undertaking a post-mortem examination rather than the 'price' of a post-mortem examination – i.e. it's the costs borne by the supplier of post-mortem examinations, not the costs recovered from or paid by commissioners of post-mortem examinations.

Maximum level of NHS staff involvement

Question 26 (IA): Do you agree with our assumption that a coronial investigation of a stillbirth could require up to 6 members of NHS staff (medical consultant, junior doctor, 3 midwives/nurses and an NHS manager) to each provide up to a maximum of 7 hours of their time?

Paediatric and perinatal pathology

Question 27.1 (IA): Do you agree with our assumption that 1 full-time equivalent (FTE) perinatal pathologist is capable of undertaking between 100 and 200 stillbirth post-mortem examinations a year whereby if coronial investigations of stillbirths result in an additional 450 post-mortem examinations per year, this implies between 2.25 and 4.5 additional FTE perinatal pathologists would be required to meet the anticipated additional workload? If not, please explain why, preferably with supporting evidence.

Question 27.2 (IA): What percentage of the additional stillbirth post-mortem examinations that may be requested in your region would there be a capacity and willingness to complete?

Question 27.3 (IA): If your answer to question 27.2 is not 100%, what alternative funding arrangements do you think would be required to support the increased demand for post-mortem examinations of term stillbirths?

Existing investigations of stillbirths

Question 28 (IA): What impact do you think coronial investigations of stillbirths will have on investigations of stillbirths undertaken: a) locally; and b) by the Healthcare Safety Investigation Branch (HSIB)? Will the current investigation of stillbirths continue independently of coronial investigations or will some current activity be displaced or otherwise impacted by coronial investigation of stillbirths?

Chapter 8 – Equalities

- 109. Section 149 of the Equality Act 2010 ("the 2010 Act") requires Ministers and the Departments, when exercising their functions, to have 'due regard' to the need to:
 - eliminate discrimination, harassment, victimisation and any other conduct prohibited by the 2010 Act;
 - advance equality of opportunity between different groups (those who share a relevant protected characteristic and those who do not); and
 - foster good relations between different groups (those who share a relevant protected characteristic and those who do not).
- 110. Paying 'due regard' needs to be considered against the nine "protected characteristics" under the 2010 Act namely race, sex, disability, sexual orientation, religion and belief, age, marriage and civil partnership, gender reassignment, pregnancy and maternity.
- 111. We are currently gathering evidence to prepare an assessment of how the proposals set out in the consultation document or any policy introducing coronial investigations of stillbirths following this consultation would affect the aforementioned groups.
- 112. In order to help us make this assessment, we would welcome views on whether any groups with a protected characteristic may be affected by the proposals set out in this consultation document, and if so, how.

Question 29 (IA)

Q29 (IA). Do you think the proposals in chapters 1 to 6 may have any further impact on a group with a protected characteristic? If so, please explain what these impacts would be and which groups could be affected.

About you

Please use this section to tell us about yourself

Full name	
Job title or capacity in which you are responding to this consultation exercise (e.g. member of the public etc.)	
Date	
Company name/organisation (if applicable):	
Address	
Postcode	
If you would like us to acknowledge receipt of your response, please tick this box	(please tick box)
Address to which the acknowledgement should be	
sent, if different from above	

If you are a representative of a group, please tell us the name of the group and give a summary of the people or organisations that you represent.

Contact details/How to respond

Please respond by 18 June 2019 using the Ministry of Justice's online consultation hub at https://consult.justice.gov.uk/digital-communications/coronial-investigations-of-stillbirths.

You may also send your response via email to <u>CoronerReview@justice.gov.uk</u> or in hard copy to:

Coroners, Burial, Cremation and Inquiries Policy Team Ministry of Justice 102 Petty France London SW1H 9AJ

Responses will be received and processed by officials in both the Ministry of Justice and Department of Health and Social Care.

Complaints or comments

If you have any complaints or comments about the consultation process you should contact the Ministry of Justice at the above address.

Extra copies

Further paper copies of this consultation can be obtained from this address and it is also available on-line at https://consult.justice.gov.uk/digital-communications/coronial-investigations-of-stillbirths.

Publication of response

A paper summarising the responses to this consultation is due to be published by 10 September 2019. The response paper will be available on-line at https://consult.justice.gov.uk/digital-communications/coronial-investigations-of-stillbirths.

Representative groups

Representative groups are asked to give a summary of the people and organisations they represent when they respond.

Confidentiality

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA), the General Data Protection Regulation (GDPR) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information

we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Ministry.

The Ministry of Justice and the Department of Health and Social Care will process your personal data in accordance with the DPA and in the majority of circumstances, this will mean that your personal data will not be disclosed to third parties.

Consultation principles

The principles that Government departments and other public bodies should adopt for engaging stakeholders when developing policy and legislation are set out in the consultation principles.

https://www.gov.uk/government/publications/consultation-principles-guidance

Annex A – List of consultees (A–Z)

Copies of this consultation document are being sent to the following consultees. This list is not meant to be exhaustive or exclusive and responses are welcomed from anyone with an interest in or views on the subject covered by this paper. The consultation document and the Impact Assessment are available on-line at https://consult.justice.gov.uk/digital-communications/coronial-investigations-of-stillbirths.

Abigail's Footsteps Aching Arms Academy of Medical Royal Colleges Antenatal Results and Choices **Birthrights** Birth Trauma Association British Association of Perinatal Medicine British Pregnancy Advisory Service Campaign for Safer Births Child Bereavement UK Care and Social Services Inspectorate Wales Care Quality Commission Chief Coroner of England and Wales Coroners' Courts Support Service Coroner's Officers and Staff Association **Coroner Service Managers Cruse Bereavement Care General Medical Council** Health and Safety Executive INQUEST Law Society Local Registration Services Association Lord Chief Justice MBRRACE-UK Miscarriage Association **Multiple Births Foundation** National Bereavement Alliance National Childbirth Trust

National Panel for Registration

Nursing and Midwifery Council

Petals Charity

Royal College of Midwives

Royal College of Nursing

Royal College of Obstetricians and Gynaecologists

Royal College of Pathologists

Royal College of Paediatrics and Child Health

Sands (Stillbirth and neonatal death charity)

Saying Goodbye

Senior Coroners, Area Coroners and Assistant Coroners

The Coroners' Society of England and Wales

TAMBA (Twin and Multiple Births Association)

Tommy's

Winston's Wish

Annex B – Useful links (A–Z)

Care Quality Commission:

https://www.cqc.org.uk/

Chief Coroner's guidance and General advice:

https://www.judiciary.uk/related-offices-and-bodies/office-chief-coroner/guidance-law-sheets/

Death certification reforms:

https://www.gov.uk/government/consultations/death-certification-reforms

Each Baby Counts:

https://www.rcog.org.uk/eachbabycounts

Guide to coroner services and Coroner investigations – a short guide:

https://www.gov.uk/government/publications/guide-to-coroner-services-and-coroner-investigations-a-short-guide

Healthcare Safety Investigation Branch maternity investigations:

https://www.hsib.org.uk/maternity/

Medical examiners:

https://www.rcpath.org/profession/medical-examiners.html

Perinatal Mortality Review Tool:

https://www.npeu.ox.ac.uk/pmrt

Putting Things Right:

www.puttingthingsright.wales.nhs.uk

Safer Maternity Care – Progress and Next Steps:

https://www.gov.uk/government/publications/safer-maternity-care-progress-and-next-steps

Serious Incident Framework:

https://improvement.nhs.uk/resources/serious-incident-framework/

Annex C – Glossary (A–Z)

-	
Amenable to care	A stillbirth is considered amenable to care if, in the light of medical knowledge and technology available at the time of the stillbirth, all or most stillbirths from that cause could be avoided through good quality healthcare
Antenatal care	Antenatal care is the care provided by skilled healthcare professionals to pregnant women in order to ensure the best health conditions for both the mother and the baby during pregnancy.
Antepartum	A baby is said to be stillborn antepartum when delivered at or after 24 weeks + 0 days (24^{+0} weeks) of gestation and when <u>fetal death</u> (see definition below) is known to have occurred before the onset of care in labour.
Attending doctor	An attending doctor, for the purpose of completing a <u>Medical</u> <u>Certificate of Cause of Death</u> (see definition below), is generally accepted to mean a doctor who has cared for the patient during the illness that led to death and so is familiar with the patient's recent medical history, investigations and treatment.
	Further guidance on completion of the Medical Certificate of Cause of Death in England and Wales can be found at: https://www.gov.uk/government/publications/guidance-notes-for- completing-a-medical-certificate-of-cause-of-death
Baby	The word 'baby', for the purposes of this document, is used interchangeably to include references to a live new-born infant human, as well as an unborn fetus of any gestation, or a delivered fetus of any gestation showing no signs of life. It does not necessarily indicate viability, signs of life or any other meaning that may distinguish between live birth and stillbirth.
Care Quality Commission	The Care Quality Commission is the independent regulator of health and adult social care in England, established by the Health and Social Care Act 2008. One of its key functions is to review how care providers operate and assess their performance.
Chief Coroner	The Chief Coroner is head of the coroner system, providing national leadership for coroners in England and Wales. The Chief Coroner's main responsibilities include provide support, leadership and guidance for coroners and setting national standards.
	More information on the Chief Coroner can be found at: www.judiciary.uk/related-offices-and-bodies/office-chief-coroner/
Child destruction	Child destruction is the offence of wilfully causing a child to die before it has existence independent of its mother, with intent to destroy its life (see section 1 of the Infant Life (Preservation) Act 1929).

Commissioner of care	A commissioner of care, within the context of the <u>Serious</u> Incident Framework (see definition below), is an organisation responsible for assessing needs, planning and prioritising, purchasing and monitoring health services, to get the best health outcomes. In England, maternity services are commissioned by Clinical Commissioning Groups (groups of general practices that come together in each area to buy the best services for their patients and population).
Conclusion	A conclusion is the decision the coroner (or jury) reaches at the end of an inquest. The conclusion is recorded on a 'record of an inquest' form which includes the legal <u>determination</u> and <u>findings</u> (see definitions below).
	It may comprise one of the following ' short-form conclusions ': accident or misadventure; alcohol/drug related; industrial disease; lawful/unlawful killing; natural causes; open; road traffic collision; stillbirth; or suicide. An ' open conclusion ' may be given if there is insufficient evidence to enable the coroner or the jury to reach one of the other conclusions. Sometimes the coroner or jury may record a more detailed ' narrative conclusion ' about the death.
	Further information on coroner services can be found at: www.gov.uk/government/publications/guide-to-coroner-services- and-coroner-investigations-a-short-guide
Coroner	A coroner is an independent judicial office holder, appointed by a local authority (council) within the coroner area. Some coroners cover more than one local authority. Coroners are usually lawyers but sometimes doctors. Coroners work within a framework of law passed by Parliament.
	Further information on coroner services can be found at: www.gov.uk/government/publications/guide-to-coroner-services- and-coroner-investigations-a-short-guide
Coroners' Courts Support Service	The Coroners' Courts Support Service (CCSS) is a charity that provides practical and emotional support in some coroner areas for bereaved families attending inquests on the day. The CCSS trained volunteers can also talk to the family before the inquest about what will happen.
Crown-rump length	The crown-rump length (CRL) is a fetal measurement used to determine gestational age (see definition below). It corresponds to the length from the top of the fetus's head to the bottom of their buttocks.
Death in custody	A death in custody occurs where the deceased was subject to confinement as a prisoner or whilst under arrest by a police officer (see below for definition of <u>state detention</u>).

Delivery	The delivery of a baby, for the purposes of this document, refers to its complete expulsion or extraction from its mother, irrespective of the duration of pregnancy, viability, signs of life or whether or not the result is a stillbirth or live birth.
Determinations	Determinations by the coroner (or jury) refer to the identity of the deceased and how, when and where he or she came by his or her death (as required under sections 5 and 10 of the Coroners and Justice Act 2009).
Each Baby Counts	Each Baby Counts is a national quality improvement programme led by the Royal College of Obstetricians and Gynaecologists aimed at reducing the number of babies who die or are left severely disabled as a result of incidents occurring during term labour.
	More information can be found at: https://www.rcog.org.uk/eachbabycounts
Fetal death	A fetal death is a death prior to the complete expulsion or extraction from its mother of a baby, irrespective of the duration of pregnancy and which is not an induced termination of pregnancy.
Findings	Findings of the coroner are the particulars about a death that the coroner establishes to enable the death to be registered (under the Births and Deaths Registration Act 1953).
Gestational age	Gestational age is a measure of the age of a pregnancy which is taken from the first day of a woman's last menstrual period, or the corresponding age of the gestation as estimated by a more accurate method if available. Such methods include adding 14 days to a known duration since fertilization (as is possible with in vitro fertilization) or by obstetric ultrasonography.
Healthcare Safety Investigation Branch (HSIB)	The Healthcare Safety Investigation Branch (HSIB) is a team of experienced safety investigators, led by the chief investigator Keith Conradi. While the HSIB is funded by the Department of Health and Social Care and hosted by NHS Improvement, it operates independently of these bodies and organisations such as the Care Quality Commission (CQC) and NHS organisations. It investigates safety incidents in order to provide meaningful safety recommendations and share lessons across the whole of the healthcare system for the benefit of everyone who is cared for by it and works in it. More information can be found at: https://www.hsib.org.uk
	More information can be found at. https://www.fisib.org.uk

Inquest	An inquest is a fact-finding inquiry in public conducted by a coroner to establish who has died, and how, when and where the death occurred. It forms part of the coroner's investigation. An inquest does not establish any matter of criminal or civil liability. It does not seek to blame anyone or apportion blame between people or organisations. In some cases, where the family does not want and does not need to attend the inquest, and where there is little or no oral evidence, the coroner may decide to hold a documentary inquest . A
	documentary inquest is held in public but, unlike other inquests, it is heard without the attendance of witnesses. Such an inquest may generally arise in cases that can be completed in one hearing (also called a 'fast-track inquest') and in cases where an inquest has been adjourned and, after receipt and consideration of evidence (e.g. evidence from a non-coronial investigation), a documentary inquest is deemed suitable by the coroner.
Interested person	 An interested person is a person who has certain rights under the Coroners and Justice Act 2009. 'Interested person' is defined in section 47(2) of the 2009 Act as follows: a spouse, civil partner, partner, parent, child, brother, sister, grandparent, grandchild, child of a brother or sister, stepfather,
	 stepmother, half-brother or half-sister a personal representative of the deceased a medical examiner exercising functions in relation to the death of the deceased;
	 a beneficiary of a life insurance policy on the deceased; an insurer who issued a life insurance policy on the deceased; a person who may by any act or omission have caused or contributed to the death, or whose employee or agent may have done so;
	 a representative from a trade union to whom the deceased belonged at the time of death (if the death may have been caused by an injury received in the course of the person's employment, or was due to industrial disease); a person appointed by, or representative of, an enforcing authority.
	 authority; the chief constable (where there may have been a homicide offence); a Provost Marshal (where there may have been a service
	 homicide offence); the Independent Police Complaints Commission (where the death is the subject of an investigation by the Independent
	 Police Complaints Commission); a person appointed by a Government department to attend the inquest or to assist in, or provide evidence to the investigation; or
	 anyone else who the coroner thinks has a sufficient interest.

Intrapartum	A baby is said to be stillborn intrapartum when delivered at or after 24 weeks + 0 days (24 ⁺⁰ weeks) of gestation showing no signs of life and known to have been alive at the onset of care in labour.
	A term intrapartum stillbirth refers to the stillbirth of a baby delivered between 37 weeks + 0 days of gestation (37^{+0} weeks) and 41 weeks + 6 days (41^{+6} weeks) of gestation showing no signs of life and known to have been alive at the onset of care in labour.
MBRRACE-UK	MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK) is the name given to the collaborative programme of work led from the National Perinatal Epidemiology Unit (NPEU) that delivers the Maternal, Newborn and Infant Clinical Outcome Review Programme, commissioned by the Healthcare Quality Improvement Partnership (HQIP) as one of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The Clinical Outcome Review Programmes, which encompass confidential enquiries, are designed to help assess the quality of healthcare, and stimulate improvement in safety and effectiveness by systematically enabling clinicians, managers, and policy makers to learn from adverse events and other relevant data. The Maternal, Newborn and Infant Clinical Outcome Review Programme is funded by NHS England, NHS Wales, the Health and Social Care division of the Scottish government, The Northern Ireland Department of Health, the States of Jersey, Guernsey, and the Isle of Man.
Medical Certificate of Cause of Death	The Medical Certificate of Cause of Death (MCCD) is a form signed by the doctor who attended the deceased during their last illness and which provides the cause(s) of death. It enables the deceased's family to register the death and to make arrangements for the disposal of the body.
	There exists an equivalent statutory form for stillbirths, the Medical Certificate of Stillbirth , which is similarly used to register the loss of a stillborn baby.
Medical examination	A medical examination in the context of this document is a detailed medical examination of the stillborn baby and/or the placenta that takes place after delivery. The purpose of the medical examination is to establish the reasons for why the baby was stillborn.
Medical examiners	From April 2019, a non-statutory medical examiners system will be introduced in the NHS to engage with the next of kin/informant and contribute to improving patient safety. A medical examiner is a trained (typically senior) doctor who will verify clinical information on Medical Certificates of Cause of Death (MCCD) (see definition above) and ensure that the right referrals are made to the coroner for further investigation. Medical examiners will take a consistent approach to the scrutiny of MCCD content, which must be clinically accurate. Medical examiners must not have been involved in the care of the deceased patients for deaths they scrutinise.

National Quality Board	The National Quality Board (NQB) in England is a forum where the key NHS oversight organisations come together regionally and nationally to share intelligence, agree action and monitor overall assurance on quality. The NQB's membership is composed of clinical leaders from NHS England, the Care Quality Commission, NHS Improvement, Health Education England, Public Health England, NICE, NHS Digital and DHSC.
National Reporting and Learning System	The National Reporting and Learning System (NRLS) is a central database of patient safety incident reports. All information submitted is analysed to identify hazards, risks and opportunities to continuously improve the safety of patient care.
Neonatal death	A neonatal death refers to the death of a live born infant, regardless of gestational age at birth, within the first 28 completed days of life.
NHS England Regional Teams	NHS England Regional Teams cover healthcare commissioning and delivery in their area and provide professional leadership on finance, nursing, medical, specialised commissioning, patients and information, human resources, organisational development, assurance and delivery. Regional teams work closely with organisations such as clinical commissioning groups (CCGs, groups of general practices that come together in each area to buy the best services for their patients and population), local authorities, health and wellbeing boards as well as GP practices. There are five regional teams in England.
NHS Wales Local Health Boards	NHS Wales Local Health Boards secure and deliver healthcare services in their areas. There are seven Local Health Boards in Wales.
Patient safety incident	A patient safety incident is an unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare.
Perinatal Mortality Review Tool	The Perinatal Mortality Review Tool is programme launched in 2018 which requires Trusts to undertake systematic, multidisciplinary, high quality reviews of the circumstances and care leading up to and surrounding each stillbirth and neonatal death, and the deaths of babies who die in the post-neonatal period having received neonatal care.
	More information can be found at: <u>https://www.npeu.ox.ac.uk/pmrt</u>

Post-mortem examination	A post-mortem examination is a medical examination of the body that takes place after death. The purpose of the post-mortem examination is to establish the medical cause of death. A coroner's post-mortem examination is independent and is carried out by a suitable medical practitioner of the coroner's choice.
	A post-mortem examination can involve the testing of blood and other samples, a scan of the body such as CT (computerised tomography) scanning or MRI (magnetic resonance imaging) and/or an operation to remove and examine organs. The coroner will determine the appropriate type of post-mortem examination that is required.
Preliminary inquiries	Preliminary inquiries are enquiries made by the coroner following a reported death to decide whether their duty to investigate applies.
Putting Things Right	Putting Things Right is the name given to the set of NHS Wales processes for the raising, investigation of and learning from patient concerns.
	Further information on Putting Things Right is available at: http://www.wales.nhs.uk/sites3/home.cfm?orgid=932
Qualified informant	 A qualified informant is a person qualified under the Births and Deaths Registration Act 1953 to give information to the <u>registrar</u> (see definition below) for registration purposes. In relation to a stillbirth, a qualified informant can be: the father and mother of the stillborn baby; any person present at the stillbirth;
	 where that applies, the occupier of the house in which the baby was delivered stillborn; the person who found the baby in the case of a stillborn baby found exposed
Report to Prevent Future Deaths	 A Report to Prevent Future Deaths is a report made by a coroner where a) something revealed by the investigation gives rise to a concern that circumstances creating a risk of other deaths will occur, or will continue to exist, in the future and b) the coroner believes action should be taken to prevent the occurrence or continuation of such circumstances, or to eliminate or reduce the risk of death these circumstances have created. This report is issued by the coroner to anyone who may take such action. Anyone insued with a Perpert to Prevent Future Deaths.
	action. Anyone issued with a Report to Prevent Future Deaths should give a written response to the senior coroner by whom the report has been issued.
Registrar	The registrar is an officer, employed by the local authority, responsible for registering births and deaths which have taken place in their district.

Serious Incident Framework	The Serious Incident Framework is a framework initiated and managed by NHS Improvement which describes the process and procedures to help ensure Serious Incidents in the NHS are identified correctly, investigated thoroughly and learned from to prevent the likelihood of similar incidents happening again.
	More information can be found at https://improvement.nhs.uk/resources/serious-incident-framework
Serious Incidents	 Serious Incidents in healthcare are adverse events, where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified. Serious Incidents include acts or omissions in care that result in: unexpected or avoidable death; unexpected or avoidable injury resulting in serious harm – including those where the injury required treatment to prevent death or serious harm; abuse; Never Events; incidents that prevent (or threaten to prevent) an organisation's ability to continue to deliver an acceptable quality of healthcare services; and incidents that cause widespread public concern resulting in a
	loss of confidence in healthcare services.
Signs of life	Signs of life , as defined by the World Health Organisation, refer to evidence of life displayed after complete expulsion or extraction from its mother of a baby, irrespective of the duration of pregnancy, such as beating of the heart, pulsation of the umbilical cord, or any definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached.
State detention	A person is in state detention if they are compulsorily detained by a public authority within the meaning of section 6 of the Human Rights Acts 1998. This includes persons detained in hospital under the Mental Health Act 1983 as well as persons detained at Immigration Detention Centres. For the purposes of coronial law, a person deprived of liberty under powers in Mental Capacity Act 2005 is not considered to be in state detention.
Term Full-term Post-term (still-)birth	Term , full-term , post-term (still-) birth – a birth or stillbirth is considered to have occurred (or a pregnancy is considered to be) at term or at full term between 37 weeks + 0 days gestation and 41 weeks + 6 days gestation. Pre-term refers to a birth or stillbirth which has occurred before 37 weeks + 0 days of gestation, whilst post-term refers to the 42 nd week of gestation or after. For the purpose of this document, 'term' and 'full term' are taken to be equivalent and interchangeable.

Annex D – References

Statistical tables

- Ministry of Justice and Office for National Statistics (2018), 'Coroners Statistics Annual 2017, England and Wales'. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachm ent_data/file/705766/coroners-statistics-annual-2017-tables.ods
- 2. Office for National Statistics (2019), 'Birth Characteristics, England and Wales', table 10. Available at: https://www.ons.gov.uk/file?uri=/peoplepopulationandcommunity/ birthsdeathsandmarriages/livebirths/datasets/birthcharacteristicsinenglandandwales/2 017/birthcharacteristicsworkbook2017.xls

Note: The total of 2830 stillbirths in England, Wales and elsewhere reported in table 10 is slightly lower than the total of 2873 figure in table 3 because it is calculated on a different basis. 'Elsewhere' here refers to stillbirths that happened in England and Wales to women whose usual residence is outside England and Wales

3. Office for National Statistics (2018), 'Child mortality statistics, 2016'. Available at: https://www.ons.gov.uk/file?uri=/peoplepopulationandcommunity/birthsdeathsandmar riages/deaths/datasets/childmortalitystatisticschildhoodinfantandperinatalchildhoodinf antandperinatalmortalityinenglandandwales/2016/cms2016corrected.xls

Reports and articles

- 4. Department of Health and Social Care (2017), *Safer Maternity Care: The National Maternity Safety Strategy Progress and Next Steps*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachm ent_data/file/662969/Safer_maternity_care_-_progress_and_next_steps.pdf
- Department of Health and Social Care (2018), The Government response to the Report of the Joint Committee on the Draft Health Service Safety Investigations Bill. Available at: <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761146/Gov_response_to_the_Report_of_the_JC_HSS_I_Bill.pdf</u>
- Draper ES, Gallimore ID, Kurinczuk JJ, Smith PW, Boby T, Smith LK, Manktelow BN, on behalf of the MBRRACE-UK Collaboration. MBRRACE-UK Perinatal Mortality Surveillance Report, UK Perinatal Deaths for Births from January to December 2016. Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester. 2018. Available at: https://www.npeu.ox.ac.uk/downloads/ files/mbrrace-uk/reports/MBRRACE-UK%20Perinatal%20Surveillance%20Full% 20Report%20for%202016%20-%20June%202018.pdf

- Draper ES, Kurinczuk JJ, Kenyon S (Eds.) on behalf of MBRRACE-UK. MBRRACE-UK 2017 Perinatal Confidential Enquiry: Term, singleton, intrapartum stillbirth and intrapartum-related neonatal death. The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester: Leicester, 2017. Available at: https://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/MBRRACE-UK%20Intrapartum%20Confidential%20Enquiry%20Report%202017%20-%20final%20version.pdf
- Ferrero DM, Larson J, Jacobsson B, Di Renzo GC, Norman JE, Martin JN Jr, et al. (2016) Cross-Country Individual Participant Analysis of 4.1 Million Singleton Births in 5 Countries with Very High Human Development Index Confirms Known Associations but Provides No Biologic Explanation for 2/3 of All Preterm Births. PLoS ONE 11(9): e0162506. https://doi.org/10.1371/journal.pone.0162506
- 9. HM Government (2018), Child Death Review Statutory and operational guidance (England). Available at: https://assets.publishing.service.gov.uk/government/uploads/ system/uploads/attachment_data/file/773431/Child_death_review_statutory_and_operational_guidance_England.pdf
- Joint Committee on Health Service Safety Investigations Bill (2018), Draft Health Service Safety Investigations Bill: A new capability for investigating patient safety incidents. Available at: https://www.parliament.uk/business/committees/committeesa-z/joint-select/draft-health-service-safety-investigations-bill/news/health-servicesafety-investigations-bill-report-published-17-19/
- 11. Lawn JE, Blencowe H, Waiswa P, Amouzou A, Mathers C, Hogan D, Flenady V, Frøen JF, Qureshi ZU, Calderwood C, Shiekh S, Jassir FB, You D, McClure EM, Mathai M, Cousens S for The Lancet Ending Preventable Stillbirths Series study group with The Lancet Stillbirth Epidemiology investigator group. Stillbirths: rates, risk factors, and acceleration towards 2030. The Lancet 2016;387(10018): 587–603. Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)00837-5/fulltext
- Mahendru A. A., Wilhelm-Benartzi C. S., Wilkinson I. B., McEniery C. M., Johnson S., Lees C. (2016). Gestational length assignment based on last menstrual period, first trimester crown-rump length, ovulation, and implantation timing. Arch. Gynecol. Obstetr. 294, 867–876. 10.1007/s00404-016-4153-3. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5018029/
- 13. National Quality Board (2017), *National Guidance on Learning from Deaths*. Available at: https://www.england.nhs.uk/wp-content/uploads/2017/03/nqb-national-guidance-learning-from-deaths.pdf
- 14. NHS England (2015), Serious Incident Framework: Supporting learning to prevent recurrence. Available at: https://improvement.nhs.uk/documents/920/serious-incidnt-framwrk.pdf
- NHS Wales (2016), Putting Things Right Raising a concern about the NHS in Wales. Available at: http://www.wales.nhs.uk/sites3/Documents/932/Healthcare%20 Quality%20%2D%2030166%5FPutting%20Things%20Right%5Fa5%20leaflet%5FEngl ish%5FWEB%20VERSION%20%2D%20FINAL%20%2D%202017%2003%2001.pdf

- 16. Office for National Statistics (2018), 'How have we defined avoidable mortality?', *Avoidable mortality in the UK: 2016*. Available at: <u>https://www.ons.gov.uk/people</u> populationandcommunity/healthandsocialcare/causesofdeath/bulletins/avoidablemort alityinenglandandwales/2016#how-have-we-defined-avoidable-mortality
- 17. Royal College of Obstetricians and Gynaecologists (2018), *Each Baby Counts 2018* progress report, available at: https://www.rcog.org.uk/globalassets/documents/guide lines/research--audit/each-baby-counts/each-baby-counts-report-2018-11-12.pdf
- 18. The British Medical Ultrasound Society, 'Obstetric (Pregnancy)'. Available at: https://www.bmus.org/obstetric-pregnancy/
- 19. *The Lancet* (2016), 'Ending Preventable Stillbirths: An Executive Summary for The Lancet's Series', *Stillbirths 2016: ending preventable stillbirths*, available at: http://www.thelancet.com/pb/assets/raw/Lancet/stories/series/stillbirths2016-execsumm.pdf

Annex E – Questionnaire

Main consultation questions (Q1 – Q20)

Q1. Do you think coroners should have a role in investigating stillbirths? Please provide reasons.

Q2. Do you consider that coronial investigations of stillbirths would achieve the policy objectives set out in paragraph 41? Are there any other policy objectives that we should consider in improving the systems for determining the causes of stillbirths and delivering better services?

Q3. Do you agree with the proposal about ascertaining who the mother of the stillborn baby is and the baby's name if they have been given one? Do you think there is anything else that should be considered?

Q4. Do you agree with the proposal about ascertaining how it was that the baby was not born alive? Do you think there is anything else that should be considered?

Q5. Do you agree with the proposal about ascertaining when fetal death occurred or was likely to have occurred and when the baby was delivered stillborn? Do you think there is anything else that should be considered?

Q6. Do you agree with the proposal about ascertaining where fetal death occurred or was likely to have occurred and where the stillborn baby was delivered? Do you think there is anything else that should be considered?

Q7. Do you agree that, as part of their findings, coroners should identify learning points and issue recommendations to the persons and bodies they consider relevant? If not, how do you think coroners should disseminate learning points?

Q8. Beyond identifying learning points in individual cases, do you think coroners should have a role in promoting best practice in antenatal care?

Q9. Is there anything else you would like to see come out of a coroner's investigation into a stillbirth? What other determinations should be made?

Q10. Do you agree that no consent or permission from the bereaved parents, or anyone else, should be required for a coronial investigation into a stillbirth to be opened? Please give your reasons.

Q11. Do you agree that the coroner's duty to hold an inquest should apply to investigations of stillbirths? Please give your reasons.

Q12. Do you agree with the proposals for the links and sequencing between coronial and non-coronial investigations? Please give your reasons.

Q13. Do you think coroners should have the same powers in relation to evidence, documentation and witnesses in stillbirth investigations, as well as in ordering medical examinations, as they do for death investigations now? Please give your reasons.

Q14. What, if any, other powers should coroners exercise to aid in their investigations into stillbirths?

Q15. Do you think it is appropriate for coroners to assume legal custody of the placenta? If not, why?

Q16. Do you agree that coroners should not have to obtain consent or permission from any third party in exercising their powers, except where existing rules already provide for such a requirement? Please give your reasons.

Q17. Do you agree with the proposal to investigate only full-term stillbirths, or do you think the obligation to investigate should encompass all stillbirths?

Q18. If you answered 'no' to both parts of the question above, which group of stillbirths do you think should be investigated?

Q19. Do you agree that coroners should investigate all full-term stillbirths (i.e. all stillbirths in scope)? Or do you think a further distinction should be made within this category?

Q20. Do you agree with the above proposal as to how a stillbirth should be registered when a coronial investigation has taken place?

Questions on the Impact Assessment (IA) (Q21 – Q28)

Proportion of investigations requiring a post-mortem examination and the cost of a post-mortem examination

Question 21.1 (IA): Do you agree with the assumption that the majority of stillbirth investigations would require a post-mortem examination (in the IA we have used an upper bound estimate of 100%)? If not, please explain why, preferably with supporting evidence.

Question 21.2 (IA): We have also assumed that an upper bound estimate of the cost³⁴ of a post-mortem examination for a stillbirth is £2,000. We recognise that this varies by region and so would appreciate views on this, and particularly any evidence on the average cost of a stillbirth post-mortem examination in your region.

Documentary and full inquest

Question 22 (IA): Do you agree with the assumption that the inquest in approximately 20% of stillbirth investigations could be conducted solely on the basis of written evidence (this is sometimes referred to as a documentary inquest) and approximately 80% would require witnesses to attend and give oral evidence? If not, please explain why, preferably with supporting evidence.

Average time needed by coroners to complete a stillbirth case

Question 23 (IA): Do you agree with our assumption that a stillbirth case is complex in nature and would require around 4 hours of coroner's time and around 15 hours of coroner's officer time to review the case (excluding time spent at the inquest)? If not, please explain why, preferably with supporting evidence.

³⁴ Please note that this is the average cost of undertaking a post-mortem rather than the 'price' of a post-mortem – i.e. it's the costs borne by the supplier of post-mortems, not the costs recovered from or paid by commissioners of post-mortems.

Question 24 (IA): Do you agree with our assumptions that:

- (i) the investigation of stillbirth cases is likely to be undertaken by a senior or area coroner and would be resourced by increasing the number of assistant coroners to deal with the less complex cases currently undertaken by senior or area coroners; and
- (ii) assistant coroners would take the same number of hours on these cases that have been redistributed as Senior/Area coroners?

Average cost of inquest

Question 25 (IA): We would welcome views on the assumption in the IA that the average cost of a documentary inquest is £400 and the average cost of a full inquest is £3,000 (including coroner costs, investigating officer costs, witness costs and court building costs).

Maximum level of NHS staff involvement

Question 26 (IA): Do you agree with our assumption that a coronial investigation of a stillbirth could require up to 6 members of NHS staff (medical consultant, junior doctor, 3 midwives/nurses and an NHS manager) to each provide up to a maximum of 7 hours of their time?

Paediatric and perinatal pathology

Question 27.1 (IA): Do you agree with our assumption that 1 full-time equivalent (FTE) perinatal pathologist is capable of undertaking between 100 and 200 stillbirth post-mortem examinations a year whereby if coronial investigations of stillbirths result in an additional 450 post-mortem examinations per year, this implies between 2.25 and 4.5 additional FTE perinatal pathologists would be required to meet the anticipated additional workload? If not, please explain why, preferably with supporting evidence.

Question 27.2 (IA): What percentage of the additional stillbirth post-mortem examinations that may be requested in your region would there be a capacity and willingness to complete?

Question 27.3 (IA): If your answer to question 27.2 is not 100%, what alternative funding arrangements do you think would be required to support the increased demand for post-mortem examinations of term stillbirths?

Existing investigations of stillbirths

Question 28 (IA): What impact do you think coronial investigations of stillbirths will have on investigations of stillbirths undertaken: a) locally; and b) by the Healthcare Safety Investigation Branch (HSIB)? Will the current investigation of stillbirths continue independently of coronial investigations or will some current activity be displaced or otherwise impacted by coronial investigation of stillbirths?

Equalities

Q29 (IA). Do you think the proposals in chapters 1 to 6 may have any further impact on a group with a protected characteristic? If so, please explain what these impacts would be and which groups could be affected.

978-1-5286-1057-5

CCS0219686644