RESPONSE TO

HM GOVERNMENT

Consultation on coronial investigations of stillbirths

CONSULTATION DUE: 18th JUNE 2019

Introduction

1. Action against Medical Accidents (AvMA) was established in 1982. It is the UK patient safety charity specialising in advice and support for patients and their families affected by medical accidents. Since its inception AvMA has provided advice and support to over 100,000 people affected by medical accidents throughout the United Kingdom.

2. AvMA offers specialist services to the public, free of charge, across the United Kingdom. This includes a helpline and an individual casework service staffed by legal and medical professionals.

3. In September 2009 AvMA committed resources to providing a specialist pro bono inquest service in England and Wales. The service was officially launched in July 2010. The service aims to find representation for people who have been affected by the death of a loved one where the death occurred in a medical setting.

4. Currently, AvMA has a small team of 4 members of staff who are committed to undertaking inquest work, along with other duties. All staff involved in the inquest work are highly trained and are qualified as either doctors, solicitors or barristers.

5. The pro bono inquest service has developed so that it now provides advice to at least 100 families each year, we prepare and arrange representation at inquest hearings for some 8 – 12 families each year, most of those inquests hearings are in excess of one day long. We will refer cases to specialist clinical negligence solicitors if that is what the family wants and where there is a potential civil claim.

6. Through our work, we have developed considerable expertise in providing assistance and representation to members of the public at inquests where the death arose in a healthcare setting.

7. Our inquest experience has enabled us to explore core issues pertinent to the patient's death and to draw attention to them as part of the investigative process of the Coroner's court.

8. Our aim is to improve patient safety and the improve services to the general public who rely on the healthcare providers service by drawing the coroner's attention to any concerns we have about a healthcare providers practice and/or procedure. AvMA will invite the Coroner to use his/her powers to remedy the failings where appropriate.

9. As an organisation our aims are to champion patient safety and access to justice. Accordingly, where appropriate we invite the Coroner to consider the need for a conclusion to reflect that neglect aggravated the cause of death and to record evidence of systemic failings. We also consider any Action Plans put forward by the Trust and where relevant address the Coroner on the need to make a Prevention of Future Death Report (PFD).

10. AvMA provides specialist support services for legal professionals through our Lawyers Resource Service including the recommendation of expert witnesses. We organise specialist training

courses and conferences for health and legal professionals, advice agencies and members of the public.

11. AvMA operates a specialist accreditation scheme and assesses solicitors for eligibility to the panel based on their experience and expertise in clinical negligence. The AvMA panel has been running since the late 1980's and is the longest running clinical negligence accreditation scheme as well as being the first accreditation scheme of its kind. We reaccredit our panel solicitors after 5 years to ensure that they are maintaining standards, both the original application for accreditation and reaccreditation process require solicitors to submit case reports. As a result we have access to over 200 case reports annually.

AvMA's Response to the Consultation

12. AvMA has confined its responses to questions where we feel able to comment based on our experience and information available to us through our services.

Executive Summary of AvMA Recommendations

13. The bereaved should be at the centre of the process: The wishes of the bereaved should be considered particularly when it comes to the issue of whether an inquest should take place or not. However, it should only be one factor that the coroner considers.

14. Greater access to Independent advice and information for the bereaved families: This should be provided by specialist organisations such as AvMA who can explain the inquest process and set out the pros and cons of going through the process. It is important to recognise that this is more than emotional support.

15. The coroner's investigation: Has the potential to bring additional learning to healthcare providers. They can identify the circumstances leading to the stillbirth of a baby and any lessons that can be applied in future pregnancies, and/or lessons to be applied to maternity or other service provisions. This is a level of learning in addition to that which HSIB can deliver. The coroner's statutory powers make the inquest process an important vehicle for effecting change.

16. **Preservation of the integrity of the placenta and body:** This is key to any effective stillbirth investigation along with enough access to peri-natal pathologists to report to the coroner on key findings.

17. Access to specialist, peri-natal pathologists: The shortage of peri-natal pathologists in England is likely to impact on coroners and their investigation into the stillbirth. This must be addressed urgently. It is of concern that the shortage of specialists is likely to result in delay to the inquest process and a family's ability to bury their child.

18. Greater parity in the court room: In inquests involving healthcare issues, typically NHS trusts will be represented by counsel who will often be in attendance with representatives from the trust.

By comparison, the bereaved family is rarely represented, and this is detrimental to their ability to participate fully in the inquest process.

19. **Specialist healthcare Coroners**: It is AvMA's view that inquests arising out of a death associated with healthcare would be improved if Coroners received specific training in healthcare or were able to demonstrate that they had the requisite medico-legal background. Investigations into the causes of stillbirth are complex and are best served by coroners experienced in healthcare related work.

Consultation on coronial investigations of stillbirths

Full Name:	Ms Lisa O'Dwyer
Job title or capacity in which you are responding to this consultation exercise (e.g. member of the public etc)	Director Medico-Legal Services
Date:	18th June 2019
Company name/organisation	Action against Medical Accidents (AvMA)
Address	Freedman House, Christopher Wren Yard, 117 High Street, Croydon CR0 1QG
Post Code	CR0 1QG
If you would like us to acknowledge receipt of your response, please tick this box	**X**
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 f the people or organisations that you represent

Please see introduction to AvMA above.

Consultation on coronial investigations of stillbirths

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

Yes, AvMA supports this proposal.

The coroner's investigation has an important role to play, this investigation is not about identify whether the treatment provided was negligent or not, although it may help to identifying failings. The coroner's primary duty is to identify how the baby died. That investigation is likely to contribute to improving practices and learning about the causes of premature death.

However, AvMA is mindful that not all parents will want to go through a coroner's investigation. AvMA believe it is important for grieving parents' views on whether an inquest should take place or not should be given due weight, it should be a factor the coroner takes into consideration. Families will find it difficult to decide whether they should proceed to inquest or not without access to independent advice and information – that does not mean that the family must go to a lawyer. It does mean that they should have access to independent and impartial agencies with specialist knowledge, such as AvMA, who can help them identify the pros and cons of the inquest process.

The consultation paper refers to the maternity investigations being carried out by HSIB, however it is important to recognise that HSIB's primary investigative aim is to identify and address any risks in the care provided by the treating NHS hospital and make suggestions for improving system practices in the NHS. The coroner's purpose is to find out how and possibly in what circumstances the stillbirth came about, this is likely to raise different issues and considerations.

HSIB Maternity investigations can only conclude with recommendations for changes in practice. It is not mandatory for a healthcare provider to accept or respond to those recommendations. By contrast, a coroner has the statutory authority and duty under paragraph 5, Schedule 5, Coroners and Justice Act 2009 & Reg 28 & 29 Coroner's (Investigations) Regulations 2013 to write reports on Action to Prevent Future Deaths (PFD). The power of those reports, unlike an HSIB recommendation is that they are written with a view to preventing future deaths. That is a very important factor for a bereaved family.

Between April 2018 – 1st April 2019 HSIB reported that it had conduct of 401 maternity related investigations (not all of these are stillbirths) during that same period HSIB had completed 4 investigations (see, questions answered in the House by Jackie Doyle Price on 26.04.19 (Hansard 243995)). We understand from the HSIB website that they have now concluded 14 maternity investigations.

AvMA is cautiously optimistic about HSIB involvement in investigating stillbirths and other maternity incidents but currently there is insufficient evidence to judge how effective HSIB maternity investigations into stillbirths are/going to be. AvMA recognises that HSIB maternity investigations are still very new, they have the potential to change the way families feel about how investigations into their child's death are carried out.

AvMA is also mindful that HSIB Maternity will only investigate a stillbirth in circumstances where a baby had reached 37 weeks gestation and was thought to be alive at the start of labour but was born without signs of life. Contrast this with the definition of stillbirth set out in **The Births and Deaths**

Registration Act 1953, which is referred to at P8, paragraph 4 Consultation document and says that the Act provides ***"a precise definition of stillbirth which specifies that the pregnancy must have concluded after the twenty fourth week of pregnancy".***

It is noted that the government's proposals are for coronial investigations to apply to full term still births, that is, those births that occur at 37 weeks gestation. However, there are cases where HSIB will not investigate a stillbirth even where the 37-week gestational qualifying period is reached.

AvMA has evidence that where healthcare professionals fail to respond to reduced foetal movements in a post term (ie 37 week plus) baby and the baby is subsequently stillborn that these cases will not fall within HSIB remit. The current proposals allow a coroner to carry out an investigation into stillbirths that meet the post term criteria and occur in these circumstances.

The failure to respond to maternal and foetal complications in late pregnancy is an important factor in learning how to avoid stillbirths. There are often issues around the crossover between community and hospital care which are frequently conducted by phone and where a lack of continuity of care and poor communication including inaccurate or poor recording of the mother's concerns is a factor.

Families have frequently reported to us that the hospital trust's Serious Incident Reporting (SIR) process has failed to involve them and/or address the key issues and/or allowed them to be involved in identifying the terms of reference and/or provide an impartial, robust investigation into the death of their child. These families have not had the opportunity to have the circumstances of their child's death investigated by an independent third party such as a coroner.

The fact that hospital staff are expected to give their evidence on oath or to affirm gives families greater faith in the inquest process, by contrast the evidence given to a hospital investigation is not given on oath and does not carry the same weight. There are repercussions for giving dishonest evidence before the coroner, witnesses risk being reported to the police for perjury, they may also be referred to their own professional regulatory bodies for investigation. The evidence given in the coroner's court tends to be treated with greater respect.

In our experience, where a family is properly informed about the coronial process and represented the coronial court can and often does provide them with answers that were not available to them through other investigation processes.

The fact that a coroner is independent, holds a judicial office and is expected to be impartial means that their coronial investigations are often perceived by many families to be robust and fair. They consider that the coroner will give due regard to the evidence and concerns raised by family who has suffered the loss and are grieving for their child.

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?

The policy objectives are expressed to be:

(i) To provide an independent assessment of the facts and causes of the stillbirth being investigated;

(ii) 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

(iii) 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.

In principle the answer to objectives (i) and (ii) is yes. Objective (iii) will depend on the extent to which healthcare providers are willing to accept the coroner's findings and act on them, the opportunity for them to identify lessons that need to be learned does exist where an inquest is full fair and fearless.

The extent to which coronial investigations can achieve their policy objectives will depend on the amount of money the government is prepared to invest in making sure the coronial process can succeed.

A key component of ensuring the success of coronial investigations into stillbirths is for the coroner conducting the independent assessment of the facts and causes of the stillbirth investigation to have enough skill and knowledge to understand the complex underlying factors that contribute to a stillbirth. In practice it can often be the case that the difference between a child being stillborn and a child being born alive but suffering profound brain injury as a result of a hypoxic event arising from the management of labour can be a matter of minutes. It is generally well recognised and accepted that investigations into the causes of a brain injured child are complicated, investigations into stillbirths are likely to be equally complex.

AvMA urges that consideration be given to coronial investigations into stillbirth being conducted solely by coroners who can demonstrate they have the requisite medico-legal experience to conduct investigations of this type. If this consideration is not adopted then AvMA recommends that as a minimum, the government fund specialist coronial training to enable coroners to carry out effective stillbirth investigations into how the child died.

The training should cover issues such as disclosure of relevant documents the coroner should typically be seeking disclosure of documents such as the mother's maternity and obstetric records for that pregnancy including a continuous copy of the CTG trace. Equally, the coroner should be aware that they should consider whether certain key witnesses such as the attending midwife/s and/or the obstetrician/s should be called. Coroner's should be trained on the type of expert they might be expected to obtain independent medical evidence from and how best to manage grieving families. In our experience all grief arising from the death of a loved one needs to be managed carefully however there is something particularly sensitive about a family's grief which arises from a stillbirth.

The government should also be prepared to recognise that independent expert evidence is more likely to be required in an investigation into a stillbirth and adequate funding to facilitate this should be made available.

At paragraph 54 this consultation paper, it proposes that the coroner's determinations should provide a "***thorough account of the circumstances leading to the stillbirth of a baby",*** they are also expected

to ***"identify any lessons"*** that could be applied to future pregnancies, maternity and any other relevant service provisions. The coroner would "***seek to ascertain when fetal death occurred***". These are difficult duties to discharge properly without designated healthcare coroners being appointed or at the very least compulsory coronial training on stillbirths being introduced. The coroner will need independent expert evidence to help them form their views on these issues.

One of the cited objectives is for parents to have 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. The Learning from Deaths review : https://www.england.nhs.uk/wp-content/uploads/2017/03/nqb-national-guidance-learning-from-deaths.pdf states at page 15, that one the key principles is that ***"bereaved families and carers should be partners in an investigation to the extent, and at whichever stages, that they wish to be involved, as they offer a unique and equally valid source of information and evidence that can better inform investigations".***

If the government is committed to achieving this objective, then families should be entitled to professional advice and information on the inquest process prior to the inquest hearing and be represented during the hearing. If families do not receive the option of representation then they are less likely to be able to access the coronial process and to derive the benefit of the process.

In our experience, NHS Trusts are very often represented by counsel or specialist advocates at healthcare related inquests, when families are not. Funding should be made available to ensure families attending inquests into their stillborn child are partners in the investigation. This means, that if the trust is represented at a stillbirth inquest then a family should be too; their ability to participate in the inquest should not be contingent upon meeting the stringent means and merits criteria set out in the Lord Chancellors Exceptional Funding Inquests code. Trusts are not subject to these rigorous means and merits requirements; families should be on an equal footing.

If coronial investigations into stillbirths are to succeed in helping to achieve a system wide learning into the causes of stillbirth then we suggest that coroners conducting stillbirth inquests should be familiar with the aims, objectives, expectations and recommendations set out in NHS England paper "National Guidance Learning from Deaths" March 2017, referred to above. That review sets out how the NHS is expected to disseminate their learning from deaths across NHS Trusts. This is relevant in so far as, if a coroner makes a prevention future death report (PFD), that report tends to pertain to the trust under investigation only. If the objective is for coronial investigations into stillbirths to contribute to a wider system of learning, then coroner's need to be aware of and understand how the NHS expects to facilitate that wider system so any PFDs can be properly directed.

AvMA believes that with the correct funding and adequate training the government's objectives should be achievable.

The stated objectives are laudable and ambitious. AvMA suggests that these objectives are reviewed periodically, and that consideration be given to expanding on those policy objectives at that time.

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?

On the face of it, this appears to be a respectful and sensible approach. However, these circumstances are likely to arise in a minority of cases, perhaps where a baby has been abandoned shortly after birth. It is foreseeable that this might also be relevant where a surrogate mother is involved. It may also affect mothers who have conceived using donor eggs and/or embryos. AvMA does not have the expertise or experience to offer any suggestions on how these matters should be best dealt with – no doubt the government has sought to consult with the relevant agencies but we anticipate that it would be important that in those circumstances that the court would be open to recognising the surrogate, egg/embryo donor and intended parent as properly interested parties.

Apart from the above, it would be important for the Coroner to ascertain who the mother is in the investigation of stillbirths as maternal factors and failures in maternal care are potentially contributory to the stillbirth and could be reflected in any conclusion or PFD. This should therefore be reflected in the record of inquest.

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?

The proposals are set out at paragraphs 54 and 55 and suggest that the coroner be responsible for:

(i) Providing a thorough account of the circumstances leading to the stillbirth of a baby,
(ii) Identifying any lessons that could be applied in any future pregnancies (for the mother concerned),
(iii) Identifying any lessons that could be applied to maternity or any other service provision more generally
(iv) Ascertaining 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.
(v) Ascertaining when fetal death 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.
(vi) Ascertaining when the baby was delivered stillborn.
(vii) Ascertaining 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.
(viii) Considering whether any lessons can be learned which could prevent a future stillbirth or otherwise improve the safety of, and care provided to, pregnant women.
(ix) If the coroner judges that there are no lessons to be learned following the inquest, this should be stated in their conclusions

AvMA reiterates its concerns about ensuring the coroner with conduct of an inquest involving a stillbirth can demonstrate that they have the requisite medico-legal knowledge and

experience to assimilate and understand the relevant factual detail and complex medical issues that will arise on a stillbirth investigation. This is difficult for a coroner to achieve through training alone.

In addition, the coroner needs to understand how maternity provision within the NHS and in private healthcare operates so they can recognise which lessons should be applied to the maternity or which lessons should apply to another service provision and which lessons might apply to say an individual involved in the delivery of the stillborn child.

These proposals emphasise the need and importance of the coroner having access to independent medical expertise, advice and evidence. In AvMA's experience many independent medical experts struggle to ascertain when the fetal death occurred – at best many will only express this on a balance of probabilities or offer a window of time on when the death was most likely to have occurred.

As the proposal includes the coroner identifying any learning lessons for the healthcare provider it is crucial that the coroner has access to all HSIB documents generated as part of their HSIB maternity investigations. The HSIB remit is to identify lessons learned, the findings from their investigation may therefore relevant to the coroner.

HSIB maternity investigations are being conducted under the duty of candour principles as opposed to so called "Safe space", providing this remains the case there shouldn't be any difficulties with disclosure and disclosure should not bring the two processes into conflict.

We do not think it is appropriate for the coroner to stipulate in their conclusions that there are no lessons to be learned. The coroner does not have this duty in relation to any other investigation into a death. The coroner's remit is to look at how a person came about their death. If the coroner is to investigate stillbirths, then the coroner's remit would remain narrow and would focus on establishing how the stillbirth came about. Potentially, the coroner would explore the circumstances of the stillbirth, it would be potentially misleading for the coroner to say no lessons need to be learned following the inquest. There may well be lessons, but those lessons may not be apparent within the context of the investigation carried out by the coroner.

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?

No, we don't agree – see response above.

If independent medical experts struggle to identify when fetal death occurred, then it is difficult to see how a coroner without this level of expertise can make such a finding. However, if the coroner hears independent expert evidence from an appropriate medical expert who can estimate the time of death then the coroner should be able to reflect that fact in their conclusion.

Consideration also needs to be given to the fact that the coroner's primary duty is to identify how and in what circumstances the death occurred. The time of fetal death is often medically very difficult to ascertain. The coroner should be able to set out in their conclusion a broad time frame during which the death is likely to have occurred, however, this does need to be a broad time frame.

The complicated nature of identifying the time of death is such that the coroner should not identify this without carrying out a full investigation. The time of death should not be identified by the coroner in the early stage, before they have heard evidence; it should not be identified by the coroner during their period when they are undertaking their preliminary enquiries

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?

AvMA does not object to the coroner ascertaining where the fetal death was likely to have occurred and where the baby was delivered. Again, this needs to be in broad terms unless there is clear evidence - where the fetal death occurred is likely to be indicated by when the fetal death occurred.

If it is difficult for a coroner to say when the fetal death occurred, then the coroner can only use their best endeavours to identify where the death occurred. The lack of certainty around this issue needs to be reflected in the language used by the coroner in their conclusion.

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?

Coroner already have a duty to make Prevention future death reports where the evidence supports this step be taken. The power of the PFD is that public bodies ie NHS trusts must respond to it. By contrast other investigating bodies such as HSIB can only make recommendations for change.

AvMA supports the proposal set out at paragraph 56 that the coroner should be able to make recommendations for learning to any person or organisation including those not involved in the case. However, where the coroner identifies early on that there is a possibility that a recommendation may be made against an individual or organisation, they should inform that individual/organisation so they are on notice as to what may happen. It is important that any such individual can be heard, offer evidence and make representations before that recommendation is made.

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

In principle yes, so far as coroner's can. Best practice is a high bar for a coroner that is not a specialist in healthcare inquests. It may be more appropriate for coroners to make PFD reports in the usual way with a commitment to all stillbirth PFDs being reviewed annually and a report prepared identifying weaknesses in the maternal healthcare systems derived from PFDs. That report could then conclude with recommendations for what constitutes best practice being set out in the review.

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?

Where there is uncertainty about whether a child was stillborn or born alive but died almost immediately after birth, the coroner's investigation should conclude with a determination on the likely facts of the case and state on a balance of probabilities whether it was most likely a stillbirth or not.

It may be that the coroner's investigations into stillbirths could in time establish whether the birth was a stillbirth or a live birth which was quickly followed by death.

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.

This is a difficult question to answer definitively. Certainly, most of the families who have come to us with concerns around the circumstances of their stillborn child want an inquest. AvMA recognises that not all families do want this.

Our experience is drawn from dealing with families who have lost a child in the neonatal period. Many parents find the thought of a post-mortem being carried out in their infant child too much to bear. They find a coroner's post-mortem to be a highly invasive process that only adds to their grief and distress.

AvMA believes that the most appropriate way forward is for families to have access to independent and impartial advice on the pros and cons of a coronial investigation. Contrary to the recommendation that parents of a stillborn should not have any choice over whether an inquest takes place AvMA believes that parents views should be given careful consideration.

When considering whether to hold an inquest or not, the coroner should have due regard to what information might be gleaned from the existing and available documents. This means that coroners should be competent in reviewing and analysing the deceased's medical notes, understanding and considering independent medical expert evidence, witness statements and findings from any other investigatory body such as HSIB Maternity. The evidence apparent from these documents should be relevant factors when the coroner considers whether a coronial investigation should take place.

It is equally important that any independent advice agency advising the family has equal access to existing and available documents; the weight of the evidence may be a factor the family wants to consider when deciding whether to support an inquest or not.

Paragraph 62 proposes that ***"Coroners, together with their officers and staff, would ensure that parents are properly informed and listened to throughout the process"*** Where representatives from the Coroner's Courts Support Service are available, they offer an excellent service in providing emotional support to families on the day of the inquest, particularly if the family is not represented. However, they are not able to provide support in helping families understand reports, the medicine or if there are or may be legal implications for the circumstances of the death.

Coroners need to remain partisan and neutral so they can consider the evidence robustly and investigate fully and fearlessly. Coroner' officers and staff are under considerable pressure already and in any event they work for the coroner service, they need to remain just as neutral and impartial as coroners. Coroners officers and staff are not trained to be able to offer advice on the evidence and what it may mean. It is not the job of the coroner, their officers or staff to ensure parents are properly informed.

For many families, the decision to proceed to an inquest will be dependent on whether a post-mortem on their infant child is necessary. Other options such as MRI scanning of the deceased infant should be considered and if appropriate offered to the family as this may have a significant bearing on their decision.

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

Yes. Please see our response to question 1 above.

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

HSIB maternity investigations are still new, it is too early to say how effective their reports are and whether they will make a difference to patient safety and/or the families involved. Where the death meets the HSIB maternity investigation criteria it is important that the coroner can see those reports and the documents that go to form the HSIB conclusions. HSIB Maternity investigations main objective are to identify patient safety improvements, the coroners duty is to identify how and possibly, in what circumstances a person died. HSIB's investigation is their own, it is not the coroners. That distinction needs to be retained.

The extent to which an NHS or HSIB report is relevant to the coroner's investigation is a matter for the coroner to decide, it may be that a coroner ***"will draw heavily on the reports",*** equally, the coroner may have concerns about those reports and choose not to draw on the reports at all, whether that is in relation to the factual conclusions or the findings.

The core purpose of compiling an HSIB report is fundamentally different to the coroner's duty to identify how a person (or foetus in this case) came about their death. If HSIB can complete their report within the 6-month period they are expected to then the coroner's investigation should wait for that report to become available. However, HSIB maternity investigations are struggling to meet the 6 months turn around time, it should not be incumbent on the coroner to wait until that report or any NHS report is completed and available before carrying out their own investigation.

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.

Yes.

The strength of the coroner's investigation is that it is independent. The coroner should not be obliged to draw on other available reports, they must have full access to all the evidence, documentation, witnesses and medical evidence including medical examinations as is appropriate for their investigation. Without access to this documentation the coroner is unable to carry out their own full, fearless investigation in stillbirth cases. Coroners have this power in relation to other hospital deaths, there is no logical reason why this should not be available in stillbirth cases too.

Any suggestion that the coroner's powers should be watered down just because they are investigating stillbirth case makes a travesty of stillbirths being included as a category of death that falls within the

coroner's jurisdiction. It would prevent a coroner from seeing all available evidence and forming their own decisions on how the person died. If the coroner's powers are going to be restricted in this way, then there is no point in allowing the inquest to happen.

Limiting the coroner's access to evidence will only serve to keep the truth out of the reach of the grieving families, and it offends the independence and therefore the strength of the inquest process.

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

Coroners must be informed of a 37 week plus gestation, fetal stillbirth as soon as possible after it has occurred.

We refer to our recommendations at Question 15 below that hospitals should be subject to mandatory provisions on how to preserve the placenta and stillborn body.

In most, if not all stillbirth cases, the Coroner will need to refer the body and the placenta to a peri-natal pathologist for proper analysis of the likely cause of death. There are very few peri-natal pathologists in England and therefore there may be a wait before the perinatal pathologist is able to analyse the placenta and body and report to the coroner. The coroner may need power over healthcare providers to ensure that the body and the placenta are kept in conditions that do not compromise their integrity.

To prevent the distress to the family the delay needs to be minimised; perhaps paediatric pathologists should be asked to prioritise coroner's inquest, stillbirth cases.

Paediatric pathologists need to be paid fairly and quickly for the work they do to ensure there are enough of them willing to undertake inquest work.

The pathologist's findings should be made available to all relevant investigating parties, including the coroner, HSIB and NHS investigations as soon as possible.

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

One of the problems with stillbirth cases is that hospitals often do not recognise the importance of keeping the placenta for analysis by a peri natal pathologist. The lack of peri-natal pathologists in England means that the coroner's investigation is likely to be delayed.

It is of paramount importance that the placenta and the body are kept in optimum conditions so that the peri-natal pathologist is able to analyse the information available from them in due course. There should be no delay to ensuring the integrity of both the body and the placenta are preserved.

AvMA understands that the placenta is recognised as being the legal custody of the mother. If that is correct, then it may also follow that the mother will have to consent to legal ownership of the placenta being transferred to the coroner. There may be reasons why a mother does not want to consent, or is unable to consent to legal ownership passing to the coroner.

AvMA is concerned that if the coroner has to first obtain legal ownership of the placenta before giving instructions on how it is to be dealt this will cause delay. If there is delay in obtaining the mother's consent and the coroner's instructions the risk is that the placenta will deteriorate as a result of the delay.

Perhaps, a more effective way of dealing with this is for there to be clear and mandatory provision for how hospitals or healthcare providers deal with preserving the integrity of the placenta in stillbirth cases.

AvMA understand that one of the difficulties with investigating stillbirth cases is that so many Trusts and hospitals are not retaining placentas and are throwing them out. Paediatric pathologists report that it the placenta gives most information on the cause of the stillbirth, not the body itself.

There needs to be a requirement that where the stillbirth occurred at hospital that the hospital is responsible for retaining the placenta and body until a peri-natal pathologist is available to review and analyse them for the purposes of reporting to the coroner. The referral to the peri-natal pathologist needs to be made as soon as possible.

There needs to be suitable arrangements for the management of the body and placenta when the stillbirth occurred at a place other than in hospital.

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.

We do agree with this as a broad principle.

The coroner does need to be sensitive to the wishes of the family. As the proposals point out, some parents may be concerned that decisions on conducting an inquest include the need for invasive post-mortems of their baby. The coroner should be mindful of the alternative options which include MRI and/or CT scanning to comply with the family's wishes. However, this is not the same as the coroner needing to obtain consent or permission from the family to exercise their powers, it is about putting the family at the centre of the inquest process. Coroner's are already expected to take this approach when dealing with inquests.

Cultural sensitivities, including religious rights associated with the death and/or burial arrangements need to be recognised as factors that the coroner must take account of. We have referred to the use of MRI scanning for autopsy purposes, in addition there is the potential for laparoscopic autopsy to be carried out. It should be mandatory for the coroner to consider these options.

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?

We do agree with this proposal at this stage. Stillbirths are only just being introduced as part of the coroner's jurisdiction we can see some sense to introducing this in a controlled way which relies on a minimum 37-week gestation period.

Once the coroner's court has undertaken stillbirth investigations for say, 2 years there should be a review to identify whether this should be rolled out to stillbirths that occur between 24 – 37 weeks

gestation. This stepped approach will also give coroners and coroner's officers the opportunity to gain experience in the management of families and inquests involving stillbirths.

In addition, there are other practical considerations such as the current shortage of perinatal paediatric pathologists available in the UK. This needs to be addressed and measures put in place for the training of more peri-natal pathologists in this highly specialised field before the gestational age for investigating inquests is extended beyond 37 weeks.

The government should consult with the Royal College Pathologists (RCPath) to explore if there are any other acceptable alternatives to training peri-natal pathologists, including other ways in which analysis of the placenta can be reliably undertaken. This may mean delegating tasks to suitably qualified lab technicians.

It is anomalous that **The Births and Deaths Registration Act 1953** recognises a stillbirth at 24 weeks, yet the coroner can only investigate stillbirths that occur at 37 weeks. We consider RCCOG should be involved in the discussions around how much benefit can be derived from coroners' investigations into stillbirths occurring at 24 – 37 weeks.

We are also mindful that according to paragraph 84 of the proposals, two thirds stillbirths occurred in babies born before 37 weeks and in two thirds of those cases, the cause of the stillbirth is unknown. There is clearly a lack of understanding and learning in relation to these earlier stillbirths and in due course this should be addressed.

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

Not applicable

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?

We consider the coroner should be able to investigate all full-term stillbirths that fall within scope. We refer to our case example referred to in our response to question 1 above.

It is important that cases where a fetus attains 37-week gestation but does not meet the HSIB criteria for investigation can be investigated by a coroner so there can be a determination on the cause of death. The coroner's investigation is the only source of independent investigation open to a family in these circumstances.

It is quite possible that the coroner can identify issues that unless addressed by way of an independent investigation will create an ongoing risk to the public. Issues around communication, recording relevant details in medical notes, referring women on for specialist investigation when necessary need to be considered to improve maternity care and promote good healthcare country wide.

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

AvMA does agree with the proposals listed in the consultation document as they largely reflect the current process applied in non-stillbirth inquests.

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.

We consider it likely that the majority of stillbirth investigations will require a post-mortem examination although we are also aware that MRI scanning has been used increasingly, to good effect. The following article from the BMJ confirms this: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5258168/

The article not only confirms that "***post-mortem MRI (PMMR) is becoming the accepted modality of choice following foetal and perinatal deaths***.[3,4] " but it also highlights that this is a growing area of medicine which requires additional and regular training, only by providing this will ***"The correct acquisition, interpretation and reporting of such images becomes increasingly important as more practitioners begin to develop and provide these services."***

Given the sensitivities around post-mortem of stillbirths we consider this a more gentle and acceptable approach which not only alleviates some of the stress of a post mortem but it is also quicker.

Question 21.2 (IA): We have also assumed that an upper bound estimate of the cost 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.

AvMA does not have any details of the average cost of a paediatric post-mortem and is unable to respond to this question.

AvMA has had regard to the figures recommended by the BMA on pathologist fees, but notes that these are only recommendations, the actual cost of post mortem reports is likely to be higher https://www.bma.org.uk/advice/employment/fees/coroners

AvMA is mindful that there is a shortage of peri-natal pathologists around England and that factor alone will create a market for this group of experts to charge a higher rate. The rate will have to be sufficiently high to make it commercially attractive to peri-natal pathologists to do this work.

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.

AvMA is unclear on how the government has arrived at this assumption. Coroners have not investigated inquests into stillbirths in England up until now and so no data exists on how many inquests would be paper inquests only and how many would require witnesses to attend.

AvMA has not been able to find any data available on the number of neonatal death cases investigated by coroners in England. Equally, we have been unable to find any available data on the number of neonatal death cases that are conducted without any witness evidence.

Northern Ireland has been conducting inquests into stillbirths for some years. AvMA has been unable to find any readily available data from Northern Ireland to support the government's assumption.

It is our experience that coroners do not keep stats on the number and type of inquests conducted, indeed their IT systems are generally known to be poor and requiring improvement.

As far as we can see, there is no rational basis for the government to make this assumption.

Given that the criteria for inquests into stillbirths starts at 37 weeks and the stated objectives in introducing this class of case is to identify if there are any lessons to be learned from the care, we believe it would be logical to assume that all reported stillbirths will proceed to a full hearing requiring witness evidence.

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.

AvMA agrees that a stillbirth case is complex in nature.

AvMA is unable to agree that 4 hours of coroner's time and 15 hours of coroner officers time will be required to review the case, excluding inquest time. The amount and type of work the coroner will need to engage in before the inquest hearing will include:

(i) Time taken to obtain and consider the mother's antenatal notes; labour and obstetric notes including any CTG trace; Paediatric notes
(ii) Reading and consideration of any HSIB report
(iii) Any other internal reports carried out by the hospital, including hospital complaint correspondence
(iv) The coroner will need to identify what issues, if any the family have with the care provided
(v) Witness statements, typically from hospital staff. This is likely to include statements from at least one midwife and obstetrician and paediatrician. There may have been more than one midwife and/or obstetrician involved especially if there was a change of shift during the mother's labour. We note that at question 26 of this consultation it has been assumed that an inquest involving 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. It would not be unreasonable to assume that the coroner would spend 30 minutes going through each of those 6 members of NHS Staffs witness statements, including cross referring the evidence. That alone would be 3 hours work.
(vi) In addition, witness statements from the mother and father and/or other family member would be expected

(vii) The coroner will need to consider what independent experts to instruct, again this will be fact specific. The relevant expert will need to be identified, instructions drafted, and the subsequent expert report considered

(viii) The coroner will need to consider the post-mortem results

(ix) It may be both necessary and prudent to hold a pre inquest hearing to manage the scope of the inquest and hear any representations on other witnesses that need to be called

(x) The coroner will need to ensure that families are advised on the developments in the case along the way and that they are put at the centre of the process. The coroner will also have to deal with any enquiries and/or questions the family may have about the process.

Based on our experience of preparing for inquests this is likely to far exceed the 4 hours allowed.

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?

Please see AvMA's response to question 2 above and the call for designated healthcare coroners to conduct investigations into stillbirths or any other healthcare related inquest.

Whilst we consider that designated healthcare coroners would provide a cost-efficient service and maximise the chances of a full and fearless enquiry, there is no evidence that this is what happens in practice. Certainly, the coroners service is better than it was before 2013. The appointment of a Chief Coroner has made a considerable difference, however there is still a long way to go before the coroner's court can be said to have achieved consistency in approach to cases. Some coroners conducting healthcare inquests recognise the importance of obtaining disclosure of the deceased's medical records, others do not.

(i) In our experience, there is no evidence that complex healthcare cases are likely to be routinely conducted by senior or area coroners. A family is just as likely to experience the case being opened by an Assistant Coroner who has initial conduct of the case and comes to terms with the issues only to find that it is then passed to another full time coroner at a later stage – it should be noted that this is an inefficient way of working which only causes duplication of work which in turn increases the amount of time a coroner spends on a case overall.

(ii) The amount of time spent on a stillbirth case will not be determined by the status of the coroner alone, that is, whether the case is conducted by a senior/area coroner versus an assistant coroner. The amount of time spent on the case will likely be determined by the facts and issues in the case as well as the coroner's experience of medico-legal matters. A coroner who has an appreciation of the complex medical issues that frequently underlie stillbirth and other healthcare related cases is more likely to deal with these cases in a time efficient and therefore a cost-efficient way.

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).

The average cost of an inquest, is more likely to be determined by the issues in the case, the cooperation of the hospital/healthcare provider involved, the number of independent experts that need to be instructed and the number of witnesses of fact that need to attend to give evidence.

We think that the complexity and issues around stillbirth cases is such that most of them will require a full hearing, very few, much fewer than 20% would be paper inquests. As to the cost of a paper hearing, we are unable to comment on this figure which does appear to be very low.

£3,000 may be representative of the bare costs of an inquest relating to coroner costs, investigating officer costs, witness costs and court building costs. We are not aware that the court IT systems are sufficiently sophisticated to time record time spent by court officers and coroners. The proposals do not set out how the government has calculated £3,000 costs.

We suggest that the real costs of the inquest extends far beyond £3,000. The cost of instructing independent experts alone will be potentially significant, not only is there the cost of the expert report but the cost of an expert attending the inquest is likely to be significant.

We are aware that the NHS cover the cost of healthcare inquests particularly where they consider the issues are likely to give rise to a legal claim. We understand remuneration for those fees are fixed between the NHS and their panel firms, we have been advised that typical NHS costs allowed for an inquest are £5,000.

The cost for families to attend inquest with representation is generally prohibitive and although exceptional funding exists, this is still subject to a means and merits test and is awarded in very few cases. Those who can, may pay privately for representation, but this is a minority of cases. Some families may be able to obtain representation by pursuing a civil claim and signing a Conditional Fee Agreement (CFA), not all families want to seek redress through litigation.

The cost of the inquest will depend on the factual issues and complexity of the case, the number of days over which the inquest hearing is likely to be held and whether any independent expert evidence has been obtained.

We do not hold any data on the average cost of an inquest but in our experience a family would be lucky to have inquest costs limited to £3,000. At best £3,000 represents the costs incurred prehearing, there will be additional costs for representation for each day of the hearing.

The figure of £3,000 is too conservative. It should be noted that when considering the cost of a stillbirth inquest we are mindful that these are particularly complex investigations and therefore likely to be more costly.

We think the estimated cost of inquests at £400 for a paper inquest and £3,000 for a full inquest is too low. The government has not offered any rationale as to how it has arrived at these figures and we do not accept this assumption.

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?

AvMA considers it possible that a coronial investigation into a stillbirth could require evidence from six members of staff as described.

The amount of time each staff member will have to spend on the case will depend on the facts and issues in the case. It is dangerous and unhelpful to assume that each NHS staff members involvement could be limited to 7 hours of their time. It is quite possible that it would take 7 hours for each staff member to give instructions, check and sign a witness statement for the purposes of the inquest hearing, particularly if the statement needs to be cross checked with the medical notes.

Staff will be expected to give their evidence to the coroner on oath or to affirm, both of which are very serious declarations which must be treated with respect, a failure to do so may result in separate action either for contempt of court and/or through their own professional regulatory bodies.

When considering the amount of time required by each member of NHS staff it should be remembered that HSIB who will carry out a patient safety investigation, replacing the trusts own internal investigations such as Serious Incident Reports (SIR) recognise that statements may be required for the coroner https://www.hsib.org.uk/maternity/investigation-process/

HSIB will not use or rely on statements from staff in the same way as SIR did, although statements may be available as a result of staff involvement in the NHS Resolution, Early Notification Scheme (ENS) – it is not entirely clear how NHS Resolutions process operates. It is therefore quite likely that staff will have to prepare a report specifically for the purpose of the coroner's investigation and that alone could be 7 hours or work. It is quite likely that staff will spend far in excess of 7 hours of their time in stillbirth inquests.

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.

AvMA is aware that there is a shortage of perinatal pathologists, it is not clear how long they will require for a stillbirth post-mortem examination of the body and placenta.

The government have not offered any explanation on how they have arrived at this assumption.

The government should make enquiries of the Royal College Pathologists (RCPath) for more information on this.

AvMA would urge that any enquiries of RCPath include identifying the cost of an MRI post-mortem as well as a surgical post mortem. It is AvMA's view that most families would find the former more acceptable and preferable to the latter.

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?

AvMA is unable to answer this question.

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?

AvMA is unable to answer this question.

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?

(a) **What impact do you think coronial investigations of stillbirths will have on investigations of stillbirths undertaken locally:** If the stillbirth does not meet the HSIB criteria for investigation then the investigation will be undertaken by the trust in accordance with Serious Incident Reports (SIR) guidelines. The quality of SIR is known to be variable. The fact that these investigations would take place in the knowledge that the case may now be reported and independently investigated by the coroner may improve the quality of the reports overall. However, this remains to be seen and there are no guarantees that this would be the outcome. The SIR would remain the trust's investigation, not the coroners.

(b) **What impact do you think coronial investigations of stillbirths will have on investigations by the Healthcare Safety Investigation Branch (HSIB**)? It is too soon to know how much of an impact HSIB Maternity investigations will have on patient safety and learning. What is clear, is that HSIB investigations are carried out with the clear purpose of identifying common themes and influencing systemic change https://www.hsib.org.uk/maternity/

HSIB is developing methods of feedback to the trust throughout the investigation process. They state they will share "concerning aspects of incidents" with the trust at an early stage, as well as quarterly summaries of the themes identified from all of the trusts referred cases, investigation progress reports are shared with the trust's head of midwifery every two weeks, and HSIB will hold workshops with the trust to help them understand the "logistical impact" of their work. AvMA is cautiously optimistic that the HSIB approach will be helpful however, the approach is clearly more trust centred than family centred. The investigation may not answer the questions that the family want answers to and to that end may be disappointing to them.

By contrast the coroner's investigation is for the purpose of identifying how, and often, in what circumstances the death occurred. Although the scope of the inquest investigation is a narrow, it is completely independent of the trust, of HSIB and is the first opportunity for families to seek answers to some of their questions. The coroner can call witnesses to give oral and written evidence, can instruct independent experts to offer opinions, should place the bereaved at the centre of the process. The coroner will also investigate those stillbirths

that have reached 37 weeks gestation but do not fit the HSIB investigation criteria. It is a hugely important development for families and will allow them the potential to be independent and equal parties to the investigation.

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? It is impossible to say at this early stage. Coronial investigations into stillbirths in England has yet to be enacted and to date there have not been any coronial investigations into stillbirths.

HSIB Maternity investigations are still at an early stage. 14 maternity reports have been completed at the time of responding to this consultation. We do not know how many of those 14 cases relate to stillbirth cases as opposed to brain injury or other HSIB qualifying criteria.

As we have set out above, the purpose of the coroner's investigation is quite different to HSIB investigation. The effect of the coroner's investigation into stillbirths will have to be monitored to identify whether any of the current investigations into stillbirths continue independently or became displaced.

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.

Those with the protected characteristics of pregnancy, maternity and being female are more likely to be affected by these proposals as women as opposed to men will experience stillbirth. The proposals need to be looked at within the context of how much more likely it is that a woman will make a complaint about the care she has received, will she be able to attend an inquest hearing and deal with the pre inquest process including considering the available documentation.

A woman's ability to do this on her own may be less likely if she has other children and she needs to spend time caring for them. The amount of time available to her may be impacted upon further if she is a working mother. The woman may or may not be supported by a husband or partner but her socio economic status is likely to further effect the extent to which she is able to manage engaging in the coroners investigation without legal advice, support, assistance, representation particularly taking into account other child care and or employment obligations she may have.
