Submission by Action against Medical Accidents (AvMA) to the Health and Social Care Select Committee Inquiry into the Safety of Maternity Services in England

September 2020

The charity for patient safety and justice

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Action against Medical Accidents

1. Action against Medical Accidents (AvMA) is the UK charity for patient safety and justice.

2. Established in 1982, AvMA provides free independent advice and support to people affected by medical accidents through our specialist helpline, written casework and inquest support service. It is our work with patients and their families that informs and drives AvMA's policy work.

3. AvMA also works in partnership with health professionals, the NHS, government departments, lawyers and, most of all patients, to improve patient safety and justice in the widest sense for people affected by medical accidents.

4. AvMA's role in advising families has given us a unique insight into the impact associated with failures in our maternity services and the challenges that families too often face in obtaining an explanation of what happened and why. No one should underestimate the very real human cost of the avoidable death of a healthy baby or a lifetime of caring for a disabled child. For the families concerned, they need assurances that appropriate action has been taken to prevent what happened to them being repeated, which is at the heart of patient safety.

Summary of key points

(i) The full extent of the role of parents and families in maternity safety needs to be recognised and supported. Families have consistently been on the frontline when it comes to raising the alarm about safety concerns in our maternity services but it still requires enormous resilience and persistence to be heard. To ensure potential problems are detected at the earliest possible stage, families need access to independent specialist advice to help amplify their concerns before more families are affected.

(ii) There is evidence to suggest from the more recent scandals in maternity care that the recommendations arising from the investigation into Morecambe Bay, particularly with respect to the need for systemic and structural changes to maternity provision and regulation, are yet to be fully realised. This would suggest the need for an overarching body with responsibility specifically for maternity care that can ensure that recommendations of this nature are enacted whether arising from an inquiry, a coroner's regulation 28 report, HSIB or other relevant agency. Such a body should also have a role in overseeing maternity services and ensuring early detection and investigation of emerging problems.

(iii) Clinical negligence litigation is the symptom not the cause of problems in maternity safety. Mothers and babies who have been harmed are entitled to be fully compensated for the losses they have suffered and the future care that they will need. Preventing families from seeking fair and just compensation will not improve patient safety, but recognising the full cost of harm whether or not a claim is brought, should and can act as a driver for change.

(iv) Undertaking high quality investigations into adverse maternity outcomes is fundamental to improving safety in maternity services as well as reducing the costs of litigation. The ongoing uncertainty around the future role of HSIB in maternity investigations needs to be addressed as well as how cases will be investigated that fall outside of HSIB and the new patient safety incident investigations. There needs to be assurance that all cases of avoidable harm in maternity care are subject to an appropriate and impartial forensic examination.

(v) The Early Notification Scheme operated by NHS Resolution whilst welcome in principle, also has some significant flaws. The role of NHS Resolution is to manage and defend claims against the NHS but under ENS, NHS Resolution is in effect acting as the adjudicator on claims they are at the same time responsible for defending. That is an untenable position and highlights the importance of independence being a fundamental principle of any such scheme. It is also essential that families have access to specialist advice to ensure they are empowered in the process. There is a need for more transparency around exactly how the scheme is operating with families often not even being aware their baby's case was being investigated. As one of the stated aims of ENS is to improve the safety of maternity care, then it should also encompass other serious incidents including stillbirths. However, given the apparent backlog of cases awaiting a determination, any scheme would need to be properly funded to avoid even further delays before families receive financial assistance.

(vi) NHS Resolution should be required to ensure that the unique and comprehensive patient safety data that they have access to is fully utilised. This is information that is not replicated elsewhere. If in past decades the lessons that could have been extracted from legal claims had been acted upon and used as a driver for change, the lives of many patients and their families may have taken a very different course. AvMA welcomes the fact that NHS Resolution is beginning to analyse the patient safety data that they hold but there is considerable potential for this to be extended. There then needs to be clear pathways for disseminating potential learning to relevant bodies that can in turn ensure action is taken.

(vii) There are some continuing as well as emerging areas of maternity care that need to be urgently addressed. This includes a potential increase in avoidable harm to babies occurring in the neonatal period, the need for improved maternal mental health services to reduce the rate of maternal suicide which is the leading cause of maternal death in the first year after pregnancy, and research to understand why women and babies from black and ethnic minority backgrounds are at much higher risk of dying in childbirth.

(viii) The blame culture that remains endemic in many NHS organisations is not as is often assumed the fault of patients but most often due to failures in leadership. AvMA fully supports the 'just culture' initiative but on the basis that just culture should apply equally to patients and their families as well as to staff. If patients are not part of the just culture discussions, there is a risk that they will be further marginalised, and their rights diminished as was seen in the context of some of the discussions around 'safe space'.

(ix) The role of HSIB in maternity investigations was a significant step forward, not least because parents are very much at the centre of the investigation. We would like to see the criteria for inclusion under the scheme extended and in particular, to include stillbirths that occur prior to the onset of labour. As exploring human factors is an important part of the investigative approach, HSIB would be in an ideal position to identify situations where families were aware that something was going wrong but their concerns were ignored. The hope would be that this could lead to developing

pathways by which families could escalate concerns before harm is caused. Any future legislation should ensure that safe space does not apply to maternity investigations.

Section 1: the impact of the work which has already taken place aimed at improving maternity safety, and the extent to which the recommendations of past work on maternity safety by Trusts, Government and its arm's-length bodies, and reviews of previous maternity safety incidents, are being consistently and rigorously implemented across the country;

Impact of work aimed at improving maternity safety:

5. Maternity care has been amongst one of the most examined areas of healthcare with the confidential enquiry into maternal deaths (CEMD) being established in 1952 and the confidential enquiry into stillbirths and deaths in infancy (CESDI) in 1992 now incorporated into MBRRACE (Mothers and Babies – reducing risks through audits and confidential enquiries).

6. Over the past 20 years, there has been a wealth of initiatives and inquiries focused on maternity care. The concern is that notwithstanding the availability of all this data, the experience of many families is that the same failures are still being repeated whether it is the inability to correctly interpret a CTG trace, failure to respond to intrauterine growth restriction or reduced fetal movements, overuse of oxytocic drugs in labour or failures in decision making.

7. This is not to take away from the successes that have been achieved. The National Maternity Transformation Programme (NMTP) set up to implement a vision for safer and more personalised care across England, included delivering a national ambition to halve the rates of stillbirths, neonatal mortality, maternal mortality and brain injury by 2025. The report "Better Births Four Years On: A review of progress"[1] published in March 2020 states that *"between 2010 and 2018 there was a 21% fall in the stillbirth rate. This means the NHS in England has met the 2020 20% reduction ambition two years ahead of schedule (although the trajectory will need to improve to meet the 50% ambition by 2025).*"

8. On page 33, the report goes on to say:

"The Maternity Transformation Programme uses the PIER framework to shape its interventions to improve safety:

- *Prevention*
- *Identification*
- *Escalation*
- *Response"*

9. The key question is the extent to which this is being realised in practice. On page 36 of the report, it states:

"*In addition, the Maternity and Neonatal Safety Improvement Programme (MatNeoSIP) is using quality improvement methodology with all maternity and neonatal provider trusts to reduce unwarranted variation in care, improve the quality and experience of care for women, and improve clinical outcomes in five national clinical drivers. The*

[1] https://www.england.nhs.uk/publication/better-births-four-years-on-a-review-of-progress/ Pg.9, para 13-14

programme brings together local organisations to work collaboratively with system partners, build improvement capability, spread improvement, and learn from areas of clinical excellence. All Maternity and neonatal provider organisations have nominated leads trained in quality improvement methodology, developed a local improvement plan, assessed their safety culture and are continuing to be supported to deliver their local and system wide improvement plans."

10. A full evaluation following completion of MatNeoSIP's most recent phase which commenced April 2020 would help ensure the momentum is maintained. Its target is to: "*build on learning from the last three years of the programme in terms of what makes changes happen, and its curricula will evolve according to the latest learning from e.g., HSIB, the Perinatal Mortality Review Tool, the Early Notification Scheme and Care Quality Commission inspections. It will therefore be the primary approach to help trusts universally turn themes emerging from learning nationally into changes to clinical practice, behaviour and service models locally.*"

Gaps in the evidence provided by surveys of women's experiences

11. The management, respect, honesty and care which is afforded to families when things go wrong are important aspects of previous recommendations and these have not been adequately tested.

12. Although the 2020 Better births report does consider the woman's experience about the care they received most of that analysis draws on findings from the Care Quality Commission's (CQC) Annual Survey. The CQC survey asks a broad range of questions which are addressed to women, most of whom will have had safe births. https://www.cqc.org.uk/publications/surveys/maternity-services-survey-2019

13. Importantly, the CQC Annual survey questionnaire excluded several groups of women including 'women whose baby had died during or since delivery, women who had a stillbirth (including where it occurred during a multiple delivery)'. AvMA are mindful that if the CQC had sought opinions from the excluded groups the outcome of the survey is likely to be quite different. If handled with sensitivity, most parents who have suffered a loss or serious harm will be keen to share their experiences if this will help improve care and prevent the same thing happening again. Understanding the experiences of these parents will provide a far more accurate health check of an organisation and the systems that surround it than only asking parents with a positive outcome.

Are the recommendations in the previous maternity safety reviews being consistently and rigorously implemented across the country?

Lessons from the Morecambe Bay inquiry

14. The Kirkup independent report [2] of the inquiry into failures in care at Morecambe Bay NHS Trust maternity and neonatal services was published in March 2015. This identified failures at all levels from ward level to the regulatory framework. There is evidence to suggest that lessons and recommendations from the inquiry have yet to be fully enacted. This is particularly with respect to the wider system and how quickly similar problems arising within a maternity unit today would be identified and addressed as well as the extent to which such problems can be pre-empted before harm is caused.

[2] https://www.gov.uk/government/publications/morecambe-bay-investigation-report

15. There are two reports currently pending into the investigation of maternity care at Shrewsbury and Telford Hospital led by Donna Ockenden and East Kent University NHS Foundation Trust led by Dr Bill Kirkup. The investigation into maternity services at East Kent was prompted by the coroner's recommendations in his conclusion at the inquest into the death of baby Harry Richford in January 2020. As happened at Morecambe Bay, it was only through the resilience and courage of the family in the midst of a tragedy that brought longstanding failures in provision of safe care to light.

16. The fact that two major reviews of maternity services in two different trusts are currently underway does not instil great confidence that the recommendations of previous reviews are being consistently and rigorously implemented across the country. At the time of the Richford inquest, East Kent trust did not show any awareness of the contents/recommendations from these reports. There were opportunities for both trusts to critically assess their own standards whether through the complaints process and or the serious investigation report but this did not appear to happen. External bodies such as CQC did not identify these problems either.

17. Consistent and rigorous implementation of lessons learned will only be achieved by policing and monitoring ideally by independent third parties.

Continuing and emerging areas of concern

18. AvMA is seeing a worrying number of cases involving significant harm to babies occurring in the neonatal period, both in hospital but also on discharge home. This includes serious brain injuries resulting from neonatal hypoglycaemia, undiagnosed or inadequately treated jaundice and neonatal infections. These are some of the most distressing cases because in many instances the harm is completely avoidable with relatively simple and timely interventions. There is an urgent need to ensure care in the neonatal period receives the same level of scrutiny as care in pregnancy and labour.

19. Maternal suicide continues to be the leading cause of maternal death in the first year after the end of pregnancy. MBRRACE published a rapid report: 'Learning from SARS-Cov-2-related and associated maternal deaths in the UK' in August 2020. The following case vignette from the report although within the context of Covid 19, still acts to illustrate the woeful state of mental health services for mothers and the urgency with which this needs to be addressed:

'*A woman revealed a history of mental health problems and early life trauma during her pregnancy. Repeated referrals were either not accepted or cancelled due to COVID-19 restrictions. A letter to the woman from the perinatal mental health service arrived two months after the cancellation (one month after she gave birth) explaining that she would not be seen due to COVID-19 restrictions as they only saw people with acute mental illness, and providing leaflets on primary care psychological services, third sector and self-help resources. She died by suicide two weeks later.'*

20. The MBRRACE annual reports continue to highlight the disproportionate number of women and babies from black and ethnic minority backgrounds dying during pregnancy and childbirth with black women having up to five times the risk of dying (Saving Lives, Improving Mothers' Care 2019) with increased rates of both stillbirth and neonatal deaths (Perinatal Mortality Surveillance Report, October 2019). There is a clear and urgent need to understand the underlying causes that lead to a significantly higher rate of deaths in these mothers and their babies.

Section 2: The contribution of clinical negligence and litigation processes to maternity safety, and what changes could be made to clinical negligence and litigation processes to improve the safety of maternity services?

Overview.

21. Although maternity cases constitute a small proportion of all litigated cases they account for 50% of the total litigation costs dealt with by NHS Resolution. It is logical to examine how these costs can be reduced whilst also recognising that this has been a catalyst and driver for improving safety but much more could be done as set out elsewhere. AvMA has always been in favour of making the litigation process work better and if an appropriate methodology can be found, avoiding litigation altogether. However, we would like to point out the grave danger in approaches which are advocated by some stakeholders to water down access to justice for injured children by making litigation even less claimant friendly than it currently is, or designing alternatives which lack robustness and objectivity or rely on under compensating children whose lives have been devastated by avoidable harm. The consequences of this would be;

    a. To reduce the number of lapses in patient safety which come to light, and consequently the opportunity to learn from these incidents. For all its faults, litigation has allowed for independent forensic consideration of cases where the family is empowered by specialist legal representation and expert evidence. This often results in recognition of failures in patient safety which would not be recognised if the original considerations of the NHS itself, or its legal and clinical advisers, had been relied upon. Litigation also provides an added incentive for the NHS to improve patient safety. It can be argued that if it were not for the eye watering costs of litigation of maternity cases, improving patient safety in maternity would not be being given the priority that is currently being afforded.

    b. Not compensating children injured by avoidable, indeed negligent harm fully and fairly is inconsistent with the concept of access to justice, which is a fundamental principle in our society. We have heard it said that there is a need to “strike a balance between access to justice and the cost to the NHS”. To dilute access to justice by making it less accessible or reducing the compensation that an injured child can receive would be morally unacceptable. To state the obvious, if patient safety was what it should be, the cases giving rise to these costs would not exist, and even more importantly the human cost would also be avoided. Diluting access to justice would be be accepting that patient safety can not be put right. Children injured by sub-standard care would in effect have to pay twice: firstly by the avoidable and often catastrophic damage to their heath and lives; and secondly by sacrificing normal access to justice in order to subsidise the NHS for the cost of its own failings. Compromising on access to justice is also inconsistent with the notion of a “Just Culture” in healthcare. Most families we deal with can appreciate that mistakes can happen and that these are usually system based. If they are faced with an unjust system, it will damage public confidence in the NHS and health professionals and families will be much more likely to take an adversarial approach and seek retribution against individuals. This would create a toxic and less trusting atmosphere which is unhelpful and unwanted by staff as well as patients/families.

Reducing the costs of litigation.

22. As stated above, litigation costs and human costs are avoided if the negligent treatment is avoided in the first place. That is why we place so much emphasis on

patient safety as described elsewhere in this submission. When avoidable harm does occur, any potential legal costs could be significantly reduced if incidents were investigated properly, failings identified, and resolution of the case sought without the need for litigation. We discuss alternatives to litigation: the current Early Notification Scheme; and HSIB Maternity Investigations in more detail below. However, even when there is litigation of these cases there is still plenty of scope for reducing the considerable legal costs, without compromising on access to justice. It is worth pointing out that these costs only arise at all if there is a settlement in favour of the claimant. If the claim is investigated properly at an early stage it should be possible to recognise that a settlement should be made without the case being unnecessarily defended. It is only where this happens that costs escalate very significantly because the claimant has had to do so much more work and obtain expert evidence to support their case. Whilst the "no-win no fee" conditional fee agreement (CFA) system provides a strong incentive for claimant lawyers to assess the case carefully and not take a case on or drop the case when it is seen as unlikely to succeed, there is no such incentive for defendant lawyers. They are paid win or lose. We strongly recommend that such an incentive be introduced.

23. Legal costs have also been increased by the replacement of legal aid funding by conditional fee agreements as a result of the Legal Aid Sentencing and Punishment of Offenders Act 2012. Whilst an element of legal aid remains for babies who have suffered a neurological injury, in practice, the current restrictions surrounding the provision of legal aid, means it can often hinder the investigation of claims including access to suitable medical experts as well as adding to delays meaning a CFA then becomes a more viable option. Most stakeholders, including the NHS Litigation Authority, agreed that legal aid was a cost-effective way of funding legal costs in clinical negligence cases. It provided for quality control, including the restriction of access to this funding to accredited specialist solicitors. As well as inflating legal costs overall, the effect of this change was to shift the costs from the Ministry of Justice to the Department of Health and Social Care / NHS. Consideration should be given to introducing a revamped and improved legal aid scheme.

Alternatives to litigation.

24. AvMA has always supported the principle of alternative approaches to resolving cases without the need for litigation, provided that this can be done fairly, without compromising access to justice; and maximising the opportunity for learning lessons for patient safety. We saw potential in the proposed Rapid Response and Redress scheme which the Department of Health consulted upon even though we had serious concerns about some elements, including the proposal that the scheme be paid for by reducing the compensation to be paid to injured children. For details, see our response to the consultation (ref https://www.avma.org.uk/wp-content/uploads/RRR-response.pdf Although there has been no formal announcement, the Department of Health and Social care appears to have shelved these proposals. The Early Notification Scheme (ENS) currently being administered by NHS Resolution can be seen as a form of limited alternative to the Rapid Response and Redress Scheme. We comment in detail on the ENS below.

Early Notification Scheme (ENS).

25. This scheme was introduced in 2017 and is administered by NHS Resolution. AvMA sees great positive potential in the ENS but does not believe that it currently goes anywhere near reaping its full potential. We recommend an overhaul of the way it is designed and administered. Disappointingly there was little or no wider stakeholder

involvement in the design of the scheme. As far as we know, no independent organisations representing the interests of injured children or their families were involved. Certainly we weren't, although we do have a constructive relationship with NHS Resolution. We have advised on improvements that could be made during the course of the scheme but few if any of our suggestions have yet materialised. Our concerns and suggestions are set out below.

26. **Administration of the scheme**. There are obvious challenges for the scheme being totally objective and for public confidence in it, if it is administered by NHS Resolution, which is best known for its role in defending claims against the NHS. Whilst we believe that the ideal would be to have an independent organisation running a scheme of this nature (as we proposed with regard to the Rapid Response and Redress scheme), we believe that public confidence and effectiveness could be greatly improved if degrees of independence were to be introduced.

27. There needs to be separation between the governance of the scheme and the rest of NHS Resolution. We recommend that a separate committee or governance group be established for the scheme. Membership should include independent organisations representing children/families (including AvMA); representatives of claimant solicitors (for example the Society of Clinical Injury Lawyers (SCIL)); representatives of the Bar; and independent clinicians as well as NHS Resolution staff and representation from NHS trusts. This group could oversee the workings of the scheme, monitor its delivery, and evaluate it.

28. **Scope of the scheme.** The scheme currently excludes some very serious incidents which occur in maternity and result in litigation. It seems to be targeted at cases of maximum financial cost rather than those with the most seriousness consequences or potential for improving patient safety. For example, stillbirths are excluded. We recommend that the criteria of the scheme be extended. Furthermore, if the scheme really is centred on learning for patient safety as well as determining eligibility for compensation, cases which do not meet the criteria for compensation should still be considered closely for patient safety issues.

29. **Transparency.** Although the scheme is intended to be an alternative to litigation, it treats families as if they were litigants by applying the principle of legal privilege. This means that information gathered to help NHS Resolution decide whether a case meets its criteria for awarding compensation is not available to the families concerned. We question the legality of this approach as it should only apply if this information is gathered for the purposes of litigation. In any case it is inconsistent with the principles of openness and honesty.

30. What is more, families are not even being advised that this approach is being taken. We have examples from families we have contact with of families not knowing about this and indeed examples of where the family has not even been told that their child's case is being considered by ENS or that the trust concerned has reported the incident to ENS and in some cases shared the mother's and baby's medical records. As we understand it, when a decision is made as to whether a case meets the criteria for compensation being offered or not, the family is not provided with the information including details of any clinical reviews which led to that decision having been reached.

31. NHS resolution's Progress Report on the ENS (September 2019) found that only *"77% (71/92) of families were notified by the trust that an incident had occurred, and 35% (32/92) were recorded as having been offered an apology".* Although this clearly

suggests that many trusts involved in the scheme were not complying with the Duty of Candour, we have not been provided with any information to suggest that this results in anything other than a quiet word with the trust.

32. **Involvement of families.** As it currently stands, families' involvement in the process is extremely limited by the lack of transparency described above. Also, the scheme relies heavily on information provided by trusts themselves. NHS Resolution's progress report on ENS found that *"An invitation for families to be actively involved in an investigation was evident for 30% (28/92) of investigations"* The lack of family involvement in the scheme means that they have little or no opportunity to correct information provided to the scheme or influence the outcome of the scheme's deliberations. This is something that is being done for / to them rather than with them

33. **Independent advice and support.** The outcome of investigations (whether conducted by NHS trusts or the HSIB) and the ENS consideration of their child's case has huge implications for the children and families concerned. Most families will need specialist independent advice and support in helping them consider all the options open to them at what is an extremely stressful time and understanding their rights and the various potential processes. Whilst in some cases NHS Resolution provides information on where to access such advice, for example from AvMA, this is clearly not proactive or clear enough. AvMA has received a very small number of enquiries. Furthermore, no funding is available for the provision of such advice. NHS Resolution agrees that specialist information and advice should be made available to families involved in the scheme but feels that it is not in their power to fund this. We recommend that funding is made available for this for families involved in HSIB Maternity investigations or the ENS.

34. **Capacity and effectiveness.** NHS resolution would appear to lack capacity and expertise to deal with cases as quickly and effectively as would be liked. An illustration of how slow the ENS investigation period is can be found in the 2019 ENS progress report where it identifies that of the 746 qualifying cases, there were 24 admissions of liability within 18 months. This begs the question, what was the status of the remaining 722 cases? It is also worrying that such a small number of cases result in admissions of liability. Given the criteria for reporting cases to ENS, it is likely that a large proportion of cases deemed by them as being ineligible for compensation go on to be litigated successfully, resulting in legal costs that could have been avoided and unnecessary stress for all those involved. The delay will also disadvantage those families both in terms of investigating the child's legal claim but also in terms of delaying much needed financial support. One of the problems is likely to be that NHS Resolution are used to looking at cases through the eyes of a defendant. The suggested measures outlined above would help, but more resources will also be necessary.

NHS Resolution and learning from litigation

35. When the NHS Litigation Authority (NHSLA), was established in1995, the anticipated focus on 'risk management' was welcomed on the basis that this would herald a new era where the failures in care which gave rise to claims would be addressed. In reality, notwithstanding the NHSLA was the only body with access to such a potentially comprehensive dataset on avoidable medical harm, the approach to risk management appeared to focus not on the underlying causes of claims but the legal claims themselves. This meant that historically attention has not been on preventing harm that gives rise to claims but preventing those who have been harmed from being able to seek redress. This is frequently evidenced by headlines referencing the rising cost of litigation, but very rarely is it reported that these claims represent only a fraction of

the number of patients harmed or the very substantial hidden costs associated with avoidable harm.

36. In reality, it is only relatively recently that any real attention has been given as to how the data derived from clinical negligence claims might be used to improve care. The report: “Ten Years of Maternity Claims. An analysis of NHS Litigation Authority data” published in October 2012 was the first indication of a new approach. This report analysed ten years of maternity claims with an incident date from 1st April 2000 to 31st March 2010.

37. In 2017, the NHSLA changed its name to NHS Resolution. In September 2017, NHS Resolution published: “Five years of cerebral palsy claims, A thematic review of NHS Resolution data”. This acknowledged that claims for avoidable cerebral palsy, had “remained relatively static over the last ten years”. Part one of that review identified several key areas of concern, including “A lack of family involvement and staff support through the investigation process”. Part two of the review identified recurring themes and areas for improvement. Four areas of clinical practice were common throughout the claims. Chief among them was fetal heart rate monitoring and staff competency and training. The NHS Annual report and accounts for 2018/19: demonstrates that over the last 14 years or so the number of claims for maternity cerebral palsy/brain damage has “remained relatively steady”.

38. The onus is now very much on NHS Resolution to ensure that full use is made of the unique dataset that they have access to, not just for maternity care but all areas of NHS medical care.

Section 3: Advice, guidance and practice on the choices available to pregnant women about natural births, home births and interventions such as C-sections, and the extent to which medical advice and decision-making is affected by a fear of the “blame culture”; which medical advice and decision making is affected by the fear of the ‘blame culture’

‘Blame culture’ to ‘just culture’

39. Our discussions with health professionals tells us that when it comes to “blame culture” what worries them most is the inappropriate blame, negative behaviour and even bullying that comes from management or other health professionals. This is about leadership and organisational culture and an unwillingness to tackle difficult issues around systemic failures. Of course there is also fear about complaints, litigation and excessive regulatory responses also. There are myths that circulate about litigiousness of patients and what is involved if there is a serious incident investigation or litigation. Training for health professionals should help allay unrealistic fears by helping staff understand that these outcomes are relatively rare, and that most patients are understanding about the pressures faced by health professionals and very reluctant to complain or take legal action when there is a patient safety incident, provided that there is openness and honesty. This is our experience based on decades of supporting thousands of people each year who have been affected by avoidable harm for over three decades. However, the leadership and culture of the organisation people work in has to be right. That is why we fully support initiatives to promote a ‘just culture’ in healthcare.

40. We are concerned that most discussion of ‘just culture’ so far has concentrated almost entirely on the need to treat staff fairly. This is essential, but we believe that in the context of healthcare a ‘just culture’ needs to embrace the needs of patients and

families equally with those of staff including the support available to patients in the aftermath of avoidable harm. This will help foster mutual understanding and trust. There should be a single agreed definition of what is meant by 'just culture' which informs policy making as well as operational issues. This would help avoid policies which are well intended but inconsistent with the principles of an inclusive just culture. For example, policies which would prevent full openness with patients such as the original 'safe space' proposals or policies restricting or diluting patients' access to justice when there has been avoidable harm. Too often patients and families are painted as the problem instead of dealing with the policy, leadership and organisational issues which give rise to a toxic culture. We have drafted a vision of what a more inclusive definition of just culture might look like, which we hope will inform discussions amongst all stakeholders of what a national definition which everyone can identify with might look like (see appendix 1).

41. Whilst choices about birth are important, we believe that patient safety should always be the top priority. Decisions should be made jointly between women and clinicians but be fully informed by an understanding of the relative risks. Until we are clear that birth options are safe, choice may have to be restricted. Birth is a very personal matter giving rise to strong emotions and personal preferences. This should be tempered by an objective assessment of the implications for the safety of mothers and babies. We have been concerned to hear almost evangelical promotion of 'natural birth' for example which may cloud women's judgement about what is optimal safety wise. There is a worrying variance between NHS trusts about the number of C-sections carried out. A significant proportion of serious incidents and claims involving cerebral palsy centre around not performing a caesarean section. There have been plenty of examples where the mother was requesting a caesarean and was denied, the concern being that this was in part target driven.

42. Much is said about 'defensive medicine'. Fortunately, in the NHS when something goes wrong and there is legal action as a result, it is the NHS that is sued and not individual clinicians (uncomfortable as it is to be involved in any legal action), so such fear should not affect decisions. 'Defensive medicine' in the sense of safety and clinically justified decisions made in partnership with women is a good thing. Decisions based on fear are not 'defensive medicine' but poor medicine.

43. The issue of blame culture is perhaps thrown into sharpest relief in the context of a criminal investigation. There are clearly instances where the actions or inactions of an individual or individuals is so egregious that referral to the criminal justice system is an entirely appropriate course of action. However, in many instances it is found that the context within which frontline staff were working meant that they were effectively set up to fail. It is only through examining that wider context that one can hope to prevent the same mistakes being repeated whereas solely focusing on the actions of one or two individuals rarely leads to safer care.

Quality of patient safety investigations

44. What has often underpinned the blame culture is a lack of forensic skills to unpick the full circumstances of what went wrong and why. Notwithstanding the introduction of investigatory tools such as root cause analysis, the evidence would suggest that these methods are still too often misapplied. The establishment of the Health Safety Investigation Branch and their investigatory process is providing a template for more contextual investigations but that still leaves a gap in terms of the ability of individual organisations to carry out an effective investigation of their own. In all the major healthcare scandals a lack of insight and the inability or unwillingness to recognise

that the quality of care being provided was putting patients at risk has invariably been a significant contributing factor to the extent and duration of harm.

45. Unless an organisation has been assessed by the CQC (or appropriate body) as capable of carrying out good quality investigations, we would recommend that any investigations into serious incidents should be carried out or directly overseen by an independent body/independent investigators.

46. The introduction of the Patient Safety Incident Framework in 2021 to replace the Serious Incident Framework, raises questions as to how cases not selected for investigation will be dealt with. It is hoped that the current work by the Parliamentary and Health Service Ombudsman to establish a Complaints Standard Framework will help improve local investigations, but this will not take away from the need for independent oversight to mitigate against the type of wilful ignorance evident in all the major healthcare scandals.

The role of patients and families in the prevention of harm

47. There has been a persistent failure to capitalise on the central role that patients and families could play in patient safety. This is both in terms of empowering patients to speak up to prevent harm as well as allowing patients to contribute fully to the investigation and understanding of what happened after an adverse outcome. This is particularly relevant in maternity care where listening to the voices of mothers, fathers and families could be key to preventing harm but also essential in the aftermath of an adverse outcome in achieving a deeper understanding of the causes of what went wrong and why.

48. In all areas of patient safety including maternity care, AvMA sees numerous examples where the patient or their family suspected that something was going wrong with the treatment but could not find anyone who was prepared to listen and act on those concerns. An example to illustrate this comes from an inquest involving the death of a young woman admitted to hospital in the final trimester of her pregnancy. Her mother who accompanied her to the hospital correctly identified the cause of her daughter's acute abdomen but her concerns were dismissed over several days. The mother became so desperate that she attempted to have her daughter transferred to another hospital but was prevented from doing so. By the time her daughter's condition was correctly diagnosed, it was too late to save her life. This type of scenario is seen repeatedly across healthcare.

49. There is a need to explore a range of different mechanisms that will enable patients and their families to have their concerns about treatment escalated and reviewed before avoidable harm is caused - an 'amber button/red button' process that can be activated when other attempts have failed. If this had happened in the above case, the death of this young woman would most likely have been avoided.

50. The other important way of empowering parents is through information and advice. MBRRACE-UK is responsible for the confidential enquiries into maternal deaths, stillbirths and infant deaths. As part of disseminating the findings of those enquiries, a lay report is also produced which includes key messages for mothers and families including the importance of raising concerns with other healthcare professionals if they are concerned they are not receiving the appropriate treatment.

51. In terms of patient safety investigations, it is extraordinary that it is only since 2018 with the introduction of the Perinatal Mortality Review Tool (PMRT) and the HSIB maternity investigations that there has been a more systematic approach to

incorporating the evidence provided by parents into the investigation of adverse maternity outcomes. However, this will only apply to cases which meet the HSIB and PMRT criteria, leaving many cases that fall outside these investigations and potentially many parents who will struggle to have their voices heard.

52. As indicated above, it is notable that it is often only as a result of persistent campaigns by patients and their families that the majority of the major healthcare scandals have come to light including amongst others Mid Staffordshire, Morecambe Bay, and East Kent Hospitals NHS Trust. Notwithstanding the essential role that patients have so often played, the type of support available to help them to raise concerns has in effect been systematically undermined over the past 20 years. It is arguable that had there been a much stronger system of advice available and the ability for those advisors to collate and identify emerging problems whilst also recognising that sometimes just one case will be sufficient to ring the alarm bell, these scandals could have been detected much earlier and a great deal of harm avoided.

Section 4: How effective the training and support offered to maternity staff is, and what improvements could be made to them to improve the safety of maternity services;

53. The fact that the same causative factors have been seen repeatedly in maternity claims over the past 30 years, highlights a failure to utilise the potential learning from litigation but also recognising that the problem goes deeper in that it is a broader issue outside of litigation around how patient safety issues are addressed more generally. Those same factors were highlighted in the CESDI reports from the early 1990s when looking at avoidable factors in relation to stillbirths and neonatal deaths. For example, the interpretation of CTG traces has continued to factor in birth injury claims over many decades and yet we know that the problem still exists in maternity units today. We recognise that identifying solutions is not always straightforward and is often multifaceted but the first step is prioritising finding those solutions.

54. The Royal College of Midwives in their report, 'The gathering storm: England's Midwifery workforce challenges' (2017), set out the challenges facing maternity services and the potential consequences of not addressing workforce shortages. This is against a backdrop where the maternal population is becoming more complex. Any improvements in maternity care can only be achieved if chronic maternity workforce shortages are addressed.

55. With the drive to introduce more midwifery support workers, there is a risk that due to workforce shortages we will see midwifery support workers being asked to undertake roles they are not competent or equipped to fulfil. This would mirror what has been seen with healthcare assistants with many examples where healthcare assistants have been expected to undertake tasks without the level of training or knowledge required to do this safely.

56. One of the key factors in Morecambe Bay was the relative isolation of the midwifery and obstetric staff from mainstream practice allowing standards of practice to regress. Particularly for more remote units, it is essential that training and professional development supports benchmarking against best practice. The move to online training should allow for more opportunities for joint training with organisations that are identified as best practice leaders. Another important way of maintaining practice standards would be through a programme of exchange placements, encouraging staff to take up temporary exchange placements with other organisations.

Section 5: The role and work of the Healthcare Safety Investigation Branch in improving the safety of maternity services, and the adequacy and appropriateness of the collection and analysis of data on maternity safety.

57. One of the most welcome aspects of the HSIB maternity investigations is the direct involvement of parents and families in the investigative process, enabling them to be integral to the learning. It is AvMA's experience that parents who have been through a traumatic birth, are often very good historians and are able to contribute a perspective that would not otherwise be available.

58. There is a very significant group of cases that do not currently fall within the remit of the HSIB maternity investigations. These are cases where the baby died after 37 weeks gestation but prior to the onset of labour. An example of the type of case currently excluded involves a mother who repeatedly reported concerns about reduced fetal movements but no action was taken for several days at which time it was too late to save the baby. That cross-over between community and hospital is an important area for examination if numbers of avoidable stillbirths are to be reduced.

59. It is relatively early days in terms of assessing the impact of HSIB maternity investigations, but the fact that HSIB can only make recommendations potentially dilutes the impact of their investigation and reporting process. There is a need for an overarching body that can collate all the evidence from the different maternity enquiry processes, lead on sharing learning and coordinating the implementation of solutions but also ensure recommendations in relation to individual healthcare providers are implemented.

60. HSIB Maternity Investigations are not covered by 'safe space'. It is essential that this continues to be the case. HSIB itself as well as other stakeholders agree that whilst 'safe space' provisions may be appropriate in its other investigations it would not be appropriate for these investigations because they are the primary investigation of individual incidents, whereas the other investigations are thematic and individual cases included in them will already have been subject to local investigations. The forthcoming legislation should make clear that maternity investigations are excluded from any 'safe space' approach which prohibits the sharing of information with the patients/families concerned.

61. In this context, it will be important that the relationship between HSIB and ENS will not in any way impact on the independence of HSIB and its investigation of maternity cases.

62. Long term certainty is also required about the future of maternity investigations. It had been suggested that these may move from HSIB. The ongoing uncertainty could destabilise the situation. The switch from local investigations to HSIB investigations of maternity investigations had already caused instability.

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Appendix 1: Just Culture

A VISION OF WHAT A "JUST CULTURE" SHOULD LOOK LIKE FOR PATIENTS AND HEALTHCARE STAFF

This draft document has been dev

eloped by Action against Medical Accidents (AvMA) in consultation with both people from a patient/family and a health professional background. We want to develop it further in partnership with a wider range of stakeholders in order to develop an agreed national vision of what a just culture should look like both for patients and health professionals.

1. Why is having a just culture in healthcare so important?

1.1 In healthcare, a truly just culture must be fair for patients and for health staff – both are equally important.

1.2 Having a just and learning culture is a vital part of patient safety. It helps prevent things going wrong as well as ensuring people are treated honestly and fairly if they do

1.3 Staff who work in a just culture are more likely to do their job well and achieve good outcomes for patients

1.4 Patients and those close to them fare better after incidents in organisations where there is a just culture and are less likely to complain or take legal action after an incident

2. When things go wrong

2.1 When things do go wrong and cause harm, it is very rare that this is because individuals deliberately depart from good practice or act maliciously. However, if that were the case, the individuals need to be held to account.

2.2 Individual members of staff should never be singled out for blame or be made scapegoats for something going wrong which is due to system failure.

2.3 Experiencing avoidable harm in healthcare often has a devastating effect on peoples' lives. How an organisation responds to patients/those close to them after such incidents can itself cause serious harm if it is done badly.

2.4 Patients are entitled to know what has happened in their healthcare. There must be full openness and transparency and the patient/those close to them must be enabled to be involved in investigations if they want to be

2.5 The Duty of Candour must be fully complied with but also with compassion. Fear of consequences such as litigation, complaints etc is no excuse for not being open and honest.

2.6 Staff involved in an incident which causes avoidable harm can themselves be traumatised by it. They should also be treated fairly and with compassion. Suitable support should be put in place for them.

3. Accountability

3.1 Senior management are responsible for creating and maintaining the right culture in their organisations. Organisations should be held to account if they do not nurture a just culture or do not demonstrate that they learn and take necessary action over failures in patient safety.

3.2 Staff should be listened to, supported and helped to learn and improve (if necessary), rather than blamed/punished.

3.3 In rare cases of intentional unsafe practice or incompetence that are proven, individuals do need to be held to account. Blame should not be avoided at all costs.

3.4 Failure, by either by organisations or by individuals, to comply with the Duty of Candour which applies to them is unacceptable and should always have serious repercussions.

3.5 Patients or those close to them have a perfectly reasonable right to raise concerns or complaints or to seek compensation and accountability through taking legal action if they need to. They should not be stigmatised for doing so, and their healthcare needs should never be compromised as a result.