Perinatal Management of Extreme Preterm Birth Before 27 Weeks of Gestation – Consultation Responses

The British Association of Perinatal Medicine is grateful to all of those members and stakeholders who responded to the draft Framework for Practice for the Perinatal Management of Extreme Preterm Birth before 27 weeks of gestation. We present a summary of our response to the feedback, and a detailed reply to each person who responded.

All comments were agreed by consensus within the Working Group.

Summary Response:

- ***Risk categories*** – these have been redefined as “extremely high risk”, “high risk” and “moderate risk”

- ***Choice of denominator*** – we have considered this very carefully and chosen to remain with using “live born babies who have received active management” as the denominator when presenting outcome data, both survival and severe disability. This has been clarified both in the text and in the infographic. The text and infographic have also been amended to emphasise that not all extremely preterm babies will survive labour, and wording has been revised to underline that there is no evidence that caesarean section, with its inherent risk to mother, improves outcomes. It was strongly the opinion of our parent support organisations that presenting more complex data, with differing denominators would be confusing to parents, and not helpful.

- ***Types of impairment*** – from an ethical point of view, when deciding whether active (survival focused) or palliative (comfort focused) management is appropriate for the family, the relevant consideration is the risk of disabilities that could affect whether it is in the baby’s best interests to survive. We propose therefore that risk assessment should, as originally suggested, focus on the most severe disabilities. The text and the appendices have however been significantly amended, with more emphasis on explaining to families both the range and unpredictability of milder impairment in surviving extremely preterm children.

- ***Requests for treatment conflicting with best interests (withholding treatment, or providing treatment)*** – we acknowledge the importance of joint decision making, but have amended the text to include always acting in the best interests of the baby. We have also alluded to the situation of the baby being born in unexpectedly poor, or unexpectedly good condition, noting that this may necessitate a change to the agreed immediate management of the baby.

- ***Resource implications of new guidance*** – we acknowledge that implementation of this Framework for Practice will have implications for resources, both in terms of antenatal transfers, and (potentially) more children surviving with disability. We note however that optimising perinatal care is likely to result in better outcomes (with lesser long term costs). Most recent UK data indicate that enhanced survival for extremely preterm babies born in maternity care facilities adjacent to a NICU is not accompanied by increased rates of disability among survivors (ref 33)

- ***Advanced resuscitation*** – the Framework is aligned with published guidance from the UK Resuscitation Council; as noted in the text, there is a paucity of evidence to guide practice in the smallest infants. We have emphasised the benefits of deferred cord clamping, and noted that bag mask ventilation may not achieve adequate lung inflation. We have also noted that prolonged resuscitation in extremely preterm infants is unlikely to be successful.

- ***Active obstetric management*** – this section of the Framework has been revised, better to align with NICE and RCOG guidance. We have added explanatory text around fetal monitoring in labour and the pros and cons of caesarean section, and further emphasised the need for mothers to be fully informed (Montgomery ruling (ref 41)).

Rita Arya <ritaarya@hotmail.com> on behalf of BMFMS	**BAPM response**
Executive summary (4. Active management of labour and neonatal stabilisation may be considered for babies born from 22+0 weeks of gestation): What does 'active management of labour' mean/imply two things: 1. Continuous EFM = no evidence of benefit <26 weeks 2. Resort to emergency CS at 22-24 weeks = no evidence	Thank you; We acknowledge that point 4 in the executive summary could be misinterpreted as recommending continuous EFM/+/- emergency CS, rather than obstetric management intended to deliver the baby in the best possible condition. As this is now covered by point 11, we have amended point 4, removing the words “active obstetric management”.

whatsoever of neonatal benefit and 100% sure there is potential compromise to future fertility/reproductive potential. At the bottom of the email, the 'Active obstetric management' section from later in the document, contains more detail it does not make any attempt to differentiate between obstetric management at 22-23 weeks compared to 26-27 weeks. Present list: The package of active care to be offered to parents may include the following: • antenatal steroids • tocolysis • antenatal transfer to a tertiary obstetric centre co-located with a NICU • magnesium sulphate for neuroprotection • intrapartum fetal heart rate monitoring • caesarean section (if potential benefits are considered to outweigh risks) • delayed cord clamping The TWO really controversial points are 'intrapartum EFM' and 'caesarean section- very different at 22-23 compared to	We have amended text to "obstetric", rather than "active" care, and "may (but not necessarily) include". We have reordered the items to move the two more controversial ones to the bottom of the list.

26-27 weeks as we know.	
The final two elements are controversial and difficult to recommend formally independently : • intrapartum continuous fetal heart rate monitoring <26 weeks (no evidence of benefit <26 weeks) • caesarean section (no evidence of benefit <24 weeks and unclear benefit 24 to 27 weeks) We propose this instead: The package of active care to be offered to parents may include the following elements - • antenatal steroids • tocolysis • antenatal transfer to a tertiary obstetric centre co-located with a NICU • magnesium sulphate for neuroprotection • delayed cord clamping	The subsequent 5 paragraphs include discussion around EFM and CS written in conjunction with obstetric colleagues. It includes the cited maternal risks, uncertainties about evidence and need for multidisciplinary discussion. We have added to the discussion that CS is rarely indicated at extreme preterm gestations We have more closely aligned obstetric management with NICE guidance, reiterated lack of evidence at the most preterm gestations and highlighted the risks to the mother. We have also referenced the Montgomery ruling, in highlighting the need for mothers to be fully informed.
11 (Para 50): Suggest have a separate paragraph on 'impact on maternal health highlighting that decision for CS is a balance between likely fetal survival and impact of a preterm CS on Mother. This section could include comment that maternal morbidity may also arise if there is a delay in delivery, for example in the setting of prolonged rupture of membranes with risk of chorioamnionitis and with a severe	

early onset pre-eclampsia. Therefore careful consideration needs to be given to both maternal and newborn health and required multidisciplinary discussion with obstetricians and neonatologists. Suggest stating that maternal morbidity may be higher in extreme preterm CS when compared to later gestation CS as they are being performed as an emergency, usually on upper uterine segment and thus may experience increased blood loss. The lower uterine segment is not well developed prior to 28 weeks gestation and therefore a caesarean section may involve a transverse incision in the upper uterine segment, which is associated with an increased blood loss, increased post-operative maternal morbidity and an increased risk of scar dehiscence in a future pregnancy. Delivery of the fetus within the intact gestation sac 'en caul' is well described as a technique to reduce fetal trauma during caesarean delivery, although substantive evidence for this approach is lacking.	
AWORINDE, Oladipo (UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST) <oaworinde@nhs.net>	**BAPM response**
14 (72-73): If the selection of babies is indeed biased towards babies with best outlook, I disagree that including all potential babies would have caused an increase in survival. If anything, I would expect it to reduce rather than increase the survival numbers. 28 (172-176): Is it appropriate to recommend active	We agree with the comment, and although the original text indicated this we have modified the text in the appendix to make the meaning clearer: *"It is also likely that selection of babies for active treatment is biased towards those with best outlook, and so expected survival for all infants born at 22 weeks of gestation is likely to be lower than the reported survival figures"*.

resuscitation for a 22 week infant with a 2 in 10 chance of not dying or having severe impairment (not to mention mild or moderate impairment), especially as the numbers are extremely low and therefore there are fewer units and doctors who have sufficient experience to manage these children? It would be interesting to know what the outcomes are for the other two in ten who survived and what resources are needed to care for them in a resource limited setting that we work in.	The Framework does not recommend active resuscitation at 22 weeks of gestation, but we present an option for parents fully appraised of outcome data. We have revised the categories of risk noting that at 22 weeks the risk is "extremely high"
BAUWENS, Nicole (NHS GRAMPIAN) <nicole.bauwens@nhs.net>	**BAPM response**
11 (2): The term "delayed cord clamping" is currently increasingly used. However, it is rather undefined, as it is not clear what the delay should be. A reasonable amount of research is currently undertaken to specify the "delay" more accurately. The physiology is based on animal studies by Hooper in Australia and there are clinical studies on the way. A leading team is the group around Te Pas in the Netherlands. Increasingly we begin to understand why the "delayed" cord clamping is beneficial and it turns out that is not related to a certain time period but to a physiological process of adaptation. Therefore these research groups are starting to replace the term "delayed cord clamping" with "physiological cord clamping". Just one example publication is: Niermeyer, Susan. "A physiologic approach to cord clamping: Clinical issues." Maternal health, neonatology and	Thank you; others have made similar comments. We have changed wording to "deferred cord clamping for 60 seconds or more"

perinatology vol. 1 21. 8 Sep. 2015, doi:10.1186/s40748-015-0022-5 I want to suggest that we use this term in this great document which is a step into the future aligning the UK with other countries with advanced levels of Neonatal Intensive care.	
BECHER, Julie-Clare (NHS LOTHIAN) <julie-clare.becher@nhs.net>	**BAPM response**
Active obstetric management Opportunity to re-phrase it as ‘optimal cord clamping’ and add ‘for 60 seconds or more’ (also in active neonatal management). In utero transfer to a tertiary centre optimises outcomes for the baby, is better than ex utero transfer and is now a prioritised NHS England recommendation. Please reference Scottish recommendation in Best Start too. Palliative obstetric management Role of placental histopathology in informing later obstetric risks. Palliative neonatal management Probably don’t want to get into too much detail but should have recommendation to follow Child Death Review Processes/PMRT as per each nation’s procedures and that parents have opportunity to contribute to this review. On average, newborn babies receiving comfort care in the delivery room live for approximately 60 minutes (41). Please	Cord clamping comments addressed in responses to others; Scottish Maternity and Neonatal Services review, “Best Start” now referenced. A comment about placental histopathology has been added to the section on palliative neonatal management. “ “Parents should also be offered the opportunity to participate in mortality reviews” has been added to the text; this is in line with the recommendations of the PMRT. Reference 41 refers to babies born before 24 weeks’ gestation – this has been added to the text. We have sought further advice from parental support organisations involved in writing the document, and made some amendments to Appendix 3

specify either the study population in this ref ie <24 weeks gestation or say extreme preterm babies. Structuring the consultation I think some of the helpful phrases are not clear /understandable enough for parents and they vary int heir level of complexity. ‘mobilise independently’ ie get around on their own without help. ‘communicate verbally’ ie talk/speech. ‘in a meaningful way’ ie? Get pleasure from simple things and build basic relationships?? General Incredibly well written, thoughtful document which will be of immense value to clinicians and parents alike. Many thanks for this excellent work.	
Behrsin Joanna - Consultant Neonatologist <Joanna.Behrsin@uhl-tr.nhs.uk>	**BAPM response**
General: It is helpful to have a framework that gives guidance around decision making at the extremes of prematurity. However I think there generally needs to be a bit more clarity in the way that the data is presented in this paper specifically around the outcome infographics that are displayed for parents that seem to be misleading and set a precedent potentially for offering intensive care to babies at 22 weeks of gestation.	Thank you: much discussion went into preparation of the infographics, including whether or not to include survival figures based on different denominators. The consensus (greatly influenced by our parental support groups/parental feedback) was that too much data can be confusing to parents. We have emphasised that the infographics should never be used alone, but utilised to support detailed conversation with parents. The Working Group noted potential for a self-fulfilling prophecy of poor outcomes if resuscitation/stabilisation is not attempted. The Working Group’s view was that presenting the proportion surviving as a percentage of

8 (Figure 1, 26) The concept of having a subgroup of babies that are felt to be extremely high risk is helpful – especially advocating that decisions should not be made on gestation alone. Figure 1 is confusing it is difficult to understand how the shading for gestation has been devised. The time point for counselling is either pre-labour in a foetal medicine clinic or around the onset of labour when mothers are admitted. The outcomes that are presented for decision making should reflect this. Point 75 table 1: At 22/40 5% of those babies alive in labour survive. At 23 weeks 28% survive. Does this not mean therefore that the shading in figure 1 should be extremely high risk up until 23 weeks. Moderate to high risk 23-24 weeks and lower risk 24 weeks onwards. The current format of this figure is misleading and potentially raises expectations of extremely preterm survival rates. It may be simpler to present a shaded risk around gestational age – ensuring that this is consistent with the rest of the data presented in the framework and then list other modifiable risk factors such as antenatal steroids that influence the outcome. In terms of modifiable risk factors perhaps the presence of a major congenital anomaly e.g. structural congenital heart disease could also be added. Perhaps a worked example to illustrate the concepts could also be included for those that do not immediately understand visual data. For example Mrs X 22+6 well grown female singleton fetus in tertiary perinatal centre has had steroids wishes	those presenting alive in labour is potentially misleading since it includes infants who die as a consequence of a decision to pursue palliative obstetric and neonatal management, but we have retitled the infographic, hopefully to aid clarity. We are also keen not to promote (non-evidence based and potentially detrimental to mother) active obstetric intervention in extreme preterm labour. Figure 1 has been modified and further scenarios have been added to Appendix 5 More detailed survival data are provided in Appendix 1 We have noted that reported outcomes are likely to be better than actual outcomes if attempted stabilisation becomes more common, but there is overwhelming evidence that overall outcomes for extremely preterm infants are improving. Text amended, thank you – we now caution against over inflation of the lungs We appreciate these concerns, and have amended the text. We have noted that extensive resuscitation is very unlikely to be successful. However, the consensus group considered that in the absence of clear evidence, it would not be appropriate to give didactic advice

active management at delivery – counselled around risks – agreed plan of active management. Mrs Y 22+0 in a SCBU, actively labouring, no steroids, male growth restricted infant. Extremely high risk active management at delivery futile. 12 (55): Caution around terminology. Lung inflation could be confused with inflation breaths initially which are not recommended in this population. Should this be made clear with 'instigate ventilation breaths to inflate the lungs, avoid over-distending with large volume inflation breaths'? 12 (56-57): What is the definition active management of the newborn? The working group recommends applying the same approach in preterm babies as to term babies in terms of NLS algorithms. Whilst most preterm babies are stabilised with airway manoeuvres and surfactant alone there are some at which this is not possible. The previous 2008 framework referenced a paper by Sims et al and concluded that there was no evidence to support the use of adrenaline by any route, or chest compressions, during resuscitation at gestational age <26 weeks (Sims DG, Heal CA, Bartle SM. Use of adrenaline and atropine in neonatal resuscitation. Arch Dis Child F&N 1994; 70: F3-9.) It is an area of concern that the latest framework by suggesting we follow standard NLS algorithms creates ambiguity in this area. Likewise standard NLS algorithms suggest continuing effective	around the extent of resuscitation that should be attempted or when this should be stopped. Of note, while we are aware that previous BAPM guidance recommended against CPR/adrenaline, neither ILCOR nor the European Research Council guidelines (which formally review all relevant literature) suggest any modification of neonatal resuscitation algorithms for extremely preterm infants. We have highlighted that *Absent heart rate or severe bradycardia persisting despite effective cardiopulmonary resuscitation for more than a few minutes is associated with high rates of mortality and neurodevelopmental impairment in extremely preterm babies* (44,45). We worked closely with RCOG/BMFMS in writing the obstetric advice. We have not advocated active intervention in labour in terms of CS, so there will still be many infants who do not survive labour at these very early gestations. The possibility of not surviving the birth process has been added to parental information

resuscitation for 10 minutes – again there is lack of clarity in this document. Specific statements of guidance around length of time to continue active resuscitations and how much this should be escalated in terms of use of chest compressions and drugs would be helpful. In summary I find the recommendation to give drugs at these extremes of viability extremely worrying. Brief CPR may be appropriate in some instances. The adoption of NLS term recommendations would mean many of these babies would receive cardiac massage and drugs (not just adrenaline). During the counselling of parents for 22/23w should this be an opportunity to discuss limiting resuscitation efforts such as airway/intubation are tried but CPR >1min and use of drugs would not appropriate. 10 and 11 (Figure 2, 48, 49 and 50): At what point should active obstetric management be considered? Has this been discussed with RCOG and other relevant midwifery & obstetric forums? Moderate high risk according to the infographic figure 1 includes babies from 23/40 gestation. Figure 2 suggests that depending on the outcome of counselling with parents that active obstetric and neonatal management may be an option. Active obstetric management includes in-utero transfer, antenatal steroids and magnesium and caesarean section. Caesarean section at <26 weeks carries greater risk for the mother as it may to be	BAPM acknowledges that adopting this Framework for Practice will result in more antenatal transfers. This will be necessary, to ensure the best outcomes, and must be encouraged. Processes to achieve this are out with the scope of the Framework. Parental support organisations have been central to the writing of this guidance. Amendments have been made to all of the original figures and the infographic. The issue of which data are appropriate was considered at length. Using, as suggested, alive at the onset of labour was considered misleading as discussed in the summary response.

a classical section. It seems contradictory to consider this in extreme prematurity < 26 weeks given the risk if continuous heart rate monitoring is contraindicated. There is surely a chance of delivering a dead baby if the heart rate is assessed by listening alone. Should there be a clear recommendation that Caesarean section should only be offered for foetal reasons when we are monitoring the foetal health and would not usually be considered at <26 weeks for these reasons. A Caesarean for maternal reasons such as an antepartum haemorrhage is completely different. In addition, the * point appears unimportant and needs to be made clearer. For example, the 22+5 weeker arriving with ruptured membranes in non-NICU centre will be high risk. However, she may not labour and delivery immediately. Therefore, addressing modifiable risks (antenatal steroids and transfer to NICU centre) will change the risks esp. if she delivers 2-3 days later. The disaster waiting to happen is not giving antenatal steroids or transferring in a timely fashion. When the gestation becomes 23+2 weeks and antenatal steroids are planned but mum delivers, the outcomes following resuscitation will be much worse. 13 (69): Network implications of offering active management to a subgroup of babies <23 weeks gestation, challenges of in-utero transfer. We recognise that being outborn worsens outcomes for extreme prematurity. As a region it is already a	We have also made amendments to the guidance around consultation with parents, and placed more emphasis on potential changes to management/reorientation of care, if the baby's condition changes.

challenge to ensure that the <27 week infants are born in the right place and we are already challenged with critical care capacity managing babies >23 weeks. An expectation of active management of babies born at <23 weeks will lead to an increased pressure on this resource. From the MBBRACE 2016 figures there were 183 live born babies nationally, guestimate around 10 for our region based on these figures. An average 23 week infant has a prolonged stay – perhaps around 120 days with around 2/3 of that being for either intensive care or high dependency care. 24: Outcome of births between 22 and 26 weeks of gestation. The style of the infographic is potentially helpful for parents and healthcare professionals however the data within it is misleading. The most helpful survival is those alive at onset of labour who survive to discharge as this is the point at which counselling takes place and decision making for a delivery management plan is needed. 23 (13.2): It would be helpful to have a separate section 22-24 weeks highlighting the poor outcomes at this gestation and the careful decisions that need to be made around the appropriateness of intensive care. It would be helpful to describe figure 1 and the text in box 1 in lay terms so that parents understand what the counselling at these extremes of prematurity will entail. It would also be helpful to have a	

section in here for more mature extremely preterm babies with adverse risk factors clarifying that the outcomes at these gestations could be worse than the norm and that difficult decisions may need to be taken around the appropriateness of intensive care at delivery.	
Boyle, Elaine (Prof.) <eb124@leicester.ac.uk> on behalf of Dr John McIntyre	**BAPM response**
I am submitting this letter as a response to the above draft document from BAPM. I hope that you will find my observations constructive and helpful in working towards a final document. I acknowledge that this undoubtedly one of the most challenging areas of clinical practice and that in tackling it, the working party are grappling with complex issues that involve enormous ethical dilemmas. To embark on updating this framework for practice it is inevitable that there will be areas of uncertainty and areas of disagreement. Nevertheless, if the document is to become the guiding framework for future practice it must have the confidence of clinicians. Has the range of views and expert opinion been adequately explored? It is important that a wide variety of views are considered and that there is input from a suitable cross section of expertise. The members of the working group are unquestionably experts but there is a danger of unconscious	The Working group was multi (albeit perinatally) professional. Additionally, we are grateful for much considered input from our parent support organisations. Prof Wilkinson is an expert in Perinatal Ethics, and we have publicised and made freely available the draft document. We are pleased to have been able to respond in this consultation to comments from a variety of professional groups; this consultation will be made freely available online in association with the revised Framework. The Framework does not emphasise active management at 22 weeks of gestation, but rather presents this as an option for those few babies without additional risk factors, where

bias arising. The landmark document from The Nuffield Council on the Bioethics "Critical Care Decisions in Fetal and Neonatal Medicine Ethical Issues", included expert opinion not only those from medical backgrounds, but also those with background in philosophy, law, ethics, disability rights. This is perhaps how such a rounded authoritative consensus was achieved. The BAPM proposal is aimed at health professionals. However it will create considerable debate in a much wider and very public domain. It is important there is adequate consideration of other issues including legal implications and wider ethical issues. The emphasis on active management at 22 weeks may result in staff embarking on intensive care that will be traumatic for their patient even when there is little prospect of benefit for the overwhelming majority. It is important as a profession we respect and give weight to parental views. It is also important to acknowledge a duty of care to patients that put their interests first and that our actions should be guided by this. It is to be hoped that in the main parents and clinicians reach agreement but it is inevitable that this will not always be the case. This is an area where there should be guidance. Is the language for risk assessment sufficiently clear and accurate? I suspect one of the most contentious issues will be the approach to management of babies less than 23+0 weeks of	parents are fully appraised of the risks. We have added text around acting in the best interests of the baby. "Is language clear and accessible?" "Are data balanced and accessible for all?" – Please see extensive response to others' comments. Informed by lay input, we have striven to produce a balance between providing relevant data, and keeping the document concise and readable. We considered the issue of impairment among survivors carefully. A decision is being made effectively to intervene with a low but significant chance of survival versus no survival. The working group concluded that we should consider the more serious conditions alongside mortality, whilst acknowledging that some will have less severe impairments that are not considered to carry the same import. This is further discussed in the summary response. We are very aware that the question of active management for infants before 23 weeks of gestation is likely to be the most controversial element to the guideline. However, we felt that the revised guidance should make clear that this is a legitimate option to be discussed with parents and considered given that a) there is evidence that many units in the UK are already actively managing infants <23 weeks gestation, b) there is evidence internationally

gestation. For the majority of practicing clinicians, both obstetricians and neonatologists, contemplating active management in this group would represent a major shift in practice. Throughout the document there is emphasis on the active intervention at this borderline gestation. At 22 weeks gestation the harsh reality is still that survival without any disabilities for all births remains very low and for many clinicians, referring to this group of babies as 'moderate to high risk' will not resonate with reality. At a personal level I would find it very difficult to talk to expectant parents at 22 weeks and use the term 'moderate risk' to describe the chances of unacceptably poor outcome. Is data balanced and accessible for all? I think the current data needs to be displayed simply and objectively. The reality for the frontline staff is that the discussions taking place before birth require outcome data for all births at these gestations. Table 1 from the appendix gives the survival rates. Figure 3 portrays survival where active care is given, a clearly 'self-selected' group. Portrayed in this way there is a danger of overlooking important but relevant detail. What needs to be clearly displayed are the current outcomes of all births and the known rates of impairment including rates of being free of any disability. In my experience, a common question from families is 'what are the chances of my baby being normal'. I think the same	that it is now regarded as acceptable to actively manage infants at this gestation, and c) the evidence (both from the UK and internationally) is that the estimated survival rates for such infants in the current era are potentially similar to those of 23 week gestation infants at the time of the Nuffield council report/previous BAPM framework which was 12 years ago. d) furthermore, there is evidence that the chance of a live outcome is directly related to the quality of the perinatal care, in particular the care given over delivery and in the first 24 hours If it was ethical in 2007 actively to manage infants (given such a prognosis) it appears ethical to do so for 22 week infants now. We have changed description of the risk for infants at 22-23 weeks gestation to "extremely high" – and recommended that risk assessment and the counselling should reflect the risks for the individual infant. We are very clear that: "*The purpose of this Framework for Practice is to assist decision-making prior to and/or at the time of birth relating to perinatal care and preterm delivery at 26 weeks and 6 days of gestation or less in the United Kingdom.* ***It does not relate to decision-making around termination of pregnancy*****".**

comments apply to appendix 4. In the figure of 'outcome of births' those between 22 and 23 weeks gestation the figure again only represents those born alive and receiving active stabilisation and will be easily misinterpreted as outcome of all births. While it is valid to include the information displayed it is only part of available data. I anticipate there will be questions about other possible scenarios/outcomes and the framework should look to ensure the predictable questions are addressed, for example including a column 'free of disability'. Have other potential implications been considered? It is foreseeable that this document will be an important statement in the wider public domain. It will be drawn into the ongoing debates about viability and thresholds for termination. It is also important in how future perinatal data may be defined especially stillbirth and miscarriage. While these areas are not the focus addressed in the draft document it may be worth considering what response BAPM will make when inevitable questions arise. Conclusion I commend the working group for all the efforts they have made in this difficult area. This is an important document to get right if it is to become the framework for practice and hope these comments are helpful. I am happy to discuss	

them in more detail if necessary.	
Porus.Bustani@sth.nhs.uk	**BAPM response**
Risk group categories - Titles of risk groups Babies that are considered extremely high risk are deemed 'not for active resuscitation' usually based on an poor outcome >90% of the time. This suggests that there may be occasions when they might be offered intervention for parental request etc. For this reason, we believe that babies below 22 weeks should form a separate category where attendance would never be offered. We also feel the nomenclature for risk is not ideal and provides rather upbeat outcomes for those babies of 24 weeks gestation, hence we would recommend the following categories. • Suggest altering category definitions: o Lower risk to be changed to 'moderate risk' o Moderate to high to be changed to 'high risk' o Extremely high risk should not encompass babies <22w o 'no hope' or 'non-viable' category (or similar phrase) to be assigned to babies <22w with the suggestion that paediatric/neonatal teams would definitely not attend these deliveries	We appreciate the need to clarify that resuscitation prior to 22 weeks of gestation is not appropriate. We have added "It is not appropriate to attempt to resuscitate babies born before 22 weeks' gestation" to executive summary point 4. This point in gestation aligns with MBRRACE data collection. We have also added "If delivery occurs prior to 22+0 weeks of gestation, active obstetric and neonatal management is not appropriate." to the section on modified risk assessment.

Risk group box (Page 8 Box 1) The phrase ‘some’ is very confusing when applied to the categories. We would suggest these are removed. Disagree with allocations of patients, suggest following amendments Recommended text Non-viable: The Working group considered that babies where there is no realistic chance of survival if active care is instigated would fit into this category. For example this would include: • all babies < 22+0 weeks of gestation (i.e. up to 21+6 weeks of gestation) • Babies of 22+0 to 22+6 weeks gestation with significant co-morbidities or multiple unfavourable risk factors. Extremely high risk: The Working Group considered that babies with a > 90% chance of either dying or surviving with severe impairment if active care is instigated would fit into this category. For example, this would include: • babies at 22+0 to 23+6 with unfavourable risk factors • severely growth restricted babies ≥ 24+0 weeks of gestation • babies with severe co-morbidities, including acute fetal	However, the consensus group (incorporating the input and feedback from parent representatives) considered that terms such as “no hope”/”non-viable” are not helpful to parents, who have access to this document. Similarly, we do not believe that use of the term “never” is helpful and have avoided using it in the Framework. We have modified the risk categories and amended text in the box along the lines suggested.

compromise High risk: The Working Group considered that babies with a 50-90% chance of either dying or surviving with severe impairment if active care is instituted would fit into this category. For example, this would include • babies at 22+0 – 22+6 weeks in the absence of unfavourable risk factors • babies of 23 to 23+6 weeks of gestation with few unfavourable risk factors • babies ≥ 24+0 weeks of gestation with unfavourable risk factors or comorbidities Moderate risk: The Working Group considered that babies with a < 50% chance of either dying or surviving with severe impairment if active care is instituted would fit into this category. For example, this would include: • babies ≥ 24+0 weeks of gestation without unfavourable risk factors • babies at 23+0 – 23+6 weeks of gestation with no unfavourable risk factors Point 29: Need clarification regarding the 'no chance' category proposed above Point 35: Detail regarding who should hold discussions about	35/60 – the Framework repeatedly refers to involvement of senior clinicians. To avoid further duplication we chose not to restate this here. No specific electronic calculators are recommended as there are none available that provide up to date evidence relevant to infants born and treated in the UK. 56 – already addressed in response to others' comments (no evidence) Appendices amended

prognosis needs to be added, in particular reference to patients at a DGH. For example, babies in the extremely high risk categories: telephone advice from the local tertiary unit should be available to assist the DGH consultant in antenatal counselling. Thus some mothers/families declining neonatal intervention should not be transferred [This relates to point 60] Point 41: Are any particular electronic risk calculators recommended? Point 56: Please define response to mask ventilation in terms of low/absent heart rate. Clarification regarding “more mature babies” – is the Working Group suggesting that we follow NLS guidance for term babies? We propose that babies in the extremely high risk group AND the moderate to high risk group should not routinely receive CPR or adrenaline. We advocate babies in the lower risk group receiving CPR and adrenaline as per NLS protocols. Appendix: Emphasis should be placed in the Appendix data on the 22 week survival figures: these percentages are based on babies receiving active care but the vast majority die in the delivery room	
Pam Cairns <pam.cairns@bristol.ac.uk>	**BAPM response**

Figure 1: While I think it is useful to use illustrations, I think that figure 1 has the potential to confuse rather than clarify. It instinctively reads as though it is a table with the gestational age categories at the top – which is how many gestational age-related outcomes are reported. I appreciate that the "good" end of the figure talks about lower rather than low risk, but I am not sure that a risk of 49% of severe impairment or death would be generally regarded as a lower risk extreme preterm. I am concerned that as one reads onwards through the document this leads to the inevitable conclusion that some 23 week babies should be resuscitated regardless of parents' wishes as it would be in her best interests according to the working group. 8 (Box 1): Did the working group consider burdens of prolonged intensive care of the baby (plus family)? There is no mention of impairments other than the most severe – this gives the impression that these children are normal. Many families would want to have information about moderate handicap. I feel that we should be telling them the likelihood of survival with no or minor disability and fully informing them about moderate and severe. Also, we should be trying to be more specific about what we mean by impairments rather than lump them together. Many would be more	Thank you; this figure has been amended, and risk categories redefined. We acknowledge your concerns regarding the suggested model implying that babies should be resuscitated against parental wishes. We have not encouraged this action, and the redefinition of risk now describes 23 weeks of gestation babies as either extremely high, or high risk. We have placed greater emphasis in the Framework upon acting in the best interests of the baby. – in terms of limiting care for "at risk" patients (of any age), generally only severe impairment would be an influencing factor, though families must be informed about the full range of possible outcomes, including lesser degrees of impairment. We have added a comment about mild impairment, and the expectation of a prolonged NICU period to the parental information leaflet. Our parental information has been inputted by parent support organisations. This Framework necessarily provides guidance; the outcome for any individual baby will always involve a degree of uncertainty. Hence the strong recommendation, that extreme preterm birth always be managed by experienced clinicians. We accept these points, and have revised both the categories of risk, and parental information. We trust that the revised document better addresses fully informing parents.

concerned about intellectual impairment that physical impairment for example. 9 (27): The working group gives clear definitions of extremely high-risk vs moderate to high risk in box 1 and makes recommendations based on that. However, the subsequent paragraph then says that there is no objective way of defining this thus contradicting itself. 9 (10): The statement that babies with a low risk of death of survival with impairment should be treated in their best interests is uncontroversial. However, this now states lower rather than low and uses figures that some parents would consider a high risk (and in fact only takes into account the most severe impairment giving no information or weight to other, probably more common impairments). I feel that this will not fully inform parents and limits their choices and rights. 9 (33): The planning consultation should not include all of this group with the family in the same room. It is incredibly intimidating for many parents, even when not in a very vulnerable situation. There should be multidisciplinary discussion to get the facts about the actual risks and choices for this family. Then a small number (1 or 2) can have an initial discussion, explaining neonatal outcomes and choices	It is anticipated that experienced clinicians would be able to facilitate appropriate parental consultation, with the correct number of persons in the room for that specific family. Page 12 – guidance has been updated from 2008, to note that bag mask ventilation may not be successful in the smallest babies. There is a paucity of evidence around extreme preterm resuscitation/ stabilisation to guide practice, and we have not encouraged use of adrenaline. While advanced resuscitation is unlikely to be useful – in practice this must be left to the discretion of the attending practitioner, guided by parental wishes. There would be no obligation for professionals to actively resuscitate a stillborn infant at 23 weeks where parents did not wish for active management. Of note, while we are aware that previous BAPM guidance recommended against CPR/adrenaline, neither ILCOR nor the European Research Council guidelines (which formally review all relevant literature) suggest any modification of neonatal resuscitation algorithms for extremely preterm infants. There is also evidence internationally that extremely preterm infants (including those less than 26 weeks of gestation) who have received CPR and/or adrenaline in the delivery room may survive long term without severe impairment, although more premature infants are less likely to survive after a 10 minute Apgar score of zero (text modified and new reference).

(assuming they are to be allowed choices). 12 (55, 56): This should be in line with the European consensus guidelines. It is unfortunate that this guidance covers all babies under 27 weeks as approaches should probably differ between the most immature and the least mature – in terms of use of LISA etc. I am not convinced that response to mask ventilation is useful in very immature preterm. If the goal is to avoid ventilation, stabilise on CPAP and then do LISA it may be appropriate. However, if that is not the case then they should be intubated ASAP and given prophylactic surfactant. Failure to respond to ventilation (in terms of heart rate response) with good chest movement is then more significant. 12 (57): I am concerned about the working groups recommendations that babies from 22 weeks should be resuscitated the same way as more mature babies including adrenaline and CPR. I am unaware of any evidence suggesting that this is likely to lead to a good outcome. It would appear unlikely given that these babies will have the double hit of extreme preterm plus probably asphyxia plus the process of cardiac massage is much more traumatic in tiny babies. Need to insert a quick umbilical line during an extreme preterm resus to give adrenaline may be challenging and if the baby survives the attempt may well reduce the	We acknowledge the need for long-term care and support, but this is out with the scope of the document. Page 24 – table legend does note small numbers of babies born at 22 weeks. We have reconsidered the colouring of the figure, to be better compatible with B&W printing The gestational ages covered by this Framework were chosen to align with other published documents More clarity now provided in Appendix 5

likelihood of having a sterile central venous access to give PN etc. The fact that the working party states this will mean that neonatologists will be obliged to resus 23 week still births or be open to criticism/legal action for failing to follow national guidance. This is a very significant change in UK practice and does not seem to be thought through. 13 (69): The working party make a brief attempt to address the societal effects of their new advice by saying that networks must ensure sufficient resources. However, the increased neonatal workload is only a small part of the societal effect. While individual doctor/patient interactions do not and should not consider this, it is very much the role of a national group who should look at the macro issues. We already know that there is insufficient help for these families as the child grows older in terms of educational support in addition to health need (let alone support for families who the evidence would suggest have a higher risk of break up). There is very little available for adults with additional needs. There is nothing to suggest that the group have examined this. 24: Most NHS printers will only permit black and white which makes this difficult to see. It is not clear that this data is based on very small numbers of 22-week babies. It gives no	

information of impairment other that very severe disability. It would be more useful to have a visual aid which includes death, severe disability, moderate and then normal/mild. The boundaries between this each could be blurred to reflect the confidence limits. Putting the confidence limits in small print will not help most parents. General: This framework should be for less that 25-week gestation babies only. It is not helpful to lump 25- and 26-week babies in with it when the decision making is already very different. General: While it is good to have a more nuanced approach this has mean that this framework is very woolly and unhelpful. It should be possible to make some clear recommendations – for example it is acceptable to consider resuscitation a 22-week baby who has had steroids and mag sulph and is born in a tertiary unit. It would generally not be appropriate to resus a 22-week baby born outside of a tertiary unit, particularly if they have not had steroids /mag sulph.	
Crosfill Fiona (LTHTR) <Fiona.CROSFILL@lthtr.nhs.uk>	**BAPM response**
11 (CTG): I agree with your comments about not performing CTG prior to 26 weeks.	

11 (CS): In general CS would not be considered prior to 25 weeks (even in the event of a cord prolapse) unless for pressing maternal reasons – although the only one that actually comes to mind is significant haemorrhage – in all other circumstances induction is a better option. The future impact of these preterm CS/hysterotomies is significant and sometimes it is better to lose one baby for the sake of the next 4 healthy ones. 11 (Dilated cervix): I think it is naïve to think you can plan an elective CS for a woman with a very dilated cervix "when birth becomes inevitable" (I agree these can last for days near full dilatation), the birth becomes inevitable when the membranes rupture – at which stage a CS becomes more difficult, more dangerous and the baby is likely to be at least halfway out. 11 (Active obstetric management): You should probably leave it at "individualised care" prior to 25+0 and trust the obstetric team to act in the Mum's best interests.	CS – we have amended text to emphasise that CS is rarely required at extreme preterm gestations (dilated cervix) – it is specifically noted that recourse to CS should not be the preferred option. This wording was agreed with RCOG and BMFMS. "Individualised care" felt to be too vague As noted above in response to others' comments, international data agree on improving outcomes for the most preterm babies particularly in units where resuscitation is commonly practised. These data are in the public domain. We have made some amendments, better to underline that data are probably skewed towards those fetuses/babies in the best condition, and that if clinicians consider stabilisation of all extremely preterm babies, the outcomes are likely to be poorer.
15 (Transfers): I am an obstetrician in a tertiary unit which accepts referrals from surrounding hospitals. Currently, we accept women from 23+0 days as transfers into our unit. It is difficult for me to comment on the survival figures that you give, except that the way you present them makes the	

outcome look a lot rosier than is the case, particularly for 22-24 weeks. Most mothers if told a 22 week baby has a 3% chance of surviving to 1 year but 33% chance of having lifelong care as a result, would probably not want to actively manage the delivery. Presumably health economics have not come into these calculations. I am not at all happy to transfer in 22 week gestations.	
Cusack Jonathan - Consultant Neonatologist <jonathan.cusack@uhl-tr.nhs.uk>	**BAPM response**
This response represents the collective views of the Leicester Neonatal Service, informed by a multidisciplinary discussion involving nurses (Band 5-7), ANNPs, junior medical staff (FY1-ST7) and consultant neonatologists. We welcome an update to the previous BAPM framework in the light of evolving neonatal practice and improving outcomes. We support the use of a risk-based approach to management in principle, and welcome the inclusion of this within the framework. We have significant concerns that the most optimistic outcomes are presented throughout the framework, which will inevitably impact upon both medical and parental decision-making. At the point of antenatal counselling, we strongly feel that the most relevant statistics are those	The Framework does acknowledge both that survival to live birth will be influenced by management of labour and birth, and that overall survival is currently biased towards those fetuses/babies in best condition at birth. Nevertheless, international data clearly and consistently demonstrate improving outcomes, especially in those units experienced in stabilisation of the most preterm infants. It was strongly the opinion of our parental advice that presenting too much data would be overly confusing, but more detailed (and UK-based) survival data are presented in Appendix 1, and "appreciable in-labour mortality" has been added to the general text describing outcomes at 22 weeks of gestation. Risk categories have been redefined

pertaining to babies alive at the onset of labour. We acknowledge that survival to live birth will be influenced by management of labour and birth, however to use the outcomes for babies who received active intervention in order to make decisions about whether active treatment should be offered we believe is misleading. 6 (8): Although we acknowledge this is outside the direct scope of the framework, we call for BAPM to be seeking a change in the legal definition of stillbirth in conjunction with development of this guidance. Under the scope of the framework, neonatal teams are asked to consider the provision of active intervention for infants who may legally be mid-trimester pregnancy losses, which is practically and ethically challenging. 8 (Figure 1): We suggest this tool needs further refinement to give greater clarity as to the relative influence of each risk factor on the baseline gestational age-based risk. We feel that the red coloured portion of the figure needs to extend further towards the right; currently (for example) a 22 week SGA male infant who was outborn with no antenatal steroids could be interpreted as falling within the 'moderate-high' risk category, whereas our consensus is that this would be an extremely high-risk scenario where palliative care would likely be the most appropriate management.	Page 6 – agreed, out with the scope of this Framework. Page 8 – figure 1. Modified Appendix 5 – new examples added for clarity More emphasis placed on consideration of change(s) to management, depending on baby's clinical condition thank you - text amended to "active neonatal care is in place". We have also added, "Obstetric management should be regularly reviewed, particularly if events suggest changing prognosis for the baby". Page 12 – Thank you for these useful suggestions - "When the baby is in unexpectedly poor condition at birth, it may not be appropriate to continue with stabilisation and/or resuscitation" and "any doubt around the adequacy of ventilation" have been added to the

10 (40): We suggest that even after a decision about the management pathway has been made, this can and should be reviewed at any point up to and after birth when either new information becomes available or at parents' request. 10 (44): We suggest the phrase 'commitment to active neonatal care' is reviewed – this could be interpreted to mean that teams are bound to continue with an active management plan regardless of any new information or changes in parental wishes. Suggest 'current decision for active neonatal care' or similar. 12: We are very concerned that as this section reads, once a decision has been made for active management, it appears to commit neonatal teams to providing full resuscitation including intubation, cardiac massage and drugs regardless of an infant's condition at birth, for at least 5 minutes, before a senior clinician can make the decision to stop resuscitation. We feel there needs to be much greater acknowledgement throughout the framework that the decision to provide active care is not irreversible and at any time point a change to a palliative pathway may become appropriate. 12: We ask that a clearer distinction is drawn between active stabilisation/supported transition of a preterm but otherwise	text. "Stabilisation" changed to "resuscitation". Text amended to include doubt about efficacy of bag mask ventilation We believe that in the absence of evidence, it would be inappropriate for BAPM to give clear guidance around the use of adrenaline/chest compressions. text amended amendment as suggested

well infant, and resuscitation of a compromised infant. 12 (56): We feel that the guidance to intubate and give surfactant to an infant who has not responded to mask ventilation is too prescriptive and does not consider the clinical condition of the infant at birth. Where an infant does not respond to adequate mask ventilation, this may be an opportunity to reconsider whether active management is appropriate before proceeding in all cases to intubation. Where there is doubt about efficacy of mask ventilation then intubation may be appropriate to ensure adequate ventilation is achieved. 12 (56 and 57): We call for a clearer BAPM position statement regarding cardiac massage and the use of drugs in extremely preterm infants. The outcome for infants who require such measures is (as stated) likely to be very poor. However, the framework could be interpreted as saying these measures should be used in all cases where active treatment has been agreed on for at least 5 minutes if the baby does not respond after establishment of adequate ventilation. 12 (57): '...when to stop attempts to stabilise the baby.' Where cardiopulmonary resuscitation is ongoing, we suggest that this is resuscitation, not stabilisation.	addition as suggested See other comments – it was strongly the opinion of he parental support organisations inputting to the Framework that too many data are not helpful to parents. We have endeavoured to clarify the denominator, and note that there is no evidence for recourse to caesarean section to improve fetal outcomes. Indeed, caesarean section may be detrimental to mother. The text has been amended, both in "conveying risk", and in Appendix 4, information for parents. Page 24 – as noted in response to others' comments, we have deliberately kept the infographic as simple as possible; it has not been designed to replace conversations with parents but to support the discussion. The data therein are one scenario and this is the best that can be expected to show parents what the alternative to certain death. We have, however, now emphasised the need for professionals to convey this information verbally to families, and made some other amendments to the infographic

14 (73): We welcome the acknowledgement that survival data for babies born at 22 weeks is likely to be better than expected due to a bias towards active treatment for those with the best outlook. However, we feel this should be given greater emphasis within the guidance for clinicians on counselling and within the parent information and infographic. 19: We suggest the addition of ‘Baby born in unexpectedly poor condition’ to this section. As per previous comments, this would provide greater clarity about how to manage the scenario where an infant with a plan for active management is born in poor condition and does not respond to initial airway manoeuvres and mask ventilation. 21 (116): We strongly disagree that ‘the most relevant statistic for parents is usually the chance of survival if active stabilisation and neonatal intensive care is attempted’. At the point of antenatal counselling, all that is known is that the baby is alive at that particular timepoint. We therefore feel that the statistics for infants alive at onset of labour are the most relevant and give the most accurate information to parents in order for them to make decisions about how the labour and birth should be managed. We acknowledge that risk is a dynamic process and that if the baby is live-born	

with active treatment attempted, the risks will change. However we feel that presenting only the best-possible outcome statistics (those of the outcomes for live-born infants with stabilisation attempted) to parents at a difficult time provides false hope and may impact upon decision-making, particularly for the most immature infants. 24 (Infographic): As per previous comments, we feel that the information provided to parents should include the risks of death and severe disability from the point of the baby being alive at the onset of labour in order to give a true, balanced picture of the risks. We felt that most parents in a stressful situation would only take in the headline numbers on the infographic and not appreciate that they applied to only a subset of infants with better outcomes. We felt that it was likely that many parents, given a chance of 2 in 10 survival without severe disability at 22 weeks, would opt for active management. However, we also felt that the same parents may choose differently if they knew that at the point of antenatal counselling, the chances of taking home a baby without severe disability were only 1-2 in 100. We acknowledge the challenges inherent in discussing risks with parents who may not always find them easy to apply to their individual situation.	
Davis, Peter <Peter.Davis@UHBristol.nhs.uk>	**BAPM response**

17): It would seem that the only outcome that is merited as significant other than death is severe neurological disability. No other morbidity is discussed, such as chronic lung disease needing long-term oxygen +/- respiratory support, or complications of necrotising enterocolitis including short gut and need for long-term TPN. Any discussion of long-term outlook has to include all major morbidity, not just neurology. Do any 22 week infants survive without long-term morbidity? Where is the evidence for this? 8 (26): I have significant issues with this particular area of the document. 22 week infants in England and Wales do not have a survival rate of somewhere between 10% and 50% (or as the document calls it “moderate to high risk”). In highly selected groups, rates of 30% survival have been reported in 22 week gestation babies, but active management of this group of babies is not routine in the UK, and we are doing a disservice to parents if we suggested that a baby born live at 22 weeks gestation “only has a moderate risk of death”. In most other areas of medical practice, 50% mortality would be deemed high risk, full stop. 15 (75): According to the MBRRACE-UK figures, of 183 live born 22 week gestation infants in 2016, only 15 survived to 1 year of age (i.e. a survival rate of 8.2%). Of those receiving active care, the rate is 15/43 (i.e. a survival rate of 34.9%). For 23 week gestation infants receiving active care the 1 year	We appreciate your concerns around longer term morbidity for extremely preterm babies, but note a growing body of international evidence demonstrating steadily improving outcomes. Twenty years ago, similar concerns would have been raised about stabilisation/resuscitation at 24 weeks of gestation. Categories of risk have been redefined 15 (75) we hope that this guidance will encourage practitioners to ensure that as many babies as possible at 23 weeks of gestation are delivered in maternity units co-located with a NICU, and having had AN steroids and magnesium, etc. We have added some text to the parental information (Appendix 4), and also, in response to others’ comments, emphasised the importance of professionals explaining to parents that the prognosis for extreme preterm birth is affected by the denominator, and will necessarily change as pregnancy and labour progress. Infographic has been amended

survival rate is little better 101/264 (i.e. a survival rate of 38.2%), while the overall rate for live births is 101/301 (survival rate of 33.6%). Tellingly it would seem that already the vast majority of 23 week infants are being resuscitated (264/301; 87.7%), so I am not quite clear how this guidance is supposed to affect the 23 week infants 24 (135): I have real problems with this particular graphic, because it is not giving a true picture to parents. If increased numbers of babies at 22 and 23 weeks gestation are treated actively, these figures are also likely to get worse. The survival rate for 22 week gestation babies needs to be more fully explained i.e. less than a quarter of babies born alive at this gestation are actively resuscitated (43/183) and only one third of those actively resuscitated survive to one year. Plus they are much more likely to have significant morbidities even if they do survive to 1 year of age. Overall, as a paediatric intensivist, who often has to care for these infants, once they leave the neonatal unit, I worry that this document has been produced by a group of neonatal enthusiasts, who are trying to do their best for parents, but have been overly optimistic in their outlook for the most extremely preterm newborns i.e. those born below 24 weeks gestation. It would seem very unlikely that neonatal teams are going to resuscitate fewer 23 week infants (in 2016, it was 87.7% of all babies born at this gestation), so the real issue appears to be about resuscitating more 22 week	We are aware that MBRRACE-UK is currently preparing guidance on determination of signs of life at extreme preterm gestations – this is outwith the scope of the current Framework.

gestation infants. The problem is that for every “miracle” in this group, there are a very large number of baby deaths, and amongst the survivors, a very high burden of morbidity, for which, most parents will have little understanding of the long-term effect on them and their families Considering a greater numbers of extreme preterm deliveries below 24 weeks gestation as live births may be having an adverse effect on the overall Infant Mortality Rate, as noted in the letter I published in the BMJ last year with Liz Draper from MBRRACE-UK (Davis PJ, Fenton AC, Stutchfield CJ, Draper ES. Rising infant mortality figures in England and Wales - we need to understand gestation-specific mortality. BMJ 2018:361:k1936). This should be mentioned somewhere in the document, as even in the latest ONS figures published on 17th June. (https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/childmortalitystatisticschildhoodinfantandperinatalchildhoodinfantandperinatalmortalityinenglandandwales) the rise in Infant Mortality Rate from 2014 to the latest figures for 2017 is due to an increase in neonatal deaths, particularly early neonatal deaths, many of which occur in the extreme prematurity group	
DOYLE, Patrick (WIRRAL UNIVERSITY TEACHING HOSPITAL NHS FOUNDATION TRUST) <pdoyle1@nhs.net>	**BAPM response**

8 (graphic): This is confusing moving from red to green will lead parents to believe that lower risk is equivalent to low risk, and yet even at 26 weeks 1 in 5 infants die and 1 in 10 are severely damaged, 2 – 3 in 10 will have moderate damage (not quoted in any part of the document). No other area of medicine would quote these risks as "low", or seek to convey that to those who need the information. Appendix 1 (Outcome of births graphic): The figure quoted are highly selective and do not give a true representation of the overall survival rate for a fetus presenting in labour (the actual clinical situation) for the gestation. This is particularly problematic at 22 weeks and 23 weeks were active admission to a NICU is not the norm in many units. The statement "some extremely preterm babies do not survive labour" is an open invitation to ask for a CS delivery and yet there is no evidence that is provided that this will alter outcome for the fetus. As CS is the only alternative (delivery method) for the mother a detailed risk document must be provided for the mother to look at.	Figure 1 has been revised – we hope you will find the revisions helpful. Categories of risk redefined Appendices 3 & 4 – the Framework now contains more explicit advice for professionals to convey to parents how risk changes as pregnancy and labour progress. We have added emphasis to lack of evidence for, and potential risks of caesarean section
evansjl5@doctors.org.uk	**BAPM response**
8: I appreciate the need to try and categorise but I am not keen on the term 'lower risk' babies. All these babies constitute high risk babies and to categorise them lower risk seems to me to underestimate the fragility of this group. I	Categories of risk have been redefined

prefer the layout of the current guideline which discusses the gestation groups separately, i.e. 22+0 – 22+6 – followed by the recommendations. Looking at Box 1 and categorising them and then going to the group which they belong to to look at the recommendations seems overly complicating matters to me. Brief example: 22+0 – 22+6. Assessment of babies at this gestation should include accuracy of gestational age, favourable and unfavourable factors including ability to give steroids and magnesium and complicating factors such as IUGR and sepsis. In a favourable situation, active resuscitation may be considered and parents counselled accordingly. 23+0 – 23+6 etc General: I felt there were a number of instances where a wide gestational group was used, in particular in the parent information sheet where it states 'Babies born between 22-26 weeks may be able to survive if they receive intensive medical treatment' Given the vast differences between these gestations with regard to outcomes it seems misleading to put them into one group. If I were a parent reading this I would interpret that my 22 week baby had similar chances to a 26 week baby given the same treatment. I would suggest this be subdivided into 22 and 23 weeks gestation and 24 weeks to 26 weeks gestation. General: Overall, I can see an awful lot of hard work and	Thank you for your comments – as you note, much deliberation went into this document. The unpredictable nature of extreme preterm birth means that didactic advice (other than not to attempt to resuscitate below 22 weeks of gestation) is simply not appropriate. We have highlighted that gestation alone does not predict outcome, and that senior management of extreme preterm birth is essential. The executive summary has been amended More information has been added to Appendix A (Parental advice), noting that prognosis is generally poorer at lower gestations, and we have added a summary to Appendix 3, hopefully to facilitate emergency consultation by trainees before senior help is available

deliberation has gone into this practice framework. What I struggle with is knowing exactly where to go to find a specific piece of information quickly. This is great for a sit down long read but on the shop floor it is helpful to have a more succinct section particularly for trainees to read when faced with an imminent preterm delivery. Ie. If I have a 23 week fetus and have been asked to counsel parents now, a slightly more quick reference guide (reminder) to what to think about before visiting the family for counselling. Of course we should all have read and digested the document fully but the way it has been written doesn't suit the way my mind works and feels very woolly	
FORTUNE, Peter-Marc (MANCHESTER UNIVERSITY NHS FOUNDATION TRUST) <peter-marc.fortune@nhs.net>	**BAPM response**
Overview: This summary and the comments below were compiled from feedback received from the membership of PICS (Paediatric Intensive Care Society) and have been reviewed by the officers of PICS council. We note that the document distinguishes principally between death/survival and severe neurodevelopmental disability as major outcomes of extreme prematurity. It omits discussion of the scarcity/lack of services to provide adequate long-term care for the survivors of extreme prematurity. We suggest that any decision to lower the age of intervention in extreme prematurity cannot be taken in isolation from the rest of the medical stakeholders providing care for such children: A child	We acknowledge that survival of more extremely preterm infants will have an impact on hospital and community resources (as well as obstetric services), but would argue that this does not mean that, in the face of international improvements in outcome, stabilisation and neonatal intensive care should not be offered to such babies. We also note that highlighting the need for these most vulnerable babies to be born in NICUs (and not transferred postnatally unless that is unavoidable) will, by improving outcomes, reduce longer term costs.

born at 22weeks, if they survive, will have a maximum of 22 weeks on the neonatal unit. Thereafter, it will be down to paediatric services, and ultimately adult services, to then look after this child. We suggest that recommendations should of this nature not be published by one sub-specialty of medicine. The potential impact on the patients and their families, society and other clinical specialties demands a multidisciplinary approach from the outset. As a minimum this should include representatives from PICS,BPNA, BPRS, BACCH, and APPM on the working party from the outset. Waiting times for Community Paediatric services can be up to 18 months during which time the greatest plasticity for brain development does occur in babies but the opportunity is lost to use this time to support their neuro-development. We suggest that building up long-term services first before proposing any changes to the guidance for extending the treatment of foetuses at the lower margin of viability. 3 (3) & 7 (24) & 9 (35): Whenever possible, extreme preterm birth should be managed in a maternity facility co-located with a NICU" / This guidance should be strengthened to "whenever possible....co-located' with a level 3 NICU" 3 & 6-9 (4 & 15-31): Active management of labour and neonatal stabilisation may be considered for babies born from 22+0 weeks of gestation" / We cannot support this	The terms “NICU” and “level 3 NICU” are synonymous We acknowledge that pre-birth mortality is high at 22 weeks’ gestation, but we have not advocated obstetric interventions to expedite delivery, and believe that babies of this gestation who survive labour are entitled at least to a reasonable attempt at stabilisation after birth, if, having been fully informed of the longer term prognosis, parents so wish. Expected fetal weight is not an exact science, and would only be one part of a senior clinician’s decision to recommend (or not) active neonatal care.

recommendation at the current time because: a) The evidence base for 22+0-22+6 gestation neonates is very limited b) In the 'extremely high risk' category, there is a > 90% chance of dying and/or surviving with severe impairment. Table 1 (no. 75) provides the key supporting data. It demonstrates that, in most cases of live births in this gestational window, a decision is made not to actively resuscitate. If recommendation 4. Is taken at face value, resuscitation will be attempted in many more 22+0-22+6 gestation neonates, resulting in a far greater number of disabled survivors. We strongly recommend that no advice regarding the changes to active resuscitation threshold are made at this time. 6 (15): In order to perform an accurate assessment of the fetal size to help with risk assessment a highly qualified antenatal ultrasound service would need to be available 24/7. This is not currently the case even in every tertiary perinatal centres. Thus, the latest relevant data will often not be available to the clinicians who need to make such difficult decisions about planning a delivery at the lower margin of viability. 7 (17): Only the outcomes of death or severe neurological disability are considered. No other morbidity is discussed, such as chronic lung disease needing long-term oxygen +/-	more information added to Appendix 5 Page 8/15/24 – more guidance to professionals in explaining risk to parents has been included. The infographic has been revised Page 13 – further information has been added regarding multi-professional perinatal mortality meetings Page 15 and 24 – addressed in response to others' comments. Infographic revised

respiratory support, or complications of necrotising enterocolitis including short gut and need for long-term TPN. Discussion of long-term outlook must include all major morbidity, not just neurology. Do any 22 week infants survive without long-term morbidity? Where is the evidence for this? 8 (26): This point is potentially misleading: 22 week infants in England and Wales do not have a survival rate of somewhere between 10% and 50% (defined in the document as "moderate to high risk"). In highly selected groups, rates of 30% survival have been reported in 22 week gestation babies, but active management of this group of babies is not routine in the UK. This position could lead to misleading prognosis being shared with parents if colleagues suggest that a baby born live at 22 weeks gestation "only has a moderate risk of death". In other areas of medical practice, 50% mortality would be deemed high risk. 13 (63): It is correct to state that the deaths of these babies should be reviewed using the PMRT. However new guidance is clear that they should also be discussed at a multi-professional perinatal mortality meeting that follows the framework set out in published statutory and operational guidance Child Death Guidance. This information should be included.	

15 (75): This table is potentially misleading (see 8/26 above). If increased numbers of babies at 22 and 23 weeks gestation are treated actively, these figures are likely to get worse. The survival rate for 22 week gestation babies needs to be more fully explained i.e. less than a quarter of babies born alive at this gestation are actively resuscitated (43/183) and only one third of those actively resuscitated survive to one year. Plus, they are much more likely to have significant morbidities even if they do survive to 1 year of age. 24 (135): This is a potentially misleading graphic (see comment for 15/75 above).	
Garcia, Mireia <Mireia.GarciaCusco@UHBristol.nhs.uk>	**BAPM response**
7 (Severe impairment): In the risk assessment, mortality and neurological morbidity are the only factors taken into account. We know that children of this GA will have significant morbidities not associated with neurological deficit that might condition their lives greatly and should be taken into consideration when information is provided for decision making. 8 (Figure 1): The classification of 22 to 24 weeks as moderate-severe risk seems too optimistic, with the reported 50-90% mortality and severe neurological impairment. Same will apply for the category of 24-26 weeks, deemed as low	We agree that longer term morbidity has a significant impact upon children and their families, but this is not predictable in the individual child, especially in the immediate post-birth period. We also agree that for some families, reorientation of care later when it becomes apparent that the child has, and will continue to have, a major morbidity, e.g. short gut syndrome, may be appropriate; this has been alluded to in the text, although specifics of management once a baby has been admitted to NICU are outwith the scope of this framework “Mindful of the baby’s best interests” has been added to the text Categories of risk have been redefined

risk with a 30-50% mortality. Similar outcomes, in other areas of medicine, will be classified as high and moderate respectively. 10 (Figure 2): The extremely high risk section includes an addendum of assessing modifiable factors that might allow for decision to resuscitate to be made. In this population, any resuscitation efforts will be futile, if not in mortality, due to extremely significant morbidity, and should not be pursued. 24 (Graphs): Graphs can be difficult to interpret when looking at global outcomes of a potential decision. A joint graph with all children that, being born alive, will die or have a neurological deficit or significant organ dysfunction (for example, chronic lung disease that requires long term oxygen or ventilation, short gut secondary to necrotising enterocolitis), will better explain the expected outcomes. With current graph, the impression is that children may die in a rather immediate way or suffer neurological impairment in a lower proportion than the chances of living without pathology. This neglects the hospital stay prior to the death, that will undoubtedly include interventions that will be painful and impact in both child and families quality of life. Proposed format: Orange: Die during hospital stay; Red: Severe neurological imp; Yellow: Other severe illness; Green: Alive. As a paediatric intensivist, I look after ex-preterm	Figure 2 – the addendum refers to subsequent change in risk factors, and is entirely consistent with our message, that decisions around care at birth must always be subject to review if circumstances change. Infographic has been amended - we completely agree that families must be fully informed – the information provided is intended to complement a full discussion with a senior neonatal practitioner.

children with severe diseases that not only account for poor neurological outcome. The impact on those children and their families can be devastating, and the prolonged medical interventions, painful and further damaging. As much as shared decision making is essential, families need to be appropriately counselled regarding expected outcomes, including gastro, respiratory and behavioural long term disease, which this framework does not include. It would be better to consider not the number necessary to treat, but the number necessary to suffer when deciding the course of action of any particular patient.	
Harrop Anne (Lead Nurse) PAHNT <Anne.Harrop@pat.nhs.uk>	**BAPM response**
9 (32): Within the service a piece of work would need to be undertaken of how we counsel and the importance of informed decision making for parents. Clarification of who is the right person to counsel and at what gestation. 24: The poster although very informative may mislead in the outcome of extreme premature infants.	We strongly recommend that counselling is undertaken by the most experienced practitioner available. As already noted, we chose to present only some data in the infographic, based on parental feedback; it has been amended. This poster is intended to complement a full discussion with a senior neonatal practitioner, and more comprehensive data are provided in Appendix 1 to facilitate such a discussion.
Jain, Anoo <Anoo.Jain@UHBristol.nhs.uk>	**BAPM response**
13 (69): What are the resource implications of this? I.e what	Thank you for your comments. Health care economics are indeed important, but outwith

is the cost benefit analysis of this proposal? Cost cannot be taken without considering the capacity required in a tertiary level CDS and then NICU to implement this. Where will the resource funds come from to deliver this. In addition, has this document been reviewed by for example the NAO in term os fht wider implications for health economics in the UK? The NICU care would need ot be aligned with the RCOG care and implementation that is different https://www.rcog.org.uk/globalassets/documents/guidelines/scientific-impact-papers/sip_41.pdf	the scope of this document. Better outcomes for delivery of extremely preterm infants in maternity units co-located with a NICU will result in lower longer term costs This document is specifically intended for UK practitioners; international survival data are relevant, but ethics/opinion less relevant
14 (72): BAPM has selected a group of countries that offer care to 22 week gestation. What is the balanced view from countries that, for whatever reason, offer something different in trms of neonatal care eg Netherlands, Canada, Austalia etc. https://www.health.qld.gov.au/__data/assets/pdf_file/0022/144382/ed-viability.pdf https://www.rcog.org.uk/globalassets/documents/guidelines/scientific-impact-papers/sip_41.pdf	
KAU, Nikolaus (NHS GRAMPIAN) <n.kau@nhs.net>	**BAPM response**
11 (2): The term “delayed cord clamping” is currently increasingly used. However, it is rather undefined, as it is not clear what the delay should be. A reasonable amount of research is currently undertaken to specify the “delay” more	“delayed” has been changed to “deferred for 60 seconds or more”

accurately. The physiology is based on animal studies by Hooper in Australia and there are clinical studies on the way. A leading team is the group around Te Pas in the Netherlands. Increasingly we begin to understand why the "delayed" cord clamping is beneficial and it turns out that is not related to a certain time period but to a physiological process of adaptation. Therefore these research groups are starting to replace the term "delayed cord clamping" with "physiological cord clamping". Just one example publication is: Niermeyer, Susan. "A physiologic approach to cord clamping: Clinical issues." Maternal health, neonatology and perinatology vol. 1 21. 8 Sep. 2015, doi:10.1186/s40748-015-0022-5 I want to suggest that we use this term in this great document which is a step into the future aligning the UK with other countries with advanced levels of Neonatal Intensive care.	
KEIGHTLEY, Amy (GREAT WESTERN HOSPITALS NHS FOUNDATION TRUST) <amykeightley@nhs.net>	**BAPM response**
11 (Point 45): Vaginal delivery and expectant management should be considered as options. I believe as we are considering offering caesarean section where 'the benefits out way the risks', the converse is also ture. This means that if the benefits of a vaginal delivery out way the risks then it should be listed as an option and recommended where appropriate. This is particularly relevant following the	We have underlined the lack of evidence of benefit, and potential risks of caesarean section as well as the need for mother to be fully informed (Montgomery). More has been added around risks of head entrapment.

Montgomery case ruling where the risks and benefits of vaginal delivery need to be actively discussed as a recommendation (where appropriate) not just a default when the risk of caesarean is not thought to out way the benefits. I believe the addition of this point would encourage documentation of the discussion that has taken place where vaginal delivery is being actively chosen rather than caesarean just not being recommended. 24: Rather than 'extremely preterm babies may not survive labour' change to 'extremely preterm babies may not survive vaginal or caesarean birth'. Having mentioned the risks to the baby that can be associated with caesarean section (page 11 point 50) i.e. fetal trauma and head entrapment, it is important that both families and healthcare professionals understand that extremely preterm babies may not survive delivery by caesarean section, not just labour.	
	Infographic: 'extremely preterm babies may not survive labour' has not been changed, for reasons of brevity (and to prevent the figure from becoming too cluttered, but it is noted in the parental information that "*Babies born from 22 weeks sometimes are not strong enough to survive labour and/or either vaginal (normal) or caesarean birth*"
Harvey Kelly <Kelly.Harvey@alderhey.nhs.uk>	**BAPM response**
3 (point 4): The statement (Active management of labour and neonatal stabilisation may be considered for babies born from 22+0 weeks of gestation) suggests women from 22+0 are now to receive steroids, In utero transfer to a co-located maternity unit with NICU facility. Will this be reflected in the RCOG guideline which currently sets the cut off for steroids	The working group acknowledges a paucity of evidence for the most immature fetuses, but felt strongly that, at any gestation, the benefits of antenatal steroids are likely to outweigh any risks. Revision of Green top guidelines is the remit of RCOG, who have been involved in preparation of this document and subsequent consultation.

at 23 weeks? General: Concerns regarding this being a freely available guideline meaning any parents in this situation will find this guideline and look at the executive summary, the risk stratification tables and the parent leaflet at the end. If these were the only sections reviewed this is likely to convey a message that an infant at 22/40 is moderate to high risk which would mean potentially 50% survive. Given that the exec summary is clear parents are integral to decision making it is likely this will lead to a high proportion of parents demanding active management and it is unclear evidence truly supports this. The Nuffield council of Bio Ethics document has not been superseded with any clear evidence base regarding initiating care at 22/40 and so advocating without strong evidence base does not meet with the standard the majority of neonatal clinicians work towards. 9 (point 33): Will there be training for paediatricians within and LNU to counsel and plan active management of such cases as most LNU's do not have experienced neonatologists available for this 24/7 and so this would lead to disparity of experience for some families. I think the information on pages 20-21 is very helpful for this and this may be good to have as a booklet/info leaflet for staff which would be easily accessible to support these conversations.	The categories of risk have been redefined We do not agree that there is no new evidence to support offering neonatal care to some infants of 22 weeks' gestation – this is currently being undertaken in some centres. We believe that all neonatologists and obstetricians should have up to date knowledge of outcomes at extreme preterm gestations, and we hope that this document will help to achieve this 9, 13 - As noted in response to others' comments, resource issues will need to be addressed both on a network level and nationally, but evidence points very clearly towards improved outcomes when these high risk births are managed in maternity units co-located with a NICU.

9 (point 35): Is there capacity within maternity units with co-located NICU regarding the potential to accept additional referrals of >22+0 infants as even if these mothers do not go on to deliver whilst delivery is a risk this framework suggests they should be transferred at the earliest opportunity.	Text clarified
13 (point 69): Whilst the sentiment of this is correct it is difficult to understand how the IUT of more women from a lower gestation to co-located maternity and NICU even if they go on not to deliver will not impact on the ability for another mother not to be able to access a bed and then potentially end up in a different hospital than her baby even for a short time.	We hope that this would be part of a discussion with senior neonatology/obstetric team.
15 (point 75): This table feels misleading in the way the figures are presented. Somewhere within this table should be the survival percentage as part of all live birth – for 22/40 only 8% of all births receive active care and only 6% make it to a neonatal unit with only half of them surviving to 1 year (3% of all births at 22/40). This feels a more realistic picture to offer to professionals and parents.	The parental information and infographic are intended as an adjunct to face to face discussion with senior neonatal and obstetric practitioners.
19 (point 99/100): As per previous comments the pressure on antenatal beds for those families at almost 22 weeks who would then request IUT as per this framework to try to	Thank you

maintain the pregnancy to 22 weeks to plan active management seems a step to far. 23 (point 132): It feels like grouping 22 weeks and 26 weeks in the same statement would mean parents would not see a difference in how these infants should be approached and it would be helpful to describe at this point just how experimental care at 22 weeks would be as this is not the same as 26 weeks. 24 (leaflet with survival data for parents): The way the data is presented is very misleading for parents and would lead to many parents believing there baby has a 30% chance of survival at 22 weeks but as described earlier it is in fact 3% survival to 1 year when seen as a percentage of all births at 22 weeks. The emphasis is on the positive not the realistic and as this is potentially all a parents will read of this framework this is likely to completely change practice for maternity and neonates as most parents given the statistics presented in this way would want active treatment. General: A lot of the content of this framework is helpful particularly the recognition of parent communication and palliative care planning.	
Fionnuala McAuliffe <fionnuala.mcauliffe@ucd.ie>	**BAPM response**

Page 11: Suggest have a separate paragraph on 'impact on maternal health highlighting that decision for CS is a balance between likely fetal survival and impact of a preterm CS on Mother. This section could include comment that maternal morbidity may also arise if there is a delay in delivery, for example in the setting of prolonged rupture of membranes with risk of chorioamnionitis and with a severe early onset pre-eclampsia. Therefore careful consideration needs to be given to both maternal and newborn health and required multidisciplinary discussion with obstetricians and neonatologists. Page 11 (paragraph 50): CS suggest stating that maternal morbidity may be higher in extreme preterm CS when compared to later gestation CS as they are being performed as an emergency, usually on upper uterine segment and thus may experience increased blood loss. The lower uterine segment is not well developed prior to 28 weeks gestation and therefore a caesarean section may involve a transverse incision in the upper uterine segment, which is associated with an increased blood loss, increased post-operative maternal morbidity and an increased risk of scar dehiscence in a future pregnancy. Page 11 (paragraph 50): CS Delivery of the fetus within the intact gestation sack 'en caul' is well described as a	"Maternal health may also be an important factor in deciding optimal timing and mode of delivery" added. More emphasis on potential risks of caesarean section has been added. As you note, there is no evidence to support delivery "en caul"

technique to reduce fetal trauma during caesarean delivery, although substantive evidence for this approach is lacking.	
Powls, Andrew <Andrew.powls@ggc.scot.nhs.uk>	**BAPM response**
I've just read the BAPM draft document. It is very good although I am still cynical about how well parents, or clinicians even, will understand the graded risk approach. I suspect that, as now with 23 weeks where we are called to a delivery at 23 weeks + 0minutes because we have passed the magical threshold. My only though is that the Red-amber-green gradation figure describes the continuum for gestation but doesn't really work for the other factors – sex, singleton, steroids etc. Was there not any data from the cohort studies to give an odds ratio for each factor? That would be much more useful. It may also give you an idea of whether one factor was more important than the others e.g. does female sex outweigh an incomplete steroid course etc	Thank you. We agree that a lot of education is required, but hopefully clinicians will be convinced of the need for a more considered approach. Figure 1 has been significantly revised; it was the opinion of the Working Group that none of the predictors of outcome is sufficiently precise as to warrant more than the graded approach to decision making.
Gopi Menon	**BAPM response**
1. This is a well-written and potentially extremely useful document. 2. Its success will depend on buy-in from all stakeholders.	Thank you. 4. The draft Framework was forwarded to the relevant committees and groups (including

3. The biggest risks are (a) that these guidelines (although written in consultation with obstetric groups) will not be actively adopted by jobbing obstetricians (b) parents will not embrace it. 4. It is thus important to spell out how consultation has been carried out amongst stakeholder groups (especially parents and obstetricians). For example, how did Bliss consult parents, and how did RCOG and BMFMS consult obstetricians.	the Each Baby Counts team) within RCOG for comment and they were asked to respond directly to BAPM 5. Once the framework is published, it will be sent out to all members via RCOG news. This is an email that is sent to members and will include a link to the BAPM Framework. RCOG will request that Guidelines Committee consider whether any existing guidelines should be updated to refer to the Framework or whether it might for the basis for a new Green Top Guideline.
5. It is also important to know exactly how this document will be incorporated into obstetric practice (?via RCOG green top guideline). There needs to be a mechanism for this to be joined up to daily obstetric practice so that when neonatologists and obstetricians speak about a case they are referring to the same guidance. 6. I would also suggest a parent-specific report (of the sort that accompanies the NNAP report). 7. A recommendation should be made that the elements of this Framework are incorporated into locally-relevant guidelines 8. It would be good to reference the BAPM Neonatal Service Quality Indicators. The following Quality Indicators are directly relevant to this document: • NSQI 4 Pathways of Care and Referral for high risk babies • NSQI 5 Collaborative multidisciplinary care for babies	We have added text around incorporation into local guidelines, and referenced BAPM NSQI. The document is aligned with NICE guidance “written and verbal information” added; abbreviation IA removed, “and/or senior trainee/ANNP removed (ideally retained);

with complex conditions • NSQI 7 Family involvement in care planning and delivery • NSQI 8 Parent Information • NSQI 14 Death and Serious Adverse Event Review Specifics 1. 46. Is it worth saying that AN steroids and Mg work at even the lowest gestations? 2. 47. Add something like "Written and verbal communication about the reason for transfer and details of the referral unit should be given to parents" 3. 48. Add something like "Intermittent auscultation can be used to check on fetal status in order to inform the care given by the neonatal team following birth" 4. 52. The abbreviation IA should be replaced with the full words. 5. 54. Shouldn't you say "stabilisation should be supervised by a consultant where at all possible"? 6. 56. Suggest this says "The most important intervention is establishment of adequate lung recruitment." 7. 85. The correct grammar is: 22+0 -22+6 weeks: 1-in-3 survivors have has severe impairment (similarly for the other gestations)	"lung recruitment" added, to replace "ventilation"; grammatical error corrected, thank you.
MIALL, Lawrence (LEEDS TEACHING HOSPITALS NHS	**BAPM response**

TRUST) <l.miall@nhs.net>	
1: Overall this is a very well written and informative document with some very useful up to date data supporting it. It will help clinicians give informed advice to parents. However it does represent a significant change in practice from the previous Nuffield guidance on babies at the limits of viability and as such needs careful review in some areas (see below). The impact on in-utero transfers will be important since whilst the numbers who deliver are small the numbers with possible threatened labour at 22 weeks may be much higher. Given the lack of neonatal nurses nationally do we actually have the resources in the UK to further extent NICU to <23 week infants and there may be a hidden cost on the larger gestation babies being moved due to lack of unit capacity. 8 (26 Fig 1): This figure is helpful but I think the colours and title need adjusting. It needs to be clear that 'extremely high risk , 'moderate to high risk' and' lower risk' are with reference only to babies born 22-26 weeks. All of these babies are at extremely high risk when compared to term or near term babies and it may create a false sense of reassurance to describe the healthier ones as lower risk. I would consider using the terms 'excessive risk' for those where we are recommending palliation only, and 'extremely high risk' for the middle group and 'moderate risk' for the	Thank you – we received a lot of feedback around figure 1, which has been modified

best group. In most areas of medicine a 50-90% chance of death or severe disability would, I believe be regarded as 'extremely high risk' rather than moderate to high. I would also suggest that in the top section of the table the red colouring extend to the whole of the 22+0-22+6 gestation band rather than stopping at 22+0 (since everything to the left of 22 is <22 anyway it is misleading in its current position. I would suggest in the lower part of the table the red and the green shaded areas are of equal size, since this is presenting just relative risk rather than categorical risk. Should there be more quantification of risk based on actual birthweight - analogous to the Draper charts that were available some years ago and the US NIHR online calculator? 8 (57): The suggestion to intubate if no response to mask ventilation is a big change from Nuffield but I feel is acceptable. The suggestion that if you are going to resuscitate to follow NLS algorithm and to give 5 mins CPR before reviewing would result in the most extreme preterms occasionally having UVC, adrenaline etc etc which I do not personally feel is appropriate. If a baby remains bradycardic / asystolic despite a few minutes of effective lung inflation at <25 weeks I think it would be reasonable not to proceed with aggressive resuscitation etc. 17 (fig 4): This is very useful but needs to be clearer what the	Page 8 – following similar feedback, we have added, "if advanced resuscitation is considered appropriate". Figure 4 – denominator clarified Thank you Thank you – this has been formatted as printable PDF

dominator is- is it live births or all births? 20-21: Communication advice- this is excellent and will be very useful 23 (126): Parental information leaflet- this is very useful. Once agreed would be nice to be in a printable PDF format with appropriate graphics / pictures of babies at these gestations? (more accurate than 'small bag of sugar') 24: Infographic is useful. Needs to explain that 22 weeks includes everything up to 22+6 etc	
Modi, Neena <n.modi@imperial.ac.uk>	**BAPM response**
3 (Summary point 5): "Decision making for babies born before 27 weeks of gestation should not be based on gestational age alone, but on assessment of the baby's prognosis taking into account multiple factors. Decisions should be made with input from obstetric and neonatal teams in the relevant tertiary centre if transfer is being contemplated." I suggest important to include the condition of the baby at birth in the decision making process. 3 (Summary point 7): "For fetuses/babies at moderate to high risk of poor outcome, the decision to provide either active management or palliative care should be based primarily on	Thank you. Summary point 5 has been amended "mindful of the need to act in the baby's best interests" has been added to the text, and the possibility of baby being born in unexpectedly poor (or good) condition

the wishes of the parents.” I wholly support the emphasis on respecting parent wishes but suggest it would be wise to beware breaching the “best interests of the child” principle, and recommend you qualify this statement by explaining that the condition of a baby at birth cannot be predicted with certainty – see below re page 28. 8: The visual risk assessment “tool” though superficially attractive has a major short-coming, namely it does not take into account the condition of the baby at birth. Clinical judgement is also insufficiently highlighted throughout the document. The commonly cited reason that many doctors attending the births of extremely preterm babies will inevitably be inexperienced is no justification. All doctors must recognise that a large part of medical care is a judgement call, a combination of the art and science of medicine that no algorithm can ever wholly replace. Be careful of suggesting to young doctors that they must never or will never be called upon to exercise clinical judgement. Be careful too of providing a “tool” that will become a football in the UK’s highly adversarial legal system. Suggest move para 95, page 19 out of appendix and into main body of text. 24: The right hand column of the table is ambiguous - one in	Some amendments to text Infographic has been modified “When the baby is born in unexpectedly poor, or unexpectedly good, condition, it is reasonable for the attending neonatologist to proceed with care in the baby’s best interests” added to text Infographic modified Scenario modified slightly

3 babies that are born or one in 3 that survive? It's stated up at the top but might have less risk of being missed if the statement is "One in 3 babies that survive have severe disability" 28 (Scenario): "In this case, the parents decide, after consultation, that they wish the baby to receive palliative care. Labour progresses and a live-born baby is delivered weighing 460 grams. The paediatric team attend to support provision of palliative care. The baby is wrapped and given to his parents to hold. He dies at approximately 30 minutes of age." This scenario does not discuss the possibility that the baby is born vigorous, and in good condition, and does not die. There is a huge danger that this advice will take us back to the days of "sluice babies"; by this I mean babies left to die who were found still alive some hours later and then resuscitated. Remember too, that parents not infrequently (and not unreasonably) change their minds. Again, the issue that is lacking is the need to explain that clinical judgement is important. I suggest parents would be better to be told truthfully that should the baby be unexpectedly vigorous and lusty, it would not be in his/her best interests to be left unsupported. However, one should also explain that should it subsequently become apparent that the prognosis is very poor, palliative care can always be instituted at a later stage.	More has been added to parental information, noting a range of potential poor health outcomes. BAPM is quite clear that this document does not relate to termination of pregnancy and this is clearly stated The point about "right to die" is valid, but out with the scope of this document. We have however noted more strongly that care must be in the baby's best interests

General: Overall, I think this is an excellent and well-written framework, and I congratulate the authors. However, I'd like to ask you to consider the issues below. General: "Risk" and "outcomes" are defined purely in terms of mortality and neurodisability, which is less than wholly truthful. Mention should also be made that preterm birth is a major risk factor for adverse health outcomes in multiple domains and that this is a field where understanding is as yet incomplete but evolving rapidly. General: Beware unintended consequences; as it stands this document is likely to be used as part of justification for a lowering in the abortion age limit. Has BAPM consider its stance were this to be the case? General: There is active debate in the adult world of the "right to die"; has BAPM considered how this might be applied to an extremely preterm neonate? If not, why not? Surely, babies should have the same rights as adults. In the case of the scenario above (page 28), and the possibility that the baby might survive the initial period of palliative care, the logical approach to avoid such an occurrence would be assisted death. Is BAPM ready to confront this issue?	
colin@morleys.net	**BAPM response**

Para 2: First line should say British not English. Para 14: Gestation specific leaflets should be given to the parents informing them about not only the chance of survival but of all the morbidities that babies are likely to suffer at these gestational ages, including duration of hospital stay, cerebral haemorrhage, BPD, home oxygen, readmissions to hospital and nature of long term problems. The purpose of this is to ensure that all members of obstetric and neonatal staff and in different hospitals are giving similar information rather than vague suggestions. If there is doubt about the gestational age, then they should be given leaflets that cover the relevant gestations. Para 14: Parents should be informed that the outcome changes with time after birth. Para 15: It needs to be highlighted that when assessing babies at extremely low gestational ages using an obstetric gestational age assessment is only accurate to about a week and so it is not possible to differentiate the outcome for babies by exact week of gestation. Para 22: Nothing is said here about the genetic background of the baby. Black babies, especially girls have a higher chance of surviving than whit girls.	Thank you - as reference 8 includes Scottish and Welsh data, “England” has been changed to “UK” Your point about gestation specific leaflets is a good one, unfortunately out with the resource of this Working Group. BAPM will give consideration to this. We accept your point about outcome changing with time after birth, but do not think that this information would be particularly helpful to parents before the birth. Data are provided around accuracy of gestational age – BAPM feels that it should be up to the discretion of the attending obstetrician to discuss this with parents. Since race is not always clearly defined and additional (or lesser) risk therefore not quantifiable, we have not included this We agree; this Framework will be freely available on the BAPM website We have tightened advice around a neonatal consultant being present at birth, but within the the current UK system of on call neonatal consultants, this may not be practical,

Para 24: The experience, knowledge and attitude to very preterm births of the obstetricians, midwives, neonatologists and neonatal nurses can have a big effect on how they manage the child and the advice they give the parents. They need to have easy access to the best available data. Para 28: Management of any very preterm baby after birth is very difficult and requires skilled and experienced staff. Delivery of all babies in these categories should be attended to by an experienced neonatal team and not left to the trainees alone Para 54: I don't think the word ideally is appropriate. Stabilisation and resuscitation of extremely preterm babies is very difficult and it is essential that only well trained and experienced staff are involved. Para 61: Many very preterm babies receiving palliative care show some sort of breathing efforts and movements. These can persist for a variable length of time. I don't think it is appropriate to tell the parents the baby my show "brief reflex movements or signs of life". Para 86: I think we should be circumspect about the EPICURE 2 data. It is good but 13 years old and A lot has	especially in level 2 units. Mandating (impractical) 100% consultant attendance could have adverse medico-legal consequences. Paragraph 61; signs of life are currently being reviewed by MBRRACE-UK. It is entirely possible that extremely preterm babies considered appropriate to receive palliative care may show signs of life after birth. We have acknowledged throughout this document that outcomes are improving. Paragraph 134 – more information added to Appendix 5

improved in that time. There is good Australian and NZ data for every year. See https://npesu.unsw.edu.au/sites/default/files/npesu/data_collection/Report%20of%20the%20Australian%20and%20New%20Zealand%20Neonatal%20Network%202013.pdf Para 134: This is very good, but the parents need more information than just chance of death or severe disability. See my comment above about paragraph 14.	
Ian Paul Morris (CAV - Paediatrics) <Ian.Morris3@wales.nhs.uk>	**BAPM response**
Please find below our comments regarding the proposed framework for the perinatal management of extreme preterm birth before 27 weeks of gestation. We have decided not to use the table template for response as our comments are broad, rather than relating to specific lines within the document. I hope this is acceptable. I would be willing to discuss any of these comments with you or the working group if you wish. Viability The key problem of premature infants is immaturity of organ systems, which is directly proportional to the gestation at birth. While most organ systems can be fully supported in extreme preterm infants, a necessary requirement for survival	Thank you. We disagree most strongly that 24 weeks is the human limit of viability – evidence of surviving infants at 22 and (increasingly) at 23 weeks of gestation bear testament to that.

outside the uterus is adequate development of the alveolar-capillary membrane of the lungs, regardless of the sophistication of machines and therapeutics available to clinicians. This stage of lung development is reached toward the end of the canalicular stage which lasts between 16-26 weeks of gestation, and the beginning of the saccular stage which lasts between 24 and 38 weeks of gestation (Wert 2017). Currently, there is no new evidence to suggest that lung development has speeded-up in human foeti; thus, the embryological limit of viability remains around 24 weeks of gestation in humans. As detailed below, data on “improved outcomes” of infants born at lower gestations need careful interpretation, especially regarding the significant limitations of such data to guide clinical practice and counselling of parents. Epidemiologically, a survival probability of 50% has been suggested to affect the perception of viability, which is achieved at 24 weeks of gestation in High Income Countries (HIC) with neonatal intensive care (Blencowe, Cousens et al. 2012, March of Dimes, PMNCH et al. 2012).	We agree that gestational age at birth is the single most important predictor of maturity and of outcome, and indeed have acknowledged this in the Framework. Gestation is not, however the sole predictor of outcome, as we have described. We have described that the outcomes of fetuses at gestational ages 22+0 to 23+6 are on a continuum, and we have not stated that outcomes for infants at both 22 and 23 weeks are similar where actively managed.
Outcomes of Extreme Preterm Infants The guideline has attempted to interpret recent papers and data on the outcome of extreme preterm infants. We have serious concerns about the recommendations in the guideline due to the following main points, which are further elaborated below.	The Framework clearly states that quoted outcomes are likely to be better than outcomes if active management was to be undertaken in all extreme preterm babies, but the point is that appreciable numbers of 22 and 23 week gestation babies **are** now surviving, and not all with significant morbidity. Most importantly, it is not possible to predict with certainty at birth which extremely preterm babies will have significant disability.

1. Data for infants born at 22 weeks of gestation needs to be separately interpreted from those born at 23 weeks of gestation. a. Gestational age at birth is the single most important predictor of maturity and of outcome. In its current form, this guideline effectively cohorts' foetuses at gestational ages 22+0 to 23+6 into one group for the purpose of risk classification which is misleading. b. It is suggested in the guideline that outcomes for infants at both 22 and 23 weeks are similar where actively managed (point 2, line 3). Due to reasons stated below, our view is that this is a mis-interpretation of data in the literature. As the significant change in the guideline is for infants born at 22 weeks of gestation, data for these infants should be separated from infants born at 23 weeks of gestation. 2. Most of the papers cited in the guideline have serious risk of selection bias (details included below). In addition, “active management” is poorly defined except in a minority of papers. Using isolated data in the form of a narrative review (as in this guideline) instead of attempting to conduct a systematic review and meta-analysis (Myrhaug, Brurberg et al. 2019) itself risks introducing bias in the recommendations. Thus, significant caution should be exercised in interpreting this data, and recommendations need to be far more conservative than its current form.	We are very grateful for your comprehensive assessment of the literature and we agree that data for the most extremely preterm gestations are few, and may subject to bias. The Framework acknowledges this in several places. Discussed in summary

3. The infographic has cherry-picked data, especially the denominator for infants born at 22 weeks of gestation. As it is intended to be used for discussion with families who present with threatened preterm labour, the correct denominator in that situation is all infants who are thought to be alive in labour (table 1, page 15). When all such infants are included, the survival outcomes are far more conservative and in keeping with current clinical experience. Choosing any other denominator is inappropriate in this situation and misrepresents current data. Critique of individual studies cited in the guideline: 1. (Mehler, Oberthuer et al. 2016): This is a single centre retrospective study using a very specific pathway including administration of antenatal corticosteroids, favouring delivery by caesarean section and the use of less invasive surfactant administration (LISA). Ex utero transfers and pregnancy terminations are excluded. The reported 61% survival in those offered active care at 22 weeks is much higher than seen elsewhere. Although even in this group survival without severe complications was 22% - below the lower margin offered in the infographic within the BAPM draft guidelines. Only 11% of infants intubated in delivery room survived without complications. The generalisability of this study to current UK practice is limited. 2. (Smith, Draper et al. 2018): Prospectively collected	

data describes improved survival from 14% to 18% for infants of 22 weeks gestation admitted to NICU between 1995 and 2014. For 2016, survival to 1 year ranged from 5% (95% CI 2-8%) for births alive at the onset of labour, to 8% (4-12%) of live births to 35% (21-49%) of those offered 'active' care. The total number of babies receiving active care was 43 and confidence intervals are accordingly wide, and conclusions should be drawn with caution. We do not have enough detail to understand why some babies were offered active care over others, and how this may have influenced outcomes. This raises serious risk of selection bias. 3. (Norman, Hallberg et al. 2019): Prospective data describing 1-year survival of infants born at 22-26 weeks of gestation in Sweden compared to two cohorts - 2004-2007 and 2014-2016. Overall survival increased between cohorts. Death in delivery room decreased from 65 to 48%. 1-year survival increased significantly at 22 weeks for live born infants (10 to 30%, p=0.01) and for infants admitted to NICU (29 to 58%, p=0.08). However, survival without any major morbidity remained very low (5.2%) for all live born infants and 17% for infants admitted to NICU (no significant difference between cohorts). Survival and survival without major morbidity was higher for all denominators in those born at 23 weeks gestation. Again, this data should make us cautious about grouping infants born at 22 and 23 weeks of gestation and raises questions about survival and disability	

outcomes estimates as provided in the BAPM document. 4. (Myrhaug, Brurberg et al. 2019): Arguably the most inclusive paper, this meta-analysis of outcome for infants born at 22-27+6 week's gestation born in high income countries, reported 22 week survival rates for all births were <1% (95% CI; 0-37.1%), rising to 7.3% (3.9-13.1%) for live births and 24.1% (17.6-32%) for infants admitted to NICU. Higher rates were seen at all stages for infants born at 23 and 24 weeks of gestation. This analysis suggests no clear improvement in survival between 2000 and 2015 for the overall extreme preterm cohort. It should also be noted that the quality of evidence at 22 weeks was graded as low and that confidence intervals are wide. Again, this data suggests that the survival estimates offered are generous, even taking in to account those infants in whom active management was given. 5. (Younge, Goldstein et al. 2017): This prospective study included in the above meta-analysis compared survival and neurodevelopmental outcome of infants born at 22-24 weeks of gestation across 3 epochs (2000-2011) at centres in the US. Whilst the overall rate of survival and survival without significant neurodevelopmental impairment increased over time, there was no significant increase seen at 22 weeks gestation. Indeed, only 3/234 (1%) infants at 22 weeks in the latest epoch (2008-2011) survived without neurodevelopmental impairment, with only 8/234 surviving	We agree that data are subject to bias, but survival does undoubtedly occur below 23 weeks of gestation Discussed above Rates of disability in different studies depend on the time point for assessment as well as the definitions of disability used. The sources used for the working group's estimate of the rate of severe disability are listed in Appendix 1. Of relevance, the recent meta-analysis by Ding (Acta Paed 2019) indicates a rate of severe disability in 22 week infants at 4-10 years of 21% (confidence interval 8-45%). We are delighted to have had feedback from a wide range of stakeholders, whose comments have been taken into account in redrafting the Framework

overall. Active management was seen to varying degrees at each week of gestation (22, 23 and 24 weeks) but did not change significantly between epochs (21-24% at 22 weeks). Whilst improved survival and survival without ND impairment was seen at 23 and 24 weeks of gestation, the same was not true at 22 weeks. In this study, it seems ‘active’ management did not impact on outcomes. It also suggests outcomes at 22 and 23 weeks should not be regarded as similar. 6. (Moore, Hennessy et al. 2012): This study compared prospectively collected data on neurodevelopmental outcomes in extreme preterm infants between 1995 and 2006. This paper showed no significant improvement in survival without disability at 22 and 23 weeks, with only 2% (0-13%) surviving without disability at 22 weeks where stabilisation was attempted. Overall survival was 7% (1-20%) in this group. 7. A number of studies suggest regional variation in survival at 22 and 23 weeks of gestation (Serenius, Sjors et al. 2014, Smith, Draper et al. 2018, Backes, Soderstrom et al. 2019). Several studies also report markedly better survival rates at 22 and 23 weeks of gestation (Kyser, Morriss et al. 2012, Mehler, Oberthuer et al. 2016, Ehret, Edwards et al. 2018). However, these were usually single or small number of centre studies in units offering very specific packages of care that are not currently generalisable to the UK wide	Yes – gender does influence outcome We (and a majority of respondents) disagree This comments was raised by others, and the relevant section of the Framework has been modified Point 63 is covered by guidance within Together for Short Lives and the National Bereavement Care Pathway

neonatal population. In considering these data, we draw the following conclusions: • Regarding outcome data for both survival, and survival without major neurodevelopmental morbidity, it is not clear that babies born at 22 weeks and 23 weeks are sufficiently similar to enable them to be grouped together for the purpose of risk stratification. Numbers are too small, confidence intervals too wide, and approaches to active versus palliative management are currently different (more likely active management at 23 versus 22 weeks) meaning that comparisons between the two groups could be subject to significant selection bias. • The statement of survival of 1/3rd in liveborn infants offered active management at 22 weeks seems on the optimistic side. Whilst it is true that some studies have shown outcomes in this range, again the numbers are small, often from selective centres and with practices not generalisable to current UK practices, and are contradicted by data from other sources. • In any case, given that counselling will often be at the start of labour, are the data within the infographic the right ones to be presenting parents with when trying to offer realistic prognoses? In addition, risk factors such as gender	

and estimated weight may not be available at the time. We would suggest data describing outcomes of infants alive at the start of the onset of labour would be more realistic, with supplementary advice given based on individualised risk assessments. • A figure of 2/3rd of survivors having no severe disability again seems generous on considering all the available body of evidence. Whilst this figure may be interpreted as reasonable considering the outcomes for the current small number of babies surviving at 22 weeks in the UK, evidence would suggest that severe disability is increased in countries and units where more active management is offered. If we accept the premise of offering more active management, then we should choose to consider units with 'best' survival figures e.g. Mehler 2016, where a figure of 1/5 would seem more accurate. Long-Term Follow-Up of Infants born Extremely Preterm • Neonatologists usually follow-up infants born extremely preterm to 18-24 months of post-menstrual (corrected) age before discharging them. The professionals who are really aware of the actual long-term outcomes of infants born extremely preterm (beyond 18-24 months) are community paediatricians, paediatricians specialising in neuro-disability, and therapists (physiotherapy, occupational	

therapy, speech and language therapy, etc.). Any additional health needs of surviving extreme preterm infants will have to be commissioned. Thus, involvement of these professionals as key stakeholders is crucial during the development of these guidelines and must be considered before ratification of this document. Miscellaneous points: • Is it appropriate, in spite of the evidence, to use gender in parental counselling and to inform decision-making? • There is insufficient evidence to routinely recommend a practice of delayed cord clamping in extreme preterm infants as per point 55. • There is insufficient evidence for the point 56 that advanced resuscitation as per term algorithms should be followed in extreme preterm infants. We would caution against overturning previous guidance to offer airway / respiratory manoeuvres only and question the ethics of such active management of babies who must be very compromised from the outset. • Point 63 – reference should be made to referral to a symptom management ("palliative care") care team where appropriate. References	

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Jenny O'Neill <Jenny.Oneill@rch.org.au>	**BAPM response**
Appendix 2 (Situations of potential uncertainty and conflict): Consider including recommendations what to do if parents can't agree on active vs palliative treatment.	If there is parental disagreement after counselling, and the baby is born in reasonable condition, it would be usual to provide active management initially and then review the situation. We note that in UK law, unless parents are married, only the mother will have parental rights at birth. A scenario has been added to describe this.
Obstetric management (Mode of birth): Consider including statement about need/no need for GA for caesarean birth – ie prematurity by itself not an indicator for GA.	Obstetric anaesthesia is out with the scope of this document
Appendix 4: This resource is excellent.	
O'reilly, Helen (NNUHFT)	**BAPM response**

<HELEN.O'REILLY@nnuh.nhs.uk>	
It is not clear from the list of authors whether this group included experts representing the fields of PICU, community paediatrics and education. If we further lower the gestation at which we resuscitate infants then there are significant implications for these services. I was asking whether any of these people had been included in the discussions. Successfully resuscitating a 22 week infant is only the very beginning of the story as I'm sure all the esteemed authors are aware. If we are to successfully support these additional preterm infants throughout their life we need to involve the professionals who will provide this support from the very beginning of any policy change.	The Working Group did not include representatives of PICU, community paediatrics or education, but we have received, and responded to, feedback from a wide spectrum of professionals
Elizabeth Osmond <elizabeth.osmond@googlemail.com>	**BAPM response**
A significant increase in the number and funding of NICU cots would be required in order to be able to offer intensive care infants below 23w gestation in an equitable fashion across the UK, with MMBRACE figures showing a similar number of foetuses of 22 and 23 w gestation alive at the start of labour. As a consultant in a tertiary UK perinatal centre, I occasionally have to refuse network referrals for specialist intensive care for term infants and those with correctable congenital anomalies and frequently have to transfer infants	Thank you. Resources are out with the scope of this Framework, but we hope that highlighting the need to manage the smallest babies in tertiary centres will help to increase/direct NHS funding in the future.

out of their local hospital who are requiring high dependency neonatal care. Parents of infants who are currently not able to have some of their neonatal care in their local tertiary centre would rightly question the ethics of further stretching NHS services by offering active care for infants of 22w gestation who would be likely to require a prolonged period of intensive care. The consideration of active care for infants below 23 weeks gestation should be regarded in the wider context of other patients for whom active pathways are usually not offered in the NHS- for example cardiac surgery for infants with trisomy 18. With limited resources and cot capacity, the allocation of NHS resources must be appropriately considered. A balanced and well-presented document, with helpful graphic figures and parent information leaflet.	
Page, Louise <Louise.Page@chelwest.nhs.uk>	**BAPM response**
3 (4): Active management of labour and neonatal stabilisation may be considered for babies born from 22+0 weeks of gestation. Although the rationale behind this statement is explained in detail in the document, when you read the executive summary [which many people will only do] it does seem to suggest actively managing all labours at	Thank you. Point 4 amended as suggested

22w is appropriate – maybe simply adding “Active management of labour and neonatal stabilisation may be considered for babies born from 22+0 weeks of gestation following multi-professional discussions with the mother and family and taking into account the clinical situation and the parents’ wishes” or something similar may help to put this in more context? General: Excellent document. Easy to read and understand. Great infographics. A much needed piece of work – thank you to BAPM for producing this document & we look forward to the finalised publication.	
Power Simon <Simon.Power@boltonft.nhs.uk>	**BAPM response**
12, active neonatal management, delayed cord clamping (Para 2): This paragraph states that we should be routinely delaying cord clamping. To do so in our unit would likely adversely affect thermal care and I wonder if this is similar for many other units. Would it not be advisable to state (something like): Delayed cord clamping should be routine practice unless the clinical condition of the infant requires immediate attention and this cannot be delivered whilst the cord remains attached to the placenta? Some units will have the mobile Resuscitaire/lLifeStart trolley, many including our own, don’t.	Thank you. The experience of members of the Working Group is that physiological cord clamping need not adversely affect thermal control – we refer you to the BAPM Normothermia toolkit, and to published literature (Bates SE, Isaac TC, Marion RL, Norman V, Gumley JS, Sullivan CD. Delayed cord clamping with stabilisation at all preterm births – feasibility and efficacy of a low cost technique. Eur J Obs Gyn Repro Bio 2019;236:109-15) Page 12 – amendments have been made to this section of the framework, including feedback from the UK Resuscitation Council

12, active neonatal management, use of adrenaline (Para 3): I read this a few times and I wonder if this paragraph could be clearer at answering the question: should I give adrenaline to an extremely preterm infant? Using NLS algorithms would indicate adrenaline is appropriate but only after lung expansion (and though not NLS, ET intubation) – these procedures along with vascular access are likely to take us to beyond 5 minutes at which point if HR remains poor the outlook is bad – so why give it? I appreciate this is a tough one to provide clear guidance on but shouldn't we be a little more committed to probably not giving adrenaline e.g. There may be occasions when the team feel adrenaline (IV or ETT) is appropriate but effective cardio-pulmonary resuscitation for more than five minutes in extremely preterm infants is associated…etc. I think this statement or one similar to it presents a subtle change of tone – as I read the draft it seems to me the issue has been somewhat dodged. I think the document is a real step forward and of a very high quality overall. Thanks.	
Puddy, Victoria <Victoria.Puddy@uhs.nhs.uk>	**BAPM response**
3 (Executive summary): Point 1 "changes" in the approach to their care, should this be developments in approach to their care and it implies that care has fundamentally changed ,	Executive summary – point 1 – "developing" added, thank you. Point 2, "in partnership" added. Throughout the Framework we have made changes to emphasise that care should

rather than progressive developments in more active approach in both obstetric and neonatal management over the last few years at lower thresholds. Point 2 “should reflect the wishes and values of the mother and partner informed by consultation with obstetric and neonatal professionals “ Whilst this ethos is appropriate it raises concerns that the parents’ wishes have to be followed at the extremes of gestation ie at 22 weeks if the view of the clinical team is that this is not in the best interests or appropriate for the clinical situation. The way it is worded implies the ultimate decision is that of the parents. Should this be worded in “partnership” to share the responsibility for decision making particularly for the less than 23 week gestation group. Point 7 “Primarily on the wishes of the parents” for the moderate to high risk outcome group : the neonatal team have serious concerns and issues with this statement for the less than 23 week gestation baby, which is currently included in this bracket further in the document. It implies that active obstetric and neonatal support will need to be offered if the parents want this and the clinical team do not think this is appropriate for this baby. Ie 22 +0 with no additional unfavourable risk factors. There should be a statement about partnership decision making that take into account the parents’ wishes. 8 (Box 1): Concerns about the terminology or language used	always be in the best interests of the baby. Categories of risk have been redefined, to include extremely high risk

with moderate to high risk, which includes the risk of 50 – 90% chance of either dying or surviving with severe impairment. Contradictory use of terminology of risk: moderate should not be used when there is up to a 9 out 10 chance of severe impairment . In this category the way it is written misinforms the true implication of the risk and severity. “Moderate” has a “value” to it, implying something is “not too bad or severe” in terms of outcome. It would be better if the terms used to differentiate categories of risk made it clear when frequency rather than severity of outcome was being described. A risk >90% should be described as “nearly all will die or have severe handicap”. A risk of 50-90% should be described as “more than half will die or have severe handicap”. A risk of <50% should be described as “less than half will die or have severe handicap”. This is a much more realistic description that accurately conveys to parents (and clinicians not regularly involved in such discussions) the risk of their child having major problems. This may help avoid desperate parents asking for CS delivery at gestations where it is very unlikely to improve the outlook for their baby (see point 48/49 page 11). 9 (27): “There is no objective way of defining a risk as ‘extremely high ‘ vs moderate to high ‘ and families differ in the outcome that they regard as unacceptably poor.” The document as written is unbalanced. For some parents they	9 (27) – we acknowledge that only severe disability has been described in detail although the parental information leaflet now gives more information around other health issues and we have added text around potential learning and behavioural problems. Page 10 (42) – more information added to guide and support professionals to act in the best interests of the baby 11 (48-49) – obstetric section has been modified. In particular, we have highlighted lack of evidence of benefit, and potential for harm, of caesarean section at extreme preterm gestations

may have a different view on what is an acceptable outcome for their baby. It provides information on severe impairment but nowhere provides information on moderate or mild impairment for parents to be able to make balanced decisions about care and what is acceptable to them. As there is no mention of moderate or mild impairment this could be construed as severe impairment or no impairment.	Suggested change to IA made under palliative care, thank you
10 (42, Figure 2): Further clarity on the moderate to high risk section is required as it currently stands. It implies that some of the mod to high risk move to active management and the lower risk group, even though there is s 50 – 90 % risk of severe impairment or death ie 50% as a minimum and 9 out of 10 as a maximum. Again states that this should be informed by parent wishes, implies that parents have the final decision making when the clinical team do not agree with active management in this situation which could be a 22 +0 week preterm delivery with no other risk factors.	12 (56-57) – text amended in response to feedback, including UK Resuscitation Council
11 (48-49): "Active obstetric management. The package of active care offered to parents may include the following:……" We regard the offer of magnesium sulphate and steroids from 22 weeks very different to offering intrapartum CTG and CS for fetal concerns with associated maternal risks and long term implications for future pregnancy. This is not clarified in the document. As obstetricians we are particularly	16 (76)/17(86) – this has been done – see summary response

concerned that active obstetric management may be interpreted by parents as offering CS under 24 weeks, Although there is reference to the lack of evidence for CS in extremely preterm babies, a clearer statement is required that CS is not indicated for fetal reasons <24 weeks. This section should be made more explicit to avoid potentially futile surgery in very premature fetuses. 11 (48): Under palliative obstetric management, the term IA (intermittent auscultation) may lead to confusion with IA performed by midwives in normal labour which involves more detailed assessment of fetal heart rate for one minute every 15 minutes in the 1st stage and every 5 minutes in the second stage. A suggested change in text such as “assessing or listening for the presence of a fetal heart to check viability” is more appropriate for the description of palliative obstetric management. 12 (56-57): “Newborn resuscitation algorithms as used in more mature babies “ and “ effective cardiopulmonary resuscitation for more than five minutes “ . “ Cardiac massage and adrenaline are rarely required following extremely preterm birth “ Our view is that there should be a further statement to here to say that it is not appropriate to undertake CPR in extreme preterm delivery, if there is no response to adequate ventilation including intubation then it	19(90) – we disagree – well documented survival in growth restricted babies below 400 g Infographic amended Appendix amended as suggested 25(137) – the wording of this section was agreed with our parental support organisations. Attending special needs school may be influenced by local authority arrangements, and is covered to some extent by severe impairment. The Framework now includes more about joint decision-making partnership and emphasis on best interests of the baby

is not appropriate undertake CPR and drugs. As written it implies that whilst rarely needed it is okay to do this for up to 5 minutes. If an extremely preterm baby is comprised to require chest compressions as per recognised resuscitation algorithms, the combined impairment risk in addition to the background risk of severe impairment, it is not in the best interests of the baby. We would like to see something like , if there is moderate to high risk of severe impairment it would not be appropriate to provide cardiopulmonary resuscitation ie chest compressions. Also, add a gestational band ie not appropriate below 23 in any circumstances and 26 weeks in circumstances where adequate ventilation has been provided. 16 (76): A description of moderate and mild neurodevelopmental impairment should be included to provide a balanced outcome view 17 (86): Tables should be provided on moderate and mild neurodevelopmental impairment to provide a balanced outcome view. 19 (90): Uncertain gestational age. < 350 gms . We have concerns about this weight cut off criteria if estimated to be greater than 350 gms and of uncertain gestational age the default is to offer face mask ventilation and stabilisation and	

assess. If a weight criteria is included the minimum we believe it should be 400 or 450 gms. 24 (Pictogram of outcomes): The small print of ** up to quarter of children without severe disability may have other functional impairments etc “ this is in small font and white and should be more prominent 25 (Appendix): Helping parents to understand. Information on mild to moderate impairment should be included to provide a balanced view. 25 (137): This does not give a real true representative of the severe impairment. “Needing extra help at school “. No mention of specialist schools or not attending mainstream school. Extra help at school implies extra help in mainstream school. Specialist schooling is meaningful to parents. Should there be a specific section in the information for parents for babies below 22 weeks. There is considerable difference in this gestational week from the beginning of the week 22 +0 to the end 22 +5 etc. The whole document does not differentiate between this at any point for babies less than 23 weeks and puts them into a single bracket of 22 weeks. Further information on expectations and approach should be highlighted to parents here. Joint decision-making partnership, emphasis on best interests of the baby.	

Quine, David <David.Quine@nhslothian.scot.nhs.uk>	**BAPM response**
General: Helpful document, with helpful terminology and support for communication with worked examples. Some more info on survival rates depending on risk factors would be helpful. 3 (7): I feel it should be stipulated clinicians should not make parents feel that they alone are making decisions, but clinicians should make recommendations even if it is to say that either active management or Palliative care is equally appropriate depending on parent's wishes. 8 (Figure 1): Feels unhelpful, some information on how this list of risk factors compare in regards to increased mortality. Table appears to make them all seam as strong as each other, where surely size and gestation are the most important. Regards steroids after 48 hour the affect on mortality wears off? 20 (108): As above feel recommendation should be made, and parents should not feel like they made the decision themselves. 26 (148): Feel this skirts around the issue, should be stated more bluntly that active management to achieve survival will	We believe that the fact that clinicians should support parents to make whatever decision is best for them is well described in the Framework, and need not be repeated in the summary Figure 1 has been amended following feedback We note that the beneficial effect of steroids lasts for around one week 20(108) "Consultation should not be directive, but for some families gentle guidance around what is likely to be in the baby's best interests will be very helpful" has been added" 26(148) – we do not agree 28(170) – "if possible" is included, to cover this situation

not be undertaken, but every measure to achieve comfort will be. 28 (170): Would a neonatologist be present at a local neonatal unit ?, more likely a paediatrician would do counselling possibly after discussing with local tertiary neonatologist.	
Amy Reid <amy.Reid@stgeorges.nhs.uk>	**BAPM response**
8: We believe that there is not enough evidence to categorise extremely preterm neonates at a gestational age 22+0 to 22+6 as being in the moderate to high risk category. We believe that they should be in the extremely high risk category and palliative care would usually be in the best interests of the baby at this gestation. While new evidence seems to suggest that outcomes at 22 weeks are similar to those at 23 weeks gestation, we are concerned that this evidence is not of sufficient quality to change practice. The evidence of outcomes at 22 weeks is based on small numbers and certainly influenced by selecting those infants likely to have the best outcome, both in terms of survival and neurodevelopmental outcome. If we change practice and offer active respiratory management to preterm neonates at 22 weeks we are concerned that we may cause suffering for a high proportion of babies with very small chances of survival. In addition, we need to consider the implications for	We acknowledge your concerns, but refer to published evidence of increasing survival at 22+ weeks' gestation Funding/resources are indeed important, but out with the scope of this Framework

health services including neonatal, paediatric, developmental and allied health, in terms of resource allocation before offering active management for this group.	
Public Affairs <publicaffairs@resus.org.uk>	**BAPM response**
6 (10 and general): The use of ‘Active’ and ‘Palliative’, referring to an apparent dichotomous choice in how care should be predetermined/offered/given throughout this document, should be changed in order to better reflect some of the sources and models of delivery of care referenced in the framework. ‘Active’ and ‘Palliative’ are not antonyms and the use of ‘active’ immediately implies that palliative care is either passive or inactive, which it absolutely is not. Good palliative care is an active process too. In line with the ReSPECT process and the holistic care described in the ARNI course, as well as the TFSL Perinatal pathway referenced throughout this document, the framework should reflect more clearly the provision of intensive care support where it is to be provided, and the provision of palliative care where this is to be provided. The term ‘active’ care is misleading as shorthand and would be best avoided to prevent inexperienced readers drawing unintended conclusions. While it is appreciated that the authors may have been trying to frame an apparent dichotomous choice in a utilitarian fashion the incorrect use of ‘active’ vs ‘palliative’ as antonyms risks, and will likely result in, inappropriate language being	Thank you for your comprehensive and thoughtful feedback 6 (10 and general) – we pondered long and hard over the terminology, and others have not noted concerns. We have clarified “active (survival focussed) and palliative (comfort focussed) care. A sentence has been added to definitions to clarify that palliative care should be actively managed.

used by those who have read the document but have little experience in counselling or providing palliative/end of life care, and who find themselves in the position of talking to parents. This document must be an exemplar for the language to be used from resource through to counselling. I note that BAPM's own Palliative Care Framework for Practice makes no such reference to 'active' care as an alternative to palliative care, and indeed outlined the very active process of preparing for and providing good quality palliative care. 7 (17 and general): Throughout the document the Framework presents an apparent dichotomous categorisation around outcome to be presented to parents when in discussion with them: either a baby will fall into 'severely disabled' or not. While the reasons for this approach are outlined to be that there is more 'certain' evidence for the severely disabled group, again it means that on face value the implied opposite is 'intact'. In truth, the mild-moderate group of disabilities may be hugely relevant for 22-23 weekers and decisions made by the family as to how to proceed. We note that the Epicure studies, for example, used the phrase 'severe' impairment to include a combined outcome of moderate-to-severe disability which, importantly, has some direct relation to how much impact on activity of daily life there might be from the impairment. If the	7 (17 and general) – this is indeed a tricky issue. We have added information to the parental leaflet, as suggested by others also. Additionally, "we note that many more extremely preterm babies will be affected by milder degrees of disability; this should be included in consultation, noting that disability is impossible to predict for individual babies at birth" has been added to paragraph 17. See summary response in regard to ethical point of view

working group feel a dichotomy needs to be pursued in the approach that the framework provides, perhaps consideration of combining none+mild vs moderate+severe, especially at the extremes of gestation, might be more easily applicable in clinical use. Use of the severe category as a comparator to 'everything else' as read currently means that the perception throughout the document is that the outcome for the babies not in the 'severe' category is perhaps more positive than the reality. In terms of parental consent to agree to a particular route of care, such a focus on severe vs. everything else also potentially risks encouraging an approach to counselling that would run foul of the Montgomery judgement. Providing information only about only one extreme as the exemplar of what disability at 22-27 weeks might look like is unlikely to fulfil the requirement to provide information that a lay person would reasonably be expected to be told. It would be sensible to provide information in this document about the mild or mild-moderate impairment as a 'middle' category and thus not risk over-presenting the number of babies who might be wholly 'intact'. This would refine the balance in use of the framework during counselling in line with the legally expected standard of information provision in a situation where consent is to be sought. This last point is perhaps best demonstrated by the cognitive cut off for 'severe disability' taken as -3 s.d. (IQ<55). Whilst this is absolutely consistent	7 (21) – text amended to "those babies born at 23 weeks of gestation who receive active care and survive

with the way the EPICure study-defined severe cognitive impairment, other studies have used – 2 s.d. Beyond the issue of lack of information about 'less than severe' outcomes, the threshold that the working group have chosen is particularly severe, thus the burden of disability prevalent outside this strict categorisation is further under-represented and may still present significant challenges for the child and their family. In particular regarding these chosen thresholds, we note here that the 2008 BAPM/RCPCH working group on Classification of health status at 2 years as a perinatal outcome observed: "The developmental cut off (<55) is extreme and, whilst it may be highly predictive, is not commonly used around the world when reporting outcomes for such populations." 7 (21): The paragraph stating: "The risk of severe impairment.....is currently approximately 25% for babies born at 23 weeks" might be construed as misleading due to the nature of the denominator chosen, and in this paragraph, the absence of comment about the denominator chosen. This is 25% of the 38% of live births receiving 'active' care who survived. The 'headline' 25% does not make this clear and is used throughout the framework without balanced clarification wherever stated. It has great potential to mislead those who do not read the full document, and by implication, parents subsequently counselled. The graph in the appendix	8 (figure 1 and box) – figure 1 has been amended after feedback. While the Framework could reasonably be described as "vague" in parts, this reflects the true-life situation. Each pregnancy and fetus/baby is individual, and so accurate prognosis will always be impossible. We hope that this guidance will help practitioners to feel confident in conveying this risk (and it's inherent uncertainty), while recognising that survival is improving for extremely preterm babies.

refers to 4 studies reporting variable rates with 25% severe disability being concluded from the 4 studies. Most look at 2-3 year follow-up. The same data could be expressed as the risk of death or severe disability at 23 weeks is 71.5%. e.g. 62% die + (25% of 38 with severe disability). The figure for all live births instead of those receiving active care would be 75.5% death/severe disability). It cannot be assumed from the data that those who were live born and did not receive ‘active’ care, were they to have had ‘active’ care at delivery then they would have been a homogenous extension of the ‘active’ care group in outcome. Indeed, many will have been reviewed with intent to consider ‘active’ care which was then not pursued (see later points around planning for assessment at birth and choice of denominator in counselling). There is a reasonable probability that a physician-led decision to not provide ‘active’ care at delivery will have selected out those likeliest to do well. While it is clear in way the framework is written that there is a wish to allow some of the statistics which have a more positive angle to shine forward, there remains a real risk this will push practitioners towards overoptimistic estimates of outcome. The choice of language and expression presented in the framework should represent a middle ground rather than an over optimistic or pessimistic presentation of the data. 8 (Figure 26): It is not clear how this figure is intended to be	9 (27) – thank you. There have been some changes in the Framework, hopefully better to highlight that there can be no certainty except < 22 weeks of gestation, or in the case of in utero demise of the fetus; the baby may be born in better or worse condition than predicted, and that any plan must be amenable to change.

used, as it presents essentially three Likert-type Scales without guidance as to how they relate to each other. It is not clear whether the three scales should be used to mark a point and then an aggregate taken or whether they are just visual representations to be taken individually. For example: If I am a 22+6 appropriately grown girl, who received antenatal steroids & magnesium, born in a level 3 centre, Part 1 has me moderate-high risk, but I am lower risk for all 4 parts of area 2 and both parts of area 3. With 2 moderate-high and 4 lower risks as stratified, how should the composite risk be presented? Lower risk is defined in the framework as <50% death or severe disability, but my risk of death alone at 23 weeks would be 62% (of live births) when considered whilst still in-utero. The lack of instruction for use and composite interpretation, without any clear guidance for possible weighting (part 1 having 'extremely high risk', but 2 and 3 being only 'higher' to 'lower' risk) presents a risk of highly variable interpretation from clinician to clinician. This would then risk mis-counselling. If the figure was intended only as visual representations of text only (i.e. not intended to be used formally in the process of 'assessing risk level' prior to counselling) then perhaps they would be better placed in the appendices with a more clear explanation of how the working group intended them to be used. We also noted that the risk strata (risk death /severe disability extremely high risk -90%+, moderately high risk 50-90% or lower <50%)	9,12, 54 – text amended

are illustrated on a 'RAG' rating transition with the categorisation and risk factors superimposed. This wording or categorisation is very broad, especially for the moderate-to-high risk band. For example, extremely highrisk changes to moderately-to-high risk at 22+0, and it is difficult to envisage that a 90% chance of death or severe disability would be perceived as in any way possibly a moderate risk (see further comments later regarding choice of recommended statistics chosen to guide counselling). The breadth of the banding presented may again be falsely interpreted as reassuring. 8 (Box 1): Use of the word 'some' in the bullet points is not defined in these sentences and sits uneasily next to the more well defined % risks in the leaders. 'Some' means many things to many people and should be defined more clearly so the reader has an appreciation of the working group's actual perspective. For example, the data in the appendix outlines 101/301 live births (or 101/223 admitted to NICU) at 23 weeks survive to 1 year. This, by the definition would suggest that the baseline for survival for 23 weeks is <50% (not including additional disability) and so using the word 'some' to describe 23 weekers as having a 50-90% chance of death or serious disability does not seem right, when clearly 'half or more' would perhaps be a better-defined descriptor. As noted elsewhere in the framework, it is also	9 (33, 34, 35, 36) – thank you; "both" removed; "including the inherent uncertainty around (risk)" added; "all such transfers much be discussed with the receiving team" added;

feels that the denominator used here (which is ‘of those receiving ‘active care’) is not well enough emphasised in the text in the box, again with respect to the likely perception of outcomes. The combined de-emphasis of the denominator and the use of undifferentiated terms like ‘most’/’some’ leaves the reader in an uncertain position when trying to realistically reflect the potential outcomes to parents in an antenatal setting. 9 (27): This paragraph is perhaps the best written paragraph in the document. However, it immediately leads the reader to the questions of: (a) why, then, is there any attempt needed to stratify risk (box 1, figure 1)? (b) why, if parents input and understanding is key to approach offered, does the framework chose not to outline mildmoderate conditions and, furthermore, go on to present the situation that antenatal risk stratification then counselling should lead to an ‘certain’ and dichotomous choice (instigate ‘active’ management or not) without acknowledgement of uncertainty? This paragraph rightly acknowledges the truth that ‘risk assessment’ a priori is cannot be accurate as the process of labour/birth/delivery all add further events which alter risk. It feels that this paragraph sits, therefore, at odds with much of the framework (for example paragraph 34 below it), even though this paragraph most closely represents the truth of the situation faced by clinicians each day in a way which	Noted – comment added. 10 (38-42). Your point is well made, and we have now included text noting that reorientation of care within NICU may be appropriate.

clinicians will recognise. Planning is wise around what care might need to be initiated at birth. Any team present at delivery will need initially to embark on instigating assessment either with a view to trying intervention/intensive care if appropriate or a process of palliative care. These decisions, out of necessity must be revisited and refined with the passage of time, beginning with the assessment at moment of birth and so setting them in stone based on available antenatal information only, as the wording of the framework sometimes seems to, could be inhibitory to a team moving forward appropriately. Postnatal trajectories are a very important factor in a babies survival and outcome chances and should be considered when counselling is revisited over time. The concept of stratifying risk antenatally is not unreasonable as an aid to managing expectations in circumstances where there may be discomfort with uncertainty, or a clear-cut extreme (e.g. <21 weeks) but finding objective risk strata to apply to all circumstances is difficult and may not be the best way forward. Parallel planning and expression of uncertainty might perhaps be aided by consideration in the framework of the severe/moderate vs mild/none approach to stratifying risk. 9, 12 and 54: There is little evidence that prolonged CPR or use of drugs is appropriate or effective in the delivery suite in extremely preterm babies. For those babies who are born	

preterm and require only stabilisation (airway management in the main), the outlook is better than those who are born unwell and receive prolonged CPR and drugs. There needs to be clarity that provision of intensive care in those babies unwell at delivery is not analogous to the intensive care given to a baby who has become unwell whilst on a neonatal intensive care. There needs to be some acknowledgement of this in the document and commentary on the appropriateness of use of prolonged CPR or drugs in ‘active’ care which cannot be assumed to be the same for a 26+6 weeker as a 22+0 weeker as the document implies by omission. 9 (33): This paragraph should have the word ‘both’ removed. Phrasing such as ‘wherever possible parents should be present when planning….’ would help remove a chance of being considered discriminatory. 9 (34): ‘The assessed category of risk should be conveyed sympathetically but unambiguously’ appears counter to the assertion that there is no objective way of defining risk (para 27) in most circumstances. Exceptions will always exist where unambiguous information can be shared. These would include occasions as defined by clinical situations unlikely to be anything other than futile (such as resuscitating a baby at 20 weeks gestation) but these situations are not in the	10 – “When there is parental uncertainty, it would be appropriate for the obstetric team to consider instigating measures to optimise the baby’s condition at birth” added. 11 (46) – “unless contraindicated” (NLS ref) added. We believe that ways should be found

majority, especially when the framework includes gestations up to just before 27 weeks. Softening this statement to convey to the reader that the clinician who has 'risk stratified' the situation before counselling would be expected to share the information they had clearly and sensitively with accompanying acknowledgement of uncertainty to build towards an agreed plan of approach for around the time of birth (with few, if any, avenues of care shut off), would be closer to the conversations which happen each day around the country. This approach would also allow for local outcome variation and future changes in practice to be taken into account. 9 (35): This paragraph reads as though there is a lack of consistency of thinking purely related to the initial stratification decision. If, as the second half of the paragraph says, prognosis can be re-assessed after scanning at a tertiary centre, then the first part of the sentence which explicitly states that transfer should only be done if an 'active approach' is agreed in a non-specialist centre seems unjustified. There is always the possibility that the tertiary centre may feel an 'active' approach is reasonable by virtue of their experience where non-specialist centres do not. The consistent theme in literature around antenatal counselling at the extremes of viability is that those working in non-tertiary centres or who are not neonatologists most often are overly	to keep baby warm, rather than using early cord clamping for temperature control. 12 – text amended. We have retained "a few minutes of effective resuscitation, as per published evidence, but highlighted "effective"

pessimistic about the chances of survival and least accurate when giving prognostic data. By virtue of only considering transfer of a baby in utero with a decision for ‘active’ care and placing the decision for ‘active’ care onto the local teams, there is a risk that the data used for counselling will not reflect that which would be given in a tertiary centre. The framework may, therefore, inadvertently work against good practice which is that delivery in the right place is key to best outcome. In those circumstances where a palliative approach is being considered in a non-tertiary centre, there must be additional guidance to require that the parents have received the correct information and counselling to the same level as they would receive in a tertiary centre. They must also ensure that parents are aware that if the framework approach is followed here, namely that there is no neonatal presence at delivery (where a palliative approach is all that is being offered) and that they then change their mind at delivery and request ‘active’ treatment, by virtue of being in a non-specialist centre, the outcome will be worse. 9 (36): All plans should be available in the maternal hand-held notes as these are potentially the only place where they will be accessible in a hurry. 10 (38-42): Paragraph 38 highlights the issue with the chosen dichotomous approach taken in this framework about	

'what to offer' outlined in para 39 onwards. Paragraph 38 needs to explicitly state WHEN the occurrence of withholding or cessation of life sustaining treatment might happen: it is not clear with current wording if this refers to events in delivery suite, in NICU or both. The working group are asked to consider strongly integrating the concept of regular assessment/reassessment from the moment of delivery (or before if monitored) to determine whether it is appropriate for an initial planned course of action to continue. We also ask that there is inclusion of specific statements outlining that it is acknowledged that a planned pathway may have to change in light of condition at birth or events that follow on NICU. The dichotomy of providing life sustaining treatment or not, which the framework mandates ("…will follow one of two pathways") as being a premade decision in place at the time of delivery is one which risks both inappropriately not stabilising babies and equally attempting futile resuscitation where clearly a baby is not going to survive in delivery suite. The truth of most deliveries at the extremes of viability is that whether or not one stratifies risk of survival or morbidity antenatally, it is difficult to anticipate condition of the baby at birth. The evidence which is available clearly shows that once born, acquired incidents in a baby's NICU course become the strongest predictor of eventual outcome and so a key determinant of whether 'active approach' is pursued delivery suite etc. is	12 -13 – we hope that the revised document now more closely aligns to practice, and better describes the inherent uncertainty in the management of extreme preterm infants.

actually the baby at the time of delivery. Babies who are preterm and sick have immediately worse outcomes than those who are well but the degree of need for resuscitation is not reliably predictable due to the burden of the process of delivery itself. Working this backwards, the assessment at time of birth being essentially a suitability test for ITU care to commence or not, there is then no situation <27 weeks in which withholding intensive care is ever not an option at the time of delivery and initial assessment. Thus arguing for a dichotomous approach decided antenatally could be considered futile in itself. I think it is reasonable to say that most UK neonatologists present to the parents the options which are available for a baby born extremely preterm, and are honest about whether they expect there to be problems. This allows, at the lower gestations/higher risk factors, the option of an assessment at delivery after which either ITU care will or will not be started thus taking into account condition at birth. If expectation under a falsely dichotomous antenatal choice was to 'start doing' then this would be potentially impossible to move away from in the case of a dying baby, losing the chance of a family to spend their baby's last moments together. It may have been the working group intention that an 'active' approach includes this assessment but the way that it is described later suggests precluding any option to decide not to intervene in the moments after delivery. To remedy this, consideration of	

adding a bidirectional arrow between 'active' and palliative could be made in the graphic (42), or insertion of a step at birth before committing to a direction of treatment. It is also noticeable strongly that here the authors have moved away in para 38 from the term 'active' which in this sentence would result in the sentence 'stopping active care'. This highlights well the pitfalls of using active as shorthand for intensive care, both here and anywhere in the document. Lastly, in para 40-41 there is acknowledgment of the futility of making a binary choice from a continuum, but no recognition that by insisting on the binary choice the framework encourages the risk of this being done badly. If the working group are prepared to explicitly state that it is almost impossible to extrapolate a binary outcome from a continuum of possibility then maybe they could more strongly acknowledge the uncertainty in this area, and pull back from the document's apparent insistence that a binary choice be made. Allowing uncertainty into the delivery suite and managing it is part of the professional role we take on providing immediate care for the newborn preterm infant. 10 (44 onwards (incl para 52)): 'Active' obstetric care is, as with the neonate, not the antonym of palliative obstetric care. The use of the term palliative obstetric care is wrong here, as the mother is not receiving the palliative care in this context. It would be more appropriate to consider using a term such	13 (69) – suggested amendment made Appendices – the appendices have been revised in line with your and others' helpful suggestions.

as ‘obstetric care anticipating preterm birth’ or ‘obstetric care optimising for preterm birth’, and where no specific care is changed in anticipation of delivery preterm, perhaps a term such as ‘unmonitored delivery’ or ‘non-interventional delivery’ (or even just ‘standard obstetric care’) might be used. There is a good argument, not addressed in this document, to say that where time is needed by the clinicians and family to come to consensus the obstetric management by default should assume an optimising approach in the antenatal period while counselling/decisions etc. are agreed. 11 (46): The use of DCC in preterms has been shown to be feasible in a planned setting or in units which routinely practice it, but there is clear guidance at present which should be followed that if there is a concern about the status of the baby at delivery (by assessment of the baby), the cord should be clamped and cut, and stabilisation/resuscitation commenced. There is not evidence currently available to show resuscitation with the cord intact in preterms is beneficial, though there are trials underway which might provide the evidence to support such a practice. The document should also state that DCC needs also to be balanced against the risks of the delivery environment and there should be ways to keep the baby warm during DCC available. In environments where preterm birth is infrequently seen, the thermal risks to an individual baby may outweigh	

the benefits seen in a preterm population who had DCC (NLS/ARNI). 12 (55-58): This paragraph does not include mention of an assessment of heart rate. All of the current newborn life support algorithms require heart rate assessment at birth and thereafter to be the core of ongoing assessment to guide treatment of babies at any gestation. This is conspicuously absent through para 55,56,57 and we ask the working group to include an explicit statement to be incorporated outlining heart rate as commonest measure of ‘response’ in newborn life support. The term ‘artificial surfactant’ should be changed to read ‘exogenous surfactant’ or perhaps just ‘surfactant’. Artificial surfactants are not in clinical use, though some are being trialled. The sentence ‘use of advanced resuscitation including cardiac massage or ET/IV adrenaline are rarely required following extreme preterm birth’ risks a reader inferring that if they were needed then they should be given. This is at odds with the evidence in terms of giving babies drugs at 22-24 weeks and outcome. The vast majority of UK neonatologists would not support an approach which would say that giving prolonged CPR in order to site a UVC and give drugs in a 22 or 23 week gestation infant with no heart beat or bradycardia is appropriate based on the available	

data for survival or morbidity in the extreme preterm group who require such intervention. Yet, this is what could be implied by or inferred from this paragraph. We ask that the working group consider an explicit statement in the framework to acknowledge the inappropriateness of administration of resuscitation drugs (e.g. adrenaline) to babies in the 22-24 week gestational age bracket, and that the appropriateness of use of any chest compressions should be very carefully considered and guided by a senior clinician. The sentence at the end of para 56 does not recognise that there are specific standard modifications to the 'term baby' algorithms outlined in most newborn life support provider courses for dealing with the preterm newborn which are expected to be used (rather than just 'following the algorithm for more mature babies'). Specifically these include altered inflation pressures, use of PEEP, and judicious use of oxygen (starting in an FiO2 of 0.21-0.3). The framework should recommend the altered approach recommended in the Newborn Life Support course for preterm babies is used. The acknowledgement of the futility of CPR (para 57) in the extremely preterm baby is welcome, though it is not helpful to put a 'time limit' (in this case beyond 5 minutes) on this as it becomes a 'target' in a delivery suite situation. There is no recommendation in any of the current newborn life support courses or resuscitation evidence to support this sort of observational data being used to guide resuscitative actions	

and we ask that the working group remove it from the framework. Indeed, at the later gestations covered by the framework, where a UVC may be sited to allow (for example) administration of blood or drugs, suggestion that stopping CPR at five minutes may preclude this as the UVC is often not placed by 5 minutes into a resuscitation. This paragraph, again perhaps as a result of the binary approach recommended earlier in the document, suggests that if an ‘active’ approach is agreed upon, then the only acceptable course is to start resuscitation/stabilisation and then decide to stop. It should remain an acceptable option, even where it was agreed to assess with a view to starting intervention, that attempts to stabilise a baby who has clearly died or who has no signs of life on delivery at the extremes of gestation (22,23,24 weeks) do not have to be undertaken. The framework needs to find a way to express this more clearly and show that an anticipated interventional approach may, quite reasonably, not be followed if circumstances at birth would clearly show it to be futile. We would suggest that it is an entirely acceptable standpoint for the working group to take to state that not all parts of a resuscitation algorithm started upon are appropriate for all babies. 12-13 (Para 59-64): In line with comments above, para 59 would be better worded to emphasise a collaborative process between parent and perinatal team leading to an	

agreement that the positive choice from counselling to be made is for palliative care to be offered, rather than implying that it is the 'nothing' in all or nothing' by leaving it unspoken when talking about 'not providing ITU care'. The wording here, especially the use of the term 'standard practice' seems to move away from individualising such a difficult decision in the case at hand. In largely futile situations it would be perhaps be a more satisfactory statement around the situation to offer palliative care (an active decision for active care but not intensive care) rather than 'not offer' intensive care. It has been emphasised in the current proposed BAPM framework (currently in draft) for joint decision making that there should be joint decision making around life or death decisions. To align with this framework the working group may consider reflecting and highlighting the collaborative nature of the discussions to be had where situations appear futile. Paragraph 60 talks of an individualised care plan as per the TFSL pathway. One of the key tenets of this document and any situation where good quality palliative care is being delivered is parallel care planning. This is present in the teaching of courses such as ARNI and in the use of documents such as the ReSPECT form. From a neonatal perspective, conceptually, parallel planning is what most neonatologists do in their approach to the extremely preterm delivery. If it is anticipated that the baby (e.g. 26 weeks) is going to be well, there may well not necessarily be emphasis	Thank you, we have considered your comments very closely and incorporated many of them in the revised version of the Framework We have justified the use of severe disability as the developmental outcome most strongly influencing a decision to provide (or not) active management, but nevertheless prov provided more information for parents around lesser degrees of impairment We have also placed more emphasis on the unpredictability of extreme preterm birth and its consequences

on problems in delivery suite, but it would likely be said that if there were problems, a discussion would occur in delivery suite parents which might appropriately outline the possibility of death in delivery suite. Thus covering possible outcomes: parallel planning. Similarly at 23+0 weeks, for example, the discussion following a parallel planning approach might lead to a plan: it might be the intention to provide airway support, but if the baby did not survive delivery the plan might also include not starting resuscitation but giving cuddles with parents. If there was slow HR the agreed plan might be to support the airway but in the case of no improvement stop at that point, with an agreement for no CPR to be attempted. Thus the attending clinicians in delivery suite would not be bound to 'absolutes' based on antenatal risk stratification, as well as taking a holistic, family centred approach. Importantly, the ethos behind the discussion leading to parallel planning does not demand a binary decision to be made, nor limit the clinician in delivery suite in using their judgement. The reference to the TFSL pathway is good to see in the Framework, but to embrace its ethos further, and use an approach inclusive of clear parallel planning to address uncertainty ("hope for the best but plan for the worst") as a start point, would remove the need for compromised binary choice. This in turn would give clinicians using the framework the opportunity to use individual care planning for all babies regardless of anticipated outcome.	

Paragraph 61 would be a summary of a good exemplar of a discussion antenatally leading to a plan to be followed through. Para 63 talks of care planning for the family after death. Again, if used effectively, parallel care planning antenatally can allow parents to be actively planning for events after death. Para 64 should start “before discharge home” and wherever possible as soon as death has occurred. Failure to notify community colleagues in advance of discharge (namely as soon as possible in working hours after death has occurred) risks visits from (for example) well-meaning health visitors who are unaware that a baby has died to the family. The speed of correspondence leaving hospital is not to be trusted to deliver the correct information to the correct people in a timely fashion. Additionally, the postnatal follow-up with family could either be those who counselled antenatally OR the consultant at delivery. 13 (69): Use of the word ‘never’ in the last sentence risks setting unachievably high standards and/or triggering punitive investigation (in line with a ‘never event’) where realistically this is an aspirational standard. The working group might consider wording such as ‘should never’ if it is felt ‘never’ needs to be retained but qualified (rather than ‘must never’). 19 (Appendix 2): Page 16, paragraph 80: The 2008 BAPM	

working group paper (Classification of Health Status at 2 years as a Perinatal Outcome) used severe neurodisability and impairment as separate categories. It does not use the term severe impairment which seems to be a mix of the two terms. The 1995 version of this group originally had only 2 categories (severe disability and other/no disability), however 2008 refined this to severe neurodisability, neurodevelopmental impairment (effectively moderate disability) and other important disabilities affecting other organ systems. The adoption of the binary severe vs. other is at odds with the more recent and refined definition, with an approach more akin to the 1995 document. Reverting to fewer 'shades of grey' risks polarising counselling inappropriately and disempowering parents in making decisions as previously noted. Situations of uncertainty (para 91) is a sensible and well through approach, though inclusion of a weight as a criterion has potential to be controversial as it may be interpreted as 'weigh before proceeding'. I think at the extremes of prematurity people are not necessarily going to be good at estimating weight. Additionally, there is no mention of heart rate assessment again here (or proxy signs of intact circulation), so the choice to wait and do DCC as outlined here is not following guidance found in any of the newborn life support provider algorithms. Paragraph 94: the use of the term 'redirecting' here, along with peculiarly neonatal phrases such as 'changing focus' or 'redirection' are	

at best euphemistic. At worst they may represent (or indeed encourage) care of an infant where despite high-risk circumstances and ongoing deterioration no-one has thought about or planned for the death of the baby. It genuinely cannot be said to be an accurate representation of the standard of care to which neonatal intensive care teams all work. Where a baby is sick or at high risk, intensive care teams plan for the worst while hoping for the best, and in no other branch of medicine is there ever a notion that there is a 'switch' in an instant from one to another. Highly effective teams all parallel plan when at, or approaching, the limits of intensive care medicine, and so language around preparation for babies who are at high risk of dying should reflect this. We suggest that such terms are not used as shorthand for the processes in place (namely good parallel planning). The experience of the authors who contributed to these comments is that it is unlikely that delivery of an extreme preterm delivery is attended without consideration that stabilisation processes might not work and that planned interventions might then be withdrawn. To this end, the comfort of the baby (the 'palliative' component) is always present in actions and approach, in parallel to the ITU interventions, and therefore the 'change' is actually cessation of life sustaining intervention rather than suddenly 'starting' palliative care. We note here that such terminology appears to be unique to Neonatology and these 'switching' phrases	

are not used in any other medical setting. Adopting and acknowledging the need for parallel planning (and calling it that) in severe illness also allows involvement of family in family centred activity planning for the worst (such as memory making, naming ceremonies, etc) in a timely and thoughtful way, making use of time most effectively during the illness. An implied care process with a sudden 'switch' does not really encourage this and thus families may miss out on opportunities to interact with their baby while still alive. The last sentence in Para 94 feels contradictory to statements elsewhere in the framework. Sustained and advanced resuscitation (not stabilisation) has been shown to be ineffective in extreme preterms and therefore it follows that it is entirely reasonable to draw inference to outcome from presentation/condition at birth, and potentially subsequent response to simple measures. An asystolic, 22 week gestation infant cannot be said to have the same prognosis as a 26 week gestation infant with a good heart rate even before any intervention is tried. Where it may be true that in published research that the condition at birth may not reliably predict outcomes, it is also true that the more resuscitation that is needed (not stabilisation), the better the predictive power there is of a poorer outcome. We would ask therefore that the working group give consideration the wording here to reflect this. Para 90 outlines and gives a good exemplar of an approach which follows a 'parallel	

planning'-type approach. It outlines nicely the benefits of considering all possibilities before the baby arrives and the importance of making assessments at delivery. As it is described here it is equally easily applied to babies where more, or even complete, antenatal information is known simply because the process of birth has an impact on survival. It shows how most neonatologists, in our experience, will handle the circumstance of uncertainty in extremely preterm birth. The approach for all babies covered by the framework could follow this exemplar, though this mean reconsidering (as mentioned in comments above) any recommendation about enforcing a binary choice before delivery has occurred. The situation described in Para 96 (effectively determined by the a-priori binary approach) feels uncomfortable because every subsequent minutes delay in 'discussing with parents' changing the planned approach, without helping the baby, will negatively impact on the baby's outcome if intensive care is eventually instituted. An expectant approach to assessment and management (that approach described paragraph 90, parallel planning) allows this baby to be supported and assessed where it has been thought through the possibility of survival, without delay. 21 (Appendix 3): As working clinicians writing this response to the framework we have some significant concerns about the emphasis given throughout this document suggesting a	

need to present statistics to parents as a core part of the consultation episodes. The framework correctly identifies that there are difficulties in parents understanding percentages, but fundamentally the parents will care only about their baby. While the population risk as outlined might seem helpful to know (and should be available if requested by parents), any neonatal outcome either happens, or not, to a baby. From this perspective a population-based statistic may therefore be actively unhelpful to decision making. Specifically in this appendix: • Outcomes described in percentages for populations will actually be binary outcomes for any individual baby. • The working group assertion in the framework is that the 'useful' statistic to quote is the outcome for babies born alive who received active management. In terms of antenatal counselling there is still significant chance of a baby not surviving the delivery. Thus this statistic may be less helpful/relevant to antenatal conversation than the risk considering outcomes for those alive at the start of labour. So if counselling someone in preterm labour whose baby is known to be alive in labour, but has not yet been born, then data relevant to that situation should be included in the counselling. • By using the 'alive and intensive care' statistic there may also be is a missed chance to plan for death during	

delivery or soon afterwards and conversely increased risk of inappropriate intervention. The decision whether to provide 'active' or 'palliative care' care is not a choice if the baby has not survived labour. • The most important feedback received from ARNI's observed counselling/communication simulations where candidates have opportunity to be both parent and counsellor is that 'less information is often more' in terms of preparing parents and allowing them opportunity to decide Para 124: As noted earlier, a written plan should be given to all professionals and a copy placed with the family (maternal notes) so that if place of delivery is unexpectedly different to plan, the discussions had to that point are easily available. 23 (Appendix 4, Para 133): This is the first and only place in the framework that (very reasonably) presents the likelihood of differences between those born after 24+7 and those below. It feels familiar to the language used in the Nuffield Bioethics document and reflects the truth that many neonatologists will feel 'ethically' comfortable investing less in resuscitating a 22-23 weeker than 25+ weeker (note: not stabilising). While it is good that the framework tries to move away from single item (GA) risk stratification to multifactorial stratification antenatally, this paragraph acknowledges the most clearly of anywhere in the document that the approach	

to care in those between 22 and 26+6 weeks cannot be assumed to be the same across this spectrum. As outlined in comments previously, this paragraph is consistent with the observations that 'moderate-high' risk is likely to be the wrong descriptor for the 50-90% bracket chance of death or severe disability, risking an overall sense of unfounded optimism. We also note that if this information is to appear in 'information for parents', it should feature more clearly within the framework text available to professionals. 24 (Infographic) 2016 UK MBRRACE data shows that one-year survival for babies alive in labour at 22 weeks was 5%, 23 weeks 28%, 24 weeks 54%, 25 weeks 71% and 26 weeks 80%. The survival figures for babies offered active care were 35%, 38%, 60%, 74% and 82% respectively. The framework uses these figures and if we follow through the maths: For 22/40 babies born alive and who received active management survival free of severe disability is 0.35 x 0.67 = 0.23 i.e. 23 %. For 22/40 babies alive at during labour survival free of severe disability is 0.05 x 0.67 = 0.03 i.e. 3 % For 23 weeks the figures are 29% and 21% and 24 weeks 51% and 46%. This feels very different from the impression given by the infographic. We acknowledge that the framework states "the [working group believe the] most relevant statistic for parents is usually the chance of survival if active stabilisation and neonatal intensive care is	

attempted.” However the risk stratification used within the framework aims to guide whether active care should be attempted (i.e. the weighting falls the step before this statistic can be quoted), and it has been outlined above why this particular statistic perhaps won’t be most helpful for antenatal counselling. The infographic also puts important qualifiers in subtext (under ‘survival’ and ‘severe disability’). These are not prominent and this belies how hugely important they are in accurately understanding and using the data quoted. In the (*) explanatory note, it should perhaps say more clearly that the true number lies to our best knowledge in the range quoted (this is what confidence intervals represent). In the (**) explanatory note it quotes a blanket rate of a quarter of babies have moderate disability which is (a) likely to be an underestimate at 22-23 weeks and (b) moderate disability is not mentioned elsewhere in the framework. We would support a more thorough inclusion of information about the mild-moderate outcomes subgroup throughout the framework. 26 (Para 148): This a lovely description of palliative care, using family-friendly and accessible language and clearly describing the active processes involved in this care option. This would have great value in appearing in the main framework alongside a reconsideration and removal of the term ‘active’ care.	

26 (Para 154): This paragraph is a little confusing: the one phenomenon routinely described in preparing parents for their baby dying is gasping. It may be that gasping is covered under the reflex movements term used but it would be better to acknowledge that occasional gasps may be seen. 27 (Para 163/164): As noted previously, we would encourage the working group to recommend a formal written plan to be given to parents (this could be a letter, or use of an established form such as the ReSPECT form or EHCP [from deciding right]). The risk of ad-hoc handwritten notes on a form in the framework is that they are less likely to capture a detailed discussion and plan than a structured letter or form. However, providing parents a lot of space for them to make their own notes during discussion is an excellent idea. General: We are interested to know whether the working group has considered how the advice around antenatal stratification of 22+ weekers in general as moderate to severe risk, and the inference that active management should be undertaken in the way it is presented following this, might have implications for the legal definitions of stillbirth and late fetal loss? The potential for this document to create conflict by encouraging the clinician to have a closed mind at time of counselling due to pre-counselling stratification seems high	

in the current form. General: We feel that the framework would benefit from more clarity on how far BAPM as an organisation will support/recommend the extent of resuscitation at 22, 23 and 24 weeks, including a stronger statement as to how heavily or not the working group would expect the parental wishes to be weighted in determining the eventually agreed course/plan of action. Does the working group feel 24 weeks currently is analogous to the previously quoted 25 week 'threshold' for routine active intervention as the default suggested by the Nuffield Bioethics document? We feel strongly that the framework needs to provide stronger wording of the justification for the developmental outcomes is recommends to be used (very severe as it stands currently) for any kind of applied value judgement in pre-determining the offered level of care if there is to continue to be no clarification of what might be expected in outcome terms outside this strata. We feel that the framework risks reducing its efficacy/utility by not including data on 'lesser' levels of disability, especially in the 22-24 week brackets. We feel that it would be immensely useful for the framework to outline the importance of postnatal trajectories on eventual outcome. This in turn allows the framework to highlight that a decision to assess a baby at delivery with a view to starting intensive care does not mean that that decision remains	

appropriate regardless in the face of a deteriorating clinical situation, either in delivery suite or on NICU thereafter. In the context of the extremes of prematurity we feel that the framework should more overtly acknowledge managing uncertainty and allow freer rein for clinicians to utilise parallel planning. In this context it is important to begin to move away from the expression of 'active vs palliative' to seeing both as positive choices in the right circumstances. The overall outcome of most antenatal counselling acknowledges that the two possibilities co-exist in planning and early care, until there is as much clarity in one direction or the other at any given time as can be achieved. General: The RCUK would like to thank the BAPM working group for their efforts in tackling this complex, difficult and challenging subject.	
Claire Rose <Claire.Rose@nbt.nhs.uk>	**BAPM response**
8 (26) Figure 1: Take out gestational age, as other risk factors are in addition to gestational age. 9 (27): Disagree with statement that there is 'no objective way of defining risk'. Suggest removing this sentence, keeping statement that families differ in the outcome they regard as unacceptably poor.	Thank you Figures 1 and 2 have been amended as per your suggestions, and those of others. Thank you – language now more consistent, Risk is used in the Framework, and "chance" in parental information

9 (29-31): Suggest consistency of language – ie use ‘risk’ or ‘chance’’ 9 (34): ‘Unambiguous’ should be replaced with ‘clarity’ – we can be clear that there is uncertainty. 10 (42 figure): Should include arrow (which can be either way) between the two management plans. 12 (56): If there is no response to mask ventilation, the baby should… Would suggest intubation and artificial surfactant could be considered (not NLS algorithm)’ 12 (57): Would like some clarity around ‘effective cardiopulmonary resuscitation’ – does this mean CPR? 16 (77: Figure 3 – has personal communication (R Higgins) been published – would recommend not using if not published data. 21 (116): Again, use with clarity instead of unambiguously. 24 (Chart): Would prefer survival to be presented before death, but can see that the outcomes align better in current format.	“Unambiguous replaced with “clarity”, thank you Amended as suggested, thank you Page 12 has been revised following feedback from UK Resuscitation Council, as well as many stakeholders and members This personal communication has been removed, and more information supplied

Karan Sampat <ksampat@doctors.org.uk>	**BAPM response**
Active obstetric management (Para 2): Regarding active obstetric management including tocolysis, I understand that the evidence for the benefits for tocolysis is limited, compared with steroids and magnesium. I worry that if tocolysis is mentioned in the same breadth as steroids and magnesium, this may lead to parents feeling that tocolysis is as effective.	Consistent with NICE we acknowledge the lack of evidence and suggest taking into consideration factors including the likely benefit of steroids/IUT (where tocolytics MAY have a role in delaying delivery). All included in “package” of active obstetric care
Smith, Richard (NNUHFT) <RICHARD.SMITH@nnuh.nhs.uk>	**BAPM response**
10: I would like to see consensus statements around the use of steroids/mag sulph in this group. 11: “to ensure that the mother is fit for transfer, and to avoid birth in transit” Suggest change to “reduce risk of birth in transit” – it reads as if we can avoid every birth in transit, which is unrealistic. 11: Typo in “although IA may be helpful in clarifying expectations around the baby’s condition at birth” 19: Threatened birth before 22+0 weeks of gestation. Based on a recent complaint, it may be worth a sentence “at this gestation the neonatal team would not normally be involved	In the interests of keeping this document as concise as possible, we have chosen not to elaborate further on use of steroids, etc and refer readers to referenced evidence Page 11 – amended as suggested, thank you

in discussions with the family, but may need to offer support in rare circumstances when requested by the senior obstetric team" or words to that effect. General: Thanks to the contributors – this will be a very helpful document, especially the infographic	
Carol Sullivan (Swansea Bay UHB - Paediatrics) <Carol.Sullivan@wales.nhs.uk>	**BAPM response**
General: We think this is an excellent document and very welcome. We tried to introduce a similar document into our region a few years ago but met resistance, so having a BAPM framework is ideal. This is a very thorough and helpful document. 8: Some have concerns that it appears a little too optimistic, <22w being extremely high risk and 22-23 being only mod-severe high risk, unless it is read carefully, when it is explained well, and may therefore raise expectations unrealistically and lead to more tiny babies being subjected to unnecessary intensive / invasive Rx. The red high risk abruptly ends at 22/40. Concern that parents / juniors looking at this visual aid would feel that the odds are so much better once fetus is 22/40 which is unrealistic and may even be a little misleading although this is well explained in the text. Could the emphasis somehow be made in the figure that only a tiny proportion of 22/40 fit into the category of 'mod to	Figure 1 and the infographic have been amended as per several suggestions

high' risk. 8 (point 26): In the figure there should be more red in the 2nd and 3rd boxes. 24 (diagram): The disability rates are in survivors not in the total population of babies at the given gestation, but the diagram can be misleading because 'in survivors' is in much smaller print.	
TOZER, Richard (TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST) <r.tozer@nhs.net>	**BAPM response**
Very much value the greater focus on information and visual representation to support shared decision making with parents I feel there needs to be encouragement/expectation for local tertiary services/NICU/retrieval consultants to offer either telephone or Skype type video conferencing with local paediatricians and parents regarding discussion/decision making regarding antenatal management and whether a woman at risk of extreme preterm delivery will be transferred to a neonatal centre. In District General Hospitals with Level 1 or 2 neonatal units where extremely preterm infants are transferred in or ex utero to Level 3 centres the onus is on the	Agree; we have emphasised the need for LNUs/SCUs to discuss cases as early as possible. The logistics of antenatal transfer are out with the scope of this Framework, but we have added a comment; "Processes should be in place to ensure timely transfer".

midwifery/obstetric staff to locate an appropriate neonatal cot. Where the network level 3 centre is full this can be a difficulty, time consuming task. As part of this consultation I ask that the responsibility is changed. There should be a 'single point of access' for midwifery/obstetric/paediatric staff to contact in each network – "I have a woman at 22 – 26 weeks gestation etc, I need to set up a conference call with a neonatologist, the woman and partner to decide what should be done and also subsequently/concurrently the network should then take responsibility for finding an obstetric bed and neonatal cot if the agreed decision is for an in or ex utero transfer".	
TYSZCZUK, Lidia (IMPERIAL COLLEGE HEALTHCARE NHS TRUST) <lidia.tyszczuk@nhs.net>	**BAPM response**
This framework is a very welcome update and guide to managing extremely preterm deliveries and will help to decrease variation in management of deliveries at 23 and 24 weeks. However the impact of this potential change in practice and offering active management at 22 weeks (obstetric and neonatal care) has not been fully explored. Although the number of live births at 22 weeks is small there is a variation in reporting these births to MBRRACE and therefore the data are limited and may not be reliable. There also needs to be more consideration of the impact on current resources in obstetric care and neonatal intensive care	Thank you – both comments already addressed

capacity as these are already stretched. There is also the added impact on public perception and unrealistic expectations. 24: More emphasis should be made that the data are for babies who receive active stabilisation. The data as presented may be easily misinterpreted by both parents and healthcare professionals.	
Uthaya, Sabita N <s.uthaya@imperial.ac.uk>	**BAPM response**
3: Decision to provide active management should not be based on gestational age and assessment of prognosis based on risk assessment alone, but also the condition of the baby at birth and response to initial resuscitation. When a decision to either withhold or provide active care is made before the delivery there is no way to predict the condition of the baby at birth. Such a decision risks not providing intensive care to a baby who is born vigorous and conversely being obliged to provide intensive care in a baby born in poor condition where the outcome is likely to be poor. 3: Risk assessment should not be based on a binary system of multiple different variables which do not have the same bearing on outcome. The categorisation in to three groups is not based on any meaningful statistical process. 3 (Point 7): While parental views should be respected the	The Working Group felt strongly that assessment of condition at birth is highly subjective, and a poor predictor of outcome- reference 43 added.
	3 (including point 7) The risk assessment is intended to be on a continuum, rather than binary; here are no existing quantifiable predictive models for these risk factors for the UK population.
	.
	– Framework revised to include more emphasis on treating in the best interests of the baby. 3 – the shading within Figure 1 is intended to illustrate that the weighting of each of these

Framework does not address what should happen if for eg. the parents of a male fetus at 23+6 weeks without antenatal steroids choose non active management. This baby may well be born alive and in good condition. Should the parents be offered a termination to respect their wishes? What is the view of the Working Group on this issue? Conversely if providing intensive care is not in a baby's best interest would we be derogating our duty of care to the baby? 4: Could the professional roles of the members of the Working Group be specified? 8: We are very concerned about the logic behind and choice of risk factors as proposed. Figure 1: The visual charts give no impression of the weight of contribution of each risk factor in the prognosis. It is also unclear why some risk factors for an adverse outcome are included and others not. There was concern expressed at the inclusion of sex as a risk factor. The latest MBBRACE report shows that males have an overall mortality rate of 3.76 per 1000 live births compared to 4.00 for females. With multiple births, the rate for a singleton was 3.86 compared to 6.16 for twins and 11.78 for higher order births. It seems odd that male sex is then given the same weighting as multiple births. The mortality for White babies was 3.74 compared to 8.29 for Black babies. Mortality in the least deprived group is 1.24	factors cannot be determined with certainty. Assessment of overall risk must necessarily be subjective although several of the variables (sex, steroids, low birthweight, multiple birth) have an impact on risk equivalent to a week of gestational age (see Lee HC, Green C, Hintz SR, Tyson JE et *al* Prediction of death for extremely premature infants in a population-based cohort. *Pediatrics* 2010;126:e644-50 explanation above). There are no existing models to quantify risk based on these factors for extremely preterm infants in the UK; Text has been added to note that weighting of risk cannot be strictly numerical Professional roles of Working Group now specified – thank you Figures 1 and 2 now revised
	Sex is an independent risk factor for mortality and morbidity in multiple analyses nationally and internationally. It appears to be a biological predictor of outcome. It has been cited internationally in studies of risk adjusted outcomes for extremely preterm infants and is both objective and knowable before birth. Like all of the other factors, sex should not be used in isolation to determine treatment, but should be used to help inform risk assessment and counselling
	Race and socio-demographic characteristics, on the other hand, are continuous and often subjective, and their impact on outcome is context dependent. We do not believe that there

compared to 1.88 in the most deprived. We would hope that this is not used as reason to not offer active management to a 23- week male, black twin born to a mother who is in the most deprived socio-economic group! What is the basis for the choice of risk factors? We would suggest that the clinical condition of the baby at birth along with background clinical risk factors should be the basis of decision-making. The moderate to high risk range of 50 – 90% is wide and open to misinterpretation. Suggesting a similar approach to a baby with a 50% vs a 85% risk of dying is questionable. 8 (Box 1): This is vague. 'Some', 'most' are ambiguous terms and do not offer the reader clear guidance. 10 (Figure 2): Again, the algorithm based on the risk factors but no assessment at birth is problematic. 11 (49-50): Considerable concern was expressed especially by the obstetric team at the suggestion that a caesarean section be done at 22 – 24 weeks for fetal reasons. It is also contradictory as the risk factors would place a baby with severe growth restriction in the BAPM defined 'high- risk' category and hence the 'palliative' category in the lower gestational age group. 12 (56-57): This is vague and the suggestion that intubation	is a clear biological rationale for including them as risk factors
	Box 1 amended 11 (49-50): the Framework clearly states the potential risks of CS, and does not advocate this in the fetal interest except (possibly) for acute cord prolapse. "CS would very rarely be indicated at extreme preterm gestations" has been added 12 (56-57): the Working group felt that bag mask ventilation may not always be carried out effectively; the RCUK did not object. We have added assessment of heart rate, which we agree was an important omission. 13 (59); respectfully, we do not agree that this is contradictory. This statement is intended to guide practitioners in consultation with parents when the baby is deemed to be at very high risk 13 (61-62): document amended, better to reflect that plans may (appropriately) change.

and indeed CPR and adrenaline should proceed despite a lack of response to mask ventilation in the absence of any evidence that this improves outcomes is not justified. Indeed, the use of the word 'stabilisation' (in points 56,57,58) in the context of a baby not responding to initial resuscitation is misleading. Nowhere in the neonatal management is reference made to assessment of the baby. This change from the previous version of the BAPM Framework of gauging the response to initial resuscitation is not explained nor justified. 13 (59): This is contrary to preceding section where it suggests that a decision not to offer active management could be made in the moderate to high risk group on the basis of parental choice. 13 (61-62): Babies may be born and be vigorous. They may indeed breathe independently for minutes or hours. Decisions on palliative care should not be made before a baby is born. Instead the parents should be counselled that a final decision would be made after an assessment of the baby at birth. Appendix 2: Point 95 suggests this is rare and discussions should follow birth, which is not appropriate. 14 (72): There was concern that BAPM was suggesting that 22 week infants be offered active management on the basis of studies conducted outside of the UK given that in	We believe, however, that most decision making before birth is entirely appropriate. 14 (72); our advice is based on UK (including recent MBRRACE) data, as well as international data 24 – Infographic modified Published data demonstrate better outcomes for male infants – we do not believe this to be discriminatory

comparison to these countries the outcomes in the UK were worse at gestations between 23 – 26 weeks and the number of babies at 22 weeks receiving intensive care was so small (Table 1 page15). Furthermore, no reference is made to morbidity. 24: This chart was felt to be confusing and potentially misleading to parents. Although the legend below clarifies what the figures represent, the actual figures could be misleading. Suggesting that 1 in 3 babies at 22 weeks do not have severe disability without clarifying that it is 1 in 10 babies who received active stabilisation or 2 in 10 births that receive active stabilisation who do not have severe disability but may have other functional impairments such as learning difficulty, mild cerebral palsy or behavioural problems may be misinterpreted. Having one diagram with all outcomes in it would be easier to understand. Concern was also expressed that the parent leaflet makes it appear that active management for 22 week births is current routine practice in the UK and not a change. General: In relation to choosing non-modifiable factors such as sex of the fetus was an equality assessment carried out? If not, why not?	
Watts Timothy <Timothy.Watts@gstt.nhs.uk>	**BAPM response**

8 (25): Table 3 refers to ‘non-tertiary NICU’ on ‘Place of birth’ line. I don’t recognise this term. A NICU is by definition a tertiary neonatal unit. ‘Non-tertiary neonatal units’ are either LNUs or SCUs. Terminology should be consistent with BAPMs own terminology. 8 (26): Under ‘Extremely high risk’, bullet point 3, I think ‘severe growth restriction’ should be clarified/defined. Would it be helpful to say ‘<0.4th centile’ or estimated fetal weight <500g? 8 (26) I agree with bullet point 4 under ‘Extremely high risk’ that ‘acute fetal compromise’ puts the baby into this group. I find the condition of the baby at birth (severe bruising, hypotonic, severe bradycardic etc, particularly after a difficult delivery) is the best indicator of acute fetal compromise in these circumstances, particularly when the baby is not being monitored with continuous fetal monitoring. However, paragraph 57 suggests that advanced resuscitation (although saying it is rarely required) is appropriate; whereas in my experience being born in the sort of condition that requires advanced resuscitation (cardiac massage, adrenaline etc) is a marker of acute fetal compromise and therefore changes the baby’s outcome and necessitates re-thinking the management plan.	Thank you – figure 1 has been revised in light of several comments; your point about NICU classification is well made. Given the lack of precision around estimated fetal weight, we have chosen not to specify further “severe fetal growth restriction” 8 (26) text has been amended further to suggest advanced resuscitation generally not appropriate 11 (47) – thank you – we agree with your sentiments, but also note the difficulty in predicting preterm labour. Text was agreed with RCOG and BMFMS

11 (47): There is increasing evidence that it is possible to assess the risk of preterm birth and that using NICE guidance to transfer all women who present in 'threatened preterm labour' can be counterproductive, by filling antenatal wards in NICU centres with women who are not going to deliver, in turn reducing maternity capacity to take women who really need in utero transfer. I think the text should at least acknowledge this and the need to have discussion at obstetric level not only about the safety of IUT, but the appropriateness, for example if the fetal fibronectin is low. 12 and 13 (52 and 61): Both these paragraphs say 'Parents should be made aware that their baby may gasp or move briefly, or show signs of life after birth', and similar. I think 'briefly' is fundamentally misleading and incorrect in this context. Elsewhere in the framework, it says that the average time babies live for is 60 minutes. It is not uncommon for babies to show signs of life for a significant length of time, at least from a parent's perspective. Saying that this is 'brief' underestimates the effect this time has on parents and also means staff underestimate it too. This in turn risks staff not providing sufficient attention to this period in the baby's life, 12 (57): I think this paragraph should be re-worded to suggest that staff might like to use the need for advanced resuscitation as a marker of acute fetal compromise and to	12 and 13 (52, 57 and 61): text amended BAPM publicised this draft Framework widely and we are pleased to have received over 50 (often extensive) responses. RCOG was involved throughout the development of the Framework.

potentially re-stratify the baby's risk of poor outcome and think about re-directing care to the palliative route. General: This framework as it is written is likely to significantly change both obstetric and neonatal management and the expectations placed upon us all by families, with respect to providing intensive care to babies born at 22 weeks gestation. I am very concerned that it requires much wider consultation and discussion than is likely to occur in the 6 weeks of a routine BAPM consultation. I have not, for example, managed to find reference to it on the RCOG website. I think BAPM should be actively seeking views from paediatricians from all levels of neonatal unit, neonatal nurses, obstetricians and midwives about this potential change in practice. At the very least, when seeking views, professionals should be specifically signposted to this part of the guidance. Without this type of engagement, we risk getting a framework approved that many in our community of professionals won't agree to follow.	
Bill Yoxall <Bill.Yoxall@lwh.nhs.uk>	**BAPM response**
6 (11): If there is a plan to provide life-sustaining treatment for the baby, then it follows that the pregnancy and birth should be managed with the aim of optimising the baby's condition at birth. This is a REALLY important point. I fully support and welcome it.	Thank you for your support. The Framework has been modified in light of comments, better to note that care must be in the best interests of the baby. This is now discussed in Appendix 4 "situations of uncertainty", and a scenario has been

9 (30): Moderate to High risk babies. I think it should be explicitly stated that the neonatologist's first duty is to the individual patient. If, in their opinion, the condition at birth suggests that there is a reasonable prospect of survival without severe impairment, they are nont bound to follow the parents pre-conceived preference for the orientation of care. In this situation life sustaining care may be instituted to enable a fuller assessment of prognosis based on subsequent progress. This is consistent with the comments on page 19 (paragraph 95). But I think it would be helpfult for this to be more obvious. 12 (56): "In the absence of sufficient evidence to justify a different approach in extremely preterm babies, the Working Group recommends applying newborn resuscitation algorithms as used in more mature babies". This is another very important point that I strongly support and welcome.	added to Appendix 5