British Association of Perinatal Medicine
Consultation Response Form

Document Title: **A Framework for Enhancing Shared Decision Making in Neonatal Care**
Closing date: **26 June 2019**
Please return this form to: **bapm@rcpch.ac.uk**

Page number/ heading / general comments	Line number/ ‘general’ for comments	Comments Please insert each new comment in a new row.	Response
The Framework was distributed to the Royal College of Midwives for feedback.			
Page 2	Introduction and overview	First paragraph, second sentence. …whereby parents are more involved in decision-making’. One would hope that parents were in fact central to the decision making around their own child rather than ‘more involved’ which suggests that they remain on the periphery and control rests with the professionals.	Thank you for your comments and we fully understand your message. The working group has to take into account the views of everyone and every situation. Some professionals feel the document is already too parent focussed (see comments below) so leaving the wording as ‘more involved’ appears appropriate.
Page 3	Principle 1	The use of the word ‘should’ implies an element of option. There could be a stronger compulsion in the language used such as use of the word ‘must’ – this can then be supplemented by the caveat unless the parents opt out.	See response above – this is a valid point but leaving the wording as ‘should’ for the moment appears appropriate.
Page 3	Principle 3	This sentence ‘All members of the neonatal unit multi-disciplinary team have a role to play in facilitating shared decision-making and should be trained appropriately’ should clarify if means with parents not the MDT	Thank you - this has been changed to make it clearer
Page 5	Principle 1	The language of the discussion points under the principle is not reflected well in the principle itself which seems a little dated and HCP centred, in comparison to the discussion which is more family focussed.	See comment above re rewording of principle 1
Page 3 & 7 - 9	Principle 4	Again the principle seems under developed in contrast to the more mature discussion that follows. Given the importance of the Montgomery ruling it would seem prudent to suggest clinicians to start with the ‘frequent and	Thank you – the wording has been changed to reflect parents’ concerns.

		serious risks' and then add something along the lines of 'ensuring that the parents own concerns are also fully addressed'	
Page 9	Paragraph 3	The aspect of best interests is a potential area of concern and debate and this document would benefit from some discussion of the rights of parents and the pitfalls in assumptions that HCPs always know best for the child etc	Thank you – the baby's welfare is paramount. Best interests is now included in greater detail in section 9 on when parents are not in agreement.
Page 9	Principle 5	The BRAIN anacronym is also useful (Benefits, Risks, Alternatives, Intuition, Nothing). It may also be useful to emphasise the importance of asking open questions to encourage parents to express their opinions and concerns as one shouldn't under estimate how intimidating it can be to challenge or questions HCPs.	Thank you – open questions has been emphasised in the final version. This should also be addressed in training and role-play practice.
Page 10 - 11	Implicit consent	The point made on page 11, para 3, sentence two that the assumption that implied consent has been gained must be made with caution should be at the start of the whole section. It should be regarded as a last resort rather than normal working practice. Overall we are not comfortable with the interpretation of implied consent-: "refers to clinicians proceeding with an intervention without necessarily having specific prior discussion with the parents; - the parents then being updated as soon as possible afterwards. This may have been agreed with the parents beforehand for babies already on a neonatal unit, such as for routine procedures". Although a greater explanation of implied consent follows, we think this section needs to have stronger wording to discourage routinely using implied consent for neonates.	Thank you – section 7 on levels of consent has been revised and reflects your comments.
Page 13	How to proceed should parents not agree with a proposed procedure	Although this is outside the scope of this document, this section could be made clearer and therefore provide better support to staff and parents. The involvement of senior clinicians and senior management as soon as possible should be the first port of call, along with parents contacting senior religious/community leaders/family members. Both are mentioned but only after suggesting referral to social services.	This section has been revised and is in line with your comments.
The Framework was distributed to the British Maternal and Fetal Medicine Society (BMFMS) for comments			
General	General	Seems pretty comprehensive appropriate advice. Useful and sensible.	Thank you
Dr Cathryn Chadwick, Consultant Paediatrician, Northampton General Hospital			
P19	general	Re risks of surfactant and considering bovine or porcine origins with regard to religious sensibilities. Our unit has had experience of a complaint from Jewish	Appendix 3 to which this refers (a list of risks) after consultation with BAPM exec has been

		parents after curosurf was given, not being aware of the religion. As this is a relatively time critical medication at a time when we may not know the religion of parents, could BAPM consider if a position on the use of bovine or porcine surfactant could be agreed with the relevant religious leaders/councils, (in much the same way that the use of DBM was addressed with the Muslim council). It seems that very few units currently proactively address the origin of surfactants in discussions with families and with more openness in decision making in general it will become more of an issue	removed from the final document. Thank you for this important issue and we agree that it would be good to sort this out. It is outside the remit of this group and will be passed onto BAPM exec for further action. Any professional who has looked into this area, or is interesting in doing so, is requested to contact the BAPM office.
Dr Rob Tinnion, Consultant Neonatologist & Medical Lead for NNeTS			
6-7	general	I agree with the concept of information being provided along a continuum and adjusted as per parental capacity to accept and take on board this, with a view to becoming more active in decision making. However, I think that the explanatory note on principle 2 conflates a few items which might actually cause problems in the circumstances of a dispute, by virtue of weighting the parent's role too much. It is true that the principle enshrined in the Mental Capacity Act (MCA) is that an individual who is deciding about something for themselves has only to have capacity for each choice, reassessed at each time a decision is to be made. Montgomery did not alter this process but changed the threshold for the information to be given. Therefore, the traditional 'signature' of consent is merely the final end point for a moment in time of both an information giving process (which Montgomery explicitly defines in terms of amount of information given) and an assessment of capacity by the HCP (as per the MCA) that the person concerned has capacity to make the decision. Where a parent is responsible for consenting for their child to have an intervention, the same process applies to them as you have noted BUT legally their consent is only one aspect of what is in NICU a shared, best interests decision: this too is very clearly set out in the MCA. Thus it is more accurately described as either assent or dissent depending on the agreement or not with the proposed course of action. Where parental assent lines up with proposed course of action there is no problem. It is where disagreement lies that there is. Here, the parental view should be informed to the same standard BUT might not be judged to be in the baby's best interests. Much has been written about this in respect of the Charlie Gard case. I feel that the way the explanatory note for section 2 has been written suggests parental 'consent for and against' is the same as autonomy for them making a judgement for themselves. I think the section needs to: 1) Refer more clearly to the standards set in the MCA and that the 'law' quoted here IS the MCA (if that is what is intended) 2) Make it clear that the process of parental joint decision making (which is to be encouraged) is a part of team assent to move towards	Thank you for your useful comments particularly on how the document read. We have added in the introduction that the term 'consent' is used to reflect 'proxy consent' or 'assent' and removed 'parents should not be influenced by carers'. We have also included the MCA best interests in section 9 (when parents disagree) and throughout the document emphasised parent's choice/beliefs are only one part of the decision and do not over-ride the best interests for the baby, the baby's welfare being paramount.

		the baby's best interests and NOT the same as an autonomous 'consent' decision, but that it <u>can</u> be held to the same, single decision-based standards of explanation and information giving outlined by the MCA and Montgomery. 3) Be clear that the ongoing process of information provision cannot be assumed to build to a point of 'knowing', because legally each treatment decision has to be considered independently on its own merits as a separate entity without reference to pre-supposed knowledge levels. I would also note that there is no process we can engage with as humans communicating information to humans that would pass your definition of 'parents should not be influenced by carers'. By virtue of the NHS providing the information (even in a balanced way) there is influence and this statement perhaps even risks disempowering parents from their right to ask 'what would you do' of a HCP. It is also true that not all parents will want to make decisions, and it feels a bit like this process will inhibit their right to delegate decision making to the 'professionals'.	
8	General	Percentages are fine in helping professionals to 'grade' risk, but perhaps this document should suggest that when talking to parents they change the language to something more tangible for example. 'not 20% will die' but 'one out of every 5 babies will die'. Humans are rubbish at risk, and using percentages in this document sets precedent that someone might decide to use them in conversation thereafter.	Thank you – this has been added and we would expect to the discussed in more detail during training
9	General	As with my point for principle 2, the concepts of 'clinical opinion' or 'consensus professional opinion' are subordinate to the clearly legally defined 'best interests' decision making process set out in law. Montgomery specifically challenged both of the former by setting the bar for information sharing at what the lay person would require, not peer professional, and I suspect that this therefore sets a much higher and more considered bar at the time of dissent of medical view from parental.	See above
9	Bullet point 1	Should this say parent rather than patient?? Again, rather than consent in the traditional sense, perhaps what we are really documenting is a parent's assent to the same standards as autonomous consent	Thank you, this has been changed to parent.
10	General	The section on implied consent is important as the description of a continuum of consent and information provision earlier in the document would suggests that what shared decision making is moving to is potentially acquired implied consent for anything. As I have outlined above my opinion is that this conflicts with the MCA requirements.	Thank you – section 7 on levels of consent has been revised and reflects your comments.

11	Section 7	Remove the reference to fax machines to future-proof the document	Thank you – we have removed this
13	General	I think that the way this document is written focuses on 'consent' heavily as a way to formally describe the interaction between HCPs and parents in the decision making process. I don't think, therefore, that dissent within that decision making process can be ignored and in fact I thought what has been written here is a reasonable first port of call in mentioning it. Perhaps this needs acknowledgement earlier in the document and in this section maybe highlight that it is rare when communication is done well, but in areas of disagreement there are tools to help progress things as listed. Again, my own view is that in this section there needs to be some clarity and reference with respect to the mental capacity act about how a true best interests decision considers but is not solely dependent upon the parents views.	See above
	References	I can't see how the MCA is not referenced here….?	We have added MCA in the references
Neonatal Intensive Care Unit, William Harvey Hospital, Kent (Jo Astbury, SSN)			
Appendix 1		How does parental responsibility work in the case of surrogacy, eg in a NICU before baby has been registered? Please clarify.	Thank you – surrogacy has now been added.
Lisa Kaiser, Advanced Neonatal Nurse Practitioner, Glan Clwyd Hospital, Rhyl, North Wales			
Page 3 'Principles of shared decision making'	2.	Obtaining a parent's signature does not necessarily equate with valid informed consent' – should read 'equate' NOT 'equate with'	Thank you – we have looked this up in the Oxford dictionary and web-based resources and we have left the phrase as it is.
Page 6 '2.A signature alone does not equal informed consent'	Principle	Obtaining a parent's signature does not necessarily equate with valid informed consent' – should read 'equate' NOT 'equate with'	See above
Page 16 'Examination and investigations'	'Implied ('implicit') consent	Scalp vein insertion (cannula or long line) – firstly, should this come under the 'Procedures and treatment' heading rather than 'Examination and investigations'? Secondly, a long line inserted into a scalp vein is still a central line, so should this not necessitate explicit consent in non-emergency situations?	Thank you – Appendix 2 on the suggestion of BAPM exec has been shortened to only give examples so that each network or unit can adapt further.

Karen Read			
Page 16/17 Implied consent		Breast milk fortifier – the use of fortifier is not an emergency or urgent intervention. It therefore does not fit in the implied consent section as the other interventions in this section. Fortifier can be discussed with parents on their next face to face contact with staff, or if there is are reasons why the parents are not with their baby, over the telephone, therefore fortifier should appear in the explicit verbal consent list.	See above
Page 16/17		Vitamin supplementation – this is also not an emergency/urgent intervention and should be under the explicit verbal consent list	See above
		The use of formula is not covered at all in this document. Parents should give explicit verbal consent for the use of formula, alongside high quality information on which to base their choices.	See above
Dr David Quine, Neonatal Consultant, Royal Infirmary, Edinburgh			
Page 3,	Point 6	Where are the information on common neonatal procedures ? surely these should be included	A footnote to sources such as BLISS will be added. Many units and networks use their own – this was in the previous BAPM guideline.
Page 4 Terminology	Line 9	Confusing terminology, so what is a procedure then ? what is and IV line, I would not regard this as an examination, investigation or treatment ?	Procedure added to the definition
Page 6	First para	I think not using relatives for translation is excessive and burdensome on resources. With regard to supporting parents with learning difficulties etc, what arrangements do you mean, I do not feel there are equitable resources around the country to achieve this.	We have added some use of relatives for translation, however it is important to recognise these concerns and work towards the recommendation of an independent translator.
	Second para	Regular updates by phone-again is a significant burden to staff resources and time consuming, this may lead to poorer care rather than concentrating on acute clinical care.	In practice most parents telephone regularly and are updated by the nurse looking after their baby when they phone. Prior to undertaking some procedures, the parents should be informed at the time, which would necessitate a telephone call. It is anticipated that this already occurs in most units.
	Para 5	“the law requires patients to be able to understand”-it may be pedantice but I am not sure this is true, It is not the parents fault or staff’s for that matter if they lack the capacity to understand. I think the law states that we should aim for this but that it is not always possible.	Thank you – the wording here has been changed as it may cause confusion, although it did originate from an editorial co-written by a lawyer

	Final section	The guidance does not state what to do if the parents lack the capacity to consent. There will be multiple non emergency procedures that are required for infants, it is not always easy or possible to appoint a guardian quickly.	Parental advocates has been added.
Page 10	General comment	I do not think that the guideline at this point makes it clear that there are a group of implicit consent procedures where these can be undertake with more limited communication with parents. The paragraph Implied consent in the appendix makes this more clear, but I was not aware of this till I got to the appendix section. This should be made more clear on page 10. At very least it should be referenced.	Section 7, levels of consent, has been revised to make this clearer.
Page 11	Documentation	Although this is ideal it is exceedingly time consuming-is there any evidence what proportion of discussions are currently recorded up to these standards even when staff are actually trying to achieve these standards ? Otherwise I feel you may be asking for something that is not practically achievable.	Thank you – the full documentation in the notes has been changed for only significant (explicit) procedures.
Page 13	First bullet point	I wonder if guidance on what is and what is not acceptable for the parents to reject consent for eg's ROP screening in extreme preterm infant, Bilirubin level in jaundiced baby etc	Section 9 on parents not agreeing has been revised and reflects these concerns
	4th Bullet point	It is not necessarily going to be possible to get this in a timely manor.	See above
Page 15	Final sentence	This is impossible in extreme preterm infants, or sick term infant-would take too long to be practical in the majority of acute cases.	Agree – this has been changed to non-urgent procedures requiring explicit written consent such as non-urgent surgery
Page 16	Procedures	Add Caffeine	Thank you – Appendix 2 on the suggestion of BAPM exec has been shortened to only give examples so that each network or unit can adapt further.
Page 17	Scalp vein	Although ideal this may lead to significant clinical delay and possibly worse outcomes for infant when minutes count (eg line for Ab's where this may already have been difficult and possibly more than an hour after decision made to give them)	See above
Page 18	Double volume exchange	How practical is it to obtain consent for this ? may delay exchange and lead to brain damage in the infant.	See above
Page 19	General comment	Think you should split up implicit, explicit verbal and explicit written into sections to make things easier to understand	Thank you for all your valid points for Appendix 3 (a list of risks) but after consultation with BAPM exec the appendix has been removed from the final document.
Page 19	CPAP/BiPAP	Where is your evidence that CPAP causes pneumothorax?	As above
Page 19	HFNC	As previous	As above
Page 19	Endotracheal	How balanced is it to mention perforation and subglottic stenosis in every	As above

	intubation	case ? I fear causing the parents more anxiety at a time when there is already significant stress.	
Page 19	Mechanical vent	Again I think including all this would be extremely upsetting to the majority of parents	As above
Page 19	Surfactant	Bleeding from lungs-what is your evidence for this ? Associated maybe but not necessarily caused by.	As above
Page 20	Peripheral arterial cannulation and UAC	Amputation-appears significant burden to parents for extremely uncommon problem.	As above
Page 22	Examination for ROP	Should mention Eye opener clips	As above
Page 22	Double volume exchange	Add death ?	As above
General comments	General Comments	While I feel we should involve parents in decision making of significant clinical consequences, and communicate with them regularly keeping them up to date as much as they wish, in general I am concerned that this framework would significantly increase the burden of communication with parents to an extent that if significant increased resources were not available to undertake this communication it could lead to significant deterioration in clinical care or leave practitioners who are trying their best to follow this advice to be criticized excessively when they make minor infringements. I am concerned there is significant burden of information to be shared with vulnerable parental groups including parents with learning disabilities, where this information may be too much and lead to increased stress to parents and leave them at risk of post traumatic stress disorder, especially where they feel they have been made to make multiple decisions when they do not feel ready or have the capacity to completely understand the complex medical decisions they are asked to share. There is also a risk that telling parents of very rare but terrifying outcomes from procedures that this will significantly increase the burden of anxiety from procedures (eg Arterial lines limb loss) I am concerned the burden of information sharing will delay important procedures such as sighting a peripheral line to give antibiotics in a timely manor, therefore leading to worse outcomes for our patients. I think you need to make clear there are minor procedures that have implicit consent and groups that need consent more clearly earlier on in the document, I was confused until I got to the appendices. I think this document is unfortunately balanced too far in favour of parents decision making which is fine in the majority of cases, but unfortunately in a minority of cases parents struggle to make balanced decisions as they are less able to think dispassionately than trained health professionals for obvious reasons. I feel that there should be more emphasis on doing the right thing for the baby and informing the parents of what our plans are, there are	Parents vary tremendously in what they want to know and how and when it should be communicated. Part of the training for staff should be on communication skills and practice including listening and adapting to each parent's needs. This is a framework for practice and units should work towards the recommendations as with other BAPM documents and within their network. There have been changes to the final document with more emphasis on doing the right thing for the baby. We agree that there is little evidence and we hope that this document will prompt units to undertake projects involving parents to get the evidence for future versions.

		not that many things I would feel comfortable about withholding from an infant just because the parents were against the particular treatment. I feel this guidance is group thought on best practice and not backed up by enough clinical evidence in neonatal outcomes and parental feedback/physiological outcomes.	
Oliver Rackham, Neonatal Consultant, Glan Clwyd Hospital, Rhyl, North Wales			
P3	Point 1	Parents should be partners in making decisions, not just included	Thank you – see comments above
P3	Point 2	Nor does consent always require a signature	Thank you – this has been added
P4	Para 2	Pharmacist should be included (I know it says “any others” – but they are key providers of information	Thank you – this has been included
P5	General	As above, parents are a central part of the team, not an “add on” to be included at the end. The implication here is that of information giving for a procedure, rather than co-decision making	Thank you – see comments above
P5	Final para	Also helped by specific consent forms for routine procedures (as is done in surgery) including risks and complications. And use of infographics to explain risk (both here and in the information leaflets referred to elsewhere)	Thank you – this has been emphasised
P7	Training	This is a really good section. Thank you	Thank you
P8	What is risk	Another good example of where visual information is very helpful (eg inforgraphics). Examples would be helpful here	We anticipate that this would be covered in more detail in the training but the wording has been changed in the final document
P8	Risk	Risk is perceived very differently for harm and benefit, so those percentages do not apply to both	This is a valid point but as the figures are not available for neonatal procedures unlike in surgical specialties we cannot give specific figures for harm and benefit. This document deals with general principles and the percentages to give HCPs ideas on which words to use to describe the incidence of each complication.
P9	Para 2	Appendix 3 should contain some description of severity and likelihood, as discussed above	Thank you for your valid point for Appendix 3 (a list of risks) but after consultation with BAPM exec the appendix has been removed from the final document

P9	Para 4	Expected or unexpected complication. And in fact, even if no complication, there should be an update to parents	Good point – parental update has now been included
P9	Para 4	Important to choose the right person for this communication; sometimes it will be the senior clinician involved, sometimes the "named consultant" and sometimes the DoC lead	Thank you - this has been added
P9	Bullet pojnt 1.	Should say "Parent" not patient	Thank you - changed
P9	Bullet pojnt 1 a	Should say "Parent" not patient	Thank you - changed
P9	Point 5	Very good section	Thank you
P10	Emergency	Talks about "pre-discussion" for potential complications. Would be worth coming up with guidance on what should be discussed and/or included in welcome booklet type information given at admission	BAPM hopes to work with BLISS regarding such a welcome booklet
P10	Implicit consent	Seems to be a bit of a mix up between explanation of what is about to happen and consent here. The final sentence, with bold, makes this even less clear.	Thank you – this section has been reworded
P11	Para 6	These leaflets should be available to other units in the neonatal network	Included thank you
P11	Para 6	We should not be faxing, unless absolutely necessary, and to a safehaven fax.	This has been removed
P13	Introduction	It should also be stated that it is not unreasonable for parents to disagree with what may usually be seen as an "implicit" consent and after discussion for the team to agree not to proceed – eg milk fortifier. And even for some explicit decisions where the evidence base is less clear – eg donor breast milk or post natal steroids. The wording "care is influenced" carries a negative connotation, when actually it may be a very positive decision. Similarly "withhold consent" is a negative phrase which could be re-worded – eg "an alternative treatment path is followed"	Thank you – this has been included and the section reworked
P15	Appendix 1	Very helpful, readable summary	Thank you
P16	Appendix 2	Scalp vein insertion (not a great term) is in both implicit and explicit	Thank you – Appendix 2 on the suggestion of BAPM exec has been shortened to only give examples so that each network or unit can adapt further.
P16	Appendix 2	You use implicit (implied) in the text, but implied (implicit) in the appendix	Thank you - changed
P17	Explicit – procedures	I think it would be clearer to say First blood transfusion	See above re Appendix 2
P17	Explicit – procedures	Peripheral arterial line insertion should not be in here	See above
P17	Explicit - procedures	Suprapubic aspiration of urine should be more "routine" (I know it isn't) and should be in implicit, with catheterisation	See above
P17	Explicit	Steroids for oedema should be in explicit – it is not (or rarely) an emergency	See above
P18	Explicit written	These should have specific consent forms (as general surgery would have)	See above

		with PARQ structure	
P19	Risk notes	High flow – nasal injury (to mucosa)	Thank you for all your valid points for Appendix 3 (a list of risks) but after consultation with BAPM exec the appendix has been removed from the final document.
P20	Needle thoracocentesis	Is need for chest drain a risk? Doesn't it mean pneumothorax (if there wasn't one to negin with)	As above
P20	Postnatal steroids	For extubation included but should we separate "peri-extubation" and longer course?	As above
P20	UVC	Include tamponade (as for long line)	As above
P20	UAC	Also malposition and extravasation, as for UVC	As above
P20	Scalp vein	Extravasation - needs to explain that it may lead to scarring which is more significant on the scalp / face	As above
P20	PDA treatment	Need to explain that many of these are also risks of the PDA	As above
P20	Under GI	Should we include H2 antagonists and increase in sepsis / NEC ?	As above
P21	Hypothermia	Coagulopathy, discomfort, bradycardia, arrhythmia, poor cardiac contractility, lack of kangaroo care	As above
P22	ROP	Discomfort	As above