Enhancing Shared Decision Making in Neonatal Care:

A Framework for Practice

British Association of Perinatal Medicine

DRAFT – FOR CONSULTATION
CONSULTATION PERIOD 1 May 2019 – 26 June 2019
Enhancing shared decision making in neonatal care

Purpose and Scope
This document provides a good practice framework for all healthcare professionals working with babies. It aims to provide guidance on communication, information sharing and explanation of foreseeable risks. However, in doing so it recognises the limited evidence base that exists to guide the recommendations. Consent for neonatal care involves providing clear information and building trust between healthcare professionals and parents. This framework is intended for professionals that look after babies in all locations (labour ward, postnatal ward, transitional care units, special care units, local neonatal units and neonatal intensive care units) and for all levels of care.

As they are covered elsewhere, this framework will not cover:

- Clinical practice at time of birth for babies < 26 weeks gestation [Link to BAPM’s upcoming framework - Perinatal management at less than 27 weeks of gestation]
- Clinical trial consent
- Palliative care decisions
- Consent for post-mortem examinations

Introduction and overview
Since the publication of the BAPM Good Practice Framework for consent (2004), there have been many advances in neonatal care. Furthermore, there has been a move toward a less paternalistic model of healthcare, whereby the parents are more involved in decision-making. There has also been the publication of several guidance documents by professional bodies (General Medical Council, Nursing and Midwifery Council, British Medical Association) and a paradigm shift in how the UK Courts view standards of information disclosure and consent (Montgomery v Lanarkshire Health Board [2015]). Further, it is the legal and ethical right of parents to be included in decision-making about their baby’s care.

This document reflects the move towards information-sharing and individualised decision-making and the role of “consent” within this. It does not aim to provide an in depth evaluation of the rationale behind involving parents in decision making but rather we hope it provides some general principles and practical guidance on how to apply these principles in day-to-day clinical practice.
Principles of shared decision-making

1. Parents should be included in making decisions about their baby’s care. It is the healthcare provider’s responsibility to provide consistent information to parents that will allow them to understand and engage meaningfully in decision-making.

2. Fostering a good relationship and developing trust with parents by effective communication is key to getting valid consent. Obtaining a parent’s signature does not necessarily equate with valid informed consent.

3. All members of the neonatal unit multi-disciplinary team have a role to play in facilitating shared decision-making and should be trained appropriately.

4. Frequent or serious risks associated with a procedure should be sufficiently explained in a simple and clear way, along with possible consequences if a procedure/treatment is not undertaken.

5. Appropriate verbal information should be provided. For example use of the PARQ format to help optimise parental understanding of a proposed treatment: P (Procedure), A (Alternatives), R (Risks) and Q (Questions).

6. Written information should be available for common neonatal procedures to complement verbal discussions.

7. The level of consent sought should be appropriate to the situation. If the treatment is deemed an emergency, it is both lawful and reasonable to provide it without information disclosure/consent from the parents at the time as the action is considered to be in the child’s ‘best interest’. Where able, parents should be given adequate time to consider their views on non-emergency treatments.

8. Clear documentation of the conversation in the clinical notes, indicating the key aspects of the information given to parents, their apparent understanding and agreement to proceed is the most important validation of consent.
**Terminology**

Throughout this document the word ‘parent’ includes the mother and her partner, however it should be noted that only persons with parental responsibility can give formal consent for procedures. (See Appendix 1 parental responsibility).

‘Healthcare professional' and ‘multidisciplinary team' denotes doctor, advanced neonatal nurse practitioner (ANNP), neonatal nurse or midwife, physiotherapist, occupational therapist, dietician and any others in contact with the baby or parent(s).

‘Neonatal unit’ will mean any area where neonates are cared for including postnatal ward, labour ward, transitional care unit, special care or intensive/high dependency care unit.

‘Procedure’ will be used to cover examination, investigation or treatment.

An ‘emergency’ is a sudden, serious, unexpected, or impending situation, often life-threatening and/or with potential to cause injury, harm or death without intervention. An emergency therefore requires immediate attention and action.
Applying the principles

1. Including parents in decision making

Principle: Parents should be included in making decisions about their baby’s care. It is the healthcare provider’s responsibility to provide consistent information to parents that will allow them to understand and engage meaningfully in decision-making.

A healthcare professional should engage in a dialogue with the parent(s) enabling information to be shared in a way that they can understand and use meaningfully. This includes discussing benefits, risks and alternative available treatments.

Whenever possible, communication with the parents should begin antenatally, taking the form of face-to-face discussion with the neonatal team, supplemented by written material. Where possible, parents should also be offered the opportunity to have a tour of the neonatal unit. The same principles apply whether discussions take place antenatally or cot-side.

Information sharing includes:

- listening to and hearing what is being said by the parents
- explanation and discussion of the risks as well as benefits
- discussion of other options, including no treatment
- answering parents’ questions to their satisfaction
- being patient, allowing time to process information and being willing to repeat information
- if time permits and is needed the parents should be given time to think with planned subsequent discussions (information sharing as a continuous process rather than a discrete occurrence)
- if applicable, there should be provision of suitable printed information or verified web based information.

In order to respect parental autonomy, it is important to recognise that, in terms of information, parents should be told what they want to know, not what the doctor thinks they should be told (Montgomery Report). Therefore healthcare professionals must not withhold information because they disagree with the decision the parent is likely to make if given that information. This also means that if parents do not want detailed information or any information at all and would prefer to follow healthcare professional advice, then this decision must also be respected. It is the healthcare professionals role to respect parental autonomy unless there is concern regarding the welfare of the baby in question.

It is the responsibility of the healthcare professional to ensure that parents understand the information they have been given. It is important to strive to have consistent information for the individual baby and parents, especially when given by different professionals. This can be assisted by clear documentation, multidisciplinary presence at discussions and good communication within the team, with handover of key information that has been provided to parents regarding treatment decisions.
When English is not the first language, provision of an approved translation service should be available. In order that both parents receive an unbiased interpretation of discussions, relatives or friends should not be used to translate, except in exceptional circumstances, for example an emergency situation where there is not time to access translation services. Arrangements should be made to support parents with learning difficulties or low literacy, or disabilities such as visual or hearing impairments, enabling all parents to engage in decision-making.

Some parents are unable to visit the neonatal unit regularly. As much as possible they should be involved in decision-making and updated regularly via telephone. If in depth discussions are needed, arrangements should be made for a senior member of the team to meet with the parents at their convenience.

It is important to individualise care and recognise that one universal strategy may not work for all parents. Further, parents may change their mind about their level of involvement in decision making over time or when circumstances change. The balance is to ensure the parents are not overburdened, yet make sure they have enough information for their needs. This can be challenging which is why information sharing should be fluid and if time permits a ‘staged’ approach may be indicated with involvement of different professionals, the process revolving around building relationships. Nursing input and a multidisciplinary approach are often vital in this assessment alongside asking the parents.

2. A signature alone does not equal informed consent

**Principle: Fostering a good relationship and developing trust with parents by effective communication is key to getting valid consent. Obtaining a parent’s signature does not necessarily equate with valid informed consent.**

The law requires patients to be able to understand, retain and communicate decision specific information. It encourages methods to optimise understanding (e.g. use of simple language) and communication (e.g. visual aids such as schematic heart diagrams when explaining congenital heart disease).

There should be a move away from the view of consent as written consent, towards a model that treats consent as a continuous process and is in line with family-centred care. Communication is the basis for such a decision-making model of care. It is a common misconception that consent has to be written for it to be valid. The process should take account of parents’ emotional needs and be flexible and responsive. Parents signing a consent form does not equate to information-sharing or obtaining valid informed consent.

The key principles for consent to be valid are:

- The patient or parent must have capacity to make an informed decision:
  - a. considered competent to give consent
  - b. able to understand and retain information provided
  - c. able to communicate their decision
• Consent must be provided voluntarily:
  The patient or parent should not be coerced or influenced by carers, family or friends
• The patient or parent should be fully informed of the following with enough time allowed to reflect and ask questions:
  a. benefits and risks of the intended procedure
  b. alternative management strategies
  c. implications of not undergoing the proposed treatment

3. Empowering the whole team

Principle: All members of the neonatal unit multi-disciplinary team have a role to play in facilitating shared decision-making and should be trained appropriately.

Communication and consent are a multi-disciplinary responsibility. Some staff, especially nursing staff, may have more continuity with the parents and so are often in a better position to assess what parents want, but they should not be expected to take on the whole role of information disclosure. Everyone in the multi-disciplinary team should be encouraged and supported in communicating and giving or receiving information from the parents. It is vital that the information provided is consistent between care providers. Counsellors and/or advocates should be available to support parents.

It is important that all healthcare professionals are given training in individualised care, information-sharing and consent. This should be fit for purpose, given on a regular basis and with evidence of engagement included in the appraisal process.

Staff training suggestions:

• All neonatal units and networks should promote access to training courses to help staff to develop their listening and communication skills and ensure they understand the benefits and are confident in delivering good communication and a family-centred approach to neonatal care.
• A list of available information leaflets, training in communication and the local policy for gaining of consent for examination and treatment should form part of the induction training of all clinical staff and be ongoing.
• Trainee doctors and nurses should, with the parents’ agreement, attend discussions between senior staff and parents for training purposes.
• The education, training and Continuing Professional Development (CPD) of all healthcare professionals should include joint courses for the whole multi-disciplinary team
• Parental feedback on the quality of information-sharing should be actively sought alongside routine feedback on care received.
Principle: Frequent or serious risks associated with the procedure should be sufficiently explained in a simple and clear way, along with possible consequences if the procedure/treatment is not undertaken.

Healthcare professionals must take care to ensure that parents are made aware of any material risks involved in the recommended treatment and the risks of any reasonable available alternatives; in particular they must disclose any risk to which that parent would attach significance, taking into account the parent’s position (Montgomery Ruling). It is useful to discuss risks that are serious or frequent for each procedure, but also by eliciting from parents risks that are important to them.

When explaining risk healthcare professionals should:
- be honest, frank and open
- check that parents have fully understood
- avoid euphemisms such as talking about a condition such as cerebral palsy in a roundabout way rather than by name

What is risk?
Risk is the chance that any activity or action could happen and harm the baby. Normally the benefits of an action should outweigh the risks. There is no such thing as a zero risk. How risk is viewed depends to a large extent on the individual parent.

Parents need to know about the benefits and risks or any uncertainties to help make an informed decision. How a parent views risk depends on one or more of the following:
- the chance of the event occurring (frequency)
- the benefits of the treatment
- how much harm may be caused:
  - if it is life-threatening
  - if it is short-term (temporary) or long-term (permanent)
- how much they feel in control of the decision
- how much they trust the person discussing the risk
- whether they feel they understand the situation sufficiently
- previous experience of similar or related scenarios

Risk can be described as numbers or words, or both. A commonly used guide is:

- Very common or expected - >50%
- Common or probable - 21 – 50%
- Uncommon or possible - 6 – 20%
- Rare or unlikely - 1 – 5%
- Very rare - < 1%

Some people find it is more useful to discuss risk using pictures such as a pie chart or colour in how many ‘counters’ out of 100 would be affected.
Risks can be serious but rare or less serious but common and parents should be made aware of this. Discussion on serious risks (death, permanent neurological damage etc) should be separated from frequently occurring risks (infection, bruising, scarring, anaemia etc). In addition, parents should be made aware of the possibility of failed or multiple attempts inherent with certain procedures e.g. cannula insertion or lumbar puncture, and in the difficulty in interpreting some results (e.g. inflammatory markers, CSF white cell count).

Less common and less serious but significant risks with minor procedures, such as extravasation injury should be considered – a guide is given in appendix 3.

The concepts of ‘best interest’ and ‘clinical opinion’ and ‘consensus of professional opinion’ should be applied to decisions balancing risk benefit, especially with high risk procedures. This may entail second opinions or discussions in ‘grand round’ environments or MDT meetings.

If an unexpected complication occurs it is important that further discussion with the parents is undertaken promptly and documented clearly. This would usually be done by, or under the direct supervision of, the most senior clinician involved. Duty of candour should be followed when a notifiable safety incident has occurred in line with the organisation’s policy.

In order to obtain and document informed consent, the questions below together with the sub-questions should be addressed:  
1. Does the patient know about the benefits and material risks of the treatment being proposed?  
   a. What sort of risks would a reasonable person in the patient’s circumstances want to know?  
   b. What sort of risks would this particular parent want to know?  
   c. Does the parent know about reasonable alternatives to this treatment?  
   d. Has reasonable care been taken to ensure that the parent knows and understands the above?  
2. Has the consent process been properly documented?

5. Verbal information

Principle: Appropriate verbal information should be provided. For example use of the PARQ format to help optimise parental understanding of a proposed treatment: P (Procedure), A (Alternatives), R (Risks) and Q (Questions).

When discussing procedures, it is important to explain not only what is to be/has been done but the justification for why it has been done. A useful aide memoire is the use of mnemonic PARQ (procedure, alternative, risks and questions) when discussing with parents. Where there is no strong evidence, and several options, it is useful to use the discussions to empower parents to make their own decision.

6. Written information
Principle: Written information should be available for common neonatal procedures to complement verbal discussions.

Written material should be available for the parents of all babies admitted to the neonatal unit, describing the nature of common procedures, including low risk procedures such as cannula insertion, for which explicit consent would not normally be sought, as well as medium and higher risk procedures. This material should be in plain language and needs to include details of risks, such as extravasation injury. Parents can also be directed to suitable internet links. Units should also provide translated versions of written patient information wherever possible.

The availability of written material, or the perception of a procedure as low risk, does not obviate the need for the clinician to explain its purpose, any risks and the implications of withholding that procedure.

7. Levels of consent

Principle: The level of consent sought should be appropriate to the situation. If the treatment is deemed an emergency, it is both lawful and reasonable to provide it without information disclosure/consent from the parents at the time as the action is considered to be in the child’s ‘best interest’. Where able, parents should be given adequate time to consider their views on non-emergency treatments.

Emergency Situation

Emergency situations are exempt from information disclosure/consent at the time as the action is considered to be under the ‘best interest’ of the patient. Ideally the possibility of this course of action will have been discussed with the parents previously such as antenatally for problems at delivery, once admitted to the neonatal unit for possibility of or complications of ventilation. However some situations may not be foreseen or occur before these discussions could take place. For all emergency procedures the treatment and the urgent need for it should be explained to parents at the earliest opportunity. Documentation should include details of what was done and why the course of action was taken at that time.

Semi-Urgent

Emergency is different to semi-urgent, and if there is time parents should be informed and updated on the change in clinical condition and need for a procedure even if this is only by telephone.

Routine Procedures

For more routine procedures it may be helpful to ask parents, once they are no-longer resident in the hospital, which procedures they would like to be contacted at home about, especially if this was to be in the middle of the night – see implicit consent below.

Implicit Consent

Implicit (or 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.

Implicit consent can also be inferred from signs or actions. For example, where a healthcare professional examines a baby and tells the parents that the baby needs admission to the neonatal unit for further management and the parents nod agreement (i.e. provide consent through body language). However the scope of what is legitimately covered by the parent’s initial consent to admission is problematic as treatments often thought of as innocuous by healthcare professionals may be of considerable significance to the parents. Therefore steps should be taken to explain specifics (details of the intervention, intended benefits and foreseeable risks) beforehand as much as possible if time permits.

Implicit consent is by its very nature dependent upon the building up of rapport and trust between clinicians and parents and it is still good practice, where time allows to inform parents before undertaking such procedures. The assumption that implied consent has been gained must be made with caution in neonatal practice; whenever possible all procedures should be explained to the parents.

Explicit consent
Explicit consent, sometimes referred to as ‘express’ or ‘direct’ consent, involves a discussion where the purpose and risks of an intervention are formally explained and consent, either verbal or written, is obtained prior to the intervention. This should be well documented in the notes.

Appendix 2 lists procedures when explicit consent is recommended or not usually required (if parents are not immediately available) and represents a suggested ‘starting point’ for the communication standard required, enabling flexibility and recognising that more detailed communication might be required in certain circumstances. All discussions and verbal consent should be recorded in the notes.

Consent for surgical procedures should be taken by a member of the surgical team who has experience of performing the proposed procedure. All surgical neonatal units should have leaflets describing common surgical procedures, including a summary of risks and options, that can be used as a basis for discussions between healthcare professionals and parents prior to transfer to the surgical centre and should the surgeon have to gain consent over the telephone. In this situation the witnessing of consent is important and consideration should be given to using a conference call or faxing a witnessed signed form. Contemporaneous notes of all such conversations are essential.

8. Documentation

**Principle:** Clear documentation of the conversation in the clinical notes, indicating the key aspects of the information given to parents, their apparent understanding and agreement to proceed is the most important validation of consent.

Discussions should be clearly documented in the notes with the key aspects of information provided. The entry in the notes following such discussions should include:
• Time and date.
• Who was present and job title of professionals
• Procedures/treatments that were discussed with the parents and why
• Alternatives that were discussed, including doing nothing
• A record that opportunities were given to the parents to consider the proposed plan and ask questions – this should also indicate the parents’ understanding. Documentation of the questions asked, and the answers to the questions, will help
• What parent information sheets were given or advice on internet resources
• Signed with name printed, GMC/NMC number (if applicable) or position

It is considered acceptable that only significant or less routine procedures are documented in the notes once parents have consented to neonatal care, such that for example, every capillary blood sample or peripheral intravenous cannulation does not need to be documented in the notes. If you have any reason to believe that consent might be disputed later it should be documented in the notes even for a low risk procedure; in this situation it is particularly important that the presence of a witness is recorded.
How to proceed should parents not agree with a proposed procedure

A full discussion on disagreement between healthcare professionals and parents is outside the remit of this document, however the following points are useful for dealing with this difficult area.

- In order to minimise distress in circumstances where difficulty in gaining consent is predictable because of cultural and religious factors, discussion about options should, if possible, begin before an emergency arises. For parents who have religious beliefs that may influence their decisions, it is recommended that the parents speak to religious leaders in their community for advice and support.
- If the baby’s clinical care is influenced because the parents disagree with the clinical team and therefore withhold consent this should be recorded in the medical notes.
- Parents should have access to a second medical opinion regarding management options.
- If a baby is likely to need a procedure requiring explicit consent and there is no means to gain valid consent, then the clinical team should seek advice from Social Services and may need to take legal advice.
- Parents should understand that they can withdraw consent for procedures not yet completed. If the clinical team believe that this is counter to the interests of the baby they should discuss this with the parents and may need to take advice which in the first instance should be from the hospital’s senior management team and/or Social Services.

Resources needed to deliver this framework

- Healthcare professional’s time
- Easy access to a quiet room for discussions.
- Family-centred care with a supportive and nurturing environment, encouraging and empowering parents to take a lead role in their baby’s care and make informed decisions.
- Emotional and psychological support for the family with psycho-social support.
- Information resources (written or web-based) for commonly performed procedures and treatments
- Translation services
- Access to training courses and local regular updates, to help staff to develop their skills to deliver good communication and a family-centred approach to neonatal care.
Appendices:

1. Parental responsibility
2. Recommendations for Implicit and Explicit consent in UK Neonatal Practice
3. A guide for healthcare professionals for discussing risks associated with neonatal procedures

References:

General Medical Council - Consent: doctors and patients making decisions together 2008

General Medical Council - Good medical practice 2013

Royal College of Nursing - Principles of Consent: Guidance for nursing staff 2017


Chan. Montgomery and informed consent: where are we now? BMJ 2017; 357 doi: https://doi.org/10.1136/bmj.j2224

Dyer C. Doctors should not cherry pick what information to give patients, court rules. BMJ 2015; 350:h1414. doi:10.1136/bmj.h1414 pmid:25769489


Appendix 1

Parental Responsibility

Parental responsibility (PR) is a legal term defined in the Children Act 1989 and the Children (Scotland) Act 1995 and the only person who can give legal consent is a person or agency who has parental responsibility.

If parents are married, valid consent can be obtained from either parent. If parents are not married, valid consent can only be obtained from the father if he is named on the birth certificate or has a court order giving him parental responsibility.

Same-sex partners will both have parental responsibility if they were civil partners or married at the time of the treatment, e.g. donor insemination or fertility treatment.

For same-sex partners who aren’t civil partners/married, the 2nd parent can get parental responsibility by:

- becoming a civil partner/spouse of the other parent and making a parental responsibility agreement
- jointly registering the birth
- applying for parental responsibility if a parental agreement was made

In a situation whether the mother is only the person with parental responsibility but for whatever reason is unable to give consent e.g. she is unconscious in an Intensive Care Unit, whilst other family members should be consulted about treatments and interventions they cannot give legal consent. Therefore, urgent life-threatening decisions must be made by the medical staff; non urgent procedures would have to be delayed until someone acquires parental responsibility.
Appendix 2
Recommendations for Implicit and Explicit consent in UK Neonatal Practice

These updated lists have been agreed by a working group convened by BAPM, with representation from medical, nursing and ANNP staff and parents (via Bliss) and were circulated to the BAPM membership for comments prior to being adopted.

The lists are to be used in conjunction with the BAPM framework for ‘Shared Decision Making in Neonatal Care, 2019’. The objective is to guide healthcare professionals when the need arises for non-emergency procedures when parents are not present on the neonatal unit/ward and to help recognise that more detailed communication is needed for certain procedures. This should also apply to predictable emergency procedures when they are able to be discussed with the parents in advance.

The gaining of consent and information disclosure is not an option and all procedures should be explained to parents in a timely manner, whether or not the working group recommends that explicit consent is obtained.

**Implied (implicit) consent:**
This list covers potentially foreseeable and recurrent procedures for babies requiring neonatal intensive care. Therefore, where parents are not present, it is reasonable to proceed with the intervention **but inform the parents at the first suitable opportunity.** If there is time and the parents are present, it is good practice to explain the details of the intervention, intended benefits and foreseeable risks. The assumption that implied consent has been gained **must be made with caution** in neonatal practice; whenever possible all procedures should be explained to the parents.

**Examination and investigations**
- Cerebral function monitoring (CFAM)
- Cranial ultrasound
- ECG
- Echocardiography
- Examining and assessing the baby
- Naso-gastric and naso-jejunal tubes
- Peripheral intravenous cannulation
- Portable X-rays
- Routine blood sampling
- Scalp vein insertion (cannula or long line)
- Screening for infection in response to positive results of maternal screening eg. known maternal HIV
- Taking blood or swab samples for culture
- Urine toxicology to screen for drugs of misuse where there is reason to believe that this may be impacting upon the baby’s clinical condition

**Procedures and treatment**
- Bilevel CPAP, CPAP or high flow respiratory support
Blood transfusion (explicit verbal consent recommended for first blood transfusion unless emergency)
Breast milk fortification
Cerebral function monitoring
Endotracheal intubation
Inotrophic or chronotropic medications
Intercostal drain insertion
Intravenous fluids
Low flow oxygen
Mechanical ventilation
Medications – antibiotics, anticonvulsants, sedation for intubation and ventilation
Needle thoracocentesis
Other vitamin supplementation
Parenteral nutrition
Peripheral arterial line insertion
Steroids for laryngeal oedema
Surfactant administration
Therapeutic hypothermia
Umbilical arterial and venous catheter insertion
Urethral catheterisation
Use of nitric oxide for treatment of term infants with pulmonary hypertension
Vitamin K for babies admitted to NICU

Explicit verbal:
Where possible, a discussion should take place with the parents to notify them of the details of the intervention, other options and any foreseeable risks and benefits. Documentation the relevant aspects of the discussion with the parents should be recorded in the medical notes.

Examination and investigations
CMV, toxoplasma, rubella and herpes screening
DNA CGH array or other specific genetic testing
Lumbar puncture
Scalp vein insertion (cannula or long line)
Screening of babies in high risk situations with no prior knowledge of maternal status e.g. suspected HIV
Urine toxicology where there is disclosed maternal history of drug misuse

Procedures and treatment
Blood transfusion (first blood transfusion)
Central venous catheter insertion (long line)
Dilutional exchange transfusion (partial exchange)
Gastrointestinal imaging involving contrast
Irrigation following extravasation injury
Peripheral arterial line insertion?
Pharmacological closure of a patent ductus arteriosus
Procedures involving the baby leaving the unit – x-rays, ultrasound, videofluoroscopy, MRI, CT scan, EEG
ROP examination on the unit
Suprapubic aspiration of urine
Use of donor breast milk
Use of nitric oxide as trial of therapy
Use of pooled blood products
Use of steroids in preterm infants with CLD to facilitate extubation
Ventricular tap or therapeutic lumbar tap (for post haemorrhagic hydrocephalus)
Vitamin K for term babies on postnatal ward

**Explicit written:**
Explicit written consent should be obtained alongside explicit verbal information. A person competent in performing the treatment should take consent using the PARQ acronym (procedure/alternatives/risks/questions). Documentation of the relevant aspects of the discussion with the parents should be recorded in the medical notes and the signed consent form filed in the medical notes (a copy should also be provided to the parents).

**Procedures and treatment**
All surgical operations involving regional or general anaesthetics
Any biopsy
Bone marrow aspiration
Clinical photography and video-recordings
Clinical research studies
Double volume exchange transfusion
Immunisations
Peritoneal dialysis
Treatment for retinopathy of prematurity
Appendix 3

A guide for healthcare professionals for discussing risks associated with neonatal procedures

To be used in combination with ‘A Framework for information disclosure, explaining risk and obtaining consent to improve shared decision making in neonatal care’, BAPM 2019.

Frequent or serious risks of any procedure should be sufficiently explained, with the information tailored to each family. It is not appropriate for this to be a list of risks for each procedure recited off for every family, however it is useful to have a guide. The table below should be used as a prompt for healthcare professionals for points to consider when discussing some common procedures, it is not exhaustive and this needs to be adapted to the family’s wants and needs, being guided by their questions, interactions and their previous requests.

In addition to the verbal discussions, parent information leaflets should include an appropriate balance of the risks for procedures and treatments.

The risks of surgery, transport and detailed radiation exposure are beyond the scope of this document. For risks associated with medication, healthcare professionals should refer to the BNFC or the Northern Neonatal Formulary.

<table>
<thead>
<tr>
<th></th>
<th>Risks Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Airway &amp; Breathing</strong></td>
<td></td>
</tr>
<tr>
<td>CPA/P/BiPAP</td>
<td>Pneumothorax. Nasal trauma. Abdominal distension. Failure and need for mechanical ventilation.</td>
</tr>
<tr>
<td>High Flow</td>
<td>Pneumothorax. Failure and need for mechanical ventilation.</td>
</tr>
<tr>
<td>Endotracheal intubation</td>
<td>Difficulty or inability to pass tube (may require a few attempts).</td>
</tr>
<tr>
<td></td>
<td>Discomfort (reduced with sedation/pre-medication). Trauma and bleeding at larynx. Perforation. Subglottic stenosis.</td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>Lung damage (CLD), pneumothorax and other air leak syndromes (such as pulmonary interstitial emphysema, pneumomediastinum), infection, accidental extubation.</td>
</tr>
<tr>
<td>Nitric oxide</td>
<td>Bleeding, difficulty in weaning off iNO, methaemoglobinemia.</td>
</tr>
<tr>
<td>Surfactant administration</td>
<td>ET tube obstruction, bleeding from lungs, surfactant not distributed evenly between lungs, surfactant delivered into stomach not lungs. If Less invasive surfactant administration (LISA) is used, there are similar risks to conventional surfactant administration and there is also a risk that the baby may require intubation. Consider porcine or bovine origins in view of religious sensibilities versus the baby’s healthcare needs.</td>
</tr>
<tr>
<td>Risks Notes</td>
<td></td>
</tr>
<tr>
<td>----------------------------------</td>
<td></td>
</tr>
<tr>
<td>Chest x-ray</td>
<td>Radiation risk (minimised by only undertaking x-rays when needed).</td>
</tr>
<tr>
<td>Needle thoracocentesis</td>
<td>Bleeding, infection, need for chest drain insertion.</td>
</tr>
<tr>
<td>Intercostal drain insertion</td>
<td>Bleeding, infection, bronchopleural fistula.</td>
</tr>
<tr>
<td>Postnatal steroids to facilitate extubation</td>
<td>Short term- high blood pressure, high blood glucose, thickening of heart muscle (cardiomyopathy), risk of infection, osteopenia. Long term- some concerns about brain growth and cerebral palsy.</td>
</tr>
<tr>
<td><strong>Circulation</strong></td>
<td></td>
</tr>
<tr>
<td>Peripheral intravenous cannulation</td>
<td>Pain, bleeding/blood loss, infection, extravasation injury.</td>
</tr>
<tr>
<td>Peripheral arterial cannulation</td>
<td>Bleeding, infection, limb circulation problems, amputation due to blood clot in circulation.</td>
</tr>
<tr>
<td>Umbilical venous catheterisation</td>
<td>Bleeding, blood stream infection, malposition, leaking, extravasation.</td>
</tr>
<tr>
<td>Umbilical arterial catheterisation</td>
<td>Bleeding, blood stream infection, limb circulation problems, amputation.</td>
</tr>
<tr>
<td>Scalp vein insertion</td>
<td>Pain, bleeding, infection, extravasation, malposition (e.g. artery), shaving of hair.</td>
</tr>
<tr>
<td>Central line (e.g. longline insertion)</td>
<td>Blood stream infection, bleeding, extravasation, rupture, malposition, cardiac tamponade.</td>
</tr>
<tr>
<td>Packed red cell transfusion</td>
<td>Extravasation, blood transfusion reaction, infection (very low risk).</td>
</tr>
<tr>
<td>Hydrocortisone for blood pressure support</td>
<td>High blood glucose, risk of infection. Concerns about brain growth and cerebral palsy.</td>
</tr>
<tr>
<td>Pharmaceutical close of PDA</td>
<td>Problems with absorbing milk and other gut problems, renal failure, low platelets (leading to bleeding). NEC/bowel perforation.</td>
</tr>
<tr>
<td><strong>Risks</strong></td>
<td><strong>Notes</strong></td>
</tr>
<tr>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Gastrointestinal</strong></td>
<td></td>
</tr>
<tr>
<td>Naso-gastric/naso-jejunal tube insertion</td>
<td>Need to be frequently replaced as dislodged. Aspiration into lungs. Perforation.</td>
</tr>
<tr>
<td>Donor breast milk</td>
<td>Pasteurisation removes some of the benefits seen with mother’s own milk. Low protein content may adversely affect growth</td>
</tr>
<tr>
<td>Formula milk</td>
<td>Short term – increased risk of NEC in babies under 34 weeks gestation. Effect of bovine breast milk fortifier Long term – increased upper respiratory infections in infancy, increased middle ear infections in childhood. Increased type 2 diabetes and obesity in adulthood.</td>
</tr>
<tr>
<td>Abdominal x-ray</td>
<td>Radiation risk. Difficulty interpreting signs.</td>
</tr>
<tr>
<td>Contrast swallow x-ray/videofluoscopy</td>
<td>Aspiration. Radiation.</td>
</tr>
<tr>
<td><strong>Renal</strong></td>
<td></td>
</tr>
<tr>
<td>Urethral catheterisation</td>
<td>Bleeding, infection, trauma to urethra.</td>
</tr>
<tr>
<td><strong>Sepsis</strong></td>
<td></td>
</tr>
<tr>
<td>Intravenous antibiotics (generic)</td>
<td>Need to have iv access. Change to baby’s microflora. Refer to neonatal formulary for each individual antibiotic.</td>
</tr>
<tr>
<td>Lumbar puncture</td>
<td>Infection, bleeding, discomfort/pain. Unable to interpret the results e.g. borderline cell numbers.</td>
</tr>
<tr>
<td>Suprapubic aspiration of urine</td>
<td>Bleeding, infection, bladder injury (rare), bowel injury (rare).</td>
</tr>
<tr>
<td><strong>Central nervous system</strong></td>
<td></td>
</tr>
<tr>
<td>Cranial ultrasound</td>
<td>Will not pick up all anomalies. Artefacts interpreted as pathology.</td>
</tr>
<tr>
<td>Therapeutic hypothermia</td>
<td>Subcutaneous fat necrosis, rectal temperature probe complications.</td>
</tr>
<tr>
<td>Ventricular tap</td>
<td>Apnoeas, bradycardias, infection, electrolyte imbalance (e.g. hyponatraemia), creation of a tract between scalp skin and ventricle.</td>
</tr>
<tr>
<td>Risks</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>CT scan brain</strong></td>
<td>Radiation exposure. Motion artefact meaning images cannot be interpreted. Incidental findings.</td>
</tr>
<tr>
<td><strong>MRI brain</strong></td>
<td>Motion artefact meaning images cannot be interpreted. Noise of MRI scanner (reduced by ear muffs). Hypothermia. Other risks related to condition of baby. Incidental findings.</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
</tr>
<tr>
<td>Examination of eyes for ROP</td>
<td>Effects of eye drops. Short lived increased risk of apnoeas and increased respiratory support post procedure. Hypertension. Short-lived increased oxygen requirement post procedure.</td>
</tr>
<tr>
<td>Dilutional exchange transfusion</td>
<td>Bleeding, infection, hypotension, heart failure, blood biochemistry derangement.</td>
</tr>
<tr>
<td>Double volume exchange transfusion</td>
<td>Bleeding, infection, hypotension, heart failure, blood biochemistry derangement. Complications related to vascular access.</td>
</tr>
</tbody>
</table>