

CONSENT

Based on BAPM Consent in Neonatal Clinical Care: Good Practice Framework (2004) |
British Association of Perinatal Medicine (bapm.org)

FOR COMMON NEONATAL INVESTIGATIONS, INTERVENTIONS AND TREATMENTS

The following guidance is taken from 'Good practice framework for consent in neonatal clinical care' produced by the British Association of Perinatal Medicine (BAPM)

- It is a legal and ethical requirement to gain valid consent before examining and initiating any investigation or treatment for any patient
- Consent is obtained from someone with parental responsibilities:
 - if married, parents
 - if not married, mother but not father, unless father has acquired parental responsibility via a court order, being registered on birth certificate or parental responsibility agreement
 - a legally appointed guardian
 - a local authority designated in a care order or holding an emergency protection order
- Consent is valid only when information has been understood by the parents and explains why the intervention is recommended, its risks and implications, and other options should consent be withheld

Documentation of information given and parents' understanding and agreement to proceed is the most important validation of consent. A signature does not in itself confirm informed consent

- Witness consent wherever possible, and record name of witness
- In neonatal practice, there are frequent occasions when no one is available to provide valid consent and treatment is initiated in its absence (e.g. emergency ABC resuscitation, stabilisation, chest drainage or exchange transfusion when delayed treatment would not be in baby's best interests, or following maternal general anaesthetic when mother is unmarried to baby's father). It should always be possible later to justify the action to the parents and to reassure them that it was in the baby's best interests

GOOD PRACTICE

- Give parents of babies admitted to NNU written information (BLISS <https://www.bliss.org.uk/health-professionals/information-and-resources/resources-for-parents>) describing low-risk procedures such as venesection, for which explicit consent is not normally sought
- Give parents information leaflet for data collection, allowing them to opt out
- Procedures that need to be done as an emergency may still carry risk and parents need to be fully informed about them and the likelihood of repeat procedure at the first suitable opportunity
- For more detailed information see **BAPM Framework for enhancing shared decision making** (<https://www.bapm.org/resources/158-enhancing-shared-decision-making-in-neonatal-care>)

LEVELS OF CONSENT

- Level of consent sought to be appropriate to situation
- in an emergency, it is reasonable and lawful to provide treatment without information disclosure/consent from parents at the time – action considered to be in baby's 'best interest'
- When possible, parents to be given adequate time to consider their views on non-emergency treatments
- Procedures can be divided into different levels of consent; implicit, explicit verbal or explicit written, depending on risk-benefit ratio

Implicit consent

- Where the nature and risk of the procedure is such that a less formal transfer of information is considered sufficient, and often retrospective

- List of investigations, procedures and treatments is long – see **Table 1** for examples

Explicit consent

- Also referred to as 'express' or 'direct' consent
- Involves discussion regarding purpose and risks of an intervention formally explained and consent, either verbal or written, obtained before intervention
- must be recorded in patient notes
- Recommended for:
 - moderate-high risk procedures
 - close risk-benefit ratios
 - surgical procedures
- See **Table 1**

Table 1

Procedure	Explicit consent not USUALLY required	Explicit consent recommended
Examination and investigations		
Examining and assessment of the patient	✓	
Clinical photographs and video-recordings		✓
Routine blood sampling	✓	
Blood culture	✓	
Lumbar puncture:		
diagnostic		✓
therapeutic		✓
Supra-pubic aspiration of urine	✓	
Screening of babies and/or their mothers in high-risk situations with no prior knowledge of maternal status e.g. suspected HIV or substance abuse		✓
Screening for infection in response to positive results of maternal screening e.g. known maternal HIV or substance abuse	✓	
CMV, toxoplasma, rubella and herpes screening	✓	
Genetic testing (including karyotype)		✓
Portable X-rays and ultrasounds	✓	
Gastrointestinal imaging involving contrast		✓
Procedures involving the baby leaving the unit		
X-rays	✓	
ultrasound	✓	
videofluoroscopy	✓	
MRI/CT with or without contrast		✓
EEG/CFAM	✓	
EEG with video recording		✓
ECG	✓	
ROP screening	✓	
Practical procedures		
All surgical procedures		✓

Umbilical arterial or venous catheterisation	✓	
Percutaneous arterial lines	Radial, ulnar or pedal	Brachial or femoral
Percutaneous long lines (including use of contrast medium to visualise tip)	✓	
Peripheral venous lines	✓	
Nasogastric/nasojejunal tubes	✓	
Tracheal intubation	✓	
Ventilation/CPAP	✓	
Chest drain insertion and replacement		These procedures usually need to be done as an emergency. However, they carry risk and parents need to be fully informed about them and the likelihood of repeat procedure at the first suitable opportunity
Abdominal drainage for perforation of ascites		✓
Irrigation following extravasation injury		✓
Urethral catheterisation	✓	
Peritoneal dialysis		✓
Bone marrow aspiration		✓
Any biopsy		✓
Treatments		
Blood transfusion		✓
Use of pooled blood products	✓	
Exchange transfusion		✓
Partial exchange transfusion		✓
Antibiotics	✓	
Vitamins/mineral supplements	✓	
IV fluids	✓	
Parenteral nutrition	✓	
Surfactant	✓	
Anticonvulsants	✓	
Sedation for intubation and ventilation	✓	
Inotropes	✓	
Indomethacin or ibuprofen for patent ductus arteriosus	✓	
Prophylactic indomethacin	✓	
Parenteral and oral vitamin K for babies admitted to NNU	✓	
Vitamin K for normal term babies		✓
Nitric oxide for term babies	✓	
Nitric oxide for preterm babies		✓
Dexamethasone for chronic lung disease		✓
Postnatal dexamethasone for laryngeal oedema	✓	
Immunisation		✓
Treatment for retinopathy of prematurity		✓
Nutrition		
Breast milk fortification	✓	
Use of donor breast milk		✓

Use of cow's milk formula		✓
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Explain all investigations, procedures and treatments to parents at earliest opportunity

DOCUMENTATION

- Documentation, supported by a signature for written explicit consent
- Documentation of oral explicit consent
- Provide parents with information sheets

Parental consent for inclusion of neonates into participating research projects must comply with project description. Study approvals etc. for the participating unit to be overseen by relevant research and development team of NNU's Trust