It is a legal and ethical requirement to gain valid consent before examining and initiating any investigation and treatment for any patient. Failure to seek consent is not an option. However in neonatal practice there are frequently occasions, particularly soon after birth, when there is no-one available to provide valid consent and the clinician has to initiate treatment in its absence. It should always be possible later to justify that action to the parents, and to reassure them that what was done was in the best interests of the baby.

This leaflet aims to provide guidance to those working with newborn babies clarifying when, from whom and how consent should be gained in different circumstances. It is not within its scope to consider, withholding and withdrawal of life sustaining treatment, nor the involvement of babies in national screening programmes or in research studies.

It is hoped that this will encourage consistency between centres and provide a standard for the gaining of consent.

In this leaflet the term explicit consent is used to describe the situation when the purpose and risks of an intervention are formally explained and consent, either verbal or written, obtained and recorded prior to the intervention. Implicit consent is used to describe situations where it is judged that the nature and risk of a procedure is such that a less formal, and often retrospective transfer of information about the intervention is considered sufficient. Implicit consent as defined here, is by its very nature dependent upon the building up of rapport and trust between clinicians and parents.

The leaflet is produced together with a list of common investigations and interventions indicating those for which it is recommended that explicit consent is gained and those where, at the present time, implicit consent is considered to be acceptable.

Principles

1. Consent is obtained from someone with parental responsibilities; this will usually be the parents.\(^1\)

2. The basis of valid informed consent is the establishment of clear two-way communication and is an on-going process. Consistent communication will increase the parents’ trust and confidence in the medical and nursing team and decrease the likelihood of problems.

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\(^1\) This leaflet has been written by a working group convened by BAPM with representation from medical and nursing staff and from BLISS, in consultation with the BAPM membership and with advice from BAPS.

\(^2\) The Children Act 1989 and Adoption and Children Act 2002: Those with parental responsibility include: parents if married, mother but not father if not married unless he has acquired parental responsibility via a court order or parental responsibility agreement, an individual caring for the child such as a childminder if authorised by the parent, a legally appointed guardian, a Local Authority designated in a care order or holding an emergency protection order.

In 2003 in England, Wales and Northern Ireland but not Scotland, an amendment to the 1989 Children Act gave parental rights to unmarried fathers named on the birth certificate.
3. Consent is valid only when the information provided has been understood by the parents and explains why the intervention is recommended, its risks and what are the implications and options should consent be withheld.

4. It will not usually be necessary to document consent to routine and low risk procedures.  

5. In emergency, if consent cannot be obtained e.g. because nobody with parental responsibility is available or the parents are too distressed to give valid informed consent, treatment may lawfully be started if clinicians believe it to be in the child’s best interests.

6. Consent may be written, verbal or implied. Documentation indicating the content of the information given to parents and of their apparent understanding and agreement to proceed is the most important validation of consent. A parental signature does not of itself confirm informed consent.

7. The gaining of explicit consent, whether with or without a signature, should be witnessed and the name of the witness recorded.

8. Parents should understand that they can withdraw consent for investigations and treatments 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.

**Good practice**

1. Whenever possible communication with the parents should begin antenatally both through meetings with neonatal staff and using written material.

2. Written material should be available for the parents of all babies admitted to the neonatal unit, describing the nature of low risk procedures such as venesection, for which explicit consent would not normally be sought.

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

4. Counsellors and advocates should be available to support parents.

5. 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.

6. 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.

7. If treatment is complex, or involves significant risks or side effects explicit consent must be gained and it is good practice for this to be signed.

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8. If the baby’s clinical care is influenced because the parents withhold consent this should be recorded in the notes.

9. If a baby is likely to need a procedure requiring explicit consent and there is no means to gain valid consent, then you should seek advice from Social Services and may need to take legal advice.

10. Consent for surgical procedures should be taken by a member of the surgical team whenever possible. It is recommended that all neonatal units have leaflets describing common surgical procedures, including a summary of risks and options, that can be used as a basis for discussions between paediatricians 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.

11. Consent for post-mortem examination should usually be taken by a member of the consultant staff unless there is a junior doctor who is trained to use the consent form and who was particularly involved with the family. In many instances pathologists are happy to talk to parents themselves and this should be encouraged.

12. In order to minimise distress in circumstances where difficulty around gaining consent is predictable because of cultural and religious factors, e.g. a Jehovah’s witness family, discussion about options should, if possible, begin early before an emergency arises.

13. 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.

14. Junior doctors and nurses should, with the parents’ agreement, attend discussions between senior staff and parents for training purposes.

15. Staff might find it helpful to consider how they would themselves respond in the parents’ place and what explanations and reassurances would make it easier for them to understand why an intervention is recommended.

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