



British Association of
Perinatal Medicine



Enhancing Shared Decision Making in Neonatal Care

A Framework for Practice

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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, nor does consent always require a signature.
3. All members of the neonatal unit multi-disciplinary team have a role to play in facilitating shared decision-making with parents and should be trained appropriately.
4. Frequent or serious risks associated with a procedure should be sufficiently explained in a simple and clear way, fully addressing the parents' own concerns, 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 reasonable and lawful to provide it without information disclosure/consent from the parents at the time as the action is considered to be in the baby'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.

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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, recognising the limited evidence base that exists. Consent for neonatal care should involve provision of clear information and the building of 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.

It does not cover:

- 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 and a move toward a less paternalistic model of healthcare, with parents more involved in decision-making. Several professional bodies (General Medical Council, Nursing and Midwifery Council, British Medical Association) [1-4] have published guidance around consent and there has been a paradigm shift in how the UK Courts view standards of information disclosure and consent. It is the legal and ethical right of parents to be included in decision-making about their baby's care. [5]

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 practical guidance on how to apply these principles in day-to-day clinical practice.

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 neonatal nurse, advanced neonatal nurse practitioner (ANNP), doctor, midwife, physiotherapist, occupational therapist, pharmacist, 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.

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- **'Consent'** relates to gaining a parent's 'assent' or 'proxy consent' for a procedure.
- **'Procedure'** will be used to cover examination, investigation, procedure or treatment.
- **'Emergency'** is a sudden, serious, unexpected, or impending situation, often life-threatening and/or with potential to cause injury, harm or death without intervention.

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. Research shows that, while parents generally want substantial information about their infant's problems, they vary considerably in the extent to which they want to take responsibility for decision-making.

Whenever possible, when neonatal problems are anticipated, communication with the parents should begin antenatally, involving 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.

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
- allowing time for parents to process information and being willing to repeat information
- if applicable, there should be provision of suitable printed information or verified web based information
- where there is genuine uncertainty as to the optimal treatment options, the healthcare professional should acknowledge this.

In order to respect parental autonomy, it is important to recognise that parents should be told what they want to know, not what the doctor thinks they should be told [5,9]. 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 to make decisions, preferring to follow healthcare professional advice, then this decision must also be respected, whilst still offering to provide the basis for the advice.

The information must be consistent, especially when given by different professionals. Consistency of information can be assisted by clear documentation, multidisciplinary presence at discussions and good communication within the team.

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.

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, nor does consent always require a signature.

In order to be involved in shared decision-making and consent, parents need to be able to understand and retain decision specific information [6-8]. The key principles for consent to be valid are:

- The parent must have capacity to make an informed decision:
 - a. considered competent to give consent
 - b. able to understand, retain, use and weigh the information provided
 - c. able to communicate their decision
- Consent must be provided voluntarily:

The parent should not be coerced 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 including no intervention
 - c. implications of not undergoing the proposed treatment

It is the responsibility of the healthcare professional to present information in terms that parents are most likely to understand and check the parents' level of understanding. When English is not the first language, provision of an approved translation service should be available. Whilst it may be appropriate for relatives or friends to translate for straightforward day-to-day updates, independent translation services should be used whenever possible in order that both parents receive an unbiased interpretation. Arrangements should be made to try to support parents with learning difficulties or low literacy (using advocates for parents when appropriate) or disabilities such as visual or hearing impairments, enabling all parents to engage in decision-making.

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 with parents 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 be 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. 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:

- All neonatal units and networks should promote access to training courses for the whole multi-disciplinary team to help staff to develop their listening and communication skills, ensuring they understand the benefits of 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.
- Parental feedback on the quality of information-sharing should be actively sought alongside routine feedback on care received.

4. Explanation of risk

Principle: Frequent or serious risks associated with the procedure should be sufficiently explained in a simple and clear way, fully addressing the parents' own concerns, along with possible consequences if the procedure/treatment is not undertaken.

Risk is the chance that an activity or action could harm the baby. Normally the benefits of an action should outweigh the risks. 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 [6-8]. 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.

How an individual 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

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- previous experience of similar or related scenarios

Risk can be described as numbers or words, or both. Although percentages can be helpful for healthcare professionals, when talking with parents it is helpful to use easier to grasp numbers such as 1 in 5, instead of 20%. Some understand pictures better, such as a pie chart or colour in how many 'counters' out of 20 would be affected.

Parents should also 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, cerebrospinal fluid white cell count).

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, the named consultant or the departmental lead. Duty of candour should be followed in line with the organisation's policy when a notifiable safety incident has occurred.

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. The use of open questions is to be encouraged and should be emphasised in training. 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 or other infographics) are beneficial.

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. Parents can also be directed to suitable internet links. Units should 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 reasonable and lawful to provide it without information disclosure/consent from the parents at the time as the action is considered to be in the baby's 'best interest'. Where able, parents should be given adequate time to consider their views on non-emergency treatments.

The important focus of neonatal care should be around doing the right thing for the baby. Therefore consent for most procedures, those with a clear benefit-risk balance, should be more about informing the parents of what our plans are, and seeking their consent, rather than asking them to make the decision about whether we should undertake the procedure [11].

Implicit and Explicit consent

Consent should be seen as a process of information sharing and communication with parents to establish and maintain collaborative working. To aid this process, procedures can be divided into requiring different levels of consent; implicit, explicit verbal or explicit written. This is primarily based on the risk-benefit ratios and the evidence or clinical opinion base supporting their use. There is little evidence base but examples are given in Appendix 2.

Implicit Consent

Implicit (or implied) consent refers to clinicians proceeding with a non-urgent low-risk intervention without necessarily having specific prior discussion for the procedure at that time with the parents. Implicit consent procedures should have been described to parents prior to or on admission, supported with written information, and expanded on by healthcare professionals as the opportunities arise.

Implicit consent is dependent upon the building up of rapport and trust between clinicians and parents. The assumption that implicit consent has been gained must be made with caution unless a thorough discussion has taken place. Procedures considered to be routine and low risk for healthcare professionals may be seen as invasive to a parent.

Explicit consent

Explicit consent, sometimes referred to as 'express' or 'direct' consent, involves a discussion whereby 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 recorded in the notes. Generally explicit consent is recommended for moderate to high risk procedures, procedures with debatable risk-benefit ratios and surgical procedures.

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 available to all the units in the network describing common surgical procedures, including a summary

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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. Should the surgeon have to gain consent over the telephone, the witnessing of consent is important and consideration should be given to using a conference call. Contemporaneous notes of such conversations are essential.

Emergency, semi-urgent, routine and integrated package of care.

Emergency situation

Emergency situations arise when treatment must be given immediately to save the life or to prevent serious deterioration. Here time does not permit seeking reasonably informed consent. Emergency procedures are exempt from information disclosure/consent at the time as the action is considered to be under the 'best interest' of the baby. Ideally the possibility of this course of action will have been discussed with the parents previously, such as antenatally for predictable problems at birth. However some situations may not be foreseen or occur before these discussions could take place. For all emergency procedures, the treatment and why there was 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 procedures

Many neonatal interventions are actually semi-urgent rather than emergency situations, such as interventions to support or monitor intensive care. For these if there is time and available personnel, parents should be informed of the procedure, but if this is not possible, as with the case for emergencies, parents should be updated as soon as possible thereafter.

Frequently performed procedures

For frequently performed procedures, such as monitoring blood tests, most parents accept these procedures as part of neonatal care and agree to blanket consent as seeking individual consent for each intervention would be too onerous and outweigh the benefits. However this needs to be clearly discussed with parents, at the initiation of care, rather than assumed. For practicality, it may be helpful to ask parents, particularly once they are no-longer resident in the hospital, which procedures they would like to be contacted about, especially if this was to be in the middle of the night.

Integrated package of care and other decision making models

Rather than seeking consent for every procedure, some units may prefer to seek consent for an integrated package of care appropriate to the infant's best interests, such as a special care or an intensive care package, or one of the other models of decision making. For an integrated package of care, by consenting the parents would authorise the healthcare professionals to conduct whatever conventional procedures entailed by that package were necessary (implicit and some explicit) rather than having to seek consent for all individual procedures. Such a package of care would help overcome difficulties in seeking consent for each procedure each time, and acknowledge the duty of the healthcare professional to act in the infant's best interests. However an integrated package of care requires thorough initial discussions and documentation and use of appropriate written information and the confidence that parents understand and agree. Such packages should not cover procedures with uncertain risk-benefit outcome without further specific discussion and shared decision making with the parents.

8. Documentation

Principle: For significant procedures, discussions or decision-making, 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.

It is considered acceptable that frequently performed day-to-day procedures, generally those of implicit consent, whilst still communicated to parents, if they are present, do not usually need to have the discussion documented in the clinical 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.

Significant procedures or decision-making discussions need clear documentation in the clinical notes with the key aspects of information provided. The entry in the notes following such discussions should include:

- Who was present
- Procedures, risks/benefits and alternatives that were discussed (PARQ)
- 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.

How to proceed should parents not agree with a proposed procedure

The guiding principle for good medical practice is to make the care of your patient your first concern; the baby's welfare should be paramount. This equates to a duty on all parties (professional and parents) to act in the baby's best interests. If communication and sharing of information is done well, it would be rare for parents to disagree strongly to a plan of care proposed by the healthcare professionals, unless there are cultural or religious reasons. When dissent occurs, is it more likely to be due to misunderstanding, too much information to process, confusion or parents feeling pressurised or anxious over complications.

Occasionally however there may not be agreement and then a decision needs to be made on how to proceed. Parents as competent adults have the right to make decisions that may compromise their own welfare, but they do not have the right to make such decisions on behalf of a child. The concept of 'best interests' for any person without capacity is laid out in the (Mental Capacity Act 2005 (England and Wales); Adults with Incapacity Act (Scotland) and Mental Capacity Act (Northern Ireland) 2016), which states that in determining the baby's 'best interests':

- the procedures must be necessary and must benefit the baby
- the procedure must be the minimum necessary to achieve the purpose
- there should be consultation with relevant others; the team needs to consider the views and the cultural, religious or other beliefs and values of the parents, and the views of other healthcare professionals involved in providing care to the child.

For procedures where there is evidence, or substantial clinical expectation of benefit, parental refusal may be overridden in the infant's best interests. This does not apply to procedures where the risk-benefit balance is debatable or where the evidence base is less clear.

A full discussion on disagreement between healthcare professionals and parents, and conflict between the parent's wishes and the baby's best interests, is outside the remit of this document.

However the following points are useful for dealing with this difficult area:

- Parents should have access to a second medical opinion regarding management options.
- 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, such as the need for a blood transfusion when parents are Jehovah's Witnesses. When religious beliefs may influence parents' decisions, it is recommended that the parents speak to religious leaders in their community for advice and support.
- If the clinical team believe that the parents' opinion 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 clinicians and senior management team as soon as possible.
- When parents are in disagreement, either with the clinical team or between themselves, about the best interests of the baby, and disputes cannot be resolved informally, they should seek legal advice about whether they should apply to the court.

Resources needed to deliver this framework

- 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.
- Healthcare professionals' time.
- Easy access to a quiet room for discussions.
- 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.

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14. Surrogacy Arrangement Act 1985
15. The Human Fertilisation and Embryology Act 1990 and 2008

Appendix 1: Parental Responsibility

Parental responsibility (PR) is a legal term defined in the Children Act 1989 (England and Wales), the Children (Scotland) Act 1995 and The Children (Northern Ireland) Order 1995. The only person who can give valid 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 signing a parental responsibility agreement
- jointly registering the birth
- applying for parental responsibility if a parental agreement was made

In a situation where 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. It is also reasonable to proceed with routine urgent or semi-urgent care, including procedures for which consent would normally be sought, but non-urgent procedures requiring explicit written consent, such as non-urgent surgery, would have to be delayed until someone acquires parental responsibility.

If a child is taken into local authority care, parents share parental responsibility with the local authority.

- Parents lose parental responsibility if a child is adopted
- Parental responsibility can be restricted by court order

Parental Responsibility in a Surrogacy Pregnancy

Surrogacy is the practice whereby one woman carries the child for another person, with the intention that the child should be handed over after birth. The surrogate or birth mother is the woman who carries the pregnancy. The commissioning or intended parents are those whose wish to bring the child up after birth. [14,15]

Under UK law: at birth, the legal mother of a child born through surrogacy is always the surrogate mother regardless of genetic makeup, and she is legally responsible for the child until such time as the intended parent(s) adopt or are granted a parental order (this could take up to 6 weeks). The surrogate mother registers the child's birth in the Register of Births, and is named as the legal mother on the Birth Certificate.

The legal father on the birth certificate depends upon other factors:

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1. If the surrogate mother is married/civil partnership, then her husband/partner is the legal father
2. If the surrogate mother is single, and the treatment did not take place at a centre licensed by the Human Fertilisation and Embryology Authority (HFEA), then the legal father is the intended father
3. If the surrogate mother is single, and the treatment took place in a HFEA licensed clinic, the child is legally fatherless

Therefore, consent for any medical care to the baby must be obtained from the surrogate mother (or her husband/civil partner), even if the baby has been handed over to the commissioning family, until a parental order has been granted or adoption has taken place. However, the surrogate mother has the right to allow the intended parents to care for the baby in the postnatal period.

Where the surrogate mother has given her consent for the commissioning parents to care for the child, it is usual practice for the commissioning parents' wishes to be considered by staff regarding the treatment of a baby, and for them to be included in any important discussions, decisions and preferences regarding the health of that child, whilst recognising that the surrogate has the overall responsibility until a parental order has been issued. The written consent of the surrogate mother should be provided, which delegates treatment-related decision-making to the commissioning parents, and this should be clearly recorded in the medical notes, again taking into consideration the legal framework for who can legally make those decisions. In any situation of conflict or disagreement, a healthcare professional's legal duty of care lies with the interests of the surrogate mother and baby, rather than the interests of the intended parents. However, in accordance with law, the interests of the baby remain paramount throughout.

Appendix 2: Examples of Implicit and Explicit consent for non-emergency procedures in UK Neonatal Practice

Rather than trying to give exhaustive lists as to when explicit or implicit consent is required, examples have been agreed by a working group convened by BAPM with representation from medical, nursing and ANNP staff and parents (via Bliss) following a list circulated to the BAPM membership for comments. There is no robust evidence base for recommendation apart from a few small studies, so these examples need to be viewed as best practice and to form a starting point for each neonatal unit or network's guideline.

The examples are to be used in conjunction with the BAPM 'Framework for Shared Decision Making in Neonatal Care, 2019'. Implicit and explicit consent suggestions apply to **non-emergency** procedures when parents are not present on the neonatal unit/ward to help recognise that more detailed communication is needed for certain procedures, but a balance of care in the best interests of the baby should be used if parents are not easily contactable. 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 this is implicit or explicit consent.

Emergency stabilisation procedures, such as intubation, ventilation, emergency drugs and use of O negative blood, should be given without delay, and explained to parents as soon as possible afterwards.

Implicit (implied) consent examples:

- Clinical Examination and assessment
- Portable X-rays
- Routine blood sampling
- Gastric tubes (insertion and use)
- Administration of frequently used drugs with a good evidence base e.g. caffeine
- Umbilical arterial and venous catheter insertion
- Peripheral arterial line insertion
- Cerebral function monitoring
- Cranial ultrasound
- Parenteral nutrition

Explicit verbal consent examples:

- Breast milk fortification
- Donor breast milk
- Cows' milk formula
- First blood transfusion
- Postnatal corticosteroids to facilitate extubation
- Screening of babies in high risk situations with no prior knowledge of maternal status e.g. suspected Human Immunodeficiency Virus (HIV)

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Explicit written consent examples:

- All surgical operations involving regional or general anaesthetics
- Any biopsy
- Clinical photography and video-recordings
- Immunisations
- Treatment for retinopathy of prematurity