Good practice in consent

Richard W.I. Cooke*

Neonatal Unit, Liverpool Women's Hospital, Crown Street, Liverpool L8 7SS, UK

Summary Informed parental consent reminds the health professional to respect parent autonomy with respect to their infant's health care. It involves at least four elements: information, assessment of understanding, assessment of capacity, and freedom to choose. Critical issues are training of staff, timing of approach, and quality and presentation of information. In the newborn period, additional problems include parental distress and competence, consent for research into emergency treatments (exceptions to this are proposed below); screening for future disease, circumcision and withdrawing intensive care are considered as special cases. Variation in practice and policies in European neonatal units is described.

© 2004 Elsevier Ltd. All rights reserved.

tel.: +44 151 702 4093; fax: +44 151 702 4313.
E-mail address: r.w.i.cooke@liv.ac.uk

Introduction

Consent, whether to a therapeutic intervention or to an involvement in research, is essential to the development of a good doctor–patient relationship. In recent decades, we have moved from an essentially paternalistic 'doctor knows best' position to the almost universal acceptance of the doctrine of 'informed patient consent'. Despite this, hardly a day goes by without a story in the national press about health professionals acting without consent, not least in the area of neonatal medicine.

'Informed consent', when correctly obtained, reminds the health professional to respect patients' autonomy and their right to bring personal values into making healthcare decisions that affect them. The concept involves at least four elements: provision of information, assessment of the patient's understanding and capacity to make decisions, and assurance of voluntariness or freedom to choose.

The concept of informed consent works well when it involves a competent adult patient and a relatively straightforward intervention in treatment or research, but there are problems in adapting it to care of the newborn. There is a general belief that parents or legal guardians have the authority or right to give consent 'by proxy', and in practice this is widely accepted and seems to work reasonably well. However, informed consent involves personal judgements about the effect of the proposed treatment or intervention, based on unique personal beliefs, values and goals, and cannot be directly determined where the newborn is concerned. Parents are assumed to
have the best interests of their children at heart and to seek the best health care available for them. In agreeing to a course of action involving their child, they cannot be assumed to know for certain what their newborn would consent to were he or she able, and at best can give only 'informed permission' to any intervention. Informed parental permission will usually coincide with what others agree to be in 'the best interests of the child', although this can be difficult to define with the many social, religious, philosophical and cultural ideas about what constitutes acceptable child rearing and welfare. Whereas parents might not always appear to fulfil their obligations to their children, the law generally tolerates a wide range of approaches to parenting.

Even accepting that 'informed parental permission' is the nearest we can come to truly informed patient consent, there are problems in the newborn period and, as with informed consent, these involve the information given, assessment of understanding and competence, and voluntariness.

Obtaining informed consent

Who should do it?

The status of the health professional charged with obtaining ‘informed consent’ will vary depending on the nature of the intervention. A phlebotomist on an intensive care unit might ask the mother at the cotside for permission to take a heel-prick blood sample whereas a senior surgeon would be involved when an infant is to be operated on for correction of a diaphragmatic hernia. Good practice requires that any member of staff involved in obtaining consent should have at least had training in the basic process involved. In most cases, this will be provided during staff induction during the first week in post, and include understanding of the need for patient autonomy, how to give information about risks and benefits clearly, and how to assess patient competence. It is important that it is made clear at what level consent is obtained for each possible intervention, from implied for, say, a change in ventilator settings, to verbal for administration of vitamin K, to written for a major surgical intervention.

It should be made clear during training that, as a rule, no one should be involved in the process of obtaining informed consent unless they are able to undertake the intervention themselves, or have received specific training in obtaining consent for certain procedures. This is to ensure that the individual is able to convey with appropriate balance the benefits and risks of the procedure, and to be aware of their frequency.

When should consent be obtained?

The timing of an approach to a parent can be crucial, and involve judgements about psychological distress, understanding and competence. Parents, and particularly the infant’s mother, might have their judgement and capacity clouded by pain, the influence of pain-relieving drugs, or simply the distress of the birth of a sick child. As a result, consent to most or all of early intensive care procedures is usually presumed to be implied by the parents agreeing verbally to their child being admitted to an intensive care unit after birth. While it is clearly impractical, and probably needlessly distressful, to seek individualised informed consent for each procedure at the time, parental autonomy with regard to decision making about their child can be protected to some extent by an information-giving discussion with parents during early labour, or even a short tour around the intensive care unit prior to delivery. Unfortunately, such methods cannot help when the delivery is sudden or unexpectedly abnormal.

The timing issue can be more problematic with research interventions, when, in addition to information about the proposed intervention, the concept of randomisation also has to be explained. The subjects for research are usually sick preterm infants or acutely asphyxiated term infants, and the parental ability to take in information even more likely to be impaired. As a result, research into better methods of acute resuscitation and management of these infants is often not undertaken, resulting in a serious lack of a sound evidence-base for acute treatments.

Giving information

All consent requires information to be valid at whatever level of risk and however recorded. Minor and very low-risk procedures are usually considered to require ‘implied consent’ or ‘verbal consent’, and those with higher risk ‘written consent’. This does not reflect the need for information but more the likelihood the fact that the process actually took place will be challenged in future. Verbal consent for high-risk surgery is valid if obtained correctly but professionally unwise. Most neonatal departments have an advisory list for the level at which consent should be recorded (Table 1).

Staff are often unsure how much and what sort of information should be given to parents about
the intervention for which consent is being sought. Too little information might render any consent given invalid, yet too much could overwhelm them with unneeded information, or needlessly worry them. The information given should be sufficient to allow the reasonable parent to make an informed decision. It needs to outline the probable benefits of the intervention, whether there are real alternatives (including no intervention), and what is the likelihood of significant adverse consequences. Some groups have suggested that adverse events occurring more than 1% of the time need to be mentioned every time but in reality the severity and consequences of the complication determine its importance in decision making, together with the special circumstances of the individual patient. The latter is in practice less important in the newborn than in an adult as we do not know the likely occupation or interests of the patient in the future.

A further problem is the availability of the probabilities of occurrence of various complications and, even if these are published, whether the given figures are relevant to your patient. The risk of death from an exchange transfusion is usually given as around 1—2%, with a 10% risk of other unwanted side-effects. Such probabilities refer to risks several decades ago, when most exchanges were in sick newborns with Rhesus isoimmunisation; more recent data are lacking because far fewer exchanges are performed today. However, this means that even quite senior staff now have little practical exposure to the technique, which might increase the probability of adverse outcomes.

Parent information sheets with agreed information and assessment of risk where available are very useful in aiding staff to give useful information, but are usually available only for major procedures. For what procedures should such written information be available? Certainly it is a requirement that all research projects should have a Research Ethics Committee approved parent information sheet, and written consent outlining what has been given in terms of information and by whom. The situation is rather different when therapeutic procedures are considered to be 'routine'. Many centres do not seek explicitly informed consent for ventilation, total parenteral nutrition, exchange transfusion or for newer technologies such as high-frequency oscillation or nitric oxide therapy. A recent publication and the accompanying editorial3 castigated neonatologists for this, but seemed to ignore the fact that many of the interventions discussed were emergency procedures (e.g. insertion of a chest drain for pneumothorax) or that in reality there was no alternative treatment except non-treatment, which limited parental choice anyway.

Perhaps a more important difficulty is that most drugs used in neonatal medicine are not licensed to be used in the neonatal period, or are used 'off label', i.e. for purposes for which the drug is not licensed. This does not mean that the drug is not effective in the neonatal period but that the evidence-base for its use in infants is lacking or

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Type of consent</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exchange transfusion</td>
<td>Implied</td>
<td>Emergency procedure</td>
</tr>
<tr>
<td>Chest drain insertion</td>
<td>Implied</td>
<td>Emergency procedure</td>
</tr>
<tr>
<td>Umbilical catheter insertion</td>
<td>Implied</td>
<td>Emergency procedure</td>
</tr>
<tr>
<td>Mechanical ventilation, nitric oxide,</td>
<td>Implied</td>
<td>Emergency procedure</td>
</tr>
<tr>
<td>high-frequency ventilation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venous cannulation, venepuncture</td>
<td>Implied</td>
<td>Routine, low risk</td>
</tr>
<tr>
<td>Spinal tap</td>
<td>Implied</td>
<td>Routine, low risk</td>
</tr>
<tr>
<td>Cranial ultrasound scans</td>
<td>Implied</td>
<td>Routine, low risk</td>
</tr>
<tr>
<td>Constant positive airway pressure</td>
<td>Implied</td>
<td>Routine, low risk</td>
</tr>
<tr>
<td>Vitamin K administration (on unit)</td>
<td>Implied</td>
<td>Routine, low risk</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>Implied</td>
<td>Routine, low risk</td>
</tr>
<tr>
<td>Unlicensed medications</td>
<td>Implied</td>
<td>Information sheet</td>
</tr>
<tr>
<td>Peripheral arterial line</td>
<td>Implied</td>
<td>Routine, low risk</td>
</tr>
<tr>
<td>Central venous line insertion</td>
<td>Implied</td>
<td>Routine, low risk</td>
</tr>
<tr>
<td>Computerised tomography, magnetic resonance</td>
<td>Written</td>
<td>Written consent required for anaesthetic, otherwise considered low risk</td>
</tr>
<tr>
<td>venous line insertion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cranial ultrasound scans with sedation or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>anaesthetic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venous cannulation, venepuncture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spinal tap</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cranial ultrasound scans</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant positive airway pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin K administration (on unit)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood transfusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unlicensed medications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral arterial line</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central venous line insertion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Computerised tomography, magnetic resonance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>venous line insertion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cranial ultrasound scans with sedation or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>anaesthetic</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1  Typical procedures on a neonatal unit and type of consents obtained
inadequate. The same applies to therapies such as high-frequency oscillation, inhaled nitric oxide, and postnatal corticosteroids for chronic lung disease, each of which is often used outside the narrow areas for which evidence for their efficacy exists. Indeed, one observer described children in the NICU as being 'part of a large out-of-control experiment, which, as conducted, does little to increase knowledge or improve care'. Opinions differ as to how far one should go to obtain 'informed' consent in such cases. If little evidence exists, to what extent can 'information' be given to parents, apart from the fact that information is lacking? A policy that has proved useful for unlicensed drugs is to use a statement such as that provided by the Royal College of Paediatrics and Child Health outlining the reasons for their use on NICUs. A good information sheet (not more than one side of A4 paper), a witness not directly involved with the treatment or study, and the presence of a friend or family member are all helpful. Information should be given in small amounts, and understanding tested regularly by asking the parent to put what has been said in his or her own words. A signature to say that the parent understood what was said and what information was given is required for all moderate–high-risk therapies and all research interventions. Such a signature will be invalid if it can be later shown that the parent did not understand.

Understanding

Testing parental understanding is often not easy, especially for research projects. The idea of a randomised controlled trial (RCT) is often not truly understood by health professionals, let alone the general population. Parents might find it difficult to accept that the doctor or nurse is truly in equipoise, i.e. does not know the best course of treatment to follow. Many parents will wish to choose one or other of the alternatives offered, or to ask advice about which is best.

A good information sheet (not more than one side of A4 paper), a witness not directly involved with the treatment or study, and the presence of a friend or family member are all helpful. Information should be given in small amounts, and understanding tested regularly by asking the parent to put what has been said in his or her own words. A signature to say that the parent understood what was said and what information was given is required for all moderate–high-risk therapies and all research interventions. Such a signature will be invalid if it can be later shown that the parent did not understand.

Parental competence

Competence to make a decision is also difficult to assess. Generally, if a parent is socially independent, then, with suitable information and time to absorb it, cognition should be adequate. Where the parent’s first language is not the same as the health professional’s, greater care needs to be taken to test understanding, or a trained interpreter should be used. It is usually better not to use family members as interpreters because they might have their own agendas. A greater problem exists when the parent (usually the mother) seems incompetent because of fear, pain or the effects of opiate drugs around the time of delivery. If the decision can be delayed, then this is the best policy. If a decision is needed immediately, then this is best considered ‘emergency treatment’, when the health professional must make a decision based on 'the child’s best interests'. Information about the need and effects of the intervention must be conveyed to the parent as soon as conditions permit.

‘Common law’ marriage has no legal status in the UK and in as many as 50% of cases, only the mother can give consent for the child because she is not legally married to the child’s father. If, however, the child’s natural father registers himself as the child’s father when the birth is being registered, he can act as the child’s legal father when consent is needed. This is not as useful in the newborn as at first it might seem because many infants are not registered for days or even weeks after their birth. The only others who can give consent are legal guardians, or the courts if the child is made a ward of court. Other relatives, such as grandparents or elder siblings, cannot give consent.

Freedom to choose

Voluntariness — real freedom to exercise choice without external pressure — can be difficult to preserve. Health professionals’ enthusiasm for a particular line of treatment, or a researcher’s passion for his or her project, can influence information giving and place pressures on a parent to make a particular decision. Pressure can also be placed on a parent through a wish to please the health professional, or to ensure that the child has priority in treatment. The best defence of voluntariness is to ensure that, wherever possible, parents are given time to consider information, the decision is made away from the clinical area, and that friends or relatives are also involved.

Consent for research

Added concerns

Whereas consent for involvement in research or for therapy is regulated by similar principles, there
are added considerations where research is involved. Concerns are around the possibility of obtaining truly informed consent for RCTs, and whether this is 'ritual' in practice, and around the possibility of obtaining consent in emergency situations. Arguments that have been raised against full informed consent in neonatal research include causing distress by disclosing more information than usual on a child's future risks or prognosis, and undermining parental confidence in the medical practitioner when 'equipoise' is explained. In many research projects, the risks to the child are minimal and include only collecting extra blood, a urine sample or some already-recorded clinical data. Explaining the whole project and why it is being done might increase anxiety needlessly. In some studies of parental responses or beliefs, knowing that they are part of a research project can bias results. One could argue that we all benefit from advances in medical knowledge from past research, and so all have a duty to contribute to future knowledge by taking part in research today. Increasing acknowledgement of parent autonomy makes these objections more difficult to sustain.

A modified consent procedure has been tried for neonatal projects involving low risk, such as those comparing different approaches to delivering primary care to preterm infants after discharge from hospital. Mothers were seen soon after birth and were offered either the standard information leaflet and a conventional consent form, which included a non-compensation statement and a detailed list of patient's rights, or the information leaflet alone. The group receiving the conventional consent form designed for higher-risk trials had to sign if they consented to joining the study, whereas the other group simply signed a form if they wished to opt out of the study. There was equal maternal satisfaction between the two groups but the simplified procedure resulted in greater recall of the study purpose and methods.

Perhaps the greatest difficulty with parental informed consent in the newborn period comes when consent is required for trials of emergency treatments, a common problem in all intensive care medicine. There simply is not adequate time for the usual information giving and consideration, yet this is the area of neonatal practice most in need of scientific evaluation, and where non-evidence-based treatments have the greatest potential for harm. Where attempts have been made to follow best practice in obtaining consent in these situations the results have been less than successful. Recent studies have shown that in many cases parents had little idea what the trial involved or how their child was treated, when interviewed a year later. This was even when the parent information and consent arrangements were considered exemplary.

Parents and consent for research

What determines whether parents agree to let their infant take part in clinical research? Recent studies suggest the parental perception of the balance of risk and benefit, their personal beliefs about the role of research, and the integrity of the consent process. The importance of the perceived balance of risk and benefit is interesting, particularly where clinical trials are concerned because it will have been explained that the researchers will be in equipoise. Of further interest was that a 3rd of parents interviewed would have preferred their physician to decide for them, or at least give a strong steer.

There have been a number of ways in which researchers have tried to overcome the difficulties outlined. Zelen randomisation is a process by which children are randomised before consent is sought. Consent is then sought only for those who are to receive the new intervention, the controls receiving current management. This process reduces the amount of information that needs to be given and the problem of information overload. The parents of controls will not know that their infant is not to receive the new treatment. In a study to assess parents' attitude to such a process, they were evenly divided as to whether they found it acceptable. Those whose children had been allocated to the control arm were more likely to reject the process. Objections were raised to the use of clinical data without parental knowledge, and parents felt that finding out about the study much later would have an adverse impact on them. This method has rarely been adopted in practice.

Various methods for advanced consent have been put forward, or tried, to overcome the problem of obtaining valid consent for research in emergency situations. An opt-out from studies at the obstetric booking clinic would identify those who would not wish to be included under any circumstances. The amount of information that could be usefully given would be limited, and parental interest probably minimal if the project was not likely to be relevant to their child. Alternatively, high-risk patients could be selected in advance, but this might alarm parents unnecessarily. Consent during labour, especially preterm labour, has been used, but criticised strongly by patients' groups. As with therapy, the validity of consent under the effects of opioids and the pain
and distress of labour must be questionable. Exception from consent at the time, but later disclosure and a process of ‘continuing consent’, i.e. daily discussions about the study with parents, has been proposed as a better way forward with suitable controls.

**Exception from informed consent**

Regulatory bodies in the USA have developed a Code for Exception from Informed Consent Requirements for Emergency Research. This has not been accepted in many States to date. It requires the study to be an interventional study in an otherwise life-threatening condition for which the present treatment is unsatisfactory. Treatment must be needed before consent can be obtained and there should be a prospect of direct benefit to the patient. The patient (parent?) should not have indicated an unwillingness to take part at any time previously. A therapeutic window must be specified, and how much of that window might practically be used to obtain consent. The process has to be controlled by an Institutional Review Board and regular reporting to them and to the Food and Drugs Agency must be carried out. The local community must be involved in consultation before and after the research has been done. All attempts to obtain consent must be recorded and patients (parents?) can withdraw later or agree to continue. The process has rarely been used in the newborn period, although a good example is Wiswell et al. who conducted an RCT of universal intubation and suctioning versus a selective approach in the meconium-stained neonate at birth. A similar but less rigorous approach was used for the Resair-2 study, which compared resuscitation at birth with air or oxygen in 11 centres in six countries. No advance consent was obtained, although the project was approved by local research review committees and ‘parents were informed later’. Fortunately, the non-use of oxygen proved beneficial.

**Some special circumstances**

The general points already made about parental involvement in the consent process in neonatal practice might need some modification in certain circumstances such as screening, withdrawal of intensive care, and circumcision in boys.

**Screening**

Newborn screening for a range of genetic and metabolic diseases has been carried out around the world for several decades. In most cases, the procedures are mandated by law and parental consent for collecting and testing of blood samples is not required; at best implied consent is obtained. Should improvements be made in the consent procedures for newborn screening? For a screening programme to be acceptable, it is usually required that an effective test should be available and that early management should improve the eventual prognosis. Recent qualitative research has indicated that parents in a wide range of racial groups were in favour of mandatory newborn screening for treatable conditions, and also supported access to predictive genetic testing for childhood-onset conditions even when there are no proven treatments. They felt that this information should be available to enable them to make reproductive and non-reproductive plans and decisions. Ethicists and public health doctors have also concluded that parents should be able to opt for predictive testing of their children, but that this should not be state-sponsored if the conditions do not fulfil the usual public health screening criteria. Although implied consent is felt appropriate for ‘traditional’ neonatal screening, written informed consent is recommended for all other screening. In Germany, with the introduction of mass-spectrometry screening for metabolic disorders, written informed parental consent was sought, and a very high level of compliance achieved. Screening was refused by only 0.1% of the target population. With the increasing availability of such techniques, serious thought must be given as to how appropriate information can be given to parents about the implications of their consenting to their child being screened for a large number of differing disorders in the neonatal period.

**Withdrawal of intensive care**

In the UK and many other countries, the courts have long accepted that it is lawful to withdraw medical treatment ‘when the quality of life the child would have to endure if given the treatment would be so afflicted as to be intolerable to that child’. There is no obligation to give treatments that can be shown to be futile. When the patient is a newborn child, the decision as to when such a point has been reached can be resolved only by discussions between the healthcare team and the child’s parents, which need to be both open and timely. When there is an agreement, it is not too difficult to accept that the child’s best interests are being served. When there is no agreement, the doctor or health team is in a difficult position.
A doctor who continues to treat an infant when the parents do not wish it could be said to be acting against the child’s best interests if there is room for reasonable doubt about the likely benefits of that treatment. Resort to the courts in England and Wales might result in a treatment being prohibited or authorised if considered to be in the patient’s interests, although a doctor cannot be forced to perform a specific intervention. In Scotland, the courts have little authority to sanction treatment decisions in advance.

In almost all cases, if the parents and healthcare team are openly and fully informed of the circumstances, consensus about such decisions will be achieved. Apparent dissent often stems from misunderstandings or a fear of making final decisions, rather than open opposition. Further discussion, the involvement of family or religious advisors and adequate time will usually defuse disagreements. The use of ‘second opinions’ is also recommended but doctors should be alert to the fact that it is easy for them to invite such an opinion that will reflect their own ideas. In some centres, particularly in North America, hospitals will have an Intensive Care Review Committee, which can assist in such situations by providing a neutral and an independent opinion.

Although the final decision on how to proceed must be that of the doctor in charge, the parents must feel that their opinions have been taken into account and respected. However, consulting parents might make them feel that they are being asked to make a final decision about their infant’s life on their own, and it should be emphasised that — ultimately — it is the physician who is acting on their advice. This might help to relieve the guilt that some parents feel later about their actions, although studies carried out over two decades show that parents are more likely to have fewer residual problems if they take part in such decision making. It is important that the thinking behind the decision to discontinue intensive care is clearly recorded in the case record. It is not usual to get parents to sign consent to discontinuation of treatment but their signature, and that of anyone else involved, after the entry in the case record has been suggested as good practice.

Male circumcision

Circumcision of male babies at the request of their parents is an increasingly controversial area, particularly when the procedure is non-therapeutic. Most paediatric surgeons maintain that there is rarely a clinical indication for circumcision, although many medical arguments are put forward for why circumcision has health-promoting (reduction in penile cancer and HIV infection) or health-reducing (reduction in penile sensitivity and sexual satisfaction) effects. Inexpertly performed, circumcision can certainly cause permanent injury. In the past, however, it was considered to be medically and/or socially beneficial, or at least neutral in its effect. Organisations such as the British Medical Association have advised their members that they should in such cases ‘act in the best interests of the child’ but that it is the parents who have the responsibility to demonstrate what was in the child’s best interest. Certainly, the law in the UK permits non-therapeutic circumcision. Arguments about the social and cultural background of the child are not particularly helpful because they are similar to those used to justify harmful cultural procedures, such as female genital mutilation and ritual scarification. Any decisions about non-therapeutic circumcision, then, are for the parents to make, although the doctor involved must try to put the balance of risks and benefits to them and need not perform a procedure with which he or she disagrees. With a non-therapeutic procedure, the duty to refer on in such circumstances to another practitioner is unclear. Both parents should agree about the procedure and, in cases of disagreement, the courts need to be consulted. In the few cases that have come to court, the decision has usually been not to circumcise.

International variations in practice

Understandably, policies and practice concerning the involvement of parents in making decisions affecting their infants vary between countries. A recent study of practices in Europe showed this clearly in cases in which decisions about discontinuation of intensive care was concerned. In 89% of units in the UK, parents were involved in such decisions to some degree, although this figure was lower in all other countries reported and 0% in France. In the latter case it was stated parental views were ‘taken into account’. Reasons given for low participation were ‘the psychological state of the parents, their lack of medical knowledge and a wish to protect them from difficult choices and later feelings of guilt’. Countries’ attitudes to this and other policies in the neonatal unit appeared to relate to whether their traditions were ‘Anglo-Saxon’, with a traditionally greater importance placed on personal autonomy. North American attitudes are seen to be broadly similar, and based on Protestant ethics.
A similar study in nine European countries looked at the processes of obtaining parental informed consent in newborn research that led to valid consent being obtained.\textsuperscript{26} Interviews about their experiences were conducted with parents and clinicians who had been involved in giving or obtaining consent. In 70% of cases, one or more problems were identified. When parental competence was assessed, 60% parents were judged to be competent, although 74% clinicians felt that parents were not fully competent when they consented. Information giving was considered not to be a problem by 48% of parents but 80% of the clinicians; 21% of parents thought that they could not withdraw their child from a study after it started and few were neither aware that research ethics committees existed nor understood their role. Opinions varied amongst parents and clinicians about the extent of information that should be given; 10% of parents reported a problem with voluntariness, compared with 55% of clinicians. In all areas, consent was more likely to be invalid if emergency treatment was the focus of the study.

The study concluded that researchers should receive specific training in seeking informed consent; that clinicians should not be over-reliant on information sheets because half of the parents did not use them in deciding whether to take part; and that information about the function of research ethics committees should be available. Parents found that fully informed consent was a burden but few found it unnecessary. Whether the need for consent impeded important research remained unclear but in the light of the importance parents placed on being involved, a very strong argument would be needed to avoid it.

**Practice points**
- Parental informed consent is needed to protect the child, not the health professional
- Appropriate training and knowledge on behalf of the professional seeking consent is essential
- Research into emergency treatments presents special problems in obtaining timely informed consent
- Wide international variations occur in the degree to which parents are involved in ethical decisions

**Research directions**
- The amount of information wanted by parents and the degree of involvement desired in choosing neonatal therapies
- An agreed approach to consent for research into emergency treatments
- Better understanding of best practice for conveying necessary information to parents to aid decision making

**References**
16. Saugstad OD, Rootweil T, Aalen O. Resuscitation of asphyxiated newborn infants with room air or oxygen: an


