Ethical considerations in neonatal end-of-life care

Vic Larcher

Great Ormond Street Hospital, Great Ormond Street, London WC1N 3JH, UK

Keywords: Best interests Double effect End-of-life care Ethics Neonates Organ donation

SUMMARY

Decisions regarding the end-of-life care of neonates, especially those at the limits of viability, cannot be made on the basis of clinical facts alone. They should take into account the values and beliefs of all concerned. Application of classical moral theories may take insufficient account of the interests of small babies. Due consideration needs to be given to the value and quality of babies' lives, their best interests, and the interests of their parents in practical decision-making. Life-sustaining treatments can be withheld or withdrawn if they no longer serve the baby's best interests, but active euthanasia (though an acceptable practice in The Netherlands) remains illegal in the UK. Withdrawal of clinically assisted nutrition and hydration can be ethical but remains controversial. If organ donation in UK neonates is to become established it will need to respond to the changing characteristics of neonatal deaths in ways that are ethically and socially sensitive.

© 2012 Elsevier Ltd. All rights reserved.

1. Introduction

This article will focus on the ethical considerations that underpin the care of babies born at the limits of viability, but many of the principles can be applied to others with life-limiting conditions, whatever their gestation. Detailed longitudinal studies have defined survival and neurodevelopmental outcomes for extremely preterm babies, whereas others have elucidated the emotional, psychosocial and economic costs to families and society. However, uncertainties over the outcome for individual babies remain. Decisions about the treatment and care of babies cannot be made solely on the basis of the clinical facts or scientific evidence. They should also take account of the values and beliefs of all those concerned and must be made within society's existing legal framework.

1.1. Basic moral considerations

A rational ethical approach to practical clinical decision-making has parallels with evidence-based medicine. It seeks clarity over the use of terms, e.g. quality of life and best interests, and requires consistency in the application of moral values. Any proposed framework for decision-making should be examined for its coherence with appropriate value systems that can be expressed as moral theories and principles which are briefly outlined below and which can be applied to determine the moral acceptance of actions.

1.2. Consequentialist theories

Consequentialist theories (of which utilitarianism is a form) are concerned with the reasonably foreseeable consequences of an action on those involved, rather than the intentions behind it. An action is morally correct if it maximises welfare or individual preferences or happiness of those involved — 'the greatest good for the greatest number'. Formal calculation of risks and benefits is necessary, but this is compatible with reflective, evidence-based, clinical practice. Although outcomes for relevant individuals are important, no individual is of greater moral worth than another, which presents difficulties in circumstances where there are strong emotional attachments between individuals, e.g. parents and children.

1.3. Deontological theories

Deontological theories are concerned with duty; to be moral is to do one's duty, or intend to do it, regardless of the consequences. This involves obeying moral rules that are universal, unconditional and imperative. Four principles (beneficence, non-maleficence, respect for autonomy and justice) can be derived from deontological considerations and establish prima facie duties, i.e. those that, other things being equal, we ought to fulfil.
Moral individuals require certain characteristics/abilities (rationality, self-determination, autonomy) to formulate and carry out life plans in accordance with relevant moral rules and values. They have intrinsic value and are worthy of respect; but it does not necessarily follow that individuals who lack these characteristics, e.g. extremely young children, have no intrinsic value.

1.4. Rights-based theories

Rights are justifiable moral claims made by or on behalf of individuals; they confer duties (to act, or to forebear) on others. Positive rights, e.g. the right to healthcare, require action by others. Negative (‘natural’ or ‘liberty’) rights entail an obligation by others not to infringe them; they usually take precedence over positive rights. Rights may not be absolute or unconditional and can (in law) be infringed if it is proportionate to do so.

Some rights can appear to conflict, e.g. the right to life versus freedom from inhuman and degrading treatment. Rights claimed by various parties in clinical situations (children/professionals/parents) may constrain each other and it is not clear whose rights take precedence, especially when individuals may be unable to claim rights for themselves, e.g. preterm babies.

1.5. Virtue-based theories

In virtue-based ethics an action is right if it is performed by a virtuous person, for the right reasons; the focus is on the moral character of the person whose act it is. Whereas virtue ethics may shape expectations of professional behaviours towards others, it does not directly provide solutions to the difficulties encountered in daily practice. It does not clarify the moral status of small babies, but in this it is hardly unique.

2. Practical applications

Simply applying moral theories to practical dilemmas will not resolve sincerely held differences in moral beliefs and values held by individuals, e.g. parents and professionals. In some cases application of any of the types of moral theory will enable the same judgement of the rights or wrongness of an action to be reached, e.g. resuscitation of babies, albeit for different reasons. In other cases application of moral theories may lead to different and incompatible moral judgements, e.g. over the withdrawal of fluids and nutrition in end-of-life care.

Therefore complete unanimity on issues of fundamental moral concern such as resuscitation or the limitation of treatment is unlikely, especially when outcomes are uncertain. But this does not remove the desirability of seeking pragmatic agreement on a course of action even if there is underlying disagreement about the moral reasons for doing so.

Ethical analysis may assist this process by reducing ambiguity and confusion over terms used and seeking rational reasons for beliefs and values held. It can therefore lead to a shift in views and more coherent judgements.

2.1. The value of life of small babies

Moral theories are primarily concerned with sentient rational beings (rather than babies), the value that their life has and how they should behave towards each other. If the lives of babies do not have the same value as those of adults there are important moral and practical consequencs.

One approach regards all human life as sacred because all human beings are of the same intrinsic value and should be treated with equal respect. Hence any action that shortens life is wrong and life-sustaining treatment (LST) should never be limited or withdrawn. But the sanctity-of-life principle, though important, may not be absolute and it may not be imperative to sustain life at any cost. When the quantity of life is severely limited and death is imminent and inevitable, there may be no obligation to continue LST to the very moment of death. This would apply as much to babies as it does to adults.

An alternative approach is to consider whether life has limited value because certain qualities are lacking or diminished. The latter include the ability for active self-development, a sense of happiness or wellbeing and a capacity for meaningful social interaction. These are difficult concepts to define for adults and it is difficult to know what ‘quality’ means for an extremely preterm baby whose ability to perceive the world and react to it is, and may always be, limited. There are no absolute measures of quality on which all can agree. Surrogate decision-making on behalf of babies is fraught with significant ‘assessment errors’ regarding the baby’s current and future quality of life and suffering, as such assessments inevitably convey the surrogate’s own projected feelings about the baby’s situation.

2.2. The moral status of babies and commencement of life

If life has intrinsic value, the time at which it begins (and which individuals acquire moral status) has implications for how embryos, fetuses and babies are treated. An absolutist position might hold that life begins at conception. A gradualist position would accord increasing moral status to the developing embryo/fetus/baby. Thus greater justification would be required for potentially harmful actions involving babies than it would for those involving embryos or fetuses. Although philosophically attractive, this does pose difficulties in how we develop ethical and legal definitions that are of practical value in the management of those born at the threshold of viability. The Nuffield Council on Bioethics has endorsed birth as the crucial legal and moral threshold; once ‘born alive’, a newborn baby has the same legal status and entitlement to respect as older children or adults. This raises further questions as to what being ‘born alive’ means in the current environment of high technology medicine and what implications flow from it.

2.3. Best interests

The principle of best interests is regarded as fundamental to good medical practice. It entails two, sometimes conflicting, moral duties.

The first duty is to respect patients’ life and health by preserving life, restoring health and preventing disease; and to do so to an acceptable standard, fairly and justly. Any proposed treatment should confer maximum benefit and produce minimal harm. Analysis of harms and benefits should include not only clinical outcomes but also emotional, psychological and social consequences for patients and their families.

The second duty is to respect patients’ autonomy by respecting their right to make as many informed, freely determined choices as they are capable of, and respecting their known or ascertainable wishes, beliefs, preferences and values.

A precise definition of best interests is difficult; most legal and professional guidelines therefore list the factors that should be taken into account when considering them.

Babies can neither directly define their own best interests nor actively participate in decision-making, so questions remain as to how and by whom their best interests are to be determined. Determinations of best interests for babies include consideration of their physical and emotional needs (and the family’s ability to meet...
them) and the obligation to select options that least restrict future choices.

Guidelines on critical care decisions stress the fundamental moral obligation to provide treatments that are in the best interests of all patients. Most have rejected other concepts, e.g. intolerability, as primary considerations in deciding whether to limit LST. But it is permissible to withhold or withdraw treatments that are no longer in a neonate’s best interests, because of the unreasonable or intolerable burdens that they involve. The current RCPCH guidance outlines five circumstances in which further LST could be regarded as not in the baby’s best interests. Essentially they comprise situations in which: the treatment cannot achieve its desired objective and where death is imminent or inevitable; treatment is possible but the burdens of the disease and/or its treatment outweigh possible benefits; and where the child and his family feel that more treatment is more than they can reasonably bear.

2.4. Parental interests and role in determining best interests

Parents have ethical and legal authority to make decisions for babies provided they act in their best interests. Normally professionals and parents act in partnership to determine a baby’s best interests and how they are to be met. Society accepts that parents, because of their special relationship with their baby, will normally be best placed to determine which course of action will best promote his/her interests.

Parental considerations of a baby’s best interests are likely to be determined by their own medical history, psychosocial circumstances and moral framework. Their religious beliefs, political and cultural attitudes, family and peer pressures, neighbours, life experiences and outside influences (e.g. media reports) all shape their collective value judgement systems. Difference between parental and professional value systems can be further compounded by power imbalance inherent in the professional—parent relationship.

Nevertheless it is usually appropriate to give significant weight to the interests of parents (because they are so intimately related to the baby’s) unless to do so would be harmful to the baby. Therefore paediatricians increasingly use an approach that considers total family welfare rather than the best interests of an individual. This does not mean that parental views will necessarily determine outcomes, especially when there are serious concerns over possible harms to the baby if parental views prevail.

2.5. Management of babies at limits of viability at the time of birth

If extremely preterm birth is likely, it would be regarded as good practice to agree a management plan for the baby’s birth. This would involve a detailed assessment of obstetric history and of the likelihood of the baby being born alive. The plan should take into account likely prognosis, treatment options and parental wishes: it would help clarify postnatal options if parental capacity to make choices were compromised by circumstance.

Whether a baby is born alive and acquires moral status depends on gestational age, birth weight and absence of other abnormalities that might compromise survival. Babies of less than 23 weeks of gestation are conventionally considered non-viable because their response to resuscitation and neonatal intensive care is so poor. The term ‘limit of viability’ refers to the gestational age at which 50% of babies survive to discharge from hospital; in the UK this is currently 25 weeks. It would be considered good practice to offer resuscitation and intensive care to babies who are above this limit.

Between 23 and 25 weeks of gestation is a ‘grey zone’ where practice varies according to the values of those concerned. In countries where great emphasis is placed on sanctity of life, resuscitation and intensive care are offered from 23 weeks onwards, e.g. Italy. If the paramount considerations are a child’s future interests or quality of life, the balance may be in favour of non-resuscitation or early withdrawal of LST, e.g. The Netherlands. Others adopt a more gradualist approach, broadly in keeping with the view that the baby’s moral status increases with gestation. Even so, current UK guidance on management of preterm babies places differing emphasis on the respective roles of parents and professionals in determining what treatment is in the best interests of a baby of 23 weeks’ confirmed gestation. Guidance from the British Association of Perinatal Medicine would regard a decision not to start resuscitation as usually being in the best interests of such a baby, especially if parents were of the same view. If parents wanted ‘everything done’ the implementation of intensive care would be dependent on the baby’s response to simple lung inflation and assessment by an experienced clinician. By contrast, the Nuffield Council on Bioethics lays greater emphasis on the views of parents being determinative in this situation.

In the UK parents have a significant but not determinative role in decision-making, but this may not be so in other European countries, e.g. France, where paediatricians have previously had major decision-making roles.

3. Withholding and withdrawing life-sustaining treatments (LSTs)

It is conventional to regard withholding or withdrawal of LSTs as ethically equivalent. Hence it is permissible to withdraw a treatment a patient is receiving, if it would have been permissible to withhold the same treatment (if not already provided) and vice versa. Many jurisdictions accept the equivalence thesis, but not all professionals do so. Surveys of professionals have shown that only 20–54% believe that withholding and withdrawing LSTs are morally equivalent. This standpoint has problems, especially if there are no relevant differences between the intentions of doctors, the outcomes for patients or the mode of death that pertain to either. Nevertheless thresholds for withholding treatments may be set higher than those for withholding them. A practical consequence is that some babies might benefit from the withholding of a certain treatment because of fear that it would be harder to withdraw it later. Conversely, continuing treatment that has marginal benefit for some babies may mean that others who could benefit to a greater extent might not be able to access it. A higher withdrawal threshold has potential advantages in enabling diagnostic and prognostic uncertainties to be resolved, but, if prognostic facts are identical, there seems no reason to prefer withdrawal to withholding.

Reasons for professional attitudes may reflect: a general tendency to favour the status quo (continue treatment); a widespread belief in the distinction between acts and omissions (even when the outcome, e.g. death, is the same); and factual differences (in terms of prognosis) between those in whom treatment is withdrawn and those in whom it is withheld. Although a baby has strong prior moral claim to continue existing treatment, this may not be absolute when resources are limited and others may have an equal need and better prognosis. This notion is morally disquieting because it involves...
discriminating between babies on the basis of prognosis. Such choices, though regularly made in triage of casualties, are more difficult when professionals have established a relationship with babies and their parents, and are aware of the prejudices, preferences and values of all parties are concerned. Moral and emotional disquiet will be intensified if all concerned feel that such decisions are driven by economic considerations. Some professionals fear that increasing acceptance of moral arguments for withdrawal of treatment might lead to a situation in which assisted dying becomes acceptable (see below).

Furthermore professionals may prefer withholding treatments to withdrawing them because withholding decisions may not involve difficult conversations with parents or request the latter's formal consent to the extent that withdrawal does. This is morally problematic since all clinical decision-making requires transparency, openness and accountability.

Practical implementation of the equivalence thesis in the care of small babies remains difficult.26 One option is to reduce the mortality threshold for considering treatment withdrawal so that it more equates to that for considering withholding treatment. A second is to consider time-limited trials of treatments when babies might be offered evidence-based treatment for a defined time with the understanding that this could be withdrawn unless there was a definite response.

4. Palliative care and the principle of double effect (PDE)

Palliative care of neonates from whom LST is withdrawn or withheld is morally justified because its intention is to provide comfort and relieve pain and suffering. Opiates and anxiolytics are used to achieve this end but can also shorten life, a practice that is justifiable by application of the principle of double effect (PDE). According to the PDE, an action that has two possible outcomes — one good, the other bad — may be permissible provided that the bad outcome, though foreseen, is not intended and is proportionate, whereas the good outcome is the intended one.8,27,28

PDE requires there to be a moral distinction between intending an outcome and foreseeing it. Critics of PDE have questioned whether such a distinction exists, and, if it does, whether it is sufficient to permit such an act or exonerate a person who carries it out. PDE does not sanction acts in which both the good and bad outcomes are intended. Defenders of PDE have argued that foreseeing an outcome, e.g. death, but not intending it are different, since actions and intentions are experientially, conceptually and legally different.29 Such actions can be defended by appeal to deontology (a fundamental duty to relieve pain and suffering exists irrespective of its consequences) or utility (relief of pain is morally acceptable because it has better consequences, irrespective of its intentions).

Application of the PDE and of best interests justifies the use of analgesics and anxiolytics in end-of-life care. More problematic is the use of muscle relaxants (MRs), which are used to facilitate mechanical ventilation but do not provide sedation, analgesia or reduce anxiety.

MRs have been used after withdrawal of mechanical ventilation to treat or prevent terminal gasping, a common and distressing symptom in dying infants. Some argue that use of MRs to treat terminal gasping is ethically justifiable because the intention is to relieve any pain and suffering rather than a desire to end life.30 But if terminal gasping is associated with distress, MRs will mask any underlying symptoms of respiratory distress without treating it, while giving the appearance of a peaceful death to observers. They will also lead to lack of respiratory effort and rapid death, and their use can be interpreted as an intention by medical staff to hasten death.

Whereas there is general agreement that MRs should not be commenced before extubation, opinion remains divided as to whether it is necessary or desirable to complete weaning of MRs (where their use is established before a decision to withdraw treatment is made) in all cases before ventilation is withdrawn. Effective management of the process, using established palliative care techniques such as gradual weaning from the ventilator, adequate sedation, and use of short acting benzodiazepines (e.g. midazolam), is likely to lessen the risk of terminal gasping.

4.1. Practice in other countries: the Groningen protocol30

Administration of a drug or treatment with the deliberate intention of causing death — thereby providing the ultimate relief from pain and suffering (active euthanasia) — is illegal in the UK. This is consistent with the importance attached to the principle of the sanctity of life in UK Law. But some feel this position is morally inconsistent with the values of a society that sanctions the withholding or withdrawal of LST, even if death follows.

In The Netherlands active euthanasia has been legal since 1985 for those aged >16 years who are competent to request it. Parents of newborns cannot request euthanasia on behalf of their baby; any case must be reported to the legal authorities for appropriate clinical and procedural scrutiny. But surveys of Dutch neonatologists have suggested that a significant number of cases of euthanasia were not reported. In order to prevent underreporting and provide transparency and accountability for euthanasia, a protocol (the Groningen protocol) for management of cases was developed. Obligatory medical requirements are:

1. diagnosis and prognosis certain;
2. presence of hopeless and unbearable suffering;
3. independent confirmation of 1 and 2 by independent doctor(s);
4. informed consent of both parents;
5. procedure to be performed in accord with accepted medical standard.

Detailed information under the above headings is required to clarify the decision-making and consultation process, the procedures undertaken and inform the independent legal assessment.

The protocol was developed to meet the specific needs of The Netherlands. It is not clear to what extent it might be applied in other settings, especially those where assisted dying for adults remains illegal.

5. Administration of food and fluids during neonatal palliative care

Providing adequate nutrition and hydration fulfils basic human needs and has strong emotional and socio-anthropological connotations. Although small babies cannot feed themselves, giving them food by mouth is considered part of basic care and should be provided for those who can tolerate it and those who appear hungry and thirsty.31,32

Babies at borderline viability and others with acute or chronic medical conditions are unable to tolerate oral intake and require clinically assisted nutrition and hydration (CANH). This is usually provided by the intestinal route (via tube or PEG) or in some cases by the intravenous route. Even where there is agreement that palliative care rather than LST should be administered, there remains debate as to whether it is ethical to withdraw or withdraw CANH.

Some regard tube-feeding in these circumstances as basic care that cannot be withdrawn, even if other forms of LST are withdrawn, because of the risk of hunger and thirst adding to the baby's
pain and suffering. The extent to which this occurs in adult or neonatal practice is disputed.

However, most published guidance on the provision of CANH in end-of-life settings regards it as medical treatment. Legal support for this view is largely limited to such adult cases that have come to court. These have to be interpreted in their individual circumstances, e.g. adults in persistent vegetative states, but there is general consensus that the same principles apply to paediatric practice.

CANH can be used for symptom relief and may increase the quality of life, but it carries risks and burdens. It may produce pain and suffering by prolonging the dying process, especially when it cannot be tolerated, e.g. in intestinal failure, or when it cannot alleviate the baby’s underlying medical condition, e.g. renal agenesis, severe congenital heart disease. The role and purpose of CANH should therefore be considered very carefully. Separate assessment of a child’s fluid and nutrition needs should take place alongside assessment of their clinical condition and prognosis.

Because CANH is an LST, it may be withheld or withdrawn in the same circumstances and for the same reasons as other forms of LST. It may for example be inappropriate to provide CANH in a baby who is unlikely to develop self-awareness or capacity for meaningful social interaction.

Although withholding or withdrawing of CANH may be morally permissible it is not obligatory. Moreover no specific UK statute or case law governs the provision of CANH in babies or children, although there is no legal obligation to provide it in those who are close to death.

Decisions concerning use of CANH in palliative care should be based on whether it provides overall benefit to the child. Justifying withholding or withdrawing CANH is a matter for individual agreement rather than policy implementation. Parents should be fully involved in the decision-making process, understand the likely outcomes and receive appropriate spiritual and emotional support. It is important that comprehensive palliative care measures for the child, including appropriate sedation and oral hygiene, are in place.

6. Organ donation

Most neonatal deaths occur in intensive care settings and an increasing proportion of deaths occur after withdrawal of treatments. This is particularly important in considering how the sensitive question of neonatal organ donation might be approached.

Transplantation of vital organs is a well-established treatment for acute or chronic severe organ failure. Although the number of neonates requiring organs is small, problems of insufficient donor organs are compounded by the application of brain death criteria and by concerns about increasing use of donation after circulatory death.

6.1. Dead donation and definitional aspects of death in children

Potential organ donors must be declared dead before donation can occur (the ‘dead donor rule’). UK criteria for the diagnosis of death following (i) irreversible cessation of brainstem function and (ii) cessation of cardiorespiratory function have been developed. However, the need for procedural consensus over definition and confirmation of death in neonates remains.

6.2. Donation after brain death (DBD)

The most viable organs for transplant are retrieved from heart-beating donors in whom neurological death has been certified following irreversible cessation of brainstem function (e.g. UK, Canada and Australia) or after whole-brain death (e.g. France, USA).

However, current UK guidelines state: ‘Between thirty-seven weeks of gestation and two months of age, it is rarely possible confidently to diagnose death as a result of cessation of brain-stem reflexes and below thirty-seven weeks of gestation the criteria to establish this cannot be applied.’

The USA, Australia, Canada and many European countries accept the concept of brain death in infants and hence the possibility of organ donation. This means that UK infants in the above age range can receive hearts donated from infants in other European countries, but cannot donate if brain-death criteria are applied. Some up-to-date justification for current UK practice seems necessary.

6.3. Donation after circulatory death (DCD)

Shortage of organs for transplantation has led to a resurgence of interest in DCD, in which organs are retrieved following circulatory arrest. Where circulatory death occurs after planned consensual withdrawal of LST, potential donations occur in ‘controlled’ circumstances. Additional measures to minimise the warm ischaemic injury to donated organs have been developed. They include: use of drugs, e.g. inotropes or heparin, and other techniques, e.g. extracorporeal support.

All these measures potentially maximise the benefits that can be derived from donor organs but may be ethically problematic for families of the dying child and those caring for them. There may be perceived conflicts of interests for staff who may have a duty of care to both donors and potential recipients. Separating decisions to limit life-sustaining treatment (LST) from organ procurement enables some potential conflicts to be addressed.

Current UK guidance suggests that death certification should follow 5 min continuous circulatory arrest, but, in a US series of cardiac transplants in infants, DCD certification occurred after as little as 1.25 min of cessation of ‘cardio-circulatory function’. This raises particular ethical concerns about the irreversibility of cessation of cardiac activity and the place of the ‘dead donor rule’ in contemporary paediatric practice.

6.4. The ‘dead donor rule’ and contemporary paediatric practice

Although the ‘dead donor rule’ was intended to safeguard the interests of all, it has been criticised for relying on conceptually flawed and ethically problematical definitions of death. For example it has been argued that those currently considered brain-dead are actually living individuals with severe brain injury, and that it could be ethical to remove organs from them subject to valid consent and other safeguards. Subject to the latter conditions, no patient would die of vital organ failure that would not die from withdrawal of LST.

This is a relevant consideration in contemporary end-of-life care in small babies in whom death increasingly follows consensual withdrawal of LST because it is no longer in their best interests to continue it. In these circumstances it would be reasonable to propose that parents/guardians should be given the opportunity of donating organs if they so wished, although staff reluctance to burden grieving families with the sensitive topic of organ donation would be a potential barrier. Although understandable, this seems unfortunate given that the majority of the UK population appears to support organ donation. Whereas attempts to increase organ donation should not compromise respect for human life or the provision of high quality palliative care, sensitively offering families opportunities to donate is not inconsistent with these values.
7. Conclusions

This article has been concerned with the ethical considerations that pertain to end-of-life care in neonates and the values that should underpin this. It may not be possible to achieve complete unanimity on issues of fundamental moral concern. However, an understanding of the ethical principles and theories that might be used to justify or to challenge practice is just as important as the need for clinical practice to have a sound evidence base. In the interest of all concerned, decisions that underpin end-of-life care should be justifiable, reasonable, accountable, open, transparent, inclusive, and responsive. Babies and families deserve no less.

Conflict of interest statement

None declared.

Funding sources

None.

References


36. Re J (A Minor) [wardship medical treatment] [1990] 3 All ER 930.


