Birth at the margins of viability: reconciling clinical care with ethical standards

This paper examines the ethical standards that apply to infants born at the margins of viability and explores how clinical care might be reconciled with them. The importance of serial clinical assessment is stressed while the infant undergoes what is effectively a "trial of life". The central role of informed parents is highlighted in decisions to withdraw life support.

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Keywords

extreme prematurity; viability; resuscitation; ethics; counselling; neonatal intensive care; neurodevelopmental outcome

Key points

Chiswick, M. Birth at the margins of viability: reconciling clinical care with ethical standards. *Infant* 2008; 4(3): 84-88.

1. Reconciling clinical practice with ethical standards is arguably the greatest challenge in the care of infants of borderline viability.
2. The need to act in the infant's 'best interests' goes without saying. The concept helps us to define issues but only with hindsight do we know if we chose the best course of action.
3. Clinical staff are unlikely to be better at knowing the infant's best interests than properly informed parents.
4. Individual maternity hospitals need to develop protocols for delivery room care so staff of all grades know what is expected of them.
5. After 'a trial of life' decisions may need to be made in the delivery room or the NICU to withdraw life support in favour of comfort care.

Neonatal intensive care of babies born at the margins of viability (22-25 weeks' gestation) saves lives but creates ethical and clinical dilemmas.[1,2] For some parents and infants the burden of intensive care is so huge that death might come as a relief. Those infants who do survive to be discharged home may subsequently be shown to have neurodevelopmental impairments. Problems at the mild-moderate end of the spectrum may go undetected until school age or even later. Although our understanding of the causes of impairments is improving it has lagged behind our ability to prevent them.

What is the basis for deciding whether a baby of borderline viability should be offered resuscitation in the delivery room and continuing treatments in the neonatal intensive care unit (NICU)? The purpose of this article is to highlight issues that are important in decision making and to explore the extent to which clinical practice can be reconciled with ethical standards.

Outcome studies

Knowledge of survival rates and long-term outcomes at different gestational ages provide a broad indication to parents of what might be expected. In this respect national data based on sound research methodology and a relatively large number of infants is more helpful than results from individual hospitals. Variation in practice between hospitals and between countries accounts for much of the differences in published survival rates. Important factors are the extent to which live births at borderline viability are notified, the attitude of obstetricians to threatened delivery, and policies with respect to withholding resuscitation at birth and withdrawing intensive care in the NICU[3,4]. Neurodevelopmental outcome studies also lack consistency because of non-standard definitions of outcomes and different ages at follow-up[5].

The EPICure study of all births from 20 to 25 weeks of gestation in the British Isles during a 10-month period in 1995 benefits from a relatively large numbers of recorded live births[6,7]. Survival and neurodevelopmental disability rates are summarised in **TABLES 1 and 2**. A further 11-year neurodevelopmental follow-up is due to be published shortly. The EPICure study highlights the importance of long-term assessments. In this way we will gain a better understanding of the extent to which children are resilient and might overcome cognitive difficulties, and the extent to which unsuspected problems emerge only later.

Preliminary data from EPICure 2, a study of babies born in England in 2006 at less than 27 weeks' gestation, show that survival rates for infants at 23 weeks and less have not changed significantly, whereas there has been a significant improvement in the survival of infants born at 24 weeks and over (**TABLE 1**).

Some ethical and legal issues

A pregnant woman has the right to determine whether or not she will accept treatments. She may decline a treatment that might potentially benefit her fetus. For example, if labour occurs prematurely she may refuse antenatal steroids – a treatment known to reduce the risk to her baby of respiratory distress, intraventricular brain haemorrhage and overall mortality. Once

	Completed weeks of gestation			
	22	**23**	**24**	**25**
EPICure 1 (1995)[6]				
Live births (n)	**138**	**241**	**382**	**424**
Admitted to NMU (n %)	22 (16)	131 (54)	298 (78)	357 (84)
Survival rates (n %)				
Per live births	2 (1)	26 (11)	100 (26)	186 (44)
Per admission	2 (9)	26 (20)	100 (34)	186 (52)
EPICure 2 (2006)[6a]	**22-23**		**24**	**25**
Admitted to NMU (n)	196		330	426
Survival (n %)	51 (26)		155 (47)	285 (67)

TABLE 1 Survival to discharge rates of the EPICure study[6]. [6a]Preliminary data presented at Annual Meeting of Royal College of Paediatrics and Child Health, April 2008.

	Completed weeks of gestation			
	22	23	24	25
Assessed at 6 years (n %)	**2 (100)**	**22 (88)**	**73 (74)**	**144 (79)**
Severe disability[a]	1 (50)	5 (23)	21 (29)	26 (18)
Moderate disability[b]	0	9 (41)	16 (22)	32 (22)
Mild/no disability[c]	1 (50)	5 (36)	36 (49)	86 (60)

a. Highly dependent on caregivers, eg unable to walk, severe learning impairment, profound hearing loss, blind
b. Reasonable level of independence, eg able to walk, moderate learning impairment, correctable hearing loss, impaired vision
c. Mild learning difficulty, squint (or no disability)

TABLE 2 Disability rates of the EPICure study[7].

Completed weeks of gestation	Recommendation
21	No resuscitation. Considered to be an experimental procedure carried out only as part of a research protocol
22	No resuscitation, unless at parents request if they have been fully informed of risks, implications and likely outcome
23	Open to opinion but precedence given to parents wishes
24	Resuscitation, unless parents and clinicians agree in the light of the baby's condition that it is not in his or her best interests
25	Resuscitation, unless severe abnormality (or very poor condition at birth) incompatible with any significant period of survival

This table is based on guidance published by the Nuffield Council on Bioethics, UK[8].

TABLE 3 Summary of recommendations for resuscitation at birth.

her baby is born the situation is different. Doctors and nurses have a duty to 'act in the best interests of her baby'. Although consent to treatments must be obtained, it is a defence to treat a newborn baby without consent if it can be shown that it was done in the infant's best interests. In practice, conflict between the parents and medical staff is uncommon. However, the notion of acting in a baby's best interests does require further elaboration.

The best interests argument

Choices between different forms of care may have far-reaching implications and bioethicists often refer to the need to act in the best interests of the patient. But what exactly does this mean in the context of an infant born alive at the margins of viability? There are two interpretations, which although not contradictory, have a different emphasis.

First, the infant's best interests take *precedence* over the interests of others – for example some doctors might have interests simply in the medical challenge of saving the life of an extremely preterm infant. But what about the parents' interests which are far from trivial – indeed, they are intimately wrapped up in their baby's best interests. In practice, it is uncommon for parents to refuse potentially life-saving medical care for their baby. It is more common for parents to want 'everything done' for their baby while the staff may feel it is not in the infant's best interests.

The second interpretation of 'best interests' does not infer comparisons with the interests of other groups. Instead it is an *absolute* concept that assumes the medical staff know the best interests of the infant. The balance between the burden of intensive care for the infant, and the likely outcome are key factors in determining an infant's best interests. Although doctors and nurses may understand 'burden' in terms of the procedures the infant is likely to receive, and may be familiar with survival and disability rates in various populations, they cannot confidently foresee the future for *individual infants*. In that respect they are unlikely to be better at knowing the infant's best interests than are the parents.

What it amounts to is that the best interest argument does not offer much practical help to doctors in deciding whether or not a baby of borderline viability should be resuscitated and offered on-going intensive care. In most circumstances, it is properly informed parents who will have a compelling view on their baby's interests because it is the parents who will care for their baby if he or she survives to be discharged home.

The Nuffield Council on Bioethics, UK have published recommendations about resuscitation and continuing intensive care of infants born at the borderline of viability[8] (**TABLE 3**). Considerable emphasis is given to the views of the parents but this must be based on them receiving appropriate information. When things go wrong in the delivery room leading to parents complaining, it is rarely due to conflicts of ethical opinion with the staff. Instead, the root cause is usually failure to have in place or to comply with an agreed protocol which should include appropriate counselling of parents before delivery, the importance of serially assessing the infant's condition in the delivery room as a guide to resuscitation, and the importance of having in place arrangements for care of the dying infant.

Counselling parents

The majority of births at borderline viability have complications that bring the mother to the attention of the obstetrician hours, days or weeks before delivery[6]. Joint counselling by an experienced obstetrician and neonatologist reduces the risk of parents receiving conflicting information. Discussion about survival rates and longer term outcomes is an important feature of counselling but it is not the only issue. Parents should be warned that it is impossible to predict with certainty what the outcome will be for *their individual baby*. Instead, a range of survival and longer term outcome figures should be given. Information derived from national data may be supplemented by data derived locally – but reliance should not be placed on small numbers. It is best to discuss survival and the risk of impairments as separate concepts because the latter assumes that their baby will survive until discharge.

Parents should be taken through various stages chronologically so that they understand the hurdles to be overcome, starting with management options before delivery. The EPICure 1 study showed that the use of antenatal steroids was independently associated with a decreased risk of death and a reduced risk of severe brain abnormalities in survivors; tocolysis appeared to reduce the risk of abnormal brain scan findings and long term oxygen dependency[9]. It is possible that the apparent success of these antenatal treatments may reflect a prior commitment to do everything possible for the infant after birth.

In some cases parents may be persuaded before birth that their baby is 'too immature to survive' and that fetal heart rate monitoring would serve no purpose. In these circumstances intermittent auscultation or the use of a handheld Doppler device to record the fetal heat rate for 30 minutes or so before delivery can subsequently be of help to the paediatrician at delivery as it may influence the decision about resuscitation.

Parents who are told before birth that their baby is 'too immature to survive' may misinterpret this as a signal that their baby will be born dead. It is important to stress that whatever decisions are made before delivery their baby is very likely to be born alive and that decisions about resuscitation and on-going care will need to be clarified in the light of their baby's condition at birth. In some cases, for example, examination at birth suggests that the estimate of gestational age was probably erroneous.

- Inappropriate culture in the delivery room with poor attention to detail
- Casual approach to examination of the newborn
- Distortion of birth statistics and outcome data
- Shielding of the public, health service managers, and politicians from one of the challenges in perinatal care.
- May give rise to allegations of clinical negligence

TABLE 4 Effects of ignoring signs of life in babies of borderline viability.

The first hurdle is survival in the delivery room and parents should be informed that even if it is the intention to provide resuscitation, many babies of borderline viability never reach the NICU. That is why when quoting survival data at given gestational ages it is important to distinguish rates as a percentage of *live births*, from rates as a percentage of *admissions* to the NICU.

Delivery room care

An experienced neonatologist or advanced neonatal nurse practitioner should be present at the birth and assess vital signs – in particular whether there are signs of life; whether the physical appearance and size of the infant are consistent with the presumed gestational age; whether there are overt malformations; and whether any medical intervention is appropriate, taking into account any decisions that may have been made with the parents before birth.

'*Viability*', which means the ability to sustain life, can be interpreted in different ways, whereas the meaning of *vitality*', that is being alive, is quite clear.

> "Live birth refers to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life – eg beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles – whether or not the umbilical cord has been cut or the placenta is attached. Each product of such a birth is considered live born."
>
> *World Health Organisation's definition of live birth*

When only a perfunctory examination of the newborn is made and it is felt that the infant is barely alive, then signs of life are sometimes ignored on the basis that it is 'kinder' to parents. When a culture of ignoring signs of life is prevalent in the delivery room it may have far-reaching implications (**TABLE 4**).

Management of resuscitation

Developing an agreed protocol for the delivery room care of infants born at the margins of viability is not easy because it relies on ethics and on science for which there is no strong evidence-base. Variations in practice between different maternity units are understandable but what is important is for staff to know what is expected of them. The following suggestions are based on the report of The Nuffield Council on Bioethics, UK[8].

At 21 weeks' gestation and less resuscitation should be viewed as an experimental procedure and therefore should only be carried out with parental consent in the context of a formal research protocol.

In infants of 22-23 weeks of gestation, where there is no reason to doubt the gestational age, and where parents have made an *informed* prior decision that resuscitation is not to be carried out regardless of the infant's condition, then there is no duty for doctors to countermand the parents wishes. Given the burden of intensive care, the likely outcome of death, and the risk of impairments should the infant survive, it is hard to imagine how doctors might sustain an argument *in the face of parental opposition* that resuscitation and continuing intensive care is in their baby's best interests.

Further management (comfort care) should accord with the parent's wishes. Some will want to hold their baby for extended periods while others might prefer their baby to be nursed in a cot. It is inappropriate for such infants to be admitted to the NICU for what amounts to the medical supervision of death.

Probably a more common situation is prior insistence that 'everything' be done for a baby whose condition at birth turns out to be extremely poor. At 22 and 23 weeks' gestation a pragmatic approach normally fulfils the parents' underlying wish that their baby will not simply be 'left to die' without medical intervention. Minimally invasive resuscitation, as described below, helps protect the infant from undue discomfort and harm from procedures while normally fulfilling the parents wish that 'everything' be done. In these circumstances it is unhelpful and pointless to make a stance against any sort of medical intervention; in any event, infants of 22-23 weeks' gestation in an extremely poor condition at birth are unlikely to survive to be admitted to the NICU. For those infants who are more robust at birth, then following stabilisation in the delivery room, their further management will be guided by serial assessment of their condition and this will be addressed later.

For infants born at 24 and 25 weeks' gestation a normal standard is to offer resuscitation unless there is an overt and serious congenital malformation or evidence before delivery of prolonged fetal bradycardia. Although vital signs at birth, as assessed by the Apgar score, are unreliable predictors of long-term outcome, they are a starting point for serial assessment of the response to resuscitation which in turn will determine whether attempts at resuscitation should be continued or abandoned.

Practical considerations

Infants who are not vigorous at birth and who have depressed respiration require positive pressure ventilation in order to stabilise their condition. Endotracheal intubation of extremely small infants can be difficult even in experienced hands. Attempts to intubate can convert a moderately depressed infant into one who is moribund. Based on the need to minimise discomfort and harm, a reasonable approach is to assess the infant's response to *effectively applied* bag and mask ventilation.

In this context a poor response favouring cessation of resuscitation would be a persisting bradycardia, circulatory impairment manifest as pallor, no spontaneous breaths, a low body temperature in spite of efforts to reduce heat loss, and a significant metabolic acidaemia (pH< 7.1). There is some evidence to support this approach from the EPICure 1 study which showed that a heart rate less than 100 per minute at 5 minutes, and a body temperature less than 35°C on admission to the NICU, were indicators of increased risk of mortality[6]. Those infants who do not show a response to non-invasive resuscitation may be given appropriate comfort care in accordance with the parents' wishes.

Post-resuscitation care

If the infant responds to resuscitation there is an important decision to be made concerning the use of continuing elective respiratory support and the administration of surfactant. Elective intubation has the advantage of providing the route for surfactant administration. Respiratory support may be continued with endotracheal mechanical ventilation or with endotracheal continuous positive airways pressure (CPAP) treatment, depending on the infant's respiratory drive. The disadvantage here is that the infant is exposed to complications associated with an in-dwelling endotracheal tube.

An alternative approach for infants who are stable with reasonable respiratory drive is to intubate them for the purpose of giving surfactant and then remove the endotracheal tube, continuing respiratory support with nasal CPAP. A proportion of infants managed in this minimally invasive way will eventually still require mechanical ventilation for prolonged periods. Deferring mechanical ventilation carries a theoretical risk of harmful effects of recurrent apnoea and respiratory acidaemia.

The Danish experience of a minimally invasive approach to resuscitation and subsequent respiratory support with CPAP was described by Greisen[10]. A follow-up study of infants of less than 28 weeks' gestation who were managed in this way did not suggest an increased risk of intellectual impairment, but there were relatively few infants of less than 25 weeks of gestation who survived[11]. There is insufficient experience at present of the use of alternatives to endotracheal intubation for mechanical ventilation in babies of borderline viability.

The limits of continuing care

Parents should be informed that admission to the NICU is the start of a long journey often marked by episodes of deterioration, but also by periods where their baby's condition may promote optimism. Essentially, this is a 'trial of life'. When the balance is tipped *away* from a reasonable chance of survival with prospects of an independent existence *towards* the needless burden of intensive care as implicated by 'pain and suffering' then consideration must be given to withdrawing intensive care, which for practical purposes means the withdrawal of assisted ventilation[12]. Decisions of this type require parents to be engaged with the staff on a daily and often an hourly basis. One measure of excellence of a NICU is the extent to which the staff – neonatal doctors and nurses of all grades – are able to work together to provide parents with consistent information about their baby.

Bioethicists often argue that there is no difference between withholding ventilatory support at birth and withdrawing it later, as long as decisions are made in the infant's best interests. Given the limitations of the 'best interests' argument, as described earlier, there is a huge difference in *practical* terms. The decision to withdraw assisted ventilation is made only after the infant has been given a *chance of life* and when there has been time to serially assess clinical progress and response to treatments.

Treatments, such as mechanical ventilation, may prolong the dying process rather than offer a reasonable chance of saving life. A point of *futility* is reached when it is felt that the infant has 'entered the process of dying'. This is not easily defined but it implies an infant with multiple organ failure who, in spite of treatments, shows no signs of improvement or who steadily deteriorates.

Given the importance of the burden of intensive care, is it ethically acceptable to wait until the point of dying is reached before withdrawing ventilatory support? In view of the high risk of a poor outcome, especially at 23 weeks' gestation and below, then any *additional* neonatal complications that arise, such as severe and worsening respiratory distress syndrome, sepsis, necrotising enterocolitis, and haemorrhagic or ischaemic brain scan abnormalities, add to the infant's burden while doing nothing to improve the prognosis. These are issues that need to be discussed with the parents at appropriate intervals so that they have the opportunity to consent to withdrawal of assisted ventilation.

Parents should be informed that withdrawal of assisted ventilation might not bring about a rapid end to their baby's life and that survival for many hours or days is quite common. Parents differ in how they would like their baby to be nursed in these circumstances. It does provide an opportunity for them to get to know their baby away from the paraphernalia of intensive care, and they often relate, many years later, how much they appreciated this. The expression 'comfort care' is useful because when defining the details it prompts us to focus on the infant's comfort above all else. Issues to be discussed with parents include the use of analgesia and sedatives, whether comfort will be enhanced by the use of oxygen and intravenous fluids, and whether the parents wish to be involved in intimate nursing of their baby, for example, bathing and dressing.

Each experience provides an opportunity for the neonatal team to discuss, learn and possibly review their management protocols.

Conclusions

All would agree that we should act in the best interests of our patients. However, this concept is of limited help in assisting clinicians in the care of infants born at the margins of viability. Outcomes for individual infants are often unclear and the evidence-base for many treatments offered to these infants has yet to be developed. It is because of these uncertainties that maternity units need to develop and implement agreed protocols so that babies of borderline viability and their parents are not met by confusion and crises in the delivery room and NICU. The challenge is to provide care within an ethical framework. Much of the guidance will be empirical. We may not always get it right, and with hindsight, we may wish that we had adopted an alternative approach.

Each experience provides an opportunity for the neonatal team to discuss, learn and possibly review their management protocols.

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