

# Ethical issues in neonatal intensive care

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**Summary.** Recent progress in neonatal care have significantly improved the prognosis and chances of survival of critically ill or extremely preterm neonates and have modified the limits of viability. However, in some circumstances, when the child's death can only be briefly postponed at the price of severe suffering, or when survival is associated with severe disabilities and an intolerable life for the child and his/her parents, the application of the full armamentarium of modern neonatal intensive care may not be appropriate. In such circumstances the limitation of intensive treatments (withholding or withdrawing) and shift towards palliative care, can represent a more humane and reasonable alternative. This article examines and discusses the ethical principles underlying such difficult decisions, the most frequent situations in which these decisions may be considered, the role of parents in the decisional process, and the opinions and behaviours of neonatologists of several European neonatal intensive units as reported by the EURONIC study.

*Key words:* neonatal intensive care, neonatal ethics, limitation of treatments, newborn infant.

**Riassunto** (*Principi etici in terapia intensiva neonatale*). I recenti progressi nell'assistenza neonatale hanno notevolmente migliorato la prognosi e le probabilità di sopravvivenza dei neonati in condizioni critiche o molto pretermine ed hanno di fatto modificato il concetto stesso ed i limiti della così detta "vitalità" (*viability*). Tuttavia, in alcune circostanze, quando il decesso del bambino può essere solo temporaneamente posposto, a prezzo di gravi sofferenze, o quando la sopravvivenza si associa con gravissime disabilità permanenti ed una vita intollerabile per il bambino e la sua famiglia, potrebbe non essere appropriato utilizzare tutto l'armamentario della moderna terapia intensiva neonatale. In tali circostanze la limitazione dei trattamenti intensivi ("non inizio" o "sospensione"), peraltro invasivi e dolorosi, e il passaggio alle cure palliative, potrebbe rappresentare una alternativa più umana e ragionevole. Questo articolo esamina e discute i principi etici che sottendono tali difficili decisioni, le situazioni più frequenti in cui esse possono essere prese in considerazione, il ruolo dei genitori nel processo decisionale e quali sono le opinioni e i comportamenti dei neonatologi in numerose unità di terapia intensiva neonatale Europee come riportato dallo studio EURONIC.

*Parole chiave:* terapia intensiva neonatale, etica neonatale, limitazione dei trattamenti, neonato.

## INTRODUCTION

In recent years, sociologists, ethicists, legal experts, as well as doctors and parents, have repeatedly questioned the appropriateness of applying, without distinctions, the full armamentarium of modern neonatal intensive care with the sole aim of maintaining "alive" infants with no chance of long term survival, or of acceptable development [1]. Much discussion has taken place on the role of parents, medical and nursing staff, and even of third parties such as ethics committees or, in the most controversial cases, judges and courts [2]. Gradually the concept has emerged that it may not be appropriate to always do everything that is technically possible and that there may be situations where intensive treatments should be replaced by palliative and comfort care, aiming at minimizing pain and improving the wellbeing of the patient and family, rather than at maintaining or prolonging life at any cost [1-4]. Behind this concept there are impor-

tant ethical issues, some of which will be discussed in this paper.

Following a brief historical overview, we will provide some data on the situation in Europe as emerged from the EURONIC study. We will then discuss some of the most controversial aspects that create difficulties in deciding what to do in our daily practice.

## HISTORICAL PERSPECTIVE

More than 30 years ago, Duff and Campbell were the first health care professionals to draw the attention of their Colleagues on some of the ethical and moral dilemmas faced by physicians and nurses in Neonatal Intensive Care Units (NICUs). In their paper, published in 1973 in the NEJM, they explicitly admitted that among 299 consecutive deaths occurred in their NICU at Yale, 14% (43) were related to decisions to withhold or withdraw inten-

sive treatments jointly made by staff and parents [5]. All those babies were affected by multiple and severe anomalies and even with maximal interventions their chances of surviving beyond the first few days of life were very small; furthermore, in case of survival, their perspectives in terms of quality of life were extremely poor: in such cases, any aggressive, invasive and costly treatment appeared to be not only futile, but even harmful.

The paper elicited a vehement debate in the medical and lay community, involving physicians, psychologists, philosophers, ethicists, priests, lawyers, as well as parents, with more than 100 letters written to the Authors in less than one year. The major contribution of Duff and Campbell has been not only to uncover an approach that was probably present in other NICUs in the USA, but also to have emphasized the conflicts of interests that may arise between the decision-makers, such as doctors, nurses, and parents, and the patient [6].

Duff and Campbell have indicated that in such difficult circumstances one can refer to two different philosophies of care: the traditional “*disease oriented*” approach, aimed at assuring survival at any cost, with death seen as the ultimate failure to be avoided or postponed with all available means; and a new, more flexible philosophy – “*person oriented*” – which takes into consideration the “quality” of life and sees some types of catastrophically compromised existence as more negative than death [6].

Fifteen years after this first publication, one of the two Authors, Alex Campbell, reported his experience in Scotland: among the babies that died in his NICU, only 18% of all deaths occurred under full intensive care; in 39% of the cases treatment had been discontinued, and in 43% it was not even started [7]; about 20% of the babies in this latter group were preterm infants of very low gestational age, a category of patients that was practically absent in the previous report.

In the following years, various Authors have reported on similar experiences in their NICUs, and the proportion of deaths associated with limitation of intensive treatment appeared to be increasing substantially over time, on both sides of the Atlantic [4, 8]. Towards the end of the last century, the majority of neonatal deaths were preceded or accompanied by some form of limitation of intensive care.

### THE EURONIC STUDY

In order to better understand the magnitude and other features of this phenomenon, as well as some related ethical issues, a European research project (EURONIC) was carried out in 1996-97 [9]. The aim was to investigate the opinions and experiences of the medical and nursing staff concerning ethical decisions and parents’ involvement in a representative sample of NICUs from various European countries. Initially, 8 countries were included: France, Germany, Italy, Luxembourg, The Netherlands, Spain, Sweden and the United Kingdom.

Three other countries, Hungary, Estonia and Lithuania, subsequently joined the study, leading to a total of 144 NICUs, with a response rate of 86%; more than 1400 physicians (response rate 89%) and more than 3400 nurses (response rate 86%) were interviewed. Finally, a similar study was later performed in Switzerland and in Ireland.

There is not sufficient space to present the complete data of the study: most of them, and particularly those concerning the physicians, have already been published [10-15].

For the purpose of this presentation we will discuss only part of the data from 8 Western Europe countries (Italy, France, Germany, Netherland, United Kingdom, Sweden, Spain and Ireland), and particularly the data concerning the physicians’ reports on the limitation of intensive treatments and the role of parents in the decision-making process.

As regards physicians’ opinions on the moral acceptability of limiting intensive care in selected circumstances, the great majority in every country were in favour in case of lethal/terminal conditions; however, the proportion of positive answers was lower and more variable by country in case of possible survival with severe disabilities [12-15]. In both situations, physicians from Italy and Spain were less favourable to limitation of intensive care compared to their colleagues from other countries.

Concerning what is considered as an “acceptable” approach for limiting intensive care, the differences among countries were greater. While in every country most physicians considered acceptable “to continue current treatment without adding others”, to withhold intensive interventions from the beginning, and even to refrain from treating emergencies which may arise in the course of established intensive care, opinions about more clear-cut non treatment choices varied largely. For instance, withdrawal of mechanical ventilation was acceptable especially in UK, Netherlands, Sweden and Germany, but less so in Italy. Also the administration of drugs to control pain was less acceptable in Italy than in other countries, when the risk of hastening death could be involved [12-15].

Concerning physicians’ actual experience and life-long self-reported practices in limiting intensive care, the results were coherent with their opinions. The most frequent reported practice was to abstain from treatment escalation. Here again, Italian and Spanish doctors appeared the most reluctant to withdraw intensive care, while French and, to a lesser extent, Dutch doctors admitted having applied active euthanasia at least once during their professional life [12-15].

Finally, in all countries, only a very small proportion of physicians believed that in their NICU intensive care was too often limited on ethical grounds, while a substantial proportion felt that intensive treatments were sometimes continued for too long [12-15].

From this first set of data we can conclude that limitation of intensive care, including mechanical ventilation, is considered by many European ne-

onatologists as an appropriate and ethically justified course of action in selected circumstances. There are, however, differences among physicians of different countries in both the willingness to proceed in that direction and in the appropriate approach for achieving this goal.

### THE ETHICAL ACCEPTABILITY OF LIMITATION OF INTENSIVE TREATMENTS

The first and most important controversial issue deals with the ethical acceptability of withholding or withdrawing intensive care and/or mechanical ventilation.

This issue is obviously crucial, since it implies two apparently irreconcilable philosophical and ethical positions: one that is based on the “sanctity” of life and considers human life a gift of God, with an intrinsic value independent from its quality; the other one that considers also the “quality” of life and the relationship between the burdens of continuing intensive care and its anticipated benefits [16,17].

In the first case any course of action that accelerates, facilitates or simply allow the patient’s demise is considered unethical. In the second case, when survival is deprived of certain minimal qualities that characterize human life, it is considered wiser to shift to palliative care.

### WHEN MAY WE CONSIDER THE LIMITATION OF TREATMENTS? THE PROBLEM OF VIABILITY

If limitation of treatment is accepted, then we may ask in which babies it could be appropriate and who should make the decision.

The following very simple list includes the most frequent and typical situations where the option of limiting intensive treatment are usually considered:

- extremely preterm “non viable” infants (*gestational age below 23-24 weeks*);
- infants with congenital defects incompatible with “short term” survival (*anencephaly*);
- infants with “medium term” lethal prognosis (*trisomy 13*);
- infants with longer term lethal prognosis or predicted poor quality of life (*bilateral grade 4 periventricular haemorrhage, progressive neuro-muscular paralysis*).

The first two are more relevant to withholding resuscitation or mechanical ventilation in the delivery room or very early in life. The other two are more relevant to withdrawing treatment in the NICU. However, even this simple classification is more complicated than it appears.

Let us take for example the case of a “non viable” very preterm infant.

The definition of “viability” is generally based on two major criteria: the biological one, which takes into consideration the maturity of the foetus, and the epidemiological one, which is based on the survival rates reported in the literature.

Concerning the first criterion, lung maturation, and particularly that of the surfactant system, is undoubtedly the crucial limiting factor for survival. From this point of view the lowest gestational age when survival might be possible should be around 22-23 weeks of gestation, concomitantly with the early appearance of the lamellar bodies in type two alveolar cells [18].

For the epidemiological criterion it appears that survival at 22 weeks gestation is exceptional, ranging from 0% in most studies to 6-12% in few reports [19].

In a recent study in ten European regions the survival rate of neonates with a gestational age of less than 24 weeks, who were alive at the onset of labour, only 3.1% (range 0 to 9.7%) were alive at discharge [20].

It should also be considered that a substantial proportion of surviving infants at 22-23 weeks of gestational age are afflicted by severe disabilities when evaluated at later ages [19, 21].

The real problem is that many aspects of foetal maturity are significantly influenced by numerous factors, including, not only gestational age, but also birth weight, gender, ethnicity, prenatal infection, maternal disease, etc., as well as by prenatal care, such as steroids’ prophylaxis. The same holds true for survival rates, which are influenced not only by the previous and other factors, such as type and place of delivery, post-natal care, etc., but, as we have seen, may also depend upon the “*a priori*” ethical position of the caring team [22]. Babies considered “non viable” ten years ago, are now considered “viable” in many centres, with survival rates approaching 30 to 50% [23].

Therefore, viability does not depend solely on gestational age, but it should be considered with some flexibility and on an individual basis.

### THE INVOLVEMENT OF PARENTS

The other critical issue is the one of parents’ involvement in the decision-making process concerning their baby. In the EURONIC study, there was a general consensus that parents should be involved somehow, but again there were disparities in the opinions of physicians from different countries. In every country but France and Sweden most physicians felt that their involvement should be explicit, that is they should be aware that a decision to limit treatment is considered, and that they may contribute to it. In France, however, almost 80% of respondents answered that parents’ role should be only indirect, meaning that their views should be “indirectly sounded out and taken into account” by the physician. To a lesser extent, this opinion was present also in Sweden and the Netherlands. In Italy, a substantial minority felt that parents should not be involved at all. Comments by respondents clarified the reasons for these attitudes. A physician stated that: “I personally believe that parents must be informed of the state of health and prognosis of the baby, but that they should not take part in the decision concerning limitation or withdrawal of treatment. They must in no way feel guilty for hav-

ing wished the death of their baby". However, lack of involvement in end-of-life decision could put the staff in a difficult position when the news of a baby's death is to be communicated to the parents: "Our medical team has always had a totally out-in-the-open attitude with regard to families when it comes to care, diagnosis and prognosis. This openness, however, disappears entirely in the face of ethical decisions, replaced with a "convincing lie: unexpected cardiac arrest" (a physician).

Whether or not parents are involved in decision-making, conflicts may arise between them and the staff on the best course of action for a baby. Most physicians in every country reported that this was a rare event, and that most cases could be overcome by discussion, and by giving parents the time to think about the information received and staff suggestions. In case of persistent disagreement, however, most physicians in every country felt that the parents' opinion should prevail if they asked for continuation, rather than limitation, of intensive interventions. [10, 15, 24].

So, also for the issue of parents' involvement the consensus and behaviour of European neonatologists are not uniform and differ from country to country.

### CONCLUDING REMARKS

At the end of this brief review one may ask the question: is it possible or indeed desirable to reach a consensus and a uniform approach to these ethical issues?

The EURONIC study has shown that the variability of opinions and behaviours among physicians can be only partially explained by personal variables such as: gender, age, religiousness, clinical and research experience, being married with or without children, etc.

The pattern of opinions and behaviours appeared to be country-specific. Clearly, historical, social, cultural, and legal factors are involved. Also, we do not know how physicians' opinions and practices have evolved since the time of EURONIC data collection [24].

We feel that the expectation of a consensus on these delicate ethical issues is unrealistic, particularly if one considers the uncertainties of prognosis in individual cases. It is however important to continue to openly discuss these problems both within the health care professions and with the public in general. Within the medical professions, the discussion should aim at reaching at least a common and ethically correct methodology for addressing these issues in clinical practice. Physicians, nurses, psychologists, social workers, and other professional figures are generally prepared to perform different, sometimes overlapping, tasks. Therefore, it is necessary that all those components, together with the parents, and with full reciprocal respect of one's values and ideologies, collaborate in making a shared decision.

The debate with the public is necessary to clarify the potentials but also the limitations of modern medicine, so that expectations in case of very pre-

term or very sick infants may become more realistic than they currently are [25].

However, we must recognize that in the NICU it may not be always possible to clearly identify a position that is totally appropriate and satisfactory, when considering the four most important ethical values, *i.e.*: biological life, parental authority, the infant's best interest and the dignity of a human being. Therefore, we must also consider the possibility of making imperfect or even fallible solutions. This may be disturbing in the present era of "evidence based medicine" where it is recommended that clinical decisions be made on the grounds of solid scientific evidence and undoubted proof of efficacy. However, there is no alternative and we must learn to live with doubt and uncertainty, to value the merits of compromise, to admit the possibility of erring, but at the same time to be capable of using our mistakes for making improvements [26].

We wish to conclude this brief overview with the words that our distinguished Colleague, Prof. David Baum, wrote shortly before his premature demise [27]: «*Pediatricians are vocationally committed to promoting children's health, treating their illnesses and saving their lives. There are, however, occasionally tragic circumstances in which...we are forced to wrestle with dreadful choices. ometimes it is necessary to come to the conclusion that for an individual child ...the more humane path is one of palliation, rather than continuation of life-saving treatment. To so resolve is profoundly difficult, challenging for the doctor and all members of the health care team... Nevertheless, our professional responsibilities do not allow us to walk away from such difficulties*».

The question today is how we can best honour this responsibility, considering all the components of a very complex scenario: the patient, the parents, the physician, the nurses and the other members of the care-giving team, the society with its expectations, its moral values and legal obligations.

As neonatologists, committed to the care of the neonate and his/her parents, we must accept the challenge of dealing with this relatively new aspect of our profession, where science and technology are of little or no help and where other qualities are required to satisfy our obligations to the patients and their families. We will have to navigate carefully in troublesome and dangerous waters, like Ulysses between Scilla and Cariddi: on the one side the dangerous temptation of playing God and on the other side the equally dangerous risk of abdicating one of the most important qualities of our profession, compassion.

### Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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