Withholding/withdrawing treatment from neonates: legislation and official guidelines across Europe

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Abstract
Representatives from eight European countries compared the legal, ethical and professional settings within which decision making for neonates takes place. When it comes to limiting treatment there is general agreement across all countries that overtly aggressive treatment is to be discouraged. Nevertheless, strong emphasis has been placed on the need for compassionate care even where cure is not possible. Where a child will die irrespective of medical intervention, there is widespread acceptance of the practice of limiting aggressive treatment or alleviating suffering even if death may be hastened as a result. Where the infant could be saved but the future outlook is bleak there is more debate, but only two countries have tested the courts with such cases. When it comes to the active intentional ending of life, the legal position is standard across Europe; it is prohibited. However, recognising those intractable situations where death may be lingering and unpleasant, Dutch paediatricians have reported that they do sometimes assist babies to die with parental consent. Two cases have been tried through the courts and recent official recommendations have set out standards by which such actions may be assessed.

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Introduction
The management of babies with serious incurable medical conditions has been called “our most difficult area of paediatric practice”.1 Matters of law, ethics and conscience create dilemmas to which there are no easy answers. But professional responsibility forces clinicians to face these troubling questions and to try to deal with the reality of decision making in ways which combine compassion with legal and medical integrity.

That the issues are still current is demonstrated by two recent documents from the Netherlands2 and the UK.1 The Dutch document arose from the deliberations of a discussion group set up in 1996 by the ministers of health and justice, “to make proposals regarding a notification and assessment procedure for cases in which the life of a newborn baby with a serious medical condition is deliberately ended”. The British document -instigated by a professional body, The Royal College of Paediatrics and Child Health in response to a House of Lords report1 - was produced following two years of widespread consultation. These documents address similar problems but, as will be shown later, respond differently.

It is known that responses to bioethical questions vary between European countries.4–6 Clearly, too, a number of factors influence the management of these tragic cases, for example, the legal context, prohibitions and restrictions, professional codes and guidelines.

Although an enormous literature exists on the general subject of the limitation of treatment, no publications specifically address the context for decision making on behalf of neonates across Europe. Given that every country faces the problem, it seemed important to compare existing legislation and recommendations to identify differences as well as similarities.

Our study
To this end a European biomedical research project, EURONIC, was designed to study the relevant issues within France, Germany, Italy, Luxembourg, the Netherlands, Spain, Sweden, and the United Kingdom.7 A sub-section of the project explored the legal and ethical limits to what may and may not be done. The work of this sub-group is reported in this paper. Participants from the eight European countries and from a range of backgrounds (ethics, law, medicine, nursing) held discussions on four occasions during 1994-97, and consulted other experts.
METHOD
A framework to guide the collection of comparable data was drawn up and agreed. This paper reports only data relating to treatment limitation for neonates collected in two areas: the law governing practice, and guidelines from official bodies such as government committees and professional associations. The level and depth of data obtained varied from country to country and this article reflects this imbalance. Findings from only seven of the countries are reported since information from the eighth country was too scanty to be included.

Results
Forthcoming articles will present findings from the larger study (which investigated what is actually done in clinical practice) and the implications of current restrictions. For reasons of space this paper will simply present the facts and leave ethical debate to later publications.

In all seven European countries existing laws are based on a fundamental principle of respect for human life. Almost all countries in Europe are governed by civil codes, some of which have the force of law, others being closer to professional guidelines. The UK, however, operates a system of common law - the ancient unwritten law of the land embodied in judicial decision - in addition to law enacted by parliament.

1. The issue of withholding/withdrawing treatment
The Hippocratic Oath, The Declaration of Geneva and the International Code of Medical Ethics all state that the duty of doctors is to put the welfare of their patients first. Considerations of religion, nationality, race, party politics, social standing and lifestyle should not interfere with this basic obligation to treat. When it comes to limiting treatment, however, the laws of individual countries vary.

Infants for whom aggressive treatment might not be desirable fall into two groups: those who will inevitably die whether or not there is medical intervention (the no hope situation), and those who might live if treatment is given but whose future outlook is extremely poor (the no purpose situation). All countries permit non-treatment decisions to be made for the first group but there is much more debate about withholding treatment from a child on the basis of future quality of life.

The position of parents is basically the same in all countries: they have the authority to make decisions on behalf of their children, and their consent should be sought to treatment except in cases of emergency. Where parental decisions are contrary to the best interests of the child, doctors are instructed to be the child's advocate and to apply to the courts for permission to overrule that decision.

FRANCE
In France there are no rules or guidelines relating to the cessation of treatment but until recently doctors feared that they would be prosecuted if they did not provide all necessary care. In the last few years, however, the Deontological Code (1995) has emphasised doctors' obligation to relieve pain and included a caution against inappropriate aggressive treatment. To date no cases have come to the courts so no doctor has been prosecuted for taking a non-treatment decision.

LUXEMBOURG
Luxembourg's doctors, in cases of incurable illness, have a stated duty to relieve pain and distress and maintain as good a quality of life as possible (Deontological Code art 45 and art 43 of Law of 28 August 1998), enhancing the quality of life rather than providing hopeless treatment. A law passed in 1992 (Law of August 10, 1992, art 7) entitles a doctor to give a minor appropriate treatment in spite of parental opposition, in cases where not to do so jeopardises the child's life or health, but such action has to be reported to the public prosecutor within three days. At present the law does not address a situation where parents want medically futile treatment to continue but discussions are currently going on to clarify the legal position.

ITALY
According to Italian law a doctor always has an obligation to treat. Apart from in emergencies, however, such obligation is conditional upon the consent of the patient (Italian Constitution art 32), a principle supported by the Code of Professional Medical Ethics (art 32), and the Italian National Ethics Committee (Informazione e consenso all'attesa medico, CNB 1992). The explicit refusal of consent by a competent adult, therefore, justifies non-treatment decisions (Penal Code art 50). In every other circumstance, limiting treatment may be seen as a refusal to provide the essential duty of care (Penal Code art 328). If the patient dies, it may become homicide.

The latest Italian Code of Professional Medical Ethics cautions against therapeutic aggressiveness, defined as "persisting with a treatment for which one cannot, with good reason, expect a benefit for the patient or any improvement in his/her quality of life" (Codice di Deontologia Medica 1998 art 14). This document, however, has no
legal status and the law neither makes mention of this issue nor does it differentiate between ordinary and extraordinary treatment. The clinical position is uncertain.

When it comes to newborns, Italian law is strongly protective. Non-treatment for such conditions as severe malformation or poor neurological prognosis, is considered a form of discrimination which violates article 3 of the Constitution, relating to the equality of all human beings. One court case in particular has served to clarify the Italian position.11

A child in the course of an appendicectomy, suffered a cardiac arrest. One of the surgeons massaged his heart for about ten minutes to no effect. The team were subsequently sued for manslaughter. The defence offered was that more prolonged resuscitation might have saved his life but would have left him with irreversible brain damage. The judge would not accept the legal foundation for this claim and ruled that the principle of the inalienability of human life has to be respected.

GERMANY

German doctors have until very recently been obliged to do everything medically possible to preserve life. Within the last decade however, limitation of treatment has become accepted as an integral part of medical care for neonates when treatment is simply delaying an inevitable death.12 Neither in jurisprudence nor in the literature have the limits of a doctor’s obligation to treat a damaged neonate been specifically addressed. However, the German Medical Association Guidelines on Euthanasia relating to the support of dying patients are applicable inasmuch as they emphasise the need for dignity and good palliative care.11

SWEDEN

Since medical matters are rarely subjected to public scrutiny in Sweden, there is little available information about the rules governing practice. But the National Board of Health makes one thing clear: it is the doctor’s responsibility to make the definitive decision about treating and though the opinion of close relatives should be sought, they should not be burdened by the final responsibility of choosing whether or not to treat.14 Furthermore, it states expressly that under certain circumstances a doctor has the right to limit treatment on humanitarian grounds. In May 1997 the first case relating to the management of a premature infant was brought before the Board.

A doctor was said not to have fulfilled his basic obligations following the death of an infant whose transfer to an intensive care unit was delayed. An appeal is currently with the Administrative Court of Stockholm.

UK

British doctors are not obliged to preserve the life of severely abnormal children. As the Master of the Rolls concluded after a landmark case:

“No doctor can be required to treat a child, whether by the court in the exercise of its wardship jurisdiction, by the parents, by the child or anyone else”.15

Decisions are based on judgments about the best interests of the child and his future quality of life. A series of court cases has tested the limits of what is permissible:

In 1981 in Re B, the Court of Appeal authorised surgery to correct intestinal obstruction in an infant with Down’s syndrome - treatment which the parents had refused.16

In 1989 in Re C, both a High Court judge and the Lords of Appeal agreed that a very seriously damaged four-month-old child should be permitted to die.17

In 1990 the case of Baby J concerned a child born at 27 weeks gestation who after weeks of intensive care was now severely brain damaged.18 Medical opinion was that he might live into his teens; his quality of life was very poor but he was capable of feeling pain. The courts ruled that doctors should not be required to resuscitate him when he collapsed, if they judged such management was not in his best interests.

In 1992, in a case also referred to as Baby J, the Court of Appeal upheld a decision not to order doctors to treat a patient who was 17 months old with severe problems.18 20 In spite of parental and health authority opposition, the Court of Appeal ruled that the doctors should be free to exercise their clinical judgment at the time.

Although these cases have clarified the acceptability of limiting treatment where the quality of life is “demonstrably awful”,19 uncertainty remains about exactly what constitutes an intolerable quality of life, and who should define this. Clearly “the circumstances of these tragic cases are ... infinitely various”,21 but the official legal position is governed by the Bolam decision,22 namely that a doctor is not negligent if he would be supported in his actions by a responsible body of medical opinion.

THE NETHERLANDS

Two cases involving minors have established that doctors in the Netherlands are not obliged to give
medically futile or inappropriate treatment. Although the concept of futility has proved to be elusive,23 the ruling of the Central Medical Disciplinary Board made it clear that it is a matter of medical judgment.24

Parents of a child with Down’s syndrome, and the Child Welfare Council, decided against an operation for a life-threatening intestinal obstruction. The paediatric surgeon, after consulting the hospital medical ethics committee, complied with their wishes but was subsequently prosecuted for failing to provide life-saving treatment. The Supreme Court ruled that even if an operation had been performed, both the child and the parents ran the considerable risk of a life of severe suffering, and criminal proceedings were not instituted.25

The parents of a one-year-old child with severe brain damage appealed a decision made by the paediatrician not to resuscitate if complications should occur. The Court of Utrecht held that doctors are not obliged to give medicinally futile treatment and that any decision as to futility should be based on clinical judgment.26

Ultimate responsibility for deciding the best course of action lies with the medical team caring for the child in both the Netherlands and the UK, but expert consultation is widely practised. In the Netherlands a medical ethics committee may also be consulted for advice, whereas in the UK there are few established clinical, as opposed to research, ethics committees. It is a requirement that Dutch clinicians consult colleagues when actively terminating a life.27

In all countries which allow non-treatment decisions to be taken, great emphasis is placed on the need to give good quality care to the baby for whom aggressive management is not the best option. Indeed in the Netherlands it is a criminal offence not to provide ordinary compassionate care in such a case (Criminal Code sect 255).

Active intervention to end life
Though limitation of treatment may be acceptable, the intentional ending of a life by active means is a different matter. This issue is fraught with semantic, legal and ethical problems.

For the purposes of this paper we take active intervention to mean the considered intentional termination of life (for example, giving a patient a lethal injection designed to kill). Less clear cut are other practices which may be intended to relieve symptoms but have the effect of shortening life (for example, the administration of pain-relieving drugs in high doses; or paralytic agents before withdrawal of life-sustaining treatment), or which are a response to the child’s medically futile condition (for example, failure to adjust ventilator settings or respond to worsening body chemistry; withholding of feeding). Persuasive arguments find no moral or legal distinction between acts of commission or of omission at the end of life,28 29 but clinicians recognise a powerful psychological distinction.30 31

Brief reference to the position in relation to consenting adults is relevant at this point. In no European country is euthanasia legal. In the Netherlands however, this prohibition is seen as inconsistent with the patient’s right to self-determination. Both euthanasia and assisted suicide are criminal offences, but the acts will be “legally pardoned”32 provided that certain specific criteria are met. A physician can claim force majeure where there is a conflict of duties between preserving life and relieving suffering. But recent Dutch recommendations’ specifically state that “a decision deliberately to end a patient’s life cannot be regarded as a normal part of medical practice”, and “should accordingly be carefully regulated and, most importantly, be subject to special scrutiny”.33

In the UK, France, and Italy the intentional termination of life, whether or not requested by the patient, is regarded as homicide and therefore illegal. There are no exceptions. Indeed recent official publications in the UK have reinforced that country’s stated opposition to euthanasia.3

In Germany assisting suicide (where the act itself is not performed by the doctor but he may have prescribed the means) is legal, but not the active ending of someone’s life. In Luxembourg and Sweden assisted suicide is not illegal but is generally regarded as incompatible with the obligations of doctors.

For neonates, unable to state a preference, the situation is further complicated. There have been court cases in only two countries, the UK and the Netherlands.

GERMANY
German guidelines regarding the sick neonate are even more strict than those which apply to other patients. The Einbecker Recommendations of the German Society for Medical Law12 state that even a severely damaged newborn infant’s life should be safeguarded; any deliberate shortening of that life constitutes killing.

FRANCE, ITALY, LUXEMBOURG AND SWEDEN
In France, Italy, Luxembourg and Sweden all actions which terminate a life - adult or neonatal - are prohibited.
UK
In the UK in the 1980s a high dose of the drug DF118 was given to a newborn with Down’s syndrome. The doctor was acquitted of murder when it emerged that the child had additional abnormalities and it could not be proved conclusively that his death from pneumonia was due to the DF118.

Clear distinctions have been drawn in Britain between not prolonging and terminating a life.

“The court never sanctions steps to terminate life .... There is no question of approving, even in a case of the most horrendous disability, a course aimed at terminating life or accelerating death. The court is concerned only with the circumstances in which steps should not be taken to prolong life”.35

THE NETHERLANDS
Though adult criteria do not apply to neonates, nevertheless babies’ lives are sometimes actively ended in the Netherlands.36-38 The practice is subject to the same rules of notification, namely a statement of natural death cannot be issued and the case must be reported to the coroner.

In 1992 the Dutch Paediatric Association published a report of their detailed deliberations on this subject.39 As well as recognising the concept of an intolerable life they tried to define it using parameters such as life expectancy, extent of suffering, the capacity to communicate, and degree of independence.39-41 Parental consent is an essential prerequisite for the active termination of an infant’s life.

The discussion group mentioned earlier2 discussed the issues further and suggested ways in which practice might be scrutinised. The best safeguard, they felt, would be retrospective assessment of each case by a multidisciplinary committee. They drew up an extremely detailed list of essential requirements, which includes: intolerable suffering; no viable alternatives; parental agreement; team discussion; independent consultation, and responsible practice. They concluded that the existing framework of criminal law should largely remain unchanged but recommended an examination of the framework towards reformulation of the legal definition of criminal action in this area.

The Netherlands is the only country which has openly tested the courts on the subject of doctors actively terminating the life of a child. Two recent cases drew attention to the competing duties of doctors to preserve life and to limit suffering and distress.

The first involved a gynaecologist, Dr Prins, who gave a lethal injection to a three-day-old baby girl born in 1993 with hydrocephaly, spina bifida and brain damage.42 A district court initially found him guilty of murder but he escaped punishment because of his careful treatment of his patient. In 1995, the Amsterdam Appeal Court dismissed the charges on the grounds that he had made a “justified choice” between his two conflicting duties.

One week later a district court in Groningen ruled that the action of Dr Kadijk, who ended the life of a baby with Trisomy 13, was justifiable in law. Even though the charge of murder had been legally proven, the court found that he had acted responsibly and in accordance with accepted medical ethics.43 Subsequently the Leeuwarden Appeal Court came to the same decision as the Amsterdam Appeal Court.

Both doctors were acquitted.

Discussion
The birth of children is a significant event in all societies; their death an emotive and sensitive topic. A degree of privacy from public scrutiny seems both inevitable and desirable. Even clinicians in neonatology remain unaware of what their colleagues elsewhere do, as a recent empirical study showed.44 Yet secrecy can perpetuate a difference in perception - the lay observer seeing “callous selective non-treatment”; the staff involved experiencing “a task which is extremely demanding in time and in intellectual and emotional energy”.45

There has been no dearth of literature on the ethics of managing critically ill neonates,37 45-47 but hitherto there has been little attempt to address variation in practices between countries. Our study has shown that substantial variations do exist, both in legal permissibility and in what constitutes acceptable practice.

The laws in all the countries are based on respect for human life, health and bodily integrity, as well as on respect for personal freedom and autonomy. Tensions arise when these two sets of rights conflict - as, for instance, when parents request treatment be withdrawn on humanitarian grounds. Though the laws themselves may be similar, their interpretation, guided by judicial decisions and official recommendations, varies considerably. Furthermore, rapid advances in neonatal medicine mean that the law lags behind practice, resulting in insecurity and vulnerability for the clinician.

All countries now recognise that overly aggressive management of hopeless cases is undesirable. In practice, however, doctors are unclear about their legal position. In Italy, for example, whilst the
Code of Professional Medical Ethics cautions against therapeutic over-aggressiveness, the state is strongly protective of infant life, and any discrimination on the basis of malformation or poor prognosis violates constitutional law. France has neither rules nor guidelines on the subject of cessation of treatment and no case has been heard, so clinicians are operating in a legal vacuum. Neither has there been legal clarification in either Germany or Sweden. In the UK and the Netherlands, where stopping treatment is an accepted part of medical practice, there remains some degree of uncertainty about the exact limits. Legal and professional debate continues, now focusing in the Netherlands on when lives may be actively ended.

The principle of double effect is recognised in all countries except Italy. It is considered acceptable to give drugs in sufficient quantity to relieve suffering even when to do so may shorten life. When it comes to the deliberate termination of life, however, although every country prohibits it, practice varies. In the Netherlands a notification procedure for physician-assisted death has been in operation since 1991, although doubts have been expressed about the effectiveness of control, given the low rates of actual reporting. Adult criteria are clearly inappropriate for infants, nevertheless Dutch doctors sometimes do actively end the life of a child with the specific consent of the parents; a recent survey revealed that as many as 45% of neonatologists and intensivists had intentionally done so. It is only within the last three years, however, that such cases have come to court, and the legality of active measures is still unclarified. However, recommendations for the monitoring of such practices have already been issued.

In contrast, other countries have strongly resisted a move towards deliberate termination of life. British paediatricians have officially rejected it. In Germany, while the practice of physician-assisted suicide is legal, (and indeed occurs on a much larger scale than in the Netherlands,) when it comes to babies, specific recommendations decree the practice of ending the life of even a severely damaged newborn. Of course, even where there are clear rules or laws, it does not necessarily follow that practice always mirrors legislation. Provided clinicians are discreet, actions do not necessarily come to public attention.

Conclusion

There is no doubt that bioethics constitutes a response to the high level of concern about the tremendous challenges posed by science and lays bare our societies’ uncomfortable attitude to developments which they fear may run out of control, developments which, while admittedly deemed marvellous by some, are seen as too rapid or threatening by others.” Neonatal care is one such development and the wisdom of currently accepted medical practice must be questioned.

Clarification of the legal position is a slow process. But one thing has been repeatedly reinforced by legislation, through court cases and in professional guidelines: the lack of a legal or medical imperative to treat does not mean a cessation of care. The need to provide comfort and good nursing care, even where aggressive intensive therapy is contraindicated, is a paramount consideration in all cases.

Whatever the legal prohibitions or official boundaries, decisions are required about what constitutes overly aggressive treatment in a given case. In those countries such as the UK and the Netherlands, where clinical judgments about the child’s best interests are permissible, doctors must use their intuition to determine what is best for this child and this family and what is and is not an intolerable burden. It is impossible to construct a frame of reference to fit all cases, even for a given country. And across Europe rules and practices vary so widely that it is difficult for groups to compose any universally acceptable guidelines.

It is clear from our investigation that different cultures, religious contexts and historical antecedents influence practice within Europe. Attempts have been made to try to harmonise practice but as international links grow, it is important to understand our diversity as well as our similarities. There is no country so advanced in its thinking that it cannot learn from its neighbours.

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