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Foregoing intensive care treatment in newborn infants with extremely poor prognoses

A study in four neonatal intensive care units in the Netherlands

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Within the framework of the broader ethical discussion on end-of-life decision making in neonatology and the need to obtain more quantifiable data, we performed a multicenter study in four Dutch neonatal intensive care units. All infants who died in these units in 1993 were included in the study. Aside from cases in which foregoing treatment was not under discussion, cases in which death appeared inevitable (A cases) and cases in which foregoing treatment because of extremely poor prognosis was the decisive factor (B cases) were distinguished. A total of 181 neonatal deaths occurred. Thirty-five infants died even after full continuation of treatment. In 98 A cases and 48 B cases, which together represented 81% of all deaths, treatment was foregone either because the infants had no chance to survive or because of extremely poor prognoses. In these cases, the medical team ultimately achieved consensus of opinion, although in some instances several sessions were required. In three cases, the parents did not agree with the team advice. In one A case death appeared inevitable. In two B cases, the parents' wish to continue treatment was followed. In a large majority of B cases, the decisions to forego treatment were based on the presence of severe cerebral damage. In A cases there was no real choice because death appeared inevitable. However, in B cases neonatologists were obliged to determine whether continuation of treatment was justifiable or if withdrawal of treatment in view of extremely poor prognoses was preferred. (J Pediatr 1996;129:661-6)

Many decisions in neonatal intensive care have life-or-death consequences. Aggressive interventions for and the increased survival of very premature, extremely low birth weight and seriously sick newborn infants have intensified the discussion about the ethics of such decisions.[1] The literature contains very little quantifiable data about how neonatologists deal with ethical dilemmas in daily practice. In 1973 Duff and Campbell[2] reported the withdrawal of life-sustain-

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ing therapy in 43 (14%) of 299 infants who died in a neonatal unit. In 1982 Campbell[3] reported in a similar study the withdrawal of life-sustaining therapy in 20% of the cases under review. Neonatologists in Hammersmith's Hospital reported in 1986 that active treatment had been discontinued in 47 (30%) of the 158 cases of infant death under review.[4] Eg-Anderson[5] reported the withholding of therapy in 6 of 62 deceased infants younger than 29 weeks of gestation.

This review of decision making in four Dutch neonatal intensive care units should be read in the broader context of end-of-life decision making (including assisted dying) in the Netherlands.[6] The attention has primarily been on patients past the newborn stage. For more than two decades the difficult choices faced at the end of such patients' lives have been vigorously discussed in medical, legal, political, and public settings. Decisions to withhold or withdraw intensive measures to sustain life and decisions to ensure optimal pain management are accepted as ethically and legally justifiable, even though the decisions may secondarily contribute to the hastening of a patient's death. Decisions to end intentionally a patient's life have not been removed from criminal classification under the penal code in the Netherlands. However, criteria (e.g., a competent and informed patient, who is in irremediable pain and suffering, who repeatedly requests assistance in ending life) and guidelines (e.g., proper consultation and proper reporting to the authorities) have been established and provide protection from prosecution for physicians who assist a patient's dying.

Neonatologists frequently face end-of-life decisions. We conducted this review of decision making in neonatal intensive care units to describe and, where necessary, to correct impressions about decisions now being made in cases involving critically ill newborn infants in the Netherlands. The article reports a multicenter study of end-of-life decisions conducted in 1993 by four of the 10 Dutch neonatal intensive care units.

METHODS

In 1993, 195,673 infants were born alive in the Netherlands. Of these infants, 3780 (1.9%) were admitted to the 10 Dutch level III neonatal intensive care units. Of the total admissions, 1284 (34%) occurred at the four participating units in this study. This study focuses on all infants who died in 1993 in these four units.

The infants were classified in six categories according to the report "Doen of Laten?" ("To do or not to do?") of the Dutch Society of Paediatrics.[7] The six categories and their designations are outlined as follows:

1. Cases in which intensive treatment was judged to be warranted and was continued until death
2A. Cases in which intensive treatment was withheld because of the patient's inability to survive
2B. Cases in which intensive treatment was withheld because the patient's prognosis was judged to be extremely poor
3A. Cases in which intensive treatment was withdrawn because of the patient's inability to survive
3B. Cases in which intensive treatment was withdrawn because the patient's prognosis was judged to be extremely poor
4. Cases in which intentional and active termination of the patient's life was involved

Category 1 encloses infants for whom limitation of treatment was seriously considered but ultimately rejected, and those infants who died unexpectedly while receiving maximal treatment and without prior discussion of limitation of treatment.

Judgments regarding prognosis in the 2A and 3A cases concerned strictly medical decisions and were characterized by the absence of any realistic chance for the infant's survival. Discontinuation of treatment was suggested to parents in 2A and 3A cases to prevent the continuation of useless suffering for their infants. In these cases, well-informed parents usually agreed with team decisions to forego treatment. If the parents did not agree, treatment was continued. Further discussions usually resulted in agreement between parents and the medical team.

Decisions in the 2B and 3B cases included additional ethical considerations. The burden of the treatment and the pain and suffering borne by the patient were weighed against the anticipated prognosis for later life. In these cases, all examinations necessary to establish the correct diagnosis and prognosis were performed. Once a diagnosis and prognosis had been made, the medical team sought a consensus as to what course of action to recommend. The judgment about a patient's prognosis was based on the clinical experience of the medical team members and on guidance from the literature. Careful records were kept about team consultations—the individual who initiated the consultation, the actual decision, the justification for and the process of the decision making, and at what time the decision was reached.

In most cases (except for category 1 cases), at least one formal team meeting was held in which the patient's history was discussed by members of the medical staff, by residents, and by nurses. When appropriate, other professionals (e.g., obstetricians, consulting specialists, social workers) participated in these deliberations. In most cases, more than one team meeting was held. It should be noted that in the Netherlands it is not the team as a whole, but the attending neonatologist, who is ultimately responsible for these decisions.

Once the medical team agreed on a decision, the decision was discussed elaborately and often on several occasions with the parents. Some parents had firm views about the best course of action, views they sometimes had earlier commu-

Table I. Clinical data of study group compared with total group of admitted infants in the four participating units

	Study group		All admissions	
	No.	%	No.	%
Gestational age (wk)				
<28	36	19.9	121	9.4
28-31	53	29.3	410	32.0
32-36	30	16.6	376	29.3
≥37	62	34.3	377	29.3
Birth weight (gm)				
<1000	49	27.1	177	13.9
1000-1500	40	22.1	286	22.3
1500-2500	38	21.0	389	30.3
≥2500	54	29.8	432	33.6

Table II. Classification and treatment decisions

	No.	%
Treatment continued		
Category 1	35	19.3
Treatment withheld		
Category 2A	10	5.5
Category 2B	5	2.8
Treatment withdrawn		
Category 3A	88	48.6
Category 3B	43	23.8
TOTAL	181	100

A cases: infants with no chance of survival; B cases: infants with poor prognoses.

nicated to members of the medical team. Parents who did not have such views usually allowed the medical team to make the decisions.

RESULTS

This study is based on 181 neonatal cases. Gestational ages and birth weights for the study patients and for the total number of patients admitted at the four sites are reported in Table I. The lowest gestational age and birth weight groups were overrepresented in the study group. Table II lists the classification and treatment choices of the study cases. No cases involving the intentional and active termination of the patient's life (category 4 cases) occurred in this population.

Category 1 cases (intensive treatment judged to be warranted and continued until death). A total of 35 infants were included in this category. In these cases, continuation of treatment was considered the best choice, or infants died unexpectedly without discussion of limitation of treatment. Diagnoses included perinatal asphyxia (8), idiopathic respiratory distress syndrome with complications (11), septicemia (2), serious congenital malformations (8), preterm infants with extreme growth retardation (2), and miscellaneous (4).

Table III. Results of team discussions

	A cases	B cases
Withholding treatment	10	5
Limited continuation of treatment	33	9
Withdrawing treatment	55	34
TOTAL	98	48

A cases: infants with no chance of survival; B cases: infants with poor prognoses.

Table IV. Comparison of 1990 study versus 1993 study

	1990 study (185 cases)		1993 study (181 cases)	
	No.	%	No.	%
Category 1	74	40	35	19
Category 2A	17	9	10	5
Category 2B	—		5	3
Category 3A	58	31	88	49
Category 3B	35	19	43	24
Category 4	1	1	—	

Category 2A cases (intensive treatment withheld because of the patient's inability to survive). Ten infants were included in this group. Diagnoses included gestational age less than 26 weeks with intrauterine infection (3) and severe congenital malformations (7).

Category 3A cases (intensive treatment withdrawn because of the patient's inability to survive). This group included 88 infants. Diagnoses included gestational age less than 26 weeks with severe complications (8), respiratory distress syndrome with complications (27), septicemia (12), perinatal asphyxia (7), severe congenital malformations (26), and miscellaneous (8).

Category 2B cases (intensive treatment withheld because the patient's prognosis was judged to be extremely poor). Five infants were included in this category. Diagnoses were encephalopathy after perinatal asphyxia (1), severe cerebral parenchymal bleeding (1), and severe congenital malformations (3).

Category 3B cases (intensive treatment withdrawn because the patient's prognosis was judged to be extremely poor). This group included 43 infants. Diagnoses included encephalopathy after perinatal asphyxia (21), severe cerebral parenchymal bleeding (10), severe/multiple congenital malformations (7), and miscellaneous (5).

Team discussion about these treatment decisions was usually initiated by the treating neonatologist. In a few cases, the discussion was initiated by a nurse or the parents. *Formal* team discussions were defined by the presence of at least two or more neonatologists of the medical staff. In addition,

one or more residents and one or more nurses always participated in the discussions. A social worker was present in six case discussions. In 19 cases, another consulting specialist participated. An obstetrician was present for discussions of two cases. In 81 of the 146 cases in which treatment was discussed (41 of 98 A cases and 40 of 48 B cases), the medical teams held formal discussions. In the other 65 cases (57 A cases and 8 B cases), informal discussions were routinely conducted.

Formal team discussions ultimately resulted in a consensus in the study cases. However, several discussions were often necessary before this consensus was reached. The conclusions were discussed with the parents, either in the presence of a nurse involved in the care of the infant or of another professional involved in the case.

The conclusions of the team discussions are presented in Table III. As shown in the table, a limited continuation of treatment preceded the actual withdrawal of treatment in 33 A and 9 B cases.

The time interval between the final conclusion of the medical team and the discussion with the parents was 1 hour or less in 71% of the cases, 1 to 6 hours in 24% of the cases, and more than 6 hours in 5% of the cases. The time interval between the final decision after the discussion with the parents and the implementation of the decision was 1 hour or less in 64% of the cases, 1 to 6 hours in 30% of the cases, and more than 6 hours in 6% of the cases. Sixty-five percent of the infants died within 1 hour, 30% within 1 to 6 hours, and 5% after 6 hours. Of the 181 study infants who died, 34 (19%) of the infants died in the first day of life, 96 (53%) of the infants died later in the first week of life, 27 (15%) of the infants died later in the first month, and 24 (13%) of the infants died after 1 month of life. Three of the 181 infants in the study group died after discharge from the intensive care unit.

Analgesics (opiates), sedatives, and antiepileptic drugs, either alone or in combination, were administered to 86 (48%) of the infants (60% of the B cases). Although muscle relaxants were not generally used, 12 infants received a dose because of a very prolonged dying process.

In 89% of the cases, the parents were present when their infants died. Autopsies were performed in 46% of the cases. In 79% of the cases, the parents accepted invitations for an appraisal 6 to 8 weeks after the death of their infants.

DISCUSSION

The neonatal units involved in this study also conducted a study in 1990 of the 185 patient deaths in their units in that year.[8] In that study, it was found that intensive care had not been started in 9% of the cases. In 31% of the cases intensive care had been withdrawn because of the absence of a realistic chance of survival. In 19% of the cases intensive care had been withdrawn because of extremely poor prognoses. In 40% of the cases, intensive treatment had been continued until the patient's death.

When the results of these two studies are compared, some differences are evident (Table IV). In 1993 the number of A cases was comparatively higher in category 3 decisions (i.e., stopping treatment) and lower in category 1 decisions (i.e., treatment continued until the patient's death). It seems warranted to conclude that a somewhat more liberal policy toward discontinuation of intensive care treatment has been adopted during the intervening years.

In the 1993 study population, intentional and active termination of life did not occur. Under Dutch legislation, a doctor who performs intentional and active termination of life of a newborn infant must notify the public prosecutor. Whether this act actually will be regarded and judged according to the government's Euthanasia Act was, until recently, an open question. However, in 1995 there were two test cases about the active termination of life for newborn infants. Both patients had severe congenital malformations. In both cases, the acting doctor was found guilty of homicide. However, in both cases the judge acquitted them because they were found to be in a "conflict of duties." They had the duty to cure the patient, but they also had to abolish the patient's suffering and pain. Both judges considered the choice these doctors had made justified and considered their acting in accordance with the standards of carefulness, with the scientific medical understanding, and with the standards that apply in medical ethics. Appeal confirmed this judgment in both cases.

Moreover, it currently is not clear whether Dutch legislation approves the withdrawal of treatment in very sick newborn infants who could possibly survive with continued intensive treatment, but who have extremely poor prognoses for the quality of later life. For neonatologists who follow the guidelines in the report "Doen of Laten?"[7, 9] foregoing life-sustaining intensive care is justifiable medical practice, not homicide. If death follows, these neonatologists consider it a natural death and they will not notify the legal authorities.

Some Dutch lawyers, however, hold the opinion that withdrawal of life-sustaining treatment in view of the prognosis for later life must be regarded as intentional and active termination of life and, accordingly, must be examined by the public prosecutor in accordance with criminal law. They argue that physicians do not have more knowledge of quality-of-life criteria than other people, and therefore should not be allowed to base their decisions on these criteria.

Neonatal intensive care treatment is often very invasive, very extensive, and, in a way, very artificial. Intensive care itself may result in serious damage to the infant. On the other hand, without such treatment many infants would have had no chance of survival. If life-sustaining treatment turns into

a futile act because the goal of giving the infant the prospect for a somewhat normal and healthy life without pain and suffering cannot be achieved, we are convinced that it should be permissible to stop the intervention. Such decisions are permitted in other fields of medicine.

To prevent inaccurate decision making in such cases, the Dutch Society of Paediatrics has advised that several neonatologists participate in consultations about treatment withdrawal decisions, at least in 2B and 3B cases. The absence of such consultations in eight B cases in the study population, accordingly, is without defense and not in accordance with the Dutch report "Doen of Laten?"[7]

In our study, the conclusions drawn from the team discussions ultimately were unanimous. Of course, this observation does not mean that differences of opinion did not exist. In many cases, a number of consultations were held before consensus was reached. Consultations were not separately recorded in every case.

Parents play an active role in the decision-making process. They are supposed to express their doubts, their feelings, and their agreement or disagreement with a doctor's proposal, and their view will be taken into account by the doctors when making a final decision.

During the 1993 study there was a disagreement between the medical team and the parents about foregoing treatment in three cases, one A case and two B cases. In the A case, infant death followed. In the two B cases, infants with prognoses judged to be extremely poor, treatment was started/continued and these infants survived. In both B cases, the parents' wishes to continue treatment were followed, because in the Netherlands parental agreement is a prerequisite for foregoing intensive therapies. However, this prerequisite has the undesirable consequence that some infants may continue to suffer beyond humane limits. At follow-up both infants were found to have severe developmental delay and cerebral palsy, and one had a severe visual handicap. These two surviving infants were not included in the 181 cases of infant death.

When the decision to forego treatment has been made, sufficient time should be allowed for parents to bid farewell to their infant. However, the recorded time intervals in the study cases suggest that, in many instances, the decision appears to have been implemented too quickly for this closure. We assume that this pace was influenced by the fact that, for most of these infants, the critical and often deteriorating condition was already present for some time and the parents in fact had made their farewells before the ultimate decision was made.

In all B cases and in most A cases, parents were present when their infants died. Exceptions occurred only when the patient's death could not be anticipated. Most of the parents returned for a later appraisal, suggesting that parents tend to be significantly involved in the dying process of their infants. This involvement might be a reason for the disappointingly low percentage of autopsies reported in the study group.

Sedative or analgesic drugs were administered in approximately half of the study cases. Dutch neonatologists consider relieving discomfort in the dying process, even if this may hasten death, as a good clinical practice.

Levin[10] has described the large variations in decision making that occur in neonatal intensive care units in different nations. These variations are based on differences in (1) the availability of resources, (2) social attitudes toward medical interventions and toward life with disabilities, (3) the role of physicians, parents, and other decision makers, and (4) legal considerations. Levin stressed the value of comparative research. We do not know whether current practice in the Netherlands, as reported in our study, differs significantly from practice in other countries.

The American Academy of Pediatrics' guidelines on foregoing life-sustaining medical treatment state that ethical theory and legal practice provide reasons to start or stop treatments, primarily on the basis of relative benefits and burdens for the patient.[11] These guidelines also state that decisions for patients who lack decision-making capacities are made together by physicians and families and are guided by the "best-interest standard." Families must be informed fully and adequately without withholding any details. According to these guidelines, benefits relate to prolongation of life, quality of life, physical pleasure, emotional enjoyment, and intellectual satisfaction. Burdens include intractable pain, irremediable disability or helplessness, emotional suffering, invasive or inhumane interventions designed to sustain life, or other circumstances that severely compromise the patient's quality of life.

Doyal et al.,[12] from the United Kingdom, have proposed that the only acceptable legal and ethical justification for deviating from the general obligation to provide lifesaving care is that such deviation is sometimes in the patient's best interests. Accordingly, selective nontreatment in neonatal cases is acceptable (1) when a neonate will inevitably die in a short time regardless of which therapy is provided, (2) when brain damage is so severe that death would arguably be preferable to life, and (3) when the neonate's burden of pain and suffering with treatment fails to outweigh the benefits of life, even if the infant is not in a terminal state.

Although these opinions are attempts to determine normal grounds for foregoing life-sustaining therapies, in a personal retrospective view Silverman[13] has stressed the moral aspects of (over)treatment in neonatal care. He argued that it is slowly but surely being realized by all concerned that unrestrained, intensive treatment of the smallest and most severely malformed babies is unreviewed and unlegislated social policy. He has underscored the significance of the parents' role in these decisions by stating that the right to

personhood granted by law to a newborn infant is an empty gift. Only parents or equally committed surrogates can make this gift meaningful.

In a recent review, Pearson et al.[14] studied decision-making about "futile" treatment in neonatal intensive care, by means of an individualized approach with family meetings. They found that only 19% of deaths in 1991 were *not* preceded by a decision to limit or withdraw care. Our study yields the same results—35 category 1 deaths in a total of 181 deaths.

We are convinced that neonatal intensive care is valuable and ethically justifiable. Many infants who formerly would have had no chance of survival now may be kept alive with a good outcome. We expect that neonatal intensive care will develop further and reach new milestones. The neonatal mortality rate most likely will continue to decrease. However, we are also convinced that neonatal intensive care should be applied with discretion. The burden of care must be congruent with its goals, which relate to more than patient survival. Thus withholding or withdrawing care from infants with extremely poor prognoses should be permitted. This possibility should apply to infants without any chance of survival and for infants with a small chance of survival but whose quality of life would be extremely poor.

The process of foregoing treatment must be meticulous and carefully circumscribed, because there is no means of reversal of the result. The decision to forego treatment should be made only on the basis of agreement between fully informed parents and the attending physician, with the support of medical colleagues, nurses, and other professionals.

In the Netherlands, discussions of end-of-life decision making in neonatal intensive care are held in the context of the wider societal discussions about euthanasia and assisted suicide. We believe that neonatal cases do overlap to a degree with the decision making under review in the euthanasia discussions. We recognize that intentional and active termination of a neonate's life has its adult image in "involuntary euthanasia." However, neonatal cases involving end-of-life decisions are different in essential respects from euthanasia cases. As yet there is no thorough legal or ethical analysis about such neonatal cases.

We have found that intentional and active termination of a neonate's life rarely occurs in neonatal intensive care units in the Netherlands. Withholding or withdrawing intensive therapy in view of the neonate's expected quality of life does occur more often. Such a decision places great responsibility on the doctor who carries out the decision. As argued in "Doen of Laten?"[7] we propose that responsibility of at least equal weight lies with the decision to introduce and/or sustain such aggressive therapy. Dutch neonatologists are now being pressured to prove that foregoing treatment in cases involving extremely poor prognoses is preferable to continuing treatment. An ethical and legal framework is needed in which patients benefit maximally from modern technology without becoming victims of pointless short-term or long-term suffering.

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REFERENCES

1. Lantos JD, Tyson EJ, Allen A, et al. Withholding and withdrawing life sustaining treatment in neonatal intensive care: issues for the 1990s. Arch Dis Child 1994;71:F282-F223.
2. Duff RS, Campbell AGM. Moral and ethical dilemmas in the special-care nursery. N Engl J Med 1973;289:890-4.
3. Campbell AGM. Which infants should not receive intensive care? Arch Dis Child 1982;57:569-71.
4. Whitelaw A. Death as an option in neonatal intensive care. Lancet 1986;2:328-31.
5. Eg-Andersen G. Prediction of outcome in 164 infants born after 24 to 28 weeks gestation. Acta Paediatr Scand (Suppl) 1989;360:51-61.
6. Rigter H, Borst-Eilers E, Leenen HJJ. Euthanasia across the Nord Sea. Br Med J 1988;297:1593-5.
7. Dutch Society of Paediatrics. Doen of Laten?: grenzen van het medisch handelen in de neonatologie. Utrecht, The Netherlands: 1992.
8. Kleine MJK de, Leeuw R de, Kollée LAA, Berger HM. Voortzetten of staken van levensverlengend handelen bij pasgeborenen: een onderzoek in vier centra voor neonatale intensieve zorg. Ned Ts Geneeskd 1993;137:496-500.
9. Sauer PJJ. Ethical decisions in neonatal intensive care units: the Dutch experience. Pediatrics 1992;90:729-32.
10. Levin BW. International perspectives on treatment choice in neonatal intensive care units. Soc Sci Med 1990;30:901-12.
11. American Academy of Pediatrics. Guidelines on foregoing of life-sustaining medical treatment. Pediatrics 1994;93:532-6.
12. Doyal L, Wilsher D. Towards guidelines for withholding and withdrawal of life prolonging treatment in neonatal medicine. Arch Dis Child 1994;70:66-70.
13. Silverman WA. Overtreatment of neonates? A personal perspective. Pediatrics 1992;90:971-6.
14. Pearson EB, Bose CL, Kraybill EN. Decisions about futile treatment in an intensive care nursery. N C Med J 1995;56:464-6.