

Presidenza del Consiglio dei Ministri

NATIONAL BIOETHICS COMMITTEE

THE ANENCEPHALIC NEWBORN AND ORGAN DONATION

21st July 1996

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INTRODUCTION

Very sensitive and divided about bioethical issues, which are objectively crucial, like assisted procreation, euthanasia, the status of the human embryo, public opinion certainly has very little uncertainties about the ethical legitimacy of organ donation and more in general of transplants: a practice that probably still raises (and pour cause*) complex feelings, characterised by a very close mix of admiration and fear, although it seems to have become part of our common thought, even though at a very high level. But with regards to transplants, bioethical issues continue to present themselves, even though in forms that do not involve (or no longer involve) the spasmodic attention of the mass media: a limited but exemplary case is that of organ donation during infancy, from an anencephalic child. However the* National Bioethics Committee, *even if it is profoundly convinced that it is its duty to take completely seriously and immediately answer any bioethical questions emerging from public opinion, even when they are clearly exaggerated, but it does not for this reason feel that it is irrelevant to take a position about issues that many would believe as marginal, both for their eventual theoretic sophistication, and for their limited statistical incidence. A typical case is that of the newborn who presents forms of anencephaly: a pathology that is generally known only within a small circle of people, mostly specialists. Nevertheless, the problem of anencephalic children is one of great relevance from a variety of points of view: as well as triggering a serious reflection on the personal dignity we must in any case recognise to these children, it also brings into question issues relative to the opportunity of reanimating them, to determining the moment of their death, and especially to the legitimacy of using their body as a source of organs for transplant. But these are not the only questions: we must not forget, for example, the significance a prenatal diagnosis of anencephaly can have for the parents… Such issues had already raised the interest of the NBC during the elaboration of some of its most important documents, starting with the very first,* Defining and Ascertaining Human Death *(approved on the 15th of February 1991)*; *as well as this, I simply want to recall* Prenatal Diagnosis *(18th of July 1992),* Organ Transplants During Infancy *(21st of January 1994),* Bioethics with regards to Infancy *(22nd of January 1994), until the very recent* Being Born *(15th of December 1995). The repeated, even if transversal, reappearance of the issue of anencephaly has finally convinced Committee members to put together a specific working group for this issue, led by Prof. Corrado Manni, in order to elaborate a synthetic but exhaustive text, which could serve as an indication on the bioethical status to recognise to anencephalic children, in particular with regards to the possibility of using them as*

organ donors. The group, joined by colleagues Barni, Benciolini, Coghi, Danesino, Gaddini, Leocata, Loreti Beghe', Sgreccia and Romanini, rapidly finished its work, which has been examined, discussed and in more than one case further clarified by the Committee in its plenary meeting. The drafting of the document has also been aided by Prof. Rodolfo Proietti and Doctor Lorenzo Martinelli of the Anaesthesiology and Reanimation Institute of the Universita' Cattolica Del Sacro Cuore, and Prof. Pier Paolo Mastroiacovo of the Paediatric Clinic Institute of the same University. On the 21st of June 1996 the document was finally unanimously approved.

In presenting it to the press, I feel the duty to formulate a thank you and a hope: a thank you to those who collaborated to its drafting, and especially to Corrado Manni, without whose decisive scientific and bioethical contribution, the document would never have seen the light; and the hope is that this text will be, as it deserves, read, meditated and amply discussed.

Rome, 21st of June 1996

The President
Francesco D'Agostino

PREMISE

In the last few years, the issue of the anencephalic newborn has acquired an increasingly growing importance under a variety of aspects: medical, technical, legal, but most of all, ethical.

In 1967 the first case of transplant from an anencephalic donor was reported, but the scientific report did not tackle in any way the numerous problems such a procedure raised, limiting itself to the description of the technical aspects and the observation that "anencephalic newborns were a reasonable choice as donors for children transplants" (1). Today the term "anencephaly" in the *Index Medicus* lists tens of references, with a considerable increase since 1984; many of them analyse also the ethical issues raised by this medical field (2).

This means that the growing scientific and transplantologic interest in the anencephalic foetus corresponds also to a more extensive ethical reflection, a reflection that was lacking when this issue first appeared.

The first problematic area regards the medical treatment of the anencephalic child after birth: this aspect has become more evident with the increased availability of intensive therapy and with the demands that this availability raises in this particular case.

A second area, much wider and controversial, includes all the aspects relative to the use of anencephalic foetuses as organ transplant donors: this aspect has gained considerable importance because of the progress of transplantation techniques in these last few years; progress that has made transplants possible even at a neo-natal age and this has highlighted the lack of organs for this particular age group.

Also, the causes of cerebral death are very rare in infants and the availability of donors is limited to subjects who died of prenatal asphyxia, of sudden infant death syndrome, accidents or child abuse (2).

Before discussing the ethical issues of the *anencephalic* newborn, a terminological clarification: some authors have contested as misleading the simple denomination of anencephalic because it would already consider these subjects as depersonalised beings. In the same way, we observe that it is improper to define them as organ donors, as in the neo-natal and infant stages we cannot speak of donation, an action that presumes understanding and free will (3). Even accepting the considerations expressed in these observations, the terms in question will be indifferently used here for practical reasons.

We will first consider the fundamental biological aspects, with the uncertainty boundaries that still exist and, then, the anthropological and ethical aspects relative to the issue of the newborn with anencephalic malformation.

BIOMEDICAL ASPECTS OF ANENCEPHALY

Definition: literally, anencephaly means without encephalous. In reality, with this term we define a rare malformation of the neural tube that occurs between the sixteenth and the twentieth day of gestation, which results in a “complete or partial absence of the cranial vault and of the tissues around it and various levels of malformations and distribution of the incomplete exposed brain” (4). Therefore, there are no cerebral hemispheres and no cranial tissues around them, with the presence of the encephalic trunk and of variable amounts of diencephalons. The absence of the hemispheres and of the cerebellum can be variable, and variable can also be the malformation of the cranial vault. The nervous surface is covered by a spongy tissue, made by degenerated exposed tissue.

This is the general reference framework for anencephalic malformation; however we must not think that this malformation is something that can be strictly defined. The author of a qualified text on anencephaly is surprised, with reason, by the variety of denominations and classifications existing on this topic in literature (4).

The classification difficulty comes from the fact that anencephaly is not an all-or-nothing malformation, that is, it is not present or absent, but it is a malformation that moves, without continuity, between less serious cases and cases of indubitable anencephaly. A rigid classification is therefore pretty much impossible (5).

Some central nervous system malformations are, for some, similar to anencephaly, but they must not be confused with it. Amongst them:

- amniotic band syndrome (in which we can find anencephaly associated with amputations, but rarely internal organs malformations;
- iniencephaly, where we find serious malformations of the cervical spine and multiple malformations;
- encephalocele, a neural tube defect in which a part of the encephalous, more or less seriously malformed, protrudes from the cranium due to its failure to close (6).

As well as these malformations, we also must recall hydrocephaly, the most serious form of which can have a functional significance analogous to that of anencephaly (7); for this reason this malformation is often cited in the debate about anencephalic newborns (8).

Associated malformations: there are numerous malformations associated with this pathology:

- malformations of cranial organs like eyes, ears, hipofisis are serious and frequent.

- Less frequent are the malformations of the cardio-circulatory apparatus (2-8%) in comparison to 0.4% of the general population and of the genitourinary apparatus (between 4 and 26%) (9.36) in comparison to the 8.4% of the general population.

Such incidence, although it cannot be overlooked and has still not been fully evaluated, had led us to conclude that kidneys, liver and heart, even though they are in general smaller for the body's weight and affected by a higher percentage of malformations, in the majority of anencephalic foetuses born alive, are suitable, at least initially, to be transplanted (10, 91, 36).

According to IPICM (Italian Polycentric Investigation of Congenital Malformations) data, on 55 autopsies carried out on anencephalic newborns, 20 newborns had an associated malformation, and amongst them 7 were affected by cardiopathy. The average weight was 1,982g in newborns without malformations, 1,670g in newborns with extracranial malformations and 1,355g in newborns affected by cardiopathy.

Etiology: it is not known, but it is believed that it could have a multifactorial origin, in which genetic and environmental factors have an important role; it is not a common malformation in its viral aspect and in chromosomic pathology.

Incidence: the incidence of anencephaly, although variable according to the diagnostic criteria and to pre-natal screening measures, is around 0.3-1 for a thousand born (11, 12, 13), including both those born alive and those born dead.

This data shows a decline of about 5% per year and 2.7% of anencephalic babies born alive. It is possible that, due to the increasingly extensive pre-natal screenings, the incidence of neural tube defects at birth will be gradually reduced.

According to IPICM (Italian Polycentric Investigation of Congenital Malformations) data, which refer to 1,793,000 born, observed in the period 1978-1994 in about 100 Italian hospitals, there were 185 cases of anencephalic newborns, of which 120 were born alive (64 were deceased after 24 hours) and 65 were born dead.

In the last 5-6 years the incidence of anencephaly is of about 0.5-1 for 10,000 born. Referring these data to the total of births in Italy (around 520,000/year we can predict the annual birth of 25-50 anencephalic newborns.

Diagnosis: pre-natal diagnosis is possible through the screening of maternal alpha fetoprotein and ultrasonography. The two methods have

shown, on large scale screenings, a sensitivity of between 80 and 100% (14, 15, 16, 17).

We must notice that the law, in many countries, allows the interruption of pregnancy in the presence of serious foetal malformations. A recent study has highlighted that in the case of anencephaly the voluntary interruption of pregnancy occurs in about 80% of cases (96).

Often, the diagnosis occurs before the twentieth week of gestation (18).

Functional aspects: The anencephalic foetus is gravely deficient from a neurological point of view. The functions linked to the cortex are missing: therefore all the phenomena of physical life are absent, and so is sensitivity (19, 20), motility (21), the integration of almost all corporal functions (22). Generally a more or less valid control of the respiratory and circulatory functions is maintained, functions depending on structures in the encephalic trunk.

Survival: with current therapies the survival of anencephalic newborns is very limited. Between 40 and 60% of anencephalic newborns are reported to be born alive (23, 24) whilst after birth only 8% survives more than a week and 1% survives between one and three months (25, 26). There has been only one reported case of survival to 14 months (8) and two cases of survival to 7 and 10 months, without needing a mechanical lung (97).

The *British Columbia* register in the period 1952-1981 reports 450 cases of anencephalic newborns, of which 60% born dead and 40% born alive. Of the 180 born alive, 58% did not survive over 24 hours. The mortality after 72 hours was 86% and after a week 98%. (25)

Despite such a reduced life expectancy, it is not always possible to define the imminence of death (27) and the duration of life can be greatly influenced by intensive care therapies.

Only rarely we assist to a progressive degeneration of the nervous tissue, as the lesion appears generally stabilised at birth. The moment of birth poses a high risk because of the trauma that the residual nervous tissue is subjected to, as it is not protected by a bone structure. Subsequently, death is caused mostly by respiratory failure caused by the ineffectiveness of the nervous system or by pulmonary dysplasia and in small part by multiple endocrinous anomalies (hipofisis, adrenal gland) (4, 28, 29).

Recently, there has been in the United States a medical-legal case (known as the case of Baby K) following the birth, by caesarean section, of an anencephalic baby, whose condition was known since her intrauterine life. The mother opposed the interruption of mechanical ventilation started after the birth. The District Court ruled that, on the

basis of the *Emergency Treatment Act*, the respiratory therapy by ventilator was not “futile” or “inhumane” and was therefore in line with American law. The hospital’s insistence in refusing this type of care was therefore not legitimate, as American legislation does not foresee any type of dispensation regarding the treatment of patients affected by anencephaly (98).

In any case, even with variable probabilities of survival, which also depend on the level of intensive care and on the time of the collection of data, anencephaly is a lethal condition and generally no newborns survive beyond 3 days (6).

PROBLEMS RELATED TO ANENCEPHALIC NEWBORNS AND ORGAN DONATION

In another document, the NBC has already discussed the complex bioethical problems arising with regards to infant transplantology (cf. Organ Transplants During Infancy, approved the 21st of January 1994). Therefore, it has been noticed that the need of small organs for transplant is much higher than the chance of finding any. The majority of patients waiting for a transplant die before a donor has been found (30). Infants' organs are necessary for transplants in small patients (hypoplastic left heart syndrome, biliary atresia), and they are particularly interesting also for the characteristics of survival and of growth possibilities of their functional potential.

Therefore, there are promising developments also for the heteropic use of such small organs in an auxiliary and not substitutive function, permanent of temporary (30).

In addition, we can hypothesise the future use of cellular lines, instead of entire organs, in the treatment of the neoplasia of the hematopoietic system, of enzymatic, immunologic and endocrine insufficiency.

Despite the many encouraging aspects and outcomes, the entire issue of transplants during infancy is still the subject of critical discussion, both because of the instructions than because of the techniques and the results, regardless of its ethical aspects (27, 31, 32, 33). In its evaluation, we must also remember that this is surgery at the very highest technical-organisational level, and it is unlikely that it will be available to a wide number of patients. (For another look at the issue of organs removal from an anencephalic donor, see 34).

The role that the eventual availability of the organs of anencephalic foetuses could have in satisfying the needs of small patients awaiting transplants is very controversial.

Although starting from analogous numerical considerations, different authors have arrived at diametrically opposed conclusions about the number of foetuses theoretically available in the United States every year: from 1800 living foetuses (35) to 400 available for transplants (36), to stating that only a few transplants could actually be carried out (27, 89).

The different evaluation is based on the dissimilar consideration of the number of premature babies, of associated malformations, of the difficulty of finding an adequate receiving patient, of the long term survival and of many other factors. For an extensive analysis of these data, see (8).

Even though this controversy cannot have much ethical relevance, it is however important to observe how the potential use of anencephalic foetuses has been evaluated differently: from being the only remedy to a situation of great needs for organs, to being a measure of irrelevant effect to the problem of serious malformations in infancy, able to resolve only very few particular situations.

The problem of care for the anencephalic newborn

Forgetting the possibility of using the organs of anencephalic newborns for transplant, the fundamental medical problem is establishing which care must be given to them after birth, once the diagnosis has been made and it is sure that there are no chances of long term survival.

The availability of intensive care methods, able to support vital functions, raises the question of whether these methods should be used. Generally, there is agreement on the fact that in these cases only ordinary care methods should be used, taking into account that no therapy, however aggressive, is today able to change the progress of the illness, which is always deadly and which is caused by the absence of those structures that intensive care should temporarily replace (37, 38, 39). There is no chance for these structures to work again and therefore we would be moving within the sphere of therapeutic insistence, devoid of beneficial aims and possibilities and, consequently, without reason.

The anencephalic subject and the possibility of organ donation

Instead, tackling the problems relative to the anencephalic newborn as possible donor, we can highlight numerous issues and three different conceptual positions towards the anencephalic newborn.

The common starting point is that transplant techniques are able to alleviate suffering and allow the survival of a great number of patients and that any effort must be made to meet the demand for organs. The differences of opinion are highlighted at the moment of establishing the ethical boundaries for this effort. A first consideration is that the removal of complex organs (liver, kidney and, most of all, heart) must be carried out in conditions of relative hemodynamic compensation, that is, at a moment in which the heart is still properly beating and is able to ensure sufficient perfusion to the organs involved.

In other words, waiting for the anencephalic newborn’s death according to cardio-respiratory criteria and removing the organs afterwards, is not compatible with the preservation of the organs’ functions, so that they would no longer be suitable for transplant. It is a

problem analogous to that presented by the adult donor, for which the issue of cerebral death has been discussed in depth. Various countries have given different legal interpretations to this problem, in general, almost all legislations follow the principle of the need for a complete and definitive cessation of all encephalic functions. Different methods are used to ascertain such status, even if with the only aim of demonstrating the same condition.

In the case of anencephalic newborns, demonstrating cerebral death presents considerable difficulties, linked to the still imperfect knowledge of neonatal neurophysiology in general and also to the subject's condition (37).

It is impossible to carry out an EEG because of the anatomical absence of the structures originating its potentials (cortex). In addition, the presence of EEG lines in the newborn and in the child, does not exclude the diagnosis of cerebral death (40).

Measuring the cerebral flux, although difficult, is not significant in cases of severe vascular cerebral malformations. In the same way, demonstrating a cerebral flux does not exclude, in infancy, the diagnosis of cerebral death (41).

The trunk's reflexes are variable according to the malformations in the numerous cranial nerves.

Clinical examinations aimed at determining the fact that the encephalic trunk has been compromised cannot, therefore, be fully trusted both because of the difficulty of ascertaining the trunk's reflexes as well as the answers gained. In addition to this, an even more basic aspect has arisen in neonatal SNA physiopathology.

Currently, there is a lively debate on the potentiality of the neonatal encephalous. A considerable ability to adapt, even in very serious pathological conditions, is recognised in the first days of life, during which neuroplastic phenomena seem particularly active and valid (42, 43). Wide bibliography in (8).

Today the newborn's encephalous appears to be less and less comparable to a miniature adult brain, especially with regards to the functions of conscience and contact with the environment, and more and more comparable to an organ under formation, with variable potentialities (8). The loss or the lack of a part of it in the development phase cannot be compared to the loss of the same part once the development is completely finished (8).

These considerations are particularly important in evaluating the abilities of anencephalic newborns.

Obviously, we are not talking about the possibility of the trunk replacing the functions of the missing cortex, but of admitting that the trunk's neuroplasticity could be sufficient in guaranteeing, at least in its less serious forms, a primitive conscience to the anencephalic newborn.

Therefore, we should reject the assumption that anencephalic newborns, being devoid of cerebral hemispheres, are "by definition" unable to have a conscience and to suffer (8, 44).

In order to overcome the current legal difficulties, we have highlighted three different possible evaluations of the issue of anencephalic newborns:

a) *A different classification for anencephalic subjects*

The first position highlights the fact that anencephalic newborns have the particularity of not having a cerebral cortex and of being devoid of the anatomic structures possessing the superior functions. These functions are considered by some as characteristic of humanity and this serious malformation would indicate a particular *status* for anencephalic newborns (31); therefore, speaking of "cerebral death" would make no sense, and we should instead talk of "cerebral absence". That is, a completely peculiar condition, according to the intentions of those proposing it, which should have an appropriate legal recognition. Consequently, the anencephalic newborn is a "brain dead" subject, but a particular case of cerebral death, called "brain absence" (45, 46, 47, 90).

An individual in this situation, unable to think and feel, has no interests to defend and, therefore, does not have any rights and does not need the same protection applied to all other subjects (48).

This position is open to a variety of criticisms, both from a medical point of view and a moral one. It comes from a clear utilitarian intention (3).

First of all, we have seen that the malformation is not a defined entity, but a continuum of seriousness to which we should give conventional boundaries. This would definitely lead to difficulties in the diagnosis and to possibilities of error (49, 52, 89), although the possibility of error is not in itself an element sufficient to prohibit a certain medical practice.

A second objection regards the likelihood of suffering, which cannot be excluded on the basis of the abovementioned neurophysiologic considerations and on the basis of our current knowledge (44, 53).

However, the most important objection is that these subjects are used without any benefit to them, on the contrary, possibly damaging them, for someone else's benefit. They are unable to express any kind of consent and their condition is not different from that of many other seriously ill patients.

The position illustrated, would allow us to obliterate the status of some particular subjects with the aim of making them organ "donors", on the basis of evaluations on their quality of life. There is no assessment of the advantage and the disadvantage for a subject and for others, but only

an imbalance between an individual's disadvantage and another's advantage (36).

In addition, accepting this position would mean creating an area of uncertainty which could involve many other conditions, including the persistent vegetative state (46). This argument, that is, the creation of a *slippery slope* able to lead us much further than the original intention, is stressed by many authors (3, 31, 36, 48, 51).

On the contrary, there's a need to define the phenomenon of death with a series of rules valid in any case, which do not allow any exceptions for any particular pathological conditions. A policy of clarity and essentiality of the rules is thought by many to be more promising, even for the purpose of making it easier for people to accept organ donation (27).

The definition of death must remain distinct from the need for transplants even if the need for and the possibility of transplants must be a stimulus to a more in depth scientific and clinical study. Public opinion must have the certainty that death is established with objective and non-equivocal criteria, and that such criteria are not modified by the need of finding organs for transplant.

This is every individual's fundamental right, even before being the basis for a wise transplant policy.

b) *Revising the current concept of cerebral death introducing other assessment criteria*

A second position, more radical and extensive than the previous one, is that calling for the rejection of the criterion of death of the whole encephalous, believing that it is sufficient to ascertain the death of the cerebral cortex (54, 55).

Therefore, in the definition of death, maximum importance is given to the absence of self-consciousness and of the ability to relate, which is typical of man, and less importance to vegetative functions, which are not considered typical of humanity (27, 35, 56, 57, 58, 60, 61).

As a result, it would mean redefining cerebral death, substituting to the need for a complete and definitive interruption of all functions of the whole encephalous, the death only of the cerebral cortex and this in all cases, not only with regards to anencephalic newborns. *In addition, the National Bioethics Committee has already expressed its opinion (102), stating that "We cannot share this opinion (that is, the definition of cortical death) because, if the parencephalous' centres are functioning, the body's capability of (central) homeostatic regulation and its ability to carry out vital functions in an integrated way, including autonomous respiration, are still active".*

In the particular case of anencephalic newborns, the legitimacy of organ removal is also justified by these subjects' very short life expectancy (27). According to some authors, the inevitability of the worsening of the anencephalic subject's clinical condition and the imminence of his/her death, would justify the removal of organs *ante-mortem* (85, 86).

This position gives great importance to the neurological integration of the various functions, so that, even though respiration and circulation are still active, in the absence of a superior integration, the subject is considered deceased (62).

This interpretation is subject to numerous criticisms, and in this case there is a high risk of extending the assessment of death to subjects who do not present any anatomic damage but whose cerebral cortex is unable to function. An immense problem would open and the anencephalic newborn would be only a small part of it.

We would risk authorising the removal of organs from living subjects, on the basis of considerations relative to their neurological integration and to their life expectancy (people on the verge of death) (27, 89). It must be highlighted that, hypothetically, once we accept the principle that it is licit to interrupt an individual's life, even if in particular physical conditions, for the benefit of others, a numerous amount of subjects (think about those condemned to the death penalty) could be included in this category, amongst which subjects affected by serious illnesses and waiting for a transplant (89).

The first position illustrated is, evidently, a legal attempt to apply only to anencephalic newborns the criterion of cerebral death as only death (absence) of the cortex, avoiding tackling the problems that the extension of this criterion to all subjects would undoubtedly cause.

The evaluation of the problems relative to declaring death in the presence of activity in the cerebral trunk is outside this document's purpose. Only one observation: the scientific assessment of cortical death (assessment that even with regards to the part involving the issue of anencephalic newborns presents unequivocal elements) must be accompanied also by an anthropological evaluation. Ascertaining death only by the cerebral cortex's inactivity, both in the adult or in the newborn, even anencephalic, contradicts the idea of death as it has been passed down to us for millennia, because of the presence of spontaneous respiration and of cranial nerves' reflexes.

These subjects are not dead, although a law can declare them such, and they do not seem dead to anyone who should approach the bed (36). There have been those who, maybe as a challenge, have asked this thesis' supporters whether they would be ready to bury these individuals, based on the fact that they consider them deceased (63).

Humanity would probably find it impossible to accept this position, if not at the price of a general scepticism about the assessment of death and the intangibility of the living human subject, although without any life expectancy, even for the purpose of benefiting another individual (46, 64).

Some authors (65) have also spoken of ethical *iatrogenesis* observing that, apart from whether an argument is more or less valid, if it is too subtle, it can easily generate errors (87). The moral principle must not be complex to the point that only a few people are able to understand it.

c) *Using the current criteria of cerebral death. The difficulties*

A third position believes in using the criteria of cerebral death currently in force and in waiting for total cerebral death before proceeding with the removal (66, 67). It is clear that even the hypothermia that occurs before death cannot be accepted (44).

Even this attitude, however, which satisfies the criteria of certainty and uniformity in ascertaining death, is not devoid of criticism and difficulties.

In general, the difficulties come from ascertaining cerebral death in infancy and in the first week of life because, at this age, our knowledge of the physiology of the CNS is still incomplete, in particular in the case of anencephalic malformations (68).

Mostly, there are uncertainties about the observation times necessary to be sure of the encephalous' death (longer times than in the adult) and about the greater difficulty in assessing the reflexes cranial nerves. This difficulty is, as we have said, even greater with regards to anencephalic newborns.

About this, it has been suggested to consider the presence of spontaneous respiration as a reflex of cerebral trunk, as it is certainly the trunk's most important activity, if anything, in terms of being necessary for life (69, 70, 92). The absence of spontaneous respiration could be a sufficient element to establish, in anencephalic newborns, the death of the cerebral trunk.

This hypothesis would create a type of subcategory, made up by anencephalic newborns, subjects for whom criteria that are partially different from those required in all other cases would be valid.

This point of view is in contrast with the abovementioned considerations, even if it appears justified by the presence of a malformation which poses particular diagnostic difficulties. There is still no agreement between scholars about the necessary technique to ascertain the absence of spontaneous respiration. However, this position, although

with some peculiarities, is within the same conceptual frame of the laws currently in force (56, 88, 94).

ETHICAL CONSIDERATIONS

The basis of the current laws on transplants from cadavers is the rigorous ascertaining of the so-called “dead donor rule”, that is, the precept stipulating that in any case the donor must be deceased with certainty before removing the organ.

This rule, which could at first appear to be of obvious banality, is in reality questioned by numerous proposals. For example, in a strictly utilitarian perspective it could be deemed legitimate, in order to attain a good, in this case another person’s health or life, to remove an organ from a non-consenting donor, if he/she does not suffer and his/her interests are not violated.

This is the case for anencephalic newborns, whose death is considered imminent and inevitable and who are not considered capable of feeling any type of suffering. For these reasons, anencephalic newborns are not believed to have any interests to defend and therefore none that can be violated.

As well as this case, numerous other cases can be proposed or hypothesised (terminally ill patients, patients in a persistent vegetative state, patients affected by serious dementia, patients who express the will to die, etc.) to illustrate the concept of the *slippery slope*, mentioned by many authors.

As we can see, the positions discussed are very different from each other, even when considering the future perspectives we can foresee today, and come from utilitarian cultural positions on the one hand, and personalistic ones on the other.

First of all, it is clear that death is a process in itself and that we cannot have a death by transplant and a death in itself.

The definition of death cannot be anything we choose it to be, but exists independently from our aims (3). Death cannot be defined in a utilitarian way, in order to gain the greatest good that we could derive from it for others (3, 84).

The assessment can happen with different techniques according to the circumstances and the therapies carried out (70), but any assessment will have to give a valid result in itself and independently from the possibility or not of organ donations.

The need for transplants must stimulate research in this field, but not be the basis for defining death.

This principle must be applicable to anencephalic newborns as well, even if in this case we must have appropriate diagnostic methods, capable of giving certain results.

Certainly this is an extreme case, but we are not for this reason authorised to make up a particular category, biological or legal, for these subjects.

Anencephalic newborns have a variable but certainly short life expectancy, even taking into considerations the difficulties inherent to this assessment.

However, this is a situation that for various single aspects, even if not all at the same time, is common to other categories of patients, although in different intensity. Take, for example, incurable patients, for whom any therapeutic possibility has been exhausted, or patients who have lost their intellective functions or any contact with the environment.

In the same way, it is not considered licit to shorten these subjects' life, or, even less, to cause their death, and for similar reasons it cannot be acceptable to behave in this way towards anencephalic newborns (37, 71, 71).

Also irrelevant is the duration of the life to be sacrificed, almost as if a short life can be sacrificed for the benefit of another with a longer life expectancy; about this, some have observed that if anencephalic newborns did not live for such a short time, today they would not be the focus of this debate (36).

In a perspective that considers that fact that each person is human, despite his/her state of health or development, as a fundamental value for the ethics of biological sciences, the only decision that appears acceptable is making available for organ donation exclusively the body of those subjects whose death has been ascertained.

With regards to anencephalic newborns this means that, in the current state of knowledge, it is probably premature to establish valid and verifiable criteria to determine death, by following neurological criteria (27, 73, 74, 75, 76, 77). A more in depth study is indispensable (68).

The need for a moratorium in the use of anencephalic subjects as organ donors has been supported by many authors, on the basis of the insufficiency of our current knowledge of numerous aspects that are the focus of bioethical controversy. The precept that good ethics comes from good real premises has been mentioned, recalling that many theoretical and practical problems of treating anencephalic subjects are still being discussed (3).

This wait seems amply justified, at least until the different positions on this issue will reach a more reasonable chance of agreement, on the basis of new evaluating factors.

At this point, we need to highlight at least a contradiction and a complex problem.

The contradiction is that of those legislations allowing the interruption of pregnancy in the case of serious malformations, even in advanced

stages of gestation, and then prohibiting the removal of organs from those subjects once they have been willingly brought into the world.

It is an evident contradiction, already highlighted by those who support the position of the legitimacy of removing organs from anencephalic newborns independently from neurological examinations (*brain absence* condition), but that, on the contrary, can be easily seen also as supporting the illegitimacy of interrupting the pregnancy, taking away the protection of the law from subjects that should be otherwise protected by it.

Even though the two conditions, before birth and after birth, have a different biological and legal significance, it appears evident that the two attitudes cannot be easily reconciled.

Next to this, we find the suggestion of supporting the continuation of pregnancy in the case of malformed foetuses, even in the highly humanitarian perspective of eventually donating organs after their death (78). The following problem regards the concrete realisation of the removal of organs from an anencephalic donor.

With regards to the problem of ascertaining cerebral death in anencephalic newborns for the purpose of transplantation, we have seen that these subjects do not have evolutionary neurological lesions and that the neurological damage is not one of the most important causes of death. In other words, anencephalic foetuses, although affected by a very serious neurological malformation, do not tend to evolve and it is unlikely that they would find themselves in a state of cerebral death in a short amount of time, as death occurs mostly due to respiratory causes (3, 79). This means that in order to make organs available for transplantation (and this can happen only if good perfusion has been maintained, and therefore good cardio-respiratory functions up until the moment of the removal) anencephalic foetuses must undergo intensive care treatments until cerebral death has been ascertained.

Premises to the treatment are also that cerebral death is imminent in this conditions, that it can be diagnosed with a certainty comparable to that of other potential donors and that the care given, in the sole interest of a third person and not of the newborn, is ethically acceptable (27).

The problem is in this situation: we are facing the artificial lengthening of a life with exceptional methods in a condition that does not have any chance of recovery, due to anatomical causes, and this for the purpose of preserving the organs for a subsequent transplant.

When described in this way, the risk of therapeutic insistence in its fuller sense and of the use of anencephalic foetuses only as means for someone else’s benefit, seems evident.

In the ethical evaluation of this perspective however, we must take into account also other aspects. First of all a similar practice is carried out also in other cases:

- during the adult donor's observation period (80). As death occurs at the beginning of the observation period, evidently this is not a case of therapeutic insistence on a living subject, but of a particular procedure that is carried out on already deceased subjects, in order to preserve their organs, even if this judgement can only be expressed afterwards, when the premises of cerebral death have already been verified.

In anencephalic newborns, on the contrary, intensive care treatments start already at the moment of birth or at the beginning of respiratory failure, whilst waiting to verify cerebral death, therefore before the moment of death, even when established retrospectively.

- In the case of brain dead pregnant women, in order to help the foetus to reach a prenatal age that will allow his/her survival (81).

Even in this specific case, we cannot talk about "Therapeutic insistence" because the care is evidently aimed at the foetus' survival and not at the already deceased mother.

- In the case of seriously ill newborns, for whom there is no chance of recovery, for the simply human purpose of allowing the parents to make the journey and reach their child (37).

The use of extraordinary therapies in order to preserve the organs of the anencephalic newborn is within these cases of non-routine use of intensive care, as in the case of the inevitable and imminent death of a patient who has lost consciousness permanently.

Certainly, we must establish a limit for intensive care, beyond which such care must be interrupted and, anyway, the conditions recognised by current laws as so-called cerebral death, occur.

It is evident that the exceptional circumstances of anencephalic subjects is not such that the doctor ceases to have the obligation of offering his assistance to resuscitate them, aided by their cardio-circulatory and respiratory condition, which is usually satisfactory. This obligation to assist is perfectly in line with the eventual possibility of organ donation, which can be carried out thanks to this therapeutic support, as in the case of minors or adults who are able to donate organs for transplant.

In these cases a series of factors should be safeguarded, as already discussed by the NBC in the document cited about transplantology in infants, like, in particular, the legitimacy of the transplants proposed, the team's seriousness and especially the parents' consent.

This is a factor that is debated and called to support the most disparate positions. Certainly, the parents who find themselves in this situation, whether they are given the choice of interrupting a pregnancy, or whether this is not possible, are at the centre of great tensions and

difficulties. Knowing that a personal tragedy is capable of alleviating the suffering of other patients can contribute to give meaning to an event that can be in many ways deeply traumatising. In this sense, to make the organs available for transplant, with an ethically correct practice, is certainly a great help for the parents, who can see an outlet, even if minimal, for their effort and their suffering; for this reason, their participation and their consent to all the proposed methods becomes a determining factor.

In some cases, the parents themselves insistently requested the chance of a transplant and the possibility of pressures from the parents has also been hypothesised (27, 44).

For the difficulties that the diagnosis of anencephaly can create not only for the parents but also for the doctor, who occasionally comes into contact with it, see (82). These difficulties justify an adequate psychological intervention, which is generally provided by specialist centres, but the definitive institutionalisation of which would be of great bioethical value.

The *Council on Ethical and Judicial Affairs of the American Medical Association* has recently modified its position with regards to the issue of anencephalic newborns as organ donors (99). We report, in brief, the assessment factors that have made them change their previous, 1988 position, according to which the removal of organs from anencephalic donors was believed to be acceptable only after the donor's death, ascertained with cardio-circulatory and neurological criteria (100):

Anencephaly: although anencephalic newborns' external appearance (visceral organs' functionality, suction reflex, reaction to pain, movement of eyes and limbs, making sounds, facial expressions) can give the impression of the presence of some level of conscience, there is none.

Parents: the transplant from anencephalic newborns brings benefits not only to the recipient but also to the parents, who can see a reason, although partial, for the experience they are having.

Answers to the most common objections to removing organs from anencephalic newborns:

a) *the "dead donor rule", which prohibits the removal of vital organs from living subjects, is broken*

As anencephalic newborns never had, do not have and will never have a conscience, they have no interest to life to defend. If their life is

shortened, there is no conscious trace of it and there is no improvement or worsening of their *status* due to the duration of their life.

The exception to the rule does not alarm the community or other potential donors: in fact, they cannot feel "threatened" by this decision as they can never find themselves in the same situation as anencephalic newborns.

This decision does not alter the respect for life and the consideration of its value. As anencephalic newborns have no interest in preserving their existence, the parents' authority in requesting the interruption of care is accepted, although this does not diminish our respect for life.

b) *problems relative to the accuracy of the diagnosis*

The document confirms that it is possible to erroneously diagnose anencephaly especially if the diagnosis is not carried out in specialist centres or by a specifically competent person. We propose to overcome this problem by:

- applying the diagnostic criteria for anencephaly (101).

There criteria are:

- the absence of a large portion of the cranial bone structure;
- the absence of scalp over the bone defect;
- the presence of exposed fibro-hemorrhagic tissue because of the cranial defect;
- the absence of recognisable cerebral hemispheres;
- expecting the diagnosis to be confirmed by 2 people who have particular competence in this field, but are not part of the transplant centre's team. If there is no certain diagnosis, the removal of organs must be forbidden.

c) *opinions relative to the* slippery slope argument *(the decision would open the door to future abuses against other categories of patients)*

The exception to the rule could not damage other categories (patients in a persistent vegetative state, affected by serious neurological damage, elderly patients with dementia). The fact that this danger exists must be proven, not simply argued. This risk does not exist because anencephalic newborns are a completely particular category, without a history of conscience and with no chance of getting one, and this is unlike any other categories.

d) *number of transplants that can be carried out*

Many criticisms have highlighted the fact that organ removals from anencephalic donors would have very little effect on the problem of transplants during infancy. In reality, transplant techniques evolve, allowing the use of organs in conditions that are different form the past and in addition, each donor could give 4 vital organs (2 kidneys, heart and liver). Even if there were only 20 donors per year (in the USA) as some have foreseen, it would still be an advantage in terms of chances of survival for as many children.

These are, at the moment, the issues that require a careful debate in order to formulate a judgement on the legitimacy of organ removals from anencephalic donors.

Therefore, the arguments of the Council on Ethical and Judicial Affairs *of the American Medical Association seem to be an attempt – not an acceptable one – to justify declaring dead people who are still alive, in order to allow the removal and the transplant of organs.*

Anencephalic newborns are living individuals and their short life expectancy does not limit their rights and dignity.

The suppression of a living being cannot be justified, even when suggested in order to save other beings from certain death.

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