

ORGAN DONATION FROM ANENCEPHALIC INFANTS

Report

BIOETHICS CONSULTATIVE COMMITTEE.

1. INTRODUCTION

1.1 Anencephaly

Anencephalic infants are born with a neural tube defect resulting in failure of closure of the skull, often with absence of skin closure, and absence of part of the brain. Generally there is limited cerebral cortex and cerebellum but the brain stem is present, although it may not be fully functional. Such children may live for just a few seconds but many survive without life support for hours or days while less than 10% live more than a week.¹ Other structural abnormalities may be present but internal organs, particularly the heart, liver and kidneys, are normal.

The infants can maintain spontaneous respiration, when there is a functioning brainstem, and typical newborn reflexes as these are mediated by the brainstem. There is also variable autonomic function, including cardiac and renal function, but they lack consciousness. 'Anencephalic neonates are totally unaware of their existence and the environment in which they live.'² However some think that the brainstem in anencephalics can actually exhibit function usually attributable to the cortex, due to neuroplasticity. There are also doubts as to the possibility of a degree of awareness and of subjective pain.^{3,4}

1.2 Local Prevalence

There were 12 cases in Malta between 1993 and 1998, a prevalence of 4.13 per 10000 births (live and stillbirths) (confidence interval 2.13-7.23).⁵

	Births: Live + Stillbirths	Cases	Anencephaly / 10000 births (L+SB)
1994-98	23849		4.61
1999-03	20240		2.47
2002	3805+21=3826	2 stillbirths	5.23
2003	3902+18=3920	0	0
2004	3887+15=3902	1 stillbirth	2.56
2005	2357+ 8=3865	1 live birth	2.59

Table 1 shows the data from 1994 to 2005.^{6,7,8,9}

1 affected stillbirth in 2004 gives a prevalence of 2.56/10000 births¹⁰ while 1 affected live birth in 2005 gives a prevalence of 2.59/10000 births⁹ as compared with the US average of 1 in 1000 pregnancies and 1.2 per 10000 births.¹¹ The data collected in the US aims to include the numbers of aborted fetuses.

1.3 Transplants in Children

About 30-50% of children under two years, who are waiting for a heart, liver or kidney transplant die before an organ is available.^{12,13,14,15}

The fact that there is no associated damage to internal organs has led many to question the use of these infant organs for transplantation. Naturally such organs would only be beneficial to infants of a similar age. This makes a match difficult to obtain, and organ shortage is a real issue unless there is adequate co-operation between centres.

Normally organs are harvested from: (1) either living donors, in the case of regenerative tissue, e.g. bone marrow or in the case of one of a pair of organs, e.g. a kidney; or (2) cadaver donors.

In anencephalic children, it may be possible to distinguish between essential and non essential organs, that is, organs which are essential for the survival of the child and organs which, if harvested, would not lead to the direct death of the anencephalic donor, though it may endanger the child's life. Thus it may be possible to harvest a kidney or bone marrow or liver. Reproductive organs would be excluded because of the principle of loss of identity.

However all these options pose different medical and ethical issues, which are dealt with below.

2. MEDICAL DIFFICULTIES

The common medical difficulty in ensuring organ transplantation is twofold:

1. ensuring viability of potential organs, whether obtained from living donors or dead individuals;
2. ensuring cadaver donors are really dead, to satisfy the 'dead donor rule'. There are two main schools of ideology regarding the definition of death, mainly the concept of brain stem death, in short brain death in the UK medical tradition and the concept of whole brain death, favoured in the US, and backed by legislation. There is also organ harvesting from non-heart beating donors, also called donation after cardiac determination of death, which has been the seat of controversy recently, as to whether the donors are really dead.¹⁶ This point is not discussed further in this report.

2.1 Viability

Various scientific studies have shown concern as to the viability of organs from anencephalics who were not on a life support system at the time of death^{17,18} because of gradual deterioration of already poor cardiorespiratory function, giving rise to ischaemia. If the infants are maintained on life support system from birth, the organs are not ischaemic but, according to the Canadian Paediatric Society, 'while organ function may be maintained with life support, as brainstem function deteriorates, multisystem organ failure develops before sudden death.'¹⁹

2.2 Brain Death

It has been extremely difficult to define death. In 1968, the World Medical Assembly in Sydney, defined death as 'a gradual process at the cellular level, with tissues varying in their ability to withstand deprivation of oxygen. But clinical interest lies not in the state of preservation of isolated cells but in the fate of a person. Here the point of death of the different cells and organs is not so important as the certainty that the process has become irreversible, whatever techniques of resuscitation may be employed.' Also 'it is essential to determine the irreversible cessation of all functions of the entire brain, including the brain stem.'²⁰ This definition was re-affirmed in 1983 but at the 2006 General Assembly, the definition was changed to a statement on determination of death, which 'can be made on the basis of the irreversible cessation of all functions of the entire brain, including the brain stem, or the irreversible cessation of circulatory and respiratory functions' to be 'based on clinical judgment according to accepted criteria supplemented, if necessary, by standard diagnostic procedures and made by a physician.'²¹ This definition is now a parallel of the US legislation. The WMA statement also emphasises that cells may remain alive temporarily after the determination of death but 'cessation of all life at the cellular level is not a necessary criterion for determination of death.'²²

The National Health and Medical Research Council in their Discussion Paper state that the concept of "brain death" is not intended to introduce a novel kind of death, but to identify the irreversible loss of the organic unity and integrated activity of a living human person.²³ The necessary and sufficient component of brain death is death of the brainstem

because it houses the centre responsible for respiration and also the centre that is responsible for maintaining consciousness. Permanent functional death of the brainstem constitutes brain death whether or not there is artificial maintenance of the function of the heart.

The opinion of the Maltese Bioethics Consultative Committee, BCC, is that if it is possible for doctors to establish the diagnosis of brain death when respiration has ceased in anencephalic infants, organs from such infants can be used for transplantation purposes.²⁴ However since scientific knowledge cannot clearly determine brain death in infants suffering from severe brain injury, these infants shall only be ventilated in their own interest, and no organ removal should be carried out.²⁵

2.3 Diagnosis of Brain Death in Children

Diagnosis of brain death in children is fraught with problems. Guidelines for brain death in infants were formulated in 1987 by a Task Force composed of representatives from the American Academy of Pediatrics, the American Academy of Neurology, the Child Neurology Society, the American Neurological Association, the American Bar Association, and the National Institute of Neurological Diseases and Communicative Disorders and Stroke.²⁶ These include the usual medical history and examination, to diagnose the cause of the coma, and full neurological examination and apnoea testing, supported by an observation period, and supplemented by EEG and cerebral blood flow studies. The protocol depends on age, e.g. for children between 7 days and 2 months of age, 2 sets of examinations and an EEG separated by 48 hours are recommended. However the criteria did not apply to infants below 7 days as there was insufficient data available.

Ashwal and Schneider in 1989 suggested that the diagnosis of brain death in term neonates and pre-terms above 34 weeks gestation, was possible, provided several repeated examinations are carried out and once tests are negative, with persistent coma, absent brain reflexes and apnoea, to repeat in 48 hours, or 24 hours if the EEG or cerebral blood flow, CBF, are negative.²⁷ Ashwal, chief of the Division of Pediatric Neurology at Loma Linda University School of Medicine, California, has again recommended using the same criteria for neonates, but emphasises that cranial nerve function is difficult to assess in term and preterm neonates and moreover these reflexes are still not fully developed.²⁸ Absence of cerebral blood flow, CBF, is considered confirmatory of brain death.²⁹ A 2007 article suggests that the guidelines could also be applied to neonates.³⁰

In anencephalis, there are greater problems because they can maintain an irregular function of the brain stem for up to 3 weeks.³¹ Also EEG and cerebral blood flow may be inappropriate tests as there are no cerebral hemispheres.

3. ETHICAL ISSUES

There are two main opposing views: respect and dignity for the human being versus the utilitarian view, often employed in medicine, which maximizes beneficence and minimizes nonmaleficence,³² and is here interpreted as using organs to benefit recipients, with minimal suffering.

3.1 Respect and Dignity for the Human Being

For legal and ethical issues, anencephalics should be considered as persons even though their brain has no potential for full capacity.

Human dignity and human rights are not conditional on the state of the human body. The apparent lack of cognitive function in anencephalics, does not diminish their rights,³³ in particular the right to life, health and personal identity. Thus during their brief life, such children should be given the comfort and palliative care appropriate to all human beings at the final stages of life. There is no need to resort to non-proportional (extraordinary) means of treatment, as this would unnecessarily prolong life.

The position of the church is quite clear: ‘The anencephalic child during his or her probably brief life after birth should be given the comfort and palliative care appropriate to all the dying’ but ‘this failing life need not be further troubled by using extraordinary means to prolong it.’ Organ donation from anencephalics, to ‘assist other children’ was commendable for parents, but ‘this may never be permitted before the donor child is certainly dead.’³⁴

The Catholic Church has left the definition of death to the medical and scientific community. The use of neurological criteria for the determination of death is morally acceptable to define ‘the complete and irreversible cessation of all brain activity (in the cerebrum, cerebellum and brain stem).’³⁵ The Church ‘limits herself to the Gospel duty of comparing the data offered by medical science with the Christian understanding of the unity of the person.’³⁶

Deontological ethical principles dictate that anencephalics cannot be used solely as a source of organs for others. Although others have argued that only persons have to be respected and since anencephalics lack cognitive function, there is an absence of personhood.³⁷ This led to the conclusion that the usual moral restrictions applied to killing people do not apply to anencephalic infants as they cannot be harmed by ending their biological function.

Some state emphatically that ‘anencephalics never had and cannot develop any semblance of personhood’³⁸ or that anencephalic infants are human biologically but are not persons.³⁹ A second group, although supporting organ retrieval from anencephalic infants, still considered alive by legal standards, maintain that they are persons deserving of due respect.⁴⁰ However some do argue that the anencephalic infant’s status as a person

constitutes grounds for judging organ retrieval from a living anencephalic to be morally unjustifiable.⁴¹

Others have concluded that as the brain is absent, they can be called brain dead.⁴² Holzgreve published a paper on kidney transplantation from anencephalics in West Germany, justifying organ donation without brain death assessment on the premise that despite having a heart beat, they had never been alive.⁴³

In 1994, the American Medical Association (AMA) Council on Ethical and Judicial Affairs had formulated an opinion⁴⁴, which was subsequently approved by the AMA Council, and in its report,⁴⁵ states that due to ‘the fact that the infant has never experienced, and will never experience, consciousness,’ organ harvesting from anencephalics is ethical, following parental consent, even though the infant is ‘still alive under the current definition of (US) death.’

However this decision had to be reversed because of opposition from its members.^{46,47} The United Network for Organ Sharing (UNOS) Ethics Committee attacked the AMA proposal (UNOS, Ethics Committee 1995), and argued in favour of no exceptions to the ‘dead donor rule’,⁴⁸ even though some of the Network members did favour procuring organs from anencephalic infants with beating hearts and certain lower brain functions and others were in favour of equating anencephalics with being dead.^{49,50}

The current AMA guidelines⁵¹ state that ‘retrieval and transplantation of the organs of anencephalic infants are ethically permissible only after such determination of death is made’ ‘in accordance with accepted medical standards, relevant law, and regional organ procurement organization policy’.

Robert Truog and John C Fletcher argue that brain death and anencephaly should be considered morally and legally equivalent.⁵² Truog admits that brain dead patients breathe only because they are on a ventilator but seems unwilling to accept that it is only the ventilator use that maintains a circulation.⁵³ Albeit he does concede that the loss of the capacity for consciousness is the salient feature of being brain dead.

Robert Veatch^{54,55} wants to keep the ‘dead donor rule’ but to redefine which patients can be treated ‘as if they are dead’ and to redefine the meaning. Truog prefers to go back to the traditional definition of cessation of cardiac or respiratory function.^{56,57} He claims that this is in keeping with ‘our ethical commitments to nonmaleficence and respect for autonomy’ and would be fulfilled by allowing choice regarding organ transplantation ‘when the patient is either permanently unconscious or imminently dying’, since there is minimal harm and choice.⁵⁸ Veatch states ‘The word dead has come to mean - for legal, ethical, and public policy purposes – ‘having lost full moral standing as a member of the human community.’^{59,60}

Since infants cannot consent, some ethicists have argued that anencephalic infants cannot consent to donation, and therefore they should be considered as sources of organs; and we should speak of procurement of organs rather than donation.^{61,62} Yet, however

deformed and handicapped anencephalic infants may be, they are persons under the law and should be treated as such. Using the term sources is a sign of lack of human dignity.

3.2 Benefits

On the other hand utilitarian ethics promote organ transplantation from anencephalics, who have no hope of surviving to adulthood. Caplan argues that the parents should have the right to agree to organ donation from a living anencephalic in the interests of their wishes and for the benefit of others. It is true that anencephalics cannot be said to have self interests, but the family and society has an interest in ensuring that the dignity of the human body is preserved, in life and in death.⁶³

However parents may be the ones whose interests are actually being protected, since they would obtain comfort from knowing that the death of their infant has led to some good to another child.

Anencephalics are one of the most vulnerable minorities, so how can we condone such treatment?⁶⁴ Lindholm argues that 'if one violates the inherent dignity of an individual to save lives, one cheapens the good of saving lives, much less the value of life itself.'⁶⁵

3.3 Consent

For both living and dead infants, the persons responsible for providing consent are the parents or legal guardians. They have to decide either according to their understanding of what the child would have decided when grown up (potential autonomy) or as to whether the child benefits.

Caplan⁶⁶ argues that it is 'a flight of fancy' to ascertain the desires of an infant relative to organ or tissue donation'. Any decision by the parents or guardians would be 'the imposition of a judgment rather than the substitution of one'. He also argues that 'brain dead or anencephalic infants have no interests or even potential interests'. If anything, it is the parents who have interests, respectively in obtaining consolation from the loss of a child by alleviating suffering to others, the latter also being an interest of society. He argues that the parents' interests should override those of society.

The question arises as to whether parents can be allowed to consent for their infants. One expects parents, and they generally do, to decide in their child's best interests. However is donation of non essential organs from a live anencephalic, in the best interest of the infant, or is it shortening life? One may argue that the child is dying, so has nothing to lose but this becomes a very utilitarian viewpoint, because the parents feel that their action is right since it is promoting well being to another infant and to society.

However parents-centred parental rights⁶⁷ allow parents to form their children according to their own image of life, so the parents might argue that agreeing to donate their child's non-essential organs is an extension of the child's best interests in relation to character

development, the crucial character trait here being solidarity with another child in need, a characteristic which the parent would like to foster in their child.

Some parents may request their children's organs to be donated, without realizing the medical and ethical issues involved. To ensure informed consent, counselling is essential, and this should be provided not just when parents raise the issue of transplantation but when the diagnosis of anencephaly is made, so as to prevent the request, since a refusal may then be ill understood and enhance the trauma to patients.

If there are conflicts of interest between the parents and the interests of the child, there must be a decision from third parties, principally an authorised body.

The responsibility of the physician is to the child and the parents and as such, the physician must keep the family informed as to what is happening, so that the issue of organ donation would have been already discussed.⁶⁸ However the request for organ donation should not come from the doctor providing immediate care. Health carers must become aware of how easy it is to coerce a parent into agreeing to a transplant and so the transplant team should avoid direct contact with potential donors and their relatives.⁶⁹ The transplant team should be different from the team providing clinical care and determining brain stem death. Anonymity should be maintained as much as possible but this is often not possible, given the nature of both donor and recipient.

3.4 Counselling

'Counselling of women and couples regarding organ donation should be undertaken by persons with no conflict of interest.'⁷⁰ In these guidelines by FIGO, it was considered ethical to allow a woman to continue with an anencephalic pregnancy for the purpose of organ donation and also, if the parents consent, to place anencephalic neonates on a ventilator 'for the purpose of organ donation following natural death' but to comply with local legal definitions of death, with a proviso to consider necessary review 'in the light of scientific development of criteria of brain death in neonates.'⁷¹ It is important that parents are informed of the possibility of donating their children's organs⁷² but their wishes must be respected.

This view is not supported by the Canadian Pediatric Society, which considers anencephalics as inappropriate organ donors.⁷³ Through a counselling programme, parents will be prepared to face the facts about their child's condition, even before the birth, and thus avoid any hopes that they could donate the child's organs.

4. LEGAL ISSUES

According to the EU Consultation paper, > 90% of organ donors are patients 'who died in hospitals after an irreversible cessation of all brain functions, known as brain death' and whose 'cardio-respiratory functions are artificially preserved.'⁷⁴ In the same Consultation paper, it is stated that 'Organ retrieval from the deceased may take place only after death

certification. Death certification should be a matter of national legally binding rules that should be made public.

There is no specific legislation in Malta regarding the legal definition of death, let alone brain death. However local practice follows the British practice of recognizing brain stem death as the definition of death. There is actually no UK legislation but the concept was accepted in 1976 by the Medical Royal Colleges⁷⁵ and has been recently re-affirmed.⁷⁶

On the other hand the US has adopted legislation, through the Uniform Definition of Death Act (UDDA), which defines death as either: '(1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem',⁷⁷ a concept of total brain death.

Most countries have adopted legislation to cover donation of human tissues and organs, either as a donation for transplant purposes or as an anatomical gift, including whole body gifts.^{78,79} These laws cover the issue of consent and safety of the procedure.

Likewise there is no legal obligation in Malta for obtaining consent from donors for transplantation. The new legislation, Human Blood and Transplants Act, is only aimed at ensuring safety of transplants and does not really address the issues of donation. There is however a kidney donor card scheme as well as an Ethics Committee that reviews requests for donation.

There is no legislation covering consent from adults let alone from children, although it is accepted that parents or legal guardians can give consent for minors. Consent should be informed, as defined in the Clinical Trials Regulations.⁸⁰

Caplan⁸¹ suggested that existing laws and regulations need to be changed to reach a diagnosis of brain death in anencephalics, since using the present criteria, for example until all electrical activity of the brain has stopped, would render organs unsuitable due to ischaemia.

The Canadian Paediatric Society (CPS) (1990) and the American Academy of Pediatrics (1992) agree that anencephalics are not suitable organ donors and have rejected moves to change the legal definition of death or to change the criteria.^{82,83} These views have been re-affirmed in January 2009.⁸⁴

4.1 International guidelines

There are no specific Directives but there is a Protocol to the Oviedo Convention,⁸⁵ even though Malta has not signed it.

The Council of Europe specifically states 'Organs or tissues shall not be removed from the body of a deceased person unless that person has been certified dead in accordance with the law.'⁸⁶

Article 14 protects living persons not able to consent to organ or tissue removal, by sanctioning donation of regenerative tissues, only in exceptional circumstances. These include when there is no other compatible donor with ability to consent, when the recipient is a sibling of the donor, when the donation has the potential to be life-saving and if the donor does not object and there is specific authorization, in writing, by the legally responsible person or authority.

As to organ retrieval from the deceased Article 16, states that the potential donor must have been 'certified dead in accordance with the law and requires separate medical teams for death certification and for any procedure related to the transplant. Although the protocol does not specifically address children, in the explanatory report, in relation to Article 16, it is stated that 'For the purposes of this Protocol, neonates including anencephalic neonates receive the same protection as any person and the rules on certification of death are applicable to them.'⁸⁷

Should exceptions be made to the law, respect for human life would be decreased, there will be fears that organs may be taken from other persons not yet dead, and overall donations will fall.⁸⁸

Article 17 enforces the need for consent or authorisation as required by law and excludes transplantation if the deceased had objected to it. Article 18 states that: the human body must be treated with respect and the Explanatory report states: 'A dead body is not legally regarded as a person, but nonetheless should be treated with respect'. Confidentiality is addressed by Article 23.

The views in the Oviedo Convention are fully accepted by the BCC, who issued an opinion on Transplantation,⁸⁹ published in 2000.

Article 1 states that 'transplantation of organs from persons incapable of giving consent should be prohibited' but 'in exceptional circumstances, and with the specific approval of a specially instituted Board,' minors 'may be considered as donors of organs' with the consent of the child, the parents or the competent court.

With regard to cadaver organ donation, article 3, previously expressed consent is best but otherwise, this should be from relatives. Bodies must be treated with respect and requests must come from the consultant in charge of the Intensive Therapy Unit.

Article 8 establishes that donation of regenerative tissues requires free and informed consent by the donor in writing but for minors, transplantation of bone marrow to close family members will be allowed, provided that there is no other compatible donor.

In the Explanatory report it is stated that 'It is possible for doctors to establish the diagnosis of brain death when respiration has ceased in anencephalic infants. Organs from such infants can be used for transplantation purposes.' However it continues 'Since scientific knowledge cannot clearly determine brain death in infants suffering from severe brain injury, these infants shall only be ventilated in their own interest, and no organ removal should be carried out.'⁹⁰

5. CONCLUSIONS

The 2006 Eurobarometer results for Malta showed that 44% discuss the issue with their families, 75% are willing to donate their organs after death while 10% are against, 71% are willing to donate their relatives' organs after death and 95% were in favour of organ donor cards but only 15% possessed one.⁹¹

These results indicate that the issue of transplantation in Malta is in the public agenda but it is time that we responded by actual commitment to having a donor card. However the views regarding child donors are not known. Therefore one has to be even more cautious when promoting organ donation from children.

With regard to anencephalic infants, organ donation of regenerative tissue from live anencephalic infants is not recommended because of serious doubts as to viability of organs.

Organ donation from brain dead anencephalic infants is not recommended because of serious doubts as to the possibility of establishing brain death and of the viability of organs.

6. RECOMMENDATIONS

The sub committee recommends that:

1. anencephalic infants are to be afforded the respect and dignity that any human being merits, both in life and in death;
2. the definition of death for anencephalic children is to be the same as that for adults;
3. organ donation from deceased anencephalic infants is considered to be inappropriate due to medical problems in determining brain death and in ensuring viability of organs;
4. regenerative organ donation from living anencephalic infants is considered to be inappropriate due to difficulties in ensuring viability of organs and doubts as to adverse effects on the infants' life;
5. counselling must be mandatory for newly diagnosed parents of anencephalic fetuses or infants ; and
6. efforts toward an education campaign regarding organ donation should continue.

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