

Infants with Anencephaly as Organ Sources: Ethical Considerations

Committee on Bioethics

BACKGROUND

Pediatric organ transplantation offers an increasing number of seriously ill children the opportunity for a healthy life. However, there is currently a severe shortage of pediatric organs. Young children rarely die in circumstances that would make them medically acceptable sources of organs. Among the children younger than 2 years of age registered to receive transplants, an estimated 30% to 50% die before an organ becomes available.¹ In April 1990, the United Network for Organ Sharing reported 320 children younger than 5 years of age waiting for kidney (99), liver (178), heart (34), or heart-lung (9) transplants. Although improved organization of the organ procurement system could partially ameliorate the problem, in all likelihood, pediatric organs will remain a scarce medical resource.²

Anencephaly is a congenital defect in which the cranium is absent and the cerebral cortex is virtually absent. However, vital organs, such as the heart and kidneys, are often normal. About 1000 to 2000 live anencephalic births occur annually in this country. Brain stem function enables many anencephalic infants to survive for hours or days and, in rare cases, for a few weeks.³

In recent years, some parents of anencephalic infants, as well as some transplant surgeons, medical ethicists, and state legislators, have proposed that these infants' organs be used for transplantation.^{4,5} Some parents have poignantly expressed their wish that some good might come of their loss. In their opinion, there is no compelling reason for failing to use an anencephalic infant's organs to give life and health to other children.

Numerous medical, ethical, and legal questions are raised by the proposals to use anencephalic infants as organ sources. In this statement, we summarize and analyze these proposals. We conclude that there currently is no convincing basis for deviating from the existing legal rules governing organ transplantation. Moreover, in light of the present lack of data on this subject, any attempt to use these infants' organs should be classified as experimental and constrained by the usual ethical and regulatory principles applicable to research using human subjects.

POTENTIAL APPROACHES TO OBTAINING ORGANS

Customary medical care for anencephalic infants includes warmth and feeding but no major medical interventions. Available medical evidence indicates that these infants cannot consciously experience pain; because they lack a functioning cerebral cortex, they are permanently unconscious. In most cases, anencephalic infants die from cardiorespiratory failure. Because of inadequate perfusion, their organs become medically unsuitable for transplantation.^{1,3} As a result, a change in the treatment of these infants will be necessary if their organs are to be transplanted.

Four approaches have been proposed for obtaining organs from anencephalic infants. Three of them may be consistent with the existing legal requirement for total brain death before organs are removed for transplantation. One such approach, investigated in Canada and in at least one US institution, entails resuscitation at birth and maintenance of intensive care to protect organ viability until total brain death occurs. A predetermined period of 7 to 14 days for maintenance is included in this approach. In a study of this approach in which infants were monitored for 7 days, only one of six infants lost all brain function, however.¹ A variation on this approach involves administering customary medical care to anencephalic infants until signs of impending cardiorespiratory death develop. At that point, infants are given maximal life support and monitored for loss of brain function. If brain stem activity appears absent, infants are evaluated as potential organ sources.

A third method suggested in the literature involves gradual cooling of the anencephalic newborn's body to protect the organs from ischemia.⁶ This effort to preserve the organs could also hasten death, however, and may be viewed by some as a form of killing. The doctrine of double effect is relevant to various medical procedures that can have simultaneous good and bad effects for patients. Such procedures have generally been accepted as long as they are performed with the intent to cause only the good effect, and a proportionately compelling reason exists to allow the bad effect.⁷ In the anencephalic infant's case, however, the positive effect benefits other individuals instead of the patient. This is a troubling departure from the customary principle governing treatment: that the patient's best interests are of primary importance.⁸ Despite this ethical concern, there is evidence that practices similar to the one described above are followed in standard organ procurement programs in-

The recommendations in this statement do not indicate an exclusive course of treatment or procedure to be followed. Variations, taking into account individual circumstances, may be appropriate.
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volving adult donors once there is a decision that the potential donor's condition is inevitably fatal.^{6,9}

The evidence available at this point suggests that these three approaches are likely to be unsuccessful in maintaining the viability of most anencephalic infants' organs. In addition, these techniques require the determination of brain death in very young infants. Guidelines adopted by the Task Force on the Determination of Brain Death in Children recommend that the application of brain death criteria be limited to children 7 days or older. Such criteria may not be valid in younger infants because important developmental processes may still be occurring.^{10,11} Moreover, criteria for determining brain death in anencephalic infants have not been definitively established. The Medical Task Force on Anencephaly concluded that because anencephalic infants lack a functioning cerebral cortex, cerebral blood flow and electroencephalographic testing are unnecessary to assess cortical death in these infants. The Task Force offered criteria (positive apnea test and loss of measurable cranial-nerve function and spontaneous movements for at least 48 hours) for diagnosis of brain stem death in anencephalic infants, but it warned that in some infants, it may not be possible to determine death using neurologic criteria alone.³

The final method of procuring viable organs from anencephalic infants is more controversial. Physicians in Europe have removed organs from anencephalic infants without waiting for a determination of either cardiorespiratory or brain death on the ground that these infants are "brain-absent" and may be treated as if they were brain dead or, alternatively, that they are sufficiently lacking in cognitive capacity that the usual moral constraints on killing persons do not apply.^{12,13} This approach could not legally be adopted in the United States without either a change in the legal definition of death or the creation of a special transplant law exception allowing physicians to remove the vital organs of anencephalic infants before total brain death has occurred.⁵ The effect of the latter exception would be to authorize actively causing death in this situation.

ETHICAL AND LEGAL ISSUES

Research

Although the evidence assembled thus far suggests otherwise, it remains possible that a method of organ retrieval consistent with existing US laws could be devised. For example, new techniques could be developed to assess brain death in anencephalic infants. Research on such topics generally would be governed by the federal regulations for the protection of human subjects. The regulations set stringent conditions limiting the harm to which children who serve as research subjects may be exposed. If the research presents no prospect of direct benefit to subjects but involves no greater than minimal risk, parental permission and Institutional Review Board acceptance are sufficient for approval; however, individual Institutional Review Boards may vary in their judgments. Similarly, if such research involves a minor increase

over minimal risk but is "likely to yield generalizable knowledge about the subject's disorder or condition," parental permission and Institutional Review Board approval are all that is required for the proposal. If the research fails to meet these conditions, however, special permission to proceed with the project must be obtained from the Secretary of the Department of Health and Human Services. Before granting such permission, the Secretary of the Department of Health and Human Services must consult with a panel of experts in disciplines relevant to the proposal, provide an opportunity for public review and comment, and determine that the research "presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious health problem affecting the health or welfare of children," and will be conducted according to "sound ethical principles."^{14,15}

To comply with the federal standards, further research on the feasibility of organ retrieval from brain-dead anencephalic infants thus may require special approval by the Secretary of the Department of Health and Human Services. On the other hand, one could argue that the magnitude of the risk to anencephalic infant research subjects should be evaluated in light of their extremely limited interests. The federal regulations define "minimal risk" as risks "not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."¹⁵ Those who believe that anencephalic infants cannot experience conscious awareness would argue that, because of their limited interests, it may be ethically defensible to categorize such research as posing only minimal risk to these subjects. If so, then it would require only parental permission and Institutional Review Board approval.

Another important ethical consideration raised by the prospect of future research concerns the consent process. If organ retrieval from anencephalic infants is considered as research, the child's attending physician should first discuss the matter with the parents of the anencephalic child. Research personnel must not be involved in this discussion, except as sources of information to the physician. If parents then freely and knowingly consent, their decision should carry the same weight as that of other parents who agree to their child's participation in research.

Of special concern, however, is the issue of seeking parental consent from parents whose in utero fetus has been diagnosed with anencephaly. In no case should physicians or researchers encourage a woman to alter her obstetrical management or to carry her fetus to term so that the infant can be included in a research protocol. Furthermore, parents must be thoroughly forewarned that their hopes of mitigating their own loss by contributing to the research effort could prove fruitless, given the substantial possibility that the infant may be stillborn or have other anomalies.¹⁵

Legal Definition of Death

If organ procurement continues to be difficult and present research does not yield acceptable approaches, some may exert pressure to enact legislation

allowing organs to be removed from anencephalic infants who fail to meet the existing criteria for brain death. One option some have suggested would be to modify the statutory standards for determining death to include all anencephalic infants. This would be consistent with the view held by some philosophers and legal commentators that cortical death should constitute legal death.¹⁶ These individuals argue that the irreversible absence of cognitive function represents the absence of personhood. They claim that human beings in this state fail to possess the moral value we assign to living persons; because such patients are unconscious and lack cognitive capacities, they cannot be harmed by a decision to end their biological functioning. Under this definition, permanently unconscious patients would also be classified as legally dead.

Another view held by some is that anencephalic infants are sufficiently “brain-absent” to be treated as if they were brain dead.¹⁷ A refined version of this approach suggests that because anencephalic infants lack integrated brain function and will inevitably die within a short time, they are conceptually very close to being brain-dead individuals—close enough to be considered brain dead. Conversely, because conditions such as persistent vegetative state, microcephaly, and hydranencephaly are not always accompanied by imminent somatic death and the absence of integrative brain function, they should be excluded from the brain death category.¹⁸

The arguments for adopting a less restrictive concept of brain death have been raised persistently in the literature for several years. The President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research rejected this position based on their view that it lacked persuasive moral justification and presented too many practical impediments to implementation.¹⁹

Organ Retrieval Issues

An alternate revision would change the laws governing organ transplantation to permit retrieval of organs from anencephalic infants who are not legally dead. Some have argued against allowing organ retrieval from living anencephalic infants because they are so vulnerable.⁴ This view sometimes reflects acceptance of the notion that these infants themselves have interests and can be harmed, a position that others would argue is difficult to support in light of the anencephalic infant’s assumed inability to experience pain, lack of cognitive capacities, and inevitably fatal condition. The argument also reflects concerns regarding the implications of such practices for future classes of patients.^{20–22}

Two types of societal concerns are therefore implicated by the proposal to use living anencephalic infants as organ sources. One is the danger that the practice will lead to organ retrieval in less clear-cut situations. Some of the arguments for allowing organs to be taken from anencephalic infants apply equally to other permanently unconscious patients, including infants with hydranencephaly and some with microcephaly. Although anencephaly can be diagnosed with virtual certainty, expanding the group of suitable

donors could entail greater diagnostic uncertainty and the concomitant risk of including in the group individuals who otherwise would have survived. On the other hand, if the suitable candidates were limited to strictly defined anencephalic infants, the risk of misdiagnosis would appear remote.

The second primary societal concern stems from the need to preserve the symbolic value of human life. The ethical question is whether it is an unacceptable affront to human dignity to obtain organs from humans who retain some brain function. Those arguing in the affirmative assert that retrieval of organs from living anencephalic infants would inevitably cheapen society’s overall respect for human beings. But others point out that in research and in a variety of other medical contexts, our society has accepted the use of one individual to benefit another, as long as the first individual is not harmed in the process.⁸ Accordingly, in their view, parents may choose to benefit themselves as well as potential organ recipients by donating their anencephalic infant’s organs.

A second dimension of the societal concern for respect for life is also relevant. To allow removal of the anencephalic infant’s vital organs before legal death would allow the active killing of a human being. This would contravene the current legal prohibition against active killing. Creating an exception to this rule again triggers fears that the value of human life will be reduced, and the category of living organ sources will inevitably be expanded to include infants who might otherwise have survived. Whether the feared consequences would materialize depends on how precisely the anencephalic infant category can be circumscribed and how willing society will be to protect the interests of other patients who might be considered for similar treatment.

CONCLUSIONS

At this time, a convincing case for changing the law has not been made. It is not yet clear that maintaining the current requirement for total brain death will prevent the successful retrieval of organs from anencephalic infants. If preserving organs from anencephalic infants becomes feasible, and the legal requirement of total brain death proves an insurmountable obstacle to organ retrieval, then arguments that may be adduced favoring a change in the legal definition of death might become more compelling and could be considered more seriously.

Yet even if strong support were to emerge for legislation either defining anencephalic infants as legally dead or allowing retrieval of their organs prior to legal death, serious questions would remain about the wisdom of enacting such legislation. On a purely utilitarian analysis, the actual benefits of such legislation cannot be predicted with precision. The benefits might be minimal due to the low incidence of liveborn anencephalic infants with vital organs suitable for transplantation and the even lower incidence of infants whose lives could be extended successfully through anencephalic organ retrieval.^{20,22} National incidence rates for anencephalic infants also appear to be decreasing, particularly because prenatal screen-

ing is increasingly available.³ On the other hand, changes in US abortion laws could increase the number of liveborn anencephalic infants. In addition, transplantation success rates among infants presumably will increase as techniques improve.

Similarly, the costs of amending the law on organ retrieval or definition of death can only be estimated. Such an amendment might produce decreased respect for human life in other areas, or it might have no such effect. It should also be noted that an amended law could trigger public fears that organs are or will be taken from other humans not fully brain dead. As a result, donations in general might fall, further reducing the overall gain in lives saved from changing the law.²⁰ Further research on public attitudes toward organ transplantation could clarify this matter. Although it is impossible to foresee its exact effects, sufficient questions exist to counsel extreme caution before adopting a policy permitting organ retrieval from anencephalic infants who retain brain stem function.

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