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Ethical Issues in the Use of Asystolic Donors

by

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The modern era of allogenic organ transplantation began in the mid 1960s. Then, improvement in surgical techniques, understanding of immunologic tolerance, and the development of drugs to control rejection expanded the technical feasibility of transplantation procedures. To some this represented a "crisis of success" as there was a resultant increase in demand for organs without a parallel increase in supply. According to the United Network for Organ Sharing¹ database there are now 75,000 patients waiting for an organ. Among those waiting for a heart or liver transplant approximately 1/3 will die before an organ becomes available.² The primary source of donor organs will be those who have had an irreversible cessation of total brain function and who are being maintained on ventilators in intensive care units. These are commonly called Heart Beating Cadaver Donors and will constitute a pool of 10,000-12,000 potential donors per year. Despite extensive public awareness campaigns, the ratio of actual to potential donors has not increased sufficiently. One response has been to attempt a greater reliance on living donors (kidneys) partial transplants (liver and lungs) and sources of dubious ethical propriety such as anencephalic infants³ and animals.⁴

Another potential source of transplantable organs is patients who have been declared dead by traditional cardiopulmonary, rather than brain-based criteria. These are referred to as Non-Heart Beating Cadaver Donors. The success of transplants using organs from these sources has been limited by problems with warm ischemia. Two recent strategies to

circumvent the problem of warm ischemia¹ are in situ preservation following uncontrolled pulmonary arrest and² procurement from patients who have died after choosing to forego life-support treatment. Both of these methods of procuring organs from Non-Heart Beating Cadaver Donors (NHBCD) have posed a new array of ethical problems related to¹ ethical issues related to the definition of death² potential conflicts of interest and³ acceptable behavior in controlling the dying process⁴ the consent process for procurement.⁵

The major problem with organs taken from NHBCD is the deterioration of organs from warm ischemia. This is resultant from the prolonged period between the declaration of death following asystole and the process of removing organs. Two approaches have been suggested:

1. Uncontrolled Cardiopulmonary Death

These are usually patients who are brought to an emergency room and die as a result of myocardial infarction or multiple traumas. To avoid warm ischemia a balloon catheter is inserted and inflated above and below the renal arteries and the kidneys are cooled by an infusion of cold preservative solution through this catheter and cannulas inserted through the abdominal wall.

Because of difficulty in obtaining consent from families overwhelmed by the circumstances of a sudden unanticipated demise, the Organ Bank of Illinois has proposed that the insertion of cannulas for installation of preservative solutions be carried out prior to asking for family consent. This is based on an experience of greater likelihood of getting consent if catheters are already in place and approaches to families are therefore less urgent.

Despite disclaimers that inserting catheters are non-deforming or non-mutilating,⁶ there is a great deal of concern about proceeding without family consent. There is little consensus about the morality of performing invasive procedures on dead patients to benefit others. At a minimum they are disrespectful of the dead, disregard family input and foster unwanted attitudes in medical staff.⁷

2. Controlled Timing and Place of Death

This method is what has become commonly known as the Pittsburgh Protocol. Under this protocol families who have decided to forego life support may be approached to donate organs. The decision to stop life support should in all instances precede the decision to donate. This allows time for discussion before any invasive procedure and the time and location of death are controlled. Warm ischemia time is

minimized by taking the patient to the operating room before organs are removed immediately after pronouncement of death.

For purposes of discussion, it will be assumed that the decision to stop the ventilator is appropriate given the circumstances of patient's terminal condition. The family must give fully informed consent to 1) placement of a femoral artery catheter to measure pulse pressure, 2) declaration of death following absence of pulse pressure when the ventilator is removed, 3) removal of organs after death is declared 4) If removal of life support does not result in death of the patient "in a very short time", the procedure will be cancelled and the patient returned to intensive care.

Death is declared after 1) two minutes of ventricular fibrillation 2) two minutes of asystole or 3) two minutes of electromechanical dissociation.

Ethical Issues

A fundamental question is whether increasing the number of transplants deserves to be a priority in a time of scarce resources.⁹ To what extent is the attempt to increase the number of donor organs influenced by the increase in the number of surgeons and institutions performing transplantation and the need to increase the funding of centers whose prestige, opportunities for training and funding for research depend on increasing the number of operations done? Public perception of motives other than saving lives might undermine the acceptance of dramatic programs to increase NHBCD.

Issues Regarding Defining and/or Hastening Death

Criteria for death using brain-based standards have constantly and incontrovertibly focused on irreversibility both in statutory and clinical definitions. Irreversibility confirms death to reinforce certainly that death is final with no hope of recovery. The Uniform Determination of Death Act states "An individual who has sustained either 1) irreversible cessation of respiratory and circulatory functions or 2) irreversible cessation of all functions of the entire brain including the brain stem is dead. A determination of death must be made in accordance with accepted medical standards." This standard has been enacted into statutes in most states.

The concept of irreversibility has been defined as "a lost function cannot be restored by anyone, under any circumstances at any time now or in the future." A less categorical definition states "the loss of function cannot be reversed by those present at this time."¹⁰

Under the Pittsburgh Protocol, death is declared after two minutes when the failure to restore cardiac function will result not from a lack of present means, but from a decision not to use them. The patient who has qualified as NHBCD may be in a state when organs are removed where it might be possible to restore function, but a decision has been made not to attempt to do so. This raises questions as to whether the Pittsburgh protocol fulfills the criterion of irreversibility. Defenders of the protocol argue that irreversibility should be determined by an inability to autoresuscitate. It is customary to declare those patients dead who have Do Not Resuscitate Orders and who arrest when we have no plans to resuscitate them. There are no data to confirm that autoresuscitate is impossible after the two minutes allowed in the Pittsburgh Protocol. Shewmon¹¹ has suggested a longer period of 20 minutes but he also lacks data to confirm a more prolonged period of observation precluding autoresuscitation.

How does adding the goal of procuring organs affect the morality of the situation? Is it possible to be confident that the goal of acquiring viable organs does not affect decisions made in the best interest of the dying patient?

Will the use of narcotics to control pain be altered when organ harvesting is anticipated? Will the decision to discontinue life support be derivative of the anticipated organ donation despite scrupulous attempts to separate the decision to stop the respirator from the decision to donate organs? Is it possible, in other words, to be sure that the decision to shorten life will not be influenced by the reality that death is to occur in a fashion that produces viable organs?

It will be difficult for families and health care personnel to avoid the impression that the death is staged or even ceremonial. There will be emotional consequences for those who must say their farewells to a conscious or unconscious patient who is then wheeled to the operating room to die among strangers who have heretofore not participated in his care. It would be possible to insert femoral catheters in the intensive care unit and then remove life support prior to taking the patient to the operating room. It is questionable whether this would ameliorate emotional reactions or actually aggravate them by mixing patient care and transplant procedures inseparably.

The Consent Process

When the strategy of the health care team is directed toward increasing the number of transplantable organs, the consent process may be altered. It is usually assumed that both the donor and the next of kin

would agree to the donation. In practice, different organ procurement organizations proceed differently.¹² 19% follow the deceased's wishes, 19% follow the next of kin's wishes, 10% proceed if neither party objects and 8% proceed if either party consents or neither objects. The availability of a Durable Power of Attorney or a Living Will could strongly affect the decision. There is seemingly no national consensus as to what constitutes valid consent. Clear direction from an advanced directive or a unanimous agreement between patient and family would seem to constitute a minimum requirement for most hospital settings in contrast with Organ Procurement Organizations' policies.

Public Policy Considerations

While a heroic attempt has been made in the Pittsburgh Protocol to protect the best interests of donors and to separate caregivers and transplant teams rigorously, the pervasive atmosphere, rightly or wrongly, is to guarantee an increase in available donor organs. In an institution that identifies itself as a "transplantation center" and in which the salutary goal of saving lives of critically ill patients pervades the environment, strict standards will be vulnerable to "end justifies the means" rationales. Although under the common law, no one has a property interest in a dead body¹³, a limited interest in a corpse resides with the next of kin who are expected to arrange for the disposition of the remains. A pre-mortem decision to donate one's organs is not binding on next of kin. The Uniform Anatomical Gift Act adopted in all states, made it possible for an individual to make an anatomic gift, which would take effect upon death. This was followed by the Uniform Determination of Death Act to clarify the dead donor rule, now operative in 47 states. The National Organ Transplant Act in 1984 established a mechanism for finding donors and prioritizing recipients. This system, not surprisingly, has not achieved the goal of matching organ supply with demand. The shortfall using brain-based criteria to qualify heart beating cadaver donors (HBCD) has further encouraged the development of protocols for non-heart beating cadaver donors (NHBCD).

The very sensitive background to these strategies is the public's confidence in the process. If the public perceives that the motivation is self-interest rather than life saving, the end result might be a decrease rather than an increase in the availability of transplantable organs.

Summary

Programs for the use of Non Heart Beating Cadaver Donors are subject to a variety of ethical concerns:¹⁴

- 1) Are these programs using new and invalidated criteria for determining death?
- 2) Is the dying process being engineered to accommodate the need for more usable organs?
- 3) Are rules for consent being manipulated to accomplish this same end?
- 4) Are invasive procedures being carried out on recently dead patients without consent of near relatives and what are the ethical and possible legal consequences?
- 5) Are there alterations which are possibly harmful in the case of the terminally ill patient?
- 6) Will the mourning process be affected in perhaps a long-term adverse way, by the contrived removal of the patient to the operating room prior to discontinuing life support?
- 7) Will the decision to discontinue life support be affected?

Until NHBCD programs can be evaluated for impact on concepts of life vs. death, active vs. passive hastening of death and interests of dying patients vs. interests of organ recipients, the medical professions must proceed with extreme caution. Much of what is proposed is counterintuitive and public backlashes a definite risk. In the meanwhile, much of the ambivalence about the propriety of the use of brain-based criteria has been clarified if not settled by Pope John Paul II on August 29, 2000, in his address to the International Congress on Transplants. A portion of the text of his address is appended to this document. In this highly significant statement Pope John Paul II said that the use of brain-based criteria for "ascertaining the fact of death" does not conflict with "the essential elements of a sound anthropology." He also said that "health workers responsible for ascertaining death can use these criterion in individual cases with that degree of assurance in ethical judgment which moral teaching describes as 'moral certainty'."

With this kind of endorsement of brain-based criteria for determining death, it is difficult to justify entering into the murky waters of using asystolic donors.

Appendix — John Paul II on Neurologic Criteria

The following is a portion of Pope John Paul II's "Address to the International Congress on Transplants", August 29, 2000.

When Does Death Occur?

Acknowledgment of the unique dignity of the human person has a further underlying consequence: vital organs which occur singly in the body can be removed only after death, that is from the body of someone who is certainly dead. This requirement is self-evident, since to act otherwise would mean intentionally to cause the death of the donor in disposing of his organs. This gives rise to one of the most debated issues in contemporary bioethics, as well as to serious concerns in the minds of ordinary people. I refer to the problem of ascertaining the fact of death. When can a person be considered dead with complete certainty?

In this regard it is helpful to recall that the death of the person is a single event, consisting in the total disintegration of that unitary and integrated whole that is the personal self. It results from the separation of the life principle (or soul) from the corporal reality of the person. The death of the person, understood in this primary sense, is an event which no scientific technique or empirical method can identify directly.

Yet human experience shows that once death occurs certain biological signs inevitably follow, which medicine has learnt to recognize with increasing precision. In this sense, the "criteria" for ascertaining death used by medicine today should not be understood as the technical scientific determination of the exact moment of a person's death, but as a scientifically secure means of identifying the biological signs that a person has indeed died.

Neurological Criteria Accepted

It is a well-known fact that for some time certain scientific approaches to ascertaining death have shifted the emphasis from the traditional cardio-respiratory signs to the so called "neurological" criterion. Specifically, this consists in establishing, according to clearly determined parameters

commonly held by the international scientific community, the complete and irreversible cessation of all brain activity (in the cerebrum, cerebellum and brain stem). This is then considered the sign that the individual organism has lost its integrative capacity.

With regard to the parameters used today for ascertaining death — whether the “encephalic” signs or the more traditional cardio-respiratory signs — the Church does not make technical decisions. She limits herself to the Gospel duty of comparing the data offered by medical science with the Christian understanding of the unity of the person, bringing out the similarities and the possible conflicts capable of endangering respect for human dignity.

Here it can be said that the criterion adopted in more recent times for ascertaining the fact of death, namely the complete and irreversible cessation of all brain activity, if rigorously applied, does not seem to conflict with the essential elements of a sound anthropology. Therefore a health worker professionally responsible for ascertaining death can use these criteria in each individual case as the basis for arriving at that degree of assurance in ethical judgment which moral teaching describes as “moral certainty.” This moral certainty is considered the necessary and sufficient basis for an ethically correct course of action. Only where such certainty exists, and where informed consent has already been given by the donor or the donor’s legitimate representatives, is it morally right to initiate the technical procedures required for the removal of organs for transplant.

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