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Non–Heart-Beating Organ Donation: Process and Review

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To combat the national shortage of donor organs and meet the needs of more than 60,000 patients awaiting transplant, many organ procurement organizations have reevaluated non–heart-beating organ donation (NHBD) as one solution. Non–heart-beating donation is the process by which organs are recovered from patients after the pronouncement of death by cardiopulmonary criteria. Recent media reports have misled health care providers to believe that this is a new donation procedure; however, NHBD provided the foundation for modern clinical transplantation. This article describes non–heart-beating donor evaluation criteria, the donation process, associated ethical considerations and the role of the advance practice nurse in assisting families with this end-of-life decision. A case study will be presented followed by a summary of transplant recipient patient and graft survival outcomes. (KEYWORDS: organ donation, transplantation, ethical issues, non–heart-beating donation).

Over the last 40 years, organ transplantation has progressed from an experimental technique to a preferred method of treating end-stage organ failure. Due to its success, more patients are choosing transplantation as a viable treatment option. Today, more than 60,000 people are on the national waiting list for organs.[1] In an effort to combat this health crisis, many initiatives have been undertaken: increased public and professional education, routine referral legislation, the use of organ donors with preexisting medical conditions, and the increased use of living donors. Despite these efforts, donation levels have remained relatively static, with organs being recovered from only approximately 5,000 donors per year.[1]

Brain dead donors currently comprise 99% of this cadaver organ donor pool. Brain death is defined as the complete loss of cortical and brain stem function, and is most often diagnosed by performing two bedside clinical examinations and an apnea test. Upon determining complete absence of brain stem function, the patient is pronounced legally dead. If the patient is medically suitable for organ donation and the family chooses this option after the pronouncement of death, hemodynamic and ventilatory support are continued throughout organ evaluation, allocation, and the surgical recovery of organs in the operating room.

In contrast, non–heart-beating donation (NHBD) is defined as the surgical recovery

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of organs after the pronouncement of death based on cessation of cardiopulmonary function. Patients who can be evaluated for NHBD are those who have sustained a devastating neurological injury but do not meet the strict criteria for brain death and whose families have chosen to withdraw life-sustaining therapy. Another essential criterion includes the determination that cessation of cardiopulmonary function most likely will occur within 1 hour after the withdrawal of ventilatory and hemodynamic support. If the family chooses the option of organ donation in this scenario, the timing and location for the withdrawal of support are coordinated to enable the surgical recovery of organs immediately after the pronouncement of death.

Many organ procurement organizations (OPOs) and hospitals are reevaluating NHBD not only in response to the organ donor shortage but also because of the need to address patient and family wishes surrounding end-of-life decisions. With societal changes in health care, clinicians frequently discuss the removal of life support with patients and family members when devastating trauma or critical illness strikes. A growing number of patients now execute advance directives that provide for the removal of life support systems if they become incapacitated. The recovery of organs from NHB donors should not be viewed as an attempt to circumvent brain death criteria, but as a means to provide families with an additional option of donation that complies with patient or authorized family directives.

☐History

Recent media reports have led health care providers to believe that NHBD is a new donation procedure, when actually it provided the foundation for modern clinical transplantation.[2] Prior to the Harvard Committee report in 1968, which established acceptable criteria for the determination of brain death, death was pronounced solely on the basis of cessation of cardiopulmonary function. Early pioneers in transplantation reported on the use of NHBD organs and their associated complications beginning with kidneys (1951), and to a lesser extent livers (1963), and hearts (1967).[3] Many of these pioneers reported poor organ function after transplant primarily due to rejection, prolonged warm ischemia, and inadequate organ preservation techniques. In 1954, Dr. Murray demonstrated with a successful kidney transplant between identical twins, that widespread organ transplantation was possible if problems with preservation and rejection could be resolved.

Acceptance of brain death criteria grew during the 1970s. In the 1980s legislation was finally approved in every state, which enabled the recovery of organs from "brain dead" cadavers, who are maintained on a mechanical ventilator. Organs recovered from these donors were much more likely to function well. Because the warm ischemic time was reduced, the liver, pancreas, and thoracic organs could be transplanted successfully. As a result, the original approach of recovering organs from NHB donors was practically abandoned in the United States and many western countries.[4] However, in some European countries and Japan, NHBD continues to be the primary method of organ recovery.[5]

Today, the primary organ being transplanted from NHB donors is the kidney. Based on the United Network for Organ Sharing's (UNOS) national scientific registry, 85% of the organs transplanted from NHB donors from 1993 to 1996 were kidney transplants. It has been shown that long-term patient and graft survival rates using NHBD kidneys are comparable to those of kidneys from brain dead donors.[6]

☐Non–Heart-Beating Donation Process

Donor Evaluation

A patient with a nonrecoverable brain injury, but who has not been declared brain dead, is considered a potential non–heart-beating donor. Although the patient may exhibit some primitive brain reflexes, the family, in consultation with the treating physician, elects to withdraw life-sustaining support. During the evaluation process for NHBD, the clinician must be able to determine that cardiac cessation probably will occur within 1 hour after discontinuation of support. The clinician's ability to accurately gauge the

length of time is crucial to determining the success of this donation procedure.

If organs are exposed to more than 1 hour of hypoprofusion, they are less likely to function once procured and transplanted due to prolonged ischemic damage. For this reason, 1 hour from withdrawal of ventilatory support to complete cardiac cessation is considered the maximum amount of elapsed time that is acceptable for recovering transplantable organs.

Attempting to predict time of death is admittedly difficult. The clinician must consider several factors when estimating the length of time from the withdrawal of support to complete cardiac cessation. Although the patient's entire clinical presentation must be taken into consideration, the most important factors seem to be hemodynamic and ventilatory status. When evaluating the cardiopulmonary system, patients often are removed from the ventilator for a short period and a series of hemodynamic and ventilatory parameters are monitored. Rapid decreases in heart rate, blood pressure, and oxygen saturation along with increased work of breathing typically indicate that the patient will die in a short period of time. The amount of vasopressor or other mechanical support (eg, left ventricular assist device, extracorporeal membrane oxygenation, or intra-aortic balloon pump) needed to maintain the patient also must be considered in the evaluation. Once it has been determined that the patient will most likely die within an hour after withdrawal, the remaining evaluation criteria are similar to those performed for heart-beating donors. These criteria include reasonable organ function, absence of human immunodeficiency virus, absence of extracranial malignancy, and untreated sepsis.

Methods of Recovery

Non–heart-beating donation procedures consist of two categories: controlled and uncontrolled. In controlled situations, the family decides upon the timing and location of the discontinuation of support. Because the timing of the discontinuation is controlled, the surgical recovery teams can be in place to begin the recovery procedure when cardiopulmonary arrest occurs. In this scenario, the organs typically suffer less warm ischemic time.

Support may be withdrawn in different areas of the hospital depending on what has been agreed upon by the family. The operating room is the most desirable place for the recovery of extra-renal organs. Other areas include a room near the operating room such as the postanesthesia care unit, or the patient may remain in the intensive care unit (ICU) until he or she dies and then be transported to the operating room. While the latter two options allow for the benefit of families to be present at the time of death, there is a resulting increase in warm ischemic time, which may compromise the viability of the organs for successful transplantation.

Some programs have implemented protocols to minimize the effects of warm ischemia. These protocols typically allow for the insertion of femoral cannulas prior to declaration of death, with family consent. This procedure helps to prepare for rapid organ preservation. Regardless of cannula placement, organ preservation is never initiated prior to the pronouncement of death.

In the uncontrolled scenario, the arrest of the patient is unplanned, and the patient fails to respond to cardiac resuscitation. These patients (uncontrolled NHB donors) have either suffered cardiopulmonary arrest prehospital as a result of severe illness or injury, or during their hospital stay.[4] Uncontrolled recoveries are often more problematic because of longer ischemic times and the concomitant ethical and psychosocial issues.

☐Ethical Considerations

Since the inception of transplantation, ethical debates surrounding organ donation have prevailed. In recent years, ethical issues related to NHBD have emerged. Misperceptions have been promulgated nationally because of inaccurate news reports representing NHBD as an ethically questionable procedure. These reports have purported that organs have been recovered prior to death and have implied that NHBD hastens, or even causes, the death of a patient.[7]

In April 1997, the Department of Health and Human Services commissioned the Institute of Medicine (IOM)[4] to evaluate the NHB donation procedure. The IOM, chartered by the National Academy of the Sciences, ad-

vises the federal government on public health matters. The IOM examined how "given a patient in an end-of-life situation, what are the alternative medical approaches that can be used to maximize the availability of organs from that donor, without violating prevailing ethical norms regarding the rights and welfare of donors?"[4] A panel of national experts in medical ethics, neuroscience, transplantation, critical care, nursing, law, and anesthesiology was convened to provide recommendations. In December 1997, the IOM issued a report stating that the recovery of NHB donors should be considered as a reasonable source of donor organs. The report also outlined recommendations for national policy, which were intended to assist health care professionals in developing policies and procedures for a standardized and ethically sound practice. These recommendations are summarized in Table 1. The primary ethical considerations surround issues of withdrawal of support, administration of pharmacological agents prior to death (anticoagulants and vasodilators), and the declaration of death.

Withdrawal of support in patients who have suffered a devastating neurological injury with no chance of a meaningful recovery has become common practice in caring for the dying patient irrespective of organ donation. In situations where NHBD is an option for the family, the health care team should counsel the family in making a decision about withdrawal of life support prior to mentioning any options for organ donation. This clear temporal separation between two distinctly different decisions is essential in avoiding a perception that withdrawal is occurring for the purpose of donation.

When families consent to NHBD, several ethical considerations relate to the administration of pharmacologic agents. It is important to delineate between the agents that are intended to benefit the dying patient and those intended to preserve organ viability for transplantation. Care and comfort measures such as morphine administration are routinely given to patients at the time of withdrawal of support to relieve any pain or discomfort that might occur. Although morphine can cause respiratory depression and may even hasten death in some cases, it generally is an accepted principle that administering it for the primary effect of pain relief supersedes the unintended effect of respiratory depression.[8,9]

Anticoagulants and vasodilators are administered during any organ procurement process for the purpose of improving organ preservation. Questions have been raised regarding their administration in NHB donors due to the possibility that death may be hastened. The use of heparin may extend the injury in patients who have ongoing intracranial bleeding. Additionally, the vasodilatation caused by phentolamine may cause a decrease in blood pressure. It is the discretion of the treating physician on a case-by-case basis to determine whether these agents might adversely affect the patient. The physician also must involve the family in the decision to administer these agents.

Hospital protocols should address safeguards against conflicts of interest by sepa-

TABLE 1 Institute of Medicine Recommendations for National Policy Related for National Policy Related to Non–Heart-Beating Donation (NHBD)[4]

1. Written, locally approved NHBD protocols
2. Public openness of NHBD protocols
3. Cause by case decisions on anticoagulants and vasodilators
4. Family consent for premortem cannulation
5. Conflict of interest safegaurds – seperate times and personnel for important decisions
6. Determination of death in controlled NHBDs by cessation of cardiopulmonary function for at least 5 minutes by electrocardiographic and arterial pressure monitoring
7. Family options (e.g., attendance at life support withdrawal and financial protection)

rating the role of the treating physician or nursing team involved in the care of the patient from that of the transplant or procuring physician teams. This is important not only with the withdrawal decision, but also paramount when determining death.

Organs are never surgically recovered until the donor has been declared legally dead. The Uniform Determination of Death Act, serves as a template for most state statutes, and defines death as (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of the entire brain including the brain stem.[10] There has been more debate and discussion about this related to NHBD because to date there has been no scientific evidence to identify a standard time interval between determining cessation of cardiac and respiratory function and its irreversibility in nonresuscitative patients.

The time requirement for the declaration of death in many existing NHBD protocols ranges from 2 minutes of ventricular fibrillation to 10 minutes of asystole or electromechanical disassociation.[4] In view of this ambiguity, the IOM recommended that "not less than a five minute interval, determined accurately by electronic and arterial pulse pressure monitoring, be required to determine donor death in controlled NHBD."[4] More research on this central issue needs to be conducted to maintain a level of confidence in this definition of death.

Non–heart-beating organ donation raises both scientific and ethical questions among the public as well as clinical practitioners. However, when faced with counseling a family about end-of-life decisions, NHBD is an additional donation option that often provides comfort to families who have made the difficult decision to discontinue support.

☐ Case Study

Susan sat in a dimly lit ICU waiting room occasionally wiping the tears from her cheeks. She waited for the return of her ex-husband and daughter who had gone for a walk in an attempt to absorb the news given by the neurosurgeon. Despite the physician and nursing staff's best efforts, her son, Michael, was not going to survive the head injury he had sustained 2 days prior as the result of a fall. During this moment of isolation, she privately recounted the events that had occurred over the last 48 hours. While playing with friends in an abandoned warehouse, Michael (14 years old) had fallen, striking his head. Initially, Michael was unfazed by the fall; he picked himself up, brushed himself off, and thought it might be best to call it a day and go home. It wasn't until several hours later that the severity of the neurologic injury he sustained would manifest itself.

At home, Susan noticed that more than an hour had passed since she had last seen Michael go into the bathroom. Upon entering, she discovered Michael unresponsive. Susan called 911 and when paramedics arrived, she watched them work feverishly to stabilize his condition. He was transported to a local trauma center where he was evaluated. A computed tomography scan revealed that his only hope for survival would involve undergoing an emergent craniotomy. After surgery, the family was informed that the next 24 hours would be critical. While maintaining a vigil at the bedside, Susan watched for signs of improvement, but her prayers went unanswered. Michael remained hemodynamically stable but minimal posturing was his only neurologic response.

Susan's thoughts quickly changed to the present as she noticed her ex-husband and daughter returning from their walk. They were faced with making final decisions about Michael's future based on the grave prognosis. The discussion was a short painful one but the decision was unanimous: withdrawal of life-support. It was during this conversation that Susan first mentioned "organ donation." For an explanation of what options might be available to them, Susan turned to the nurse who had been caring for her son.

Within 1 hour, a transplant coordinator from the local OPO arrived at the hospital and quickly reviewed the patient's clinical course, past medical history, current neurologic status, and family dynamics. After reviewing the case at length with the physicians and nursing staff involved, it was determined that Michael would be suitable for NHBD. A resident overseeing the trauma asked, "how can this patient be an organ donor if he does not meet the very strict criteria to be declared brain dead?" The transplant coordinator explained that in situations

where a patient sustains a nonsurvivable neurologic injury, and families have chosen to withdraw support, additional donation options might be available. If it is likely that the patient's heart stops within an hour of being removed from the ventilator there may still be an opportunity to donate abdominal organs. In this instance, the logistics regarding where discontinuation of support occurs would be changed from the ICU to the operating room. The transplant coordinator explained that if the patient's heart stops within 1 hour after the withdrawal of support, pronouncement of death would be based on cardiopulmonary criteria and then a rapid surgical recovery of organs would ensue.

A family meeting was held with the transplant coordinator and the health care team to discuss the various donation options. They were told that one of the options would be to support Michael an additional 24 hours to see if he would fulfill the criteria for brain death and the standard procedure for donation could occur. A second option would be NHBD. The family was given an opportunity to discuss the situation privately and elected to pursue NHBD.

To ensure an informed family decision, additional information was shared regarding the potential outcomes. The transplant coordinator explained that the insult Michael's organs would suffer after withdrawal of support might preclude transplant. More importantly, the family was made aware that Michael's death might not occur within the 1-hour timeframe in which case he would be returned to the ICU. Despite the uncertainty, their decision to proceed was unanimous. Susan had mentioned that this had been Michael's expressed wish only 2 months earlier.

After obtaining legal consent, additional testing was conducted to determine organ function and to rule out infectious disease. While awaiting test results, the transplant coordinator reviewed the case with hospital administration, as well as the staff from the ICU and operating room. The coordinator explained that the organ recovery would not take place until after death had been determined by one of the physicians involved in Michael's care. Once testing was complete and arrangements were made to have the transplant team present in the operating room, the family was given the opportunity at the bedside to say their "good-byes." The farewell was highly emotional for the family as well as the staff who had provided support and care for 2 days.

In the operating room, the transplant team was present as well as the physician and nursing team who participated in Michael's care. Once Michael was prepared for surgery, the transplant team left the operating room and Michael's attending physician withdrew ventilatory support. Twenty minutes after discontinuation of support, Michael's heart ceased to function and he was pronounced dead. The transplant team waited an additional 5 minutes before beginning the surgical recovery.

Only 4 minutes after making the first incision, the organs were being perfused with preservation solution. Within 24 hours of Michael's death, his liver and kidneys had been transplanted successfully into three patients.

☐ Discussion

The warm ischemia associated with NHBD contributes to delayed function but has no overall effect on graft and patient outcome.[11–13] Kidneys can tolerate up to 2 hours of warm ischemia and still function similarly to those kidneys recovered from brain dead heart-beating donors.[14,15] Although extra-renal transplants are relatively few, there have been reports of successful use of livers, lungs, pancreata, and hearts from NHBD. The main barrier to using more extra-renal grafts is intolerance to warm ischemia. Research into improving preservation techniques and solutions may provide an answer for the future of transplanting extra-renal organs.

Despite the proven clinical successes, and the long history of NHBD, the number of these donors is very small. Of the 5,417 organ donors in 1996, only 70 (1.3%) were NHB donors.[16] Of the 73,795 transplants performed between 1993 and 1996, there were only 374 organs transplanted from NHB donors.[17] It is estimated that only half of the OPOs in the United States currently recover organs using this method.[18] A recent study by Koogler and Costarino[19] showed that a single pediatric trauma center could increase

TABLE 2 Delaware Valley Transplant Program Non–Heart–Beating Donation (NHBD) Experience

	Total Donor Referrals	*NHBD Referrals*	*NHBD Procured*	*Livers Transplanted*	*Kidneys Transplanted*
1995	824	198	2	1	4
1996	949	236	12	2	17
1997	1103	301	14	3	21
1998	1158	279	25	9	37
Total	4034	1042	53	15	79

donation by 42% with the implementation of NHBD protocols. Another study by Nathan estimated that the national pool for organ donors could be increased by as much as 25% using NHBD.[20]

Delaware Valley Transplant Program, the OPO serving eastern Pennsylvania, southern New Jersey, and Delaware, initiated a NHBD protocol in 1995 to facilitate this procedure. Since the protocol's inception, the proportion of NHB donors has risen from 5% to 10% of total donors for the OPO. From 1995 to 1998, a total of 79 kidneys and 15 livers were successfully recovered and transplanted (Table 2). Initial experience indicates that graft and patient survival rates among recipients of kidneys and livers from this group of NHB donors are comparable to those among patients who have been transplanted with organs from brain dead donors.

Increases in the number of NHB donors each year at DVTP can be attributed partially to the 1994 enactment of routine referral legislation in Pennsylvania. This required hospitals to call the OPO on all patient deaths and impending deaths, increasing the total number of organ donor referrals by 84% from 528 in 1994 to 1158 in 1998. As a result, there was a dramatic increase in the number of patients referred who did not meet the strict criteria for brain death, but had sustained a devastating neurologic injury, and whose families expressed an interest in donation (101 in 1994 and 219 in 1997).

Ongoing hospital staff education and protocol development should provide more opportunities for NHBD in the future, especially in light of the the recently revised Health Care Financing Administration's Conditions of Medicare and Medicaid Participation for Hospitals. These Conditions mandated routine referral nationally and became effective in August 1998. The nurse clinician's involvement will become increasingly important as this becomes a routine part of patient and family care after death.

□Summary

The reevaluation of NHBD protocols and the pursuit of their implementation in OPOs and hospitals across the country could significantly impact the supply of donor organs nationally. In light of nationally mandated routine referral, many additional opportunities will be presented to OPOs and clinical practitioners for offering families this donation option. Although there is a certain degree of misperception surrounding the ethical issues involved, comprehensive education for physicians, advance practice nurses, and other health care professionals along with clearly defined polices will be important precursors to effective implementation. Educational messages must convey that this procedure provided the foundation for modern clinical transplantation almost 40 years ago and in essence we are going back to the future.[21]

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