Recommendations for nonheartbeating organ donation

A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine

It is feasible to procure and then successfully transplant organs from cadavers certified dead using either neurologic or cardiac criteria. Kidneys procured from asystolic (nonheartbeating) cadavers have an equivalent 1-yr graft survival as those procured from donors certified dead using neurologic criteria (1). Recent controversy has erupted regarding the use of so-called nonheartbeating cadavers (NHBC). Questions have been raised about whether the patients are in fact dead (2), whether the practice constitutes active euthanasia (3), whether there is prohibitive conflict of interest for professionals and institutions (4, 5), whether there is adequate social support of dying patients and their families (6–8), and whether unethical and illegal practice is preventable (9).

Nonheartbeating organ donation (NHBOD) was commonplace before neurologic criteria for death were introduced in the late 1960s and early 1970s. During the 1960s, success with transplanting organs from cadaver donors led to the general acceptance of the dead donor rule, which states that it is unethical to cause death by procuring organs and unethical for organ procurement to precede death (except in special circumstances like donation of a single kidney or partial liver from one family member to another). Although the use of cadaver organs rose rapidly in the late 1960s and early 1970s, the practice of procuring organs from NHBC declined and all but disappeared largely because transplanting organs from brain-dead donors had better outcomes than transplanting organs from NHBC (10). Because of patient and family requests and need for new donor sources, the practice reemerged in 1993 following introduction of the Pittsburgh Protocol (11). The practice of procuring organs from NHBC is increasing (12). As many as 20% of donors are in this class in certain procurement regions (Brosnick B, Center for Organ Recovery and Education, personal communication, February 2000). This newly resurgent practice has occurred without national consensus on guidelines. Hospital and organ procurement organization policies are therefore variable, and some centers may even procure without an approved policy (12).

There have been a number of recent publications on NHBOD that have attempted to resolve ethical issues and set standards of practice. The most influential of those, the Institute of Medicine (IOM) report on NHBOD, supported the practice in principle. The IOM was commissioned by the United States Department of Health and Human Services to study the practice and make recommendations. Among their guidelines, they include a recommendation that a 5-min observation period after the onset of circulatory arrest, apnea, and unresponsiveness be required for death certification. Although the recommendation seems reasonable, it does not appear to consider data that may bear on their conclusion. The report is also silent regarding NHBOD in pediatric patients, even though pediatric NHBOD is possible, and there is one literature report of two pediatric NHBOD (13). Finally, little has been written about the psychosocial support of patients who become nonheartbeating organ donors and their families.

The purpose of this article is to comment on the issues of timing of death, pediatric NHBOD, and support of patients and their families. Because the Society of Critical Care Medicine (SCCM) is a multidisciplinary group of critical care professionals with expertise and experience in resuscitation as well as the management of critically ill patients who are dying and refuse life support, it is uniquely positioned to address NHBOD. In addition, the psychosocial care of dying patients and their families is a major focus of those working in a critical care environment. Therefore, we will offer specific recommendations addressing this concern. This article will not define specific medical eligibility or exclusionary criteria for NHBOD, nor will it comment upon the other ethical and legal

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issues that have been raised about NHBOD.

DEFINITIONS

A *heartbeating cadaver* (HBC), usually termed brain-dead cadaver, is a corpse whose death has been determined using neurologic criteria. These criteria prove irreversible cessation of whole brain function, even while circulation continues. HBC are the most common source of organs for transplantation.

A *nonheartbeating cadaver* (NHBC) is a corpse whose death has been determined using "traditional" or "cardiopulmonary" criteria. The three required elements of the criteria are simultaneous and irreversible 1) unresponsiveness, 2) apnea, and 3) absent circulation. Loss of circulation denotes no mechanical cardiac function. It is possible that electrical cardiac activity (in the absence of contraction) may continue after death. Various diagnostic modalities may be used to determine that the three criteria have been satisfied. For example, absence of circulation can be determined using (in decreasing sensitivity) an echocardiogram (for cardiac contraction or flow), intra-arterial catheter pressure transduction, or blood pressure cuff. Because of the high level of scrutiny that NHBOD is receiving, many policies require a relatively sensitive measure like intra-arterial catheter pressure monitoring.

A *nonheartbeating organ donor* (NHBOD) is a cadaver, whose death was determined by demonstrating irreversible cessation of cardiopulmonary function, from whom organs are procured. A person in whom brain death has occurred may become a NHBOD if circulation is arrested at the time of organ procurement. For the purposes of this article, only the former category will be considered. NHBOD may occur in two patient subsets.

Controlled NHBOD. Organ procurement follows a death that occurs after planned withdrawal of life-sustaining therapy. In this situation, the patient or family has refused life-sustaining therapy, including cardiopulmonary resuscitation. Instead, they have opted to withdraw life support, and request organ donation after death. If, after the patient expires and death certification occurs, *and* the organs remain viable, then procurement may occur. Discussion of the rationale for and ethical considerations of forgoing life support are beyond the scope of this article.

Uncontrolled NHBOD. Organ procurement that follows unexpected circulatory arrest and attempted, but unsuccessful, cardiopulmonary resuscitation (CPR) is termed uncontrolled NHBOD. This occurs most commonly in the emergency room or in the intensive care unit (ICU) when a patient (or HBC) has a cardiac arrest. After resuscitation efforts have failed and the patient has been certified dead, organ preservation and procurement activities are instituted. Organ preservation interventions usually include insertion of large arterial and venous cannulae and infusion of cold organ-preserving solution.

CERTIFICATION OF DEATH

In their paper, "When Is Death?," Youngner et al. (14) review data from 108 patients who were observed dying. In those five studies, no patient who satisfied the triad of apnea, absent circulation, and unresponsiveness for at least 2 mins had a restoration of spontaneous circulation (15–19). Yet, it is likely that at least some of those patients could have achieved spontaneous circulation if the doctors had intervened. The authors argue that there are two comparison sets of patients who are dying and seem relevant to NHBOD. The ICU patient "A" (a potential NHBOD) refuses CPR whereas the second, "B", (who is not a donor) is willing to undergo CPR. According to many NHBOD policies, 5 mins after cardiopulmonary arrest, patient A is dead whereas patient B is not, because CPR can restore spontaneous circulation. This would imply that patient A was not dead at the time death was certified. As a consequence, some may argue that the observation period before death certification should be *longer* than 5 mins. A second comparison results in a different conclusion. Patient "A" is as described above and patient "C" refuses CPR but is *not* a potential NHBOD. In many ICUs, patient C would be certified dead after much less than 2 mins, usually after observation of only two or three EKG screens that demonstrate pulselessness or asystole (about 15–20 secs). Although this patient and patient A are in the same physiologic state, only C is "dead" at 30 secs. This latter comparison would imply that for physicians to treat potential NHBOD most like other ICU patients, an observation period should be much *shorter* than 5 mins.

The issue of when death is determined involves the ambiguity in the term "irreversible." If in the context of declaring death irreversible means the heart cannot be restarted *no matter what intervention is done* (a "stronger" meaning of irreversible), then clearly the observation period for asystole, apnea, and unresponsiveness must be much longer than a few minutes. It could be argued that even hours would be required because hearts can resume beating even after excision from the body. On the other hand, if irreversible means that circulation cannot be restored without CPR efforts or excluding those means refused by the patient (a "weaker" meaning of irreversible), then the observation period could and should be much shorter. In the case of NHBOD, the "weaker" meaning results in choosing the time when the heart will not restart on its own because CPR efforts have been refused. There is an important reason to choose the latter, "weaker" meaning of irreversibility. The "stronger" meaning, if employed, will require a very long observation time for certification for all deaths. The time is so long that it flies in the face of both logic and the contemporary notion of death certification. Imagine waiting with families at the bedside of an asystolic, apneic, unresponsive patient for 15 mins let alone an hour, waiting to declare death. It seems unreasonable and perhaps even cruel. On the other hand, there is no ethically or physiologically important distinction between the 2-min observation period utilized by the University of Pittsburgh, the 5 mins recommended by the IOM, and, for example, 10 mins. In this time frame (from 2 to 10 mins), 1) there are no reports that spontaneous restoration of circulation has ever occurred, 2) restoration of circulation is easily achieved if resuscitation is attempted, 3) brain function has ceased, and 4) the brain will resume some function if resuscitation is successfully performed.

Using a time shorter than 2 mins is problematic. Spontaneous resuscitation has occurred after more than 1 min of asystole, apnea, and unresponsiveness (18). Patients in this time interval, 0 to about 1 min, are physiologically and ethically distinct because they have not met even the "weaker" criteria for death. Hearts and brains have resumed function in this time frame. Xiao et al. (20) demonstrated complete recovery of neuro-

logic function in a canine model after 11 mins of circulatory and respiratory arrest. Thus, at the other end of the "waiting" spectrum, patients who are asystolic for over 11 mins are in a "stronger" state of irreversibility. They are ethically and physiologically distinct because, after this time frame has passed, full brain recovery is not currently possible (even in an experimental model), and "brain death" is highly likely even if circulation is restored.

Because of concerns regarding the potential abuse or misuse of death criteria in order to obtain better organs for transplant, it is important that specific standard criteria for death be utilized. In addition, documentation of objective evidence proving that these standard criteria have been satisfied is essential to reduce perception that organs could be procured from patients who are not quite dead. Although the Ethics Committee of the SCCM did not achieve unanimity regarding the single "best" observation period for asystole, apnea, and unresponsiveness, the committee did agree that the determination of death with less than 65 secs of observed asystole, apnea, and unresponsiveness is not supported by the data currently available. From 2 to 11 mins is equivalent from a physiologic and ethical perspective. Once a patient has been asystolic, apneic, and unresponsive for >2 mins, the exact duration of the observation of the aforementioned signs for death determination depend more on psychosocial and policy considerations than on ethics or physiology. More than 11 mins conforms to a stronger notion of irreversibility, because, by that time, recovery of brain function does not occur unless special physiologic circumstances are extant (e.g., a hypothermic patient).

In conclusion, it is the consensus opinion of the Ethics Committee of the SCCM that death determination for both ICU patients and potential nonheartbeating donors should utilize the same criteria within a single institution. No less than 2 mins is acceptable, and no more than 5 mins is necessary given the IOM recommendation and the current practice of critical care medicine.

There remains concern regarding the inherent conflict of interest in pronouncing a patient dead who may then become an organ donor. This is not unique to NHBOD, and the issue has been discussed in the context of organ donation after death determination using neurologic criteria (21). The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, citing the Uniform Anatomical Gift Act (UAGA) (22), proposed a standard for dealing with conflict of interest in death determination. They stated that two physicians should certify death. Furthermore, the physicians pronouncing death, "shall not participate in the procedures for removing or transplanting a part." The Ethics Committee of the SCCM makes a similar recommendation that physicians who are part of the transplant team or who are (or will be) responsible for care of the recipient may not determine death in the context of NHBOD as well. However, only one physician is required because of the presence of objective data (like arterial pressure transduction) that can confirm physical examination findings.

MOTIVE FOR NHBOD

In most countries, there is widespread support for organ donation and transplantation. Organ donation occurs in the setting of great need. However, the decision to donate resides with the potential donor patient and family in the case of pediatric patients. The motivation to donate is usually altruistic. In fact, altruism is so highly valued that there is legislation that prohibits compensation of donors or their families for organs procured. There are no data that decision to donate and the reasons that support the decision to donate are influenced by the criteria used to determine death (neurologic or cardiopulmonary). Before the recent reintroduction of NHBOD, patients who died in an ICU have not been able to become cadaveric donors unless their death was determined using neurologic criteria. Because there is no ethical or legal distinction between death certified using neurologic criteria and death certified using cardiopulmonary criteria, there should be no ethical or legal distinction between organs procured from the two cadavers. It is ethical to procure organs from NHBC, just as it is ethical to procure organs from a HBC.

Because the physiology of cadavers certified dead using neurologic or cardiopulmonary criteria is different, there are different logistic issues that must be considered in the setting of the NHBOD. For example, NHBOD must occur within a few minutes of the determination of death whereas organ donation following brain death can usually be postponed for hours if necessary. Therefore, NHBOD has to occur in a site that is in or near the operating rooms. Allowing families time and space to say goodbye requires special consideration in NHBOD as a result. In addition, because potential NHBOD usually follows a decision to withdraw support, there are other special issues that must be considered, including the potential conflict of interest regarding obtaining consent for organ donation and end-of-life decision-making. In any case, patients must be protected during a procedure (NHBOD), which, although ethical, has the potential for abuse or misuse. These issues have been addressed by the IOM and are outside the focus on this article.

CARE OF DYING PATIENTS WHO MAY BECOME NHBOD

The care of the dying ICU patient has been described extensively and is outside the scope of this article, however, several points referable to the NHBOD require further discussion. First, the potential NHBOD has an equivalent right to comfort care as do ICU patients who will not become NHBOD. Therefore, attempts should be made to provide the same type of support to dying patients irrespective of whether they are likely to become donors. To the extent that the support is the same, criticism that potential donors are being treated "only to procure organs" is lessened. Second, appropriate use of pain medicine is indicated. It may be reasonable to treat anxiety before transporting a conscious patient from the ICU. Not all patients wish this, however, and the Ethics Committee of the SCCM believes that the patient has the right to choose whether to receive such therapy if offered by the physician. Third, it is reasonable to withdraw support in a setting outside the ICU, (e.g., the operating room) as long as informed consent is obtained. When support is withdrawn outside the ICU, to the extent possible, continued care by staff familiar to the patient is preferable to care by those who have no prior relationship.

CARE OF FAMILIES OF NHBOD

Families of patients who may become NHBOD should receive psychosocial support. Pastoral care, social work, bereavement or grief specialists, and palliative care staff all have a place in the care of dying patients and their families. Fami-

lies may request to remain with the patient until the time of death. This is not an unreasonable request as dying alone connotes a sense of abandonment to some. A request by the family to be with the patient at the time of death should be anticipated and a plan prepared. Some institutions withdraw support in the ICU or another area near the operating room when the family wants to be present. Other institutions allow family into the operating room. The family support team must prepare the family for what they will see, what will occur, and what is requested of them (i.e., they will need to leave the room very shortly after death occurs, or organ donation may not occur). Families must receive support before, during, and after death, and staff should be specifically assigned to this task. Although some protocols currently do not allow families to be present at the time of death, we believe that offering that option is an important component of all NHBOD protocols.

NHBOD IN THE PEDIATRIC POPULATION

It is ethically and legally justifiable to withhold or withdraw life-sustaining treatment in infants, children, and adolescents when the burdens of such treatment outweigh the benefits and continued treatment is not in the best interests of the pediatric patient (23).

Decision-making for infants and children occurs by proxy decision makers using the best interest standard. This is different from the method used in adults, which uses the patients' own preferences and values to the extent determinable. In the majority of instances, parents are best suited to make healthcare decisions for their children. Medical professionals should seek to override parents' wishes only when those views clearly conflict with the best interests of the child (24). Most adolescents beyond the age of 14 yrs have fully developed decision-making capacity and are often accorded the right to participate in healthcare decisions that are appropriate to their age and maturity (16). Prior expressed wishes regarding organ donation for such adolescents should be given significant weight in the decision-making process about organ donation. Decisions to withdraw or withhold treatment in pediatric patients are often emotionally and intellectually challenging. Families and clinicians should not hesitate to enlist multidisciplinary hospital support services, including ethics consultants or committees, to aid in this process. Likewise, decisions to donate organs from children reside with the parents or guardians. Using the "best interests of the child" standard does not fit well. Even though the child is already dead at the time of the organ donation, and thus there is no perceptible harm to the child, there is also no benefit to the child. An altruistic model argues that organ donation will result in such great benefit to both the family of the deceased child and to the recipient families that the intervention is justified. Currently, there is broad support for organ donation following death in pediatric patients after appropriate informed consent.

Most pediatric candidates for NHBOD will have severe neurologic injuries but will not meet criteria for brain death. On the other hand, brain death is not a prerequisite for withdrawing and withholding life-sustaining treatment. When withdrawal of support occurs (following local and national guidelines), and if death follows, it is not unreasonable to also consider NHBOD from infants and children if the family have provided informed consent.

The Uniform Determination of Death Act defines cardiovascular death as the irreversible cessation of circulatory and respiratory functions. In pediatric patients, there are no published guidelines for the determination of cardiovascular death. The phenomenon of autoresuscitation has been observed in children where respiratory efforts resume after a brief period of asystole followed by return of a heart rate (13). There are no case reports that describe autoresuscitation occurring in pediatric patients after the withdrawal of life-sustaining support in the setting of organ donation.

An important issue in NHBOD is that incapability of pain or suffering at the time of organ donation must be assured, especially because altruist motives for donation cannot be presumed or inferred for pediatric patients. Limited studies in animals and pediatric patients suggest that a state of electrocerebral unresponsiveness is achieved within 1 min of the cessation of circulation. In studies of laboratory rats and pigs, electrocortical unresponsiveness occurs within 30 secs following cessation of cerebral circulation, and the electroencephalogram becomes isoelectric within 1 min (25–27). This time interval is somewhat longer than that described for adult humans. Rossen et al. (28) noted an average time of 6.8 secs from arrest of cerebral circulation to loss of consciousness, which was accompanied by the appearance of delta waves on the electroencephalogram. Such loss of electrical activity appears to correlate well with cerebral energy availability after death independent of age (29).

It is the consensus opinion of the Ethics Committee of the Society of Critical Care Medicine that death determination for both intensive care unit patients and potential nonheartbeating donors should utilize the same criteria within a single institution.

Based on anecdotal reports, the aforementioned basic science reports, and existing guidelines at pediatric transplant centers, it appears that a period of not less than 2 mins of asystole, apnea, and unresponsiveness is sufficient to declare death in a pediatric patient before organ donation. Therefore, although the IOM did not specifically evaluate the appropriate interval for death determination in a pediatric population, we believe their recommendation for 5 mins in adults can reasonably apply to pediatric death determination, although a somewhat shorter time interval may be acceptable as well.

RECOMMENDATIONS BY THE SOCIETY OF CRITICAL CARE MEDICINE

General Recommendations for Organ Donation.

1. Donation and procurement of vital organs after death is reasonable and ethical provided informed consent is obtained from the patient or his or her designate.
2. The ethical cornerstone of organ donation is informed consent, which is required before every donation. Spe-

cial attention to educating donors and those requesting consent is needed because of the complexity of NHBOD.
3. Organ procurement must not cause death, and death must precede procurement of unpaired organs or both paired organs. This practice is intended to prevent harm to the donor.
4. Death must be certified using standardized, objective, and auditable criteria, and must follow state law. The President's Commission on Death Determination supports two separate, complementary sets of criteria, one based on irreversible absence of circulation and respiration, and the other based on irreversible absence of whole brain function. Either is satisfactory for the determination of death before organ donation.
5. It is ethically reasonable for pediatric NHBOD to occur. However, children (especially those under the age of 14) represent a special case in organ donation because they have never achieved sufficient capacity to choose for themselves. All decisions about their care are made by guardians based upon best interest of the minor, and not based upon preservation of patient autonomy per se.
6. The critical care professional is first and foremost caring for the dying patient. Therapy that is harmful to the dying patient should be avoided even if it might improve organ viability. If, in the process of delivering high-quality end-of-life care, organ donation is possible, then critical care professionals should help enable that outcome (following existing local and national guidelines and legislation).

Proposed Recommendations for Nonheartbeating Organ Donation.

Patients who intend to become nonheartbeating organ donors have the right to humane care, including the presence of family members at their bedside as they are dying. Organ donation from cadavers whose death was certified using cardiopulmonary criteria has several special concerns that must be considered.

1. The patient must be certified dead using objective, standardized, auditable criteria that are not different from those utilized for patients not destined to be NHBOD. Observation of asystole, apnea and unresponsiveness to stimuli is required. At least two minutes of observation is required, and more than 5 mins is not recommended.
2. No patient may be certified dead by a physician who takes part in the procurement or transplantation of organs.
3. When nonheartbeating organ donation is intended to follow withdrawal of life-supporting therapy, the decision to withdraw therapy should preferably be made before, and must be made independent of any decision to donate.
4. When therapy is withdrawn, patients have the right to medications that prevent and alleviate pain and suffering.
5. No medication whose purpose is to hasten death should be given to the patient. Medications given to provide comfort are reasonable, even if they might hasten death.
6. Medications that do not harm the patient and are required to improve the chances of successful donation are acceptable.
7. Institutions should regularly review their practice of NHBOD, and should restrict physician and nurse involvement to those individuals who have received training in this procedure.
8. After organs are procured, they should be distributed according to the same fair allocation standards utilized for organs procured from brain-dead cadavers.
9. If there is a different successful transplantation rate for NHBC organs, compared with HBC organs, recipients have the right to this information and the source of their proposed organ.
10. Reasonable efforts should be made to educate patients and their families about NHBOD. Third-party assessment of understanding (e.g., by an ethics consultant) is reasonable.

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