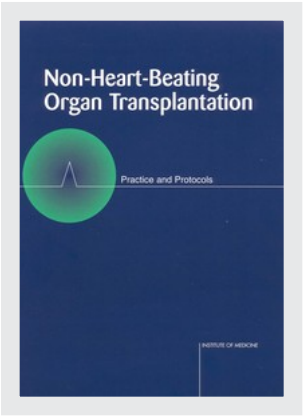


# Non-Heart-Beating Organ Transplantation: Practice and Protocols (2000)



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# Non-Heart-Beating Organ Transplantation

## Practice and Protocols

Committee on Non-Heart-Beating Transplantation II:
The Scientific and Ethical Basis for Practice and Protocols

Division of Health Care Services

INSTITUTE OF MEDICINE


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# Preface

In 1997, the Institute of Medicine published a report entitled *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement.* The findings and recommendations of that study defined the ethical and scientific basis for non-heart-beating organ donation and transplantation, and provided specific recommendations for practices that affirm patient welfare, promote patient and family choice, and avoid conflicts of interest. This report recommended that efforts be undertaken to develop consensus and consistency in non-heart-beating donation practices and protocols. Such efforts promote the integrity of the organ transplantation system and thus sustain public support for and interest in organ donation.

Following the 1997 study, the Department of Health and Human Services requested a follow up study to promote such efforts. To meet that goal, the present study was undertaken by a committee of professionals knowledgeable about organ transplantation, patient care, and patient and family concerns. The committee gathered information on the current state of non-heart-beating organ donation practices, on similarities and differences among non-heart-beating donor protocols, on the process of developing and implementing protocols, and on possible impediments to consensus on non-heart-beating organ donation practices.

The central activity for this study was a workshop held in Washington, D.C., on May 24–25, 1999. The workshop provided the opportunity for extensive dialogue on non-heart-beating organ donation among hospitals and organ procurement organizations (OPOs) that are actively involved in non-heart-beating organ and tissue donation and those with concerns about whether and how to proceed. The findings and recommendations of this report are based in large measure on the discussions and insights from that workshop.

Throughout the study, the committee emphasized a patient- and family-centered approach to organ and tissue donation. The need for organs for transplantation is a major concern, and organs from non-heart-beating donors have the potential for making a substantial contribution to meeting this need. However, the donation of organs and tissues is an intensely personal decision made by patients and families at times of great personal distress.

Meeting the needs of patients and families is the primary goal of end-of-life care, and organ donation is part of the range of options that families may wish to consider at the end of life. Focusing on the needs and concerns of donor patients and donor families is an ethical and practical imperative that sustains support for organ donation and enhances care at the end of life.

Ellen Agard
*Study Director*

# Acknowledgments

Many groups and individuals assisted in this study. The Department of Health and Human Services provided early guidance in planning the study. The Health Resources and Services Administration provided the funding; Lynn Rothberg-Wegman, deputy director of the Division of Transplantation, provided valuable input and support.

Several staff members at the United Network for Organ Sharing assisted study staff with gathering information and becoming familiar with the world of transplantation. Professional services coordinators Gloria Taylor, Debbie Seem, Lin McGaw, and Franki Chabalewski were especially generous with their time and information.

Stuart Youngner, M.D., Michael DeVita, M.D., and Robert Arnold, M.D. provided a valuable background paper and input into the workshop activities and discussions.

Mildred Solomon, Ed.D., of the Education Development Center, provided the research strategy included in the last chapter of this report.

Numerous individuals involved in patient care, organ procurement, research on the care of the dying, and ethics gave freely of their time and expertise.

Several staff at the Institute of Medicine (IOM) contributed to the success of this effort: Tracy McKay, Kelly Pike, Kathleen Nolan, and Ingrid Berger. Special thanks are due to Roger Herdman, M.D., senior scholar at the IOM and director of the 1997 study. He shared his expertise generously throughout the study and committed valuable time to coordinating the workshop discussions.

Most importantly, three family members came to the workshop to share their concerns about donation. Bob and Nancy Curran and Peggy Schaeffer pro-

vided insights from their experiences as bereaved families that helped the committee to keep the patient and family focus of this study clearly in mind.

## REVIEWERS

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the Institute of Medicine in making the published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and the draft manuscript remain confidential to protect the integrity of the deliberative process. The committee wishes to thank the following individuals for their participation in the review of this report:

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Although the individuals acknowledged have provided valuable comments and suggestions, responsibility for the final contents of the report rests solely with the authoring committee and the Institute of Medicine.

# Contents

# Acronyms

**DHHS** Department of Health and Human Services

**HCFA** Health Care Financing Administration

**HRSA** Health Resources and Services Administration

**OPO** organ procurement organization

**UNOS** United Network for Organ Sharing

# Glossary

**Autoresuscitation** Spontaneous restoration of heart function after the heart has stopped beating.

**Cannula, cannulae** Silastic (plastic) tubes inserted into large blood vessels (e.g. in the groin) for the administration of fluids or the withdrawal of blood.

**Cannulation** Placement of cannulae. The blood vessel is entered with a large needle; the needle is used as a guide for the insertion of the silastic tubing and then withdrawn. The cannula is taped or sutured in place.

**Cold perfusion** A method for preserving organs in the body (in situ) before they are removed but after death has occurred. Cold preservative solution is infused into the large vessels and blood is drained out.

**Heparin** A medication that prevents the blood from clotting. Heparin is used in organ donation to keep the large vessels open and to maximize blood flow to the organs.

**Ischemia** Lack of oxygen to the organs and tissues. **Warm ischemia** occurs when the heart and lungs are functioning but are not adequate to oxygenate blood and deliver it to the organs and tissues. It continues after cardiopulmonary function ceases, until the organs are removed or preserved in situ. At this point, **cold ischemia** occurs until the organs are transplanted and circulation is restored.

**Maastricht categories** A classification system for non-heart-beating organ donation:

Category I Dead on arrival at the hospital
Category II Unsuccessful resuscitation
Category III Awaiting death by cardiopulmonary criteria
Category IV Death by cardiopulmonary criteria following death by neurological criteria

Categories I, II, and IV are uncontrolled; category III is controlled.

**Phentolamine** A medication that dilates blood vessels. It is used in organ donation to increase blood flow to the organs and tissues.

**Pumping (kidneys)** A method for preserving kidneys after they have been removed. The kidneys are attached to a pumping device that circulates cold preservative solution through them during storage and transport.

# Executive Summary

In December 1997, the Institute of Medicine (IOM) published a report, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement.* This report presented the findings and recommendations from a study conducted by Dr. John Potts, principal investigator on the "medical and ethical issues in recovering organs from non-heart-beating donors (NHBDs) who do not meet the standard of brain death" (IOM, 1997b, p. 1).

The recommendations of the report were based on extensive information about organ supply and demand in the United States and about the policies and practices of non-heart-beating organ procurement and transplantation by organ procurement organizations (OPOs), transplant centers, and hospitals.

The study found considerable variation among OPOs and hospitals in such significant areas as criteria for the declaration of death, premortem medical interventions to preserve organs, and attention to family options (e.g., bedside attendance at the time of death). The study concluded that although considerable local variation in details was to be expected, policies and practices consistent with fundamental ethical and scientific principles ought to resemble each other in certain key areas directly related to the care of donor patients (IOM, 1997b, p. 48). Consistent approaches to non-heart-beating organ procurement support patients and their families, sustain the integrity of organ procurement efforts, and maintain public confidence in the organ transplantation system.

The IOM report made seven specific recommendations for non-heart-beating organ procurement policy (IOM, 1997b, p. 4):

1. written, locally approved non-heart-beating donor protocols;
2. public openness of non-heart-beating donor protocols;
3. case-by-case decisions about the premortem administration of medications;

4. family consent for premortem cannulation;
5. conflict-of-interest safeguards;
6. determination of death (in controlled non-heart-beating donations) by cessation of cardiopulmonary function for at least five minutes by electrocardiographic and arterial pressure monitoring; and
7. family options (e.g., attendance at life support withdrawal) and financial protection.

Following the publication of this report, the Department of Health and Human Services (DHHS) contacted the Institute of Medicine with a request for an effort designed to facilitate the adoption by all OPOs of protocols regarding non-heart-beating organ donation. In response to this request, the IOM designed a dissemination, communication, and consensus effort, sponsored by the Division of Transplantation at the Health Resources and Services Administration (HRSA). The goals of this study were defined as follows (Statement of Task, Appendix A):

1. To familiarize all relevant parties with the 1997 IOM report.
2. To identify obstacles to implementing its recommendations.
3. To facilitate the development of organ procurement practices consistent with the principles and recommendations articulated in the 1997 IOM report.

These tasks were defined as necessary steps towards the ultimate goal of the voluntary adoption of non-heart-beating donor protocols. The need for further efforts towards this goal was identified during the study.

The study was guided by a committee of experts in ethics and law, organ procurement and transplantation, and patient care. The central activity for the study was a national workshop on non-heart-beating-donor protocols held in Washington, D.C., on May 24 and May 25, 1999 (Appendix B). Participants in the workshop included care providers, organ procurement professionals, and families who supported non-heart-beating donation. In three roundtable discussions, workshop participants compared protocol content from six active non-heart-beating-donor programs, described the process of protocol development, and identified challenges encountered in implementing these protocols. Participants also reviewed and discussed work commissioned by the committee in preparation for the workshop and the report. This commissioned work included an expert paper on the determination of death (Youngner et al., 1999), a model for evaluating the outcome of non-heart-beating organ donation (Chapter 6), and a model for a family information brochure on non-heart-beating donation (Appendix E).

Following the workshop, the committee formulated seven recommendations for developing and implementing non-heart-beating-donor protocols. These recommendations were based on the findings and recommendations from the 1997 IOM report and consensus achieved among participants at the national work-

shop. The committee developed these recommendations as steps towards an approach to non-heart-beating-donor organ donation and procurement consistent with underlying scientific and ethical guidelines, patient and family options and choices, and public trust in organ donation.

**Recommendation 1: All OPOs should explore the option of non-heart-beating organ transplantation, in cooperation with local hospitals, health care professionals, and communities. A protocol must be in place in order for non-heart-beating organ and tissue donation to proceed.** Protocols to cover non-heart-beating donation are needed in order to:

- make this option available to patients and families who wish to donate organs and tissues;
- respond to increased donation referrals generated by Health Care Financing Administration (HCFA) regulations; and
- contribute to the supply of organs for transplantation.

**Recommendation 2: The decision to withdraw life-sustaining treatment should be made independently of and prior to any staff-initiated discussion of organ and tissue donation.** The decision should be based on the gravity of the patient's condition and on his or her wishes to withdraw burdensome treatment (or on guidance from a surrogate decision maker who represents or affirms the patient's wishes). It should follow established hospital protocols for withdrawing support and providing terminal care.

**Recommendation 3: As recommended in the 1997 IOM report, statistically valid observational studies of patients after the cessation of cardiopulmonary function need to be undertaken by appropriate experts.** These studies should address the following:

- conditions under which cardiac autoresuscitation might occur and at what time intervals;
- signs, symptoms, and testing technologies that could guide the determination of death by irreversible cessation of cardiopulmonary function; and
- assessment by various technological and clinical observations of the degree and permanence of loss of brain function in whole or in part following the cessation of cardiopulmonary function;

Such studies are needed in order to develop further empirical and conceptual clarity on the appropriate interval between the cessation of car-

diopulmonary function and the declaration of death. The 1997 IOM report suggested parameters for determining death by cardiopulmonary criteria, based on current expert clinical and legal opinion. However, concerns about this have not yet been resolved fully.

**Recommendation 4: Like all care at the end of life, non-heart-beating organ and tissue donation should focus on the patient and the family.** As an option for patients and families at the end of life, non-heart-beating donation should:

- follow patient and family wishes as closely as possible
- meet family needs for information, support and follow-up;
- recognize and respect patient and family social, economic and ethnic diversity; and
- follow clear mechanisms for identifying and covering all organ donation costs.

**Recommendation 5: Efforts to develop voluntary consensus on non-heart-beating donation practices and protocols should be continued.** The 1997 IOM report recommended specific protocol provisions based on underlying clinical and ethical standards. Substantial agreement on these provisions was achieved during this study (Chapter 4). However, some variations persist, and ongoing efforts towards consensus are needed.

**Recommendation 6: Adequate resources must be provided to sustain non-heart-beating organ and tissue donation. Adequate resources are required to cover (1) the costs of outreach, education and support for OPOs, providers, and the public, and (2) any increased costs associated with non-heart-beating organ and tissue recovery.** Financial barriers to the development and implementation of non-heart-beating protocols and practice must be removed. A thorough examination of costs and a commitment of adequate resources are critical to making non-heart-beating organ donation an option available to all patients and families. Adequate funding for education and outreach is needed to develop professional and public understanding of non-heart-beating donation, and to prepare patient care providers and organ donation personnel to participate in non-heart-beating donation. Adequate reimbursement mechanisms are needed to cover the costs associated with recovering and transplanting organs from non-heart-beating donors. A high priority should be placed on ascertaining the magnitude of these costs and identifying appropriate mechanisms to overcome these barriers.

**Recommendation 7: Data collection and research should be undertaken to evaluate the impact of non-heart-beating donation on families, care providers, and the public.** Further information on the burdens and benefits of this approach to donation has to be gathered in a systematic, coordinated way. Further data is needed on: patient, family, provider, and public attitudes and concerns; the costs of non-heart-beating donation; the outcomes from non-heart-beating organ transplantation, and their effect on the willingness of transplant centers to accept organs from non-heart-beating donors.

1

# Non-Heart-Beating Organ Transplantation: Background and Current Practices

**Recommendation 1: All organ procurement organizations (OPOs) should explore the option of non-heart-beating organ transplantation, in cooperation with local hospitals, health care professionals, and communities. A protocol must be in place in order for non-heart-beating donation to proceed. Protocols to cover non-heart-beating donation are needed in order to:**

- make this option available to all patients and families who wish to donate organs and tissues;
- respond to increased donation referrals generated by HCFA regulations; and
- contribute to the supply of organs for transplantation.

There are three reasons for recommending that OPOs, together with local hospitals, physicians, and communities, develop the option of non-heart-beating donation.

First, non-heart-beating donation offers an option to patients and families who may wish donation to take place after life-sustaining treatment is withdrawn, and death is determined by cardiopulmonary criteria. Several OPOs report that their non-heart-beating donation protocols were developed in response to urgent family requests. Family requests for non-heart-beating donation have been reported in the literature as well (DeVita et al., 1993). These reports are anecdotal, but they suggest a real interest on the part of families in pursuing the option to donate organs and tissues in this situation. Not all families seek or accept this option. However, research with donor families following death by neurological criteria suggests that families find comfort in salvaging some benefit to

others out of their own loss (Bartucci, 1987; Batten and Prottas, 1987; DeJong et al., 1998; Pearson et al., 1995). Family participants in the workshop confirmed this motivation for organ and tissue donation from their own experiences.

Second, recent HCFA regulations require that all deaths and impending deaths be referred to the local organ procurement organization (OPO), and that the option of organ and tissue donation be offered by a trained requester (42 U.S.C. Sect. 482.45). These regulations are in the process of being implemented. As implementation proceeds, these regulations are expected to increase substantially the number of patients that OPOs evaluate as potential donors (Ehrle et al., 1999; McCoy and Argue, 1999; Nathan et al., 1991). Comprehensive evaluation of potential donors should include the option of non-heart-beating donation, and whether the family might wish to consider this option. As is the case with any decision to donate organs and tissues, the decision about non-heart-beating donation rests with the patient and family.

Third, non-heart-beating donation has the potential to contribute substantially to the supply of organs and tissues for transplantation. Reports in the literature suggest that non-heart-beating donation might contribute 20% or more to the supply of kidneys (Koostra et al., 1991; Koogler and Costarino, 1998; Lewis and Valerius, 1999), and an undetermined amount to the supply of other solid organs (e.g., the liver and the pancreas) (D'Alessandro et al., 1995; Yersiz et al., 1999). Although this study follows a patient and family-centered approach to donation that emphasizes the needs and wishes of donor patients and families, the needs of critically ill potential recipients are an important social and medical priority as well, and warrant efforts to increase the supply of organs and tissues.

The development of non-heart-beating donor protocols is a cooperative effort among OPOs, hospitals, health care professionals, and communities. OPOs act as leaders, intermediaries and facilitators, assisting hospitals with development of protocols or providing OPO protocols to smaller hospitals with limited numbers of referrals and limited resources for protocol and staff development. Hospitals can initiate or facilitate non-heart-beating donation by developing their own non-heart-beating donor protocols. In addition, *hospital* protocols for the termination of life-sustaining treatment and the provision of palliative care are absolute prerequisites for non-heart-beating donation and for high-quality end-of-life care.

## NON-HEART-BEATING TRANSPLANTATION: BACKGROUND

### History

The procurement and transplantation of organs from non-heart-beating donors represents both a new practice and a return to a former practice in organ transplantation. During the early years of organ transplantation, all organs for transplantation were obtained from living kidney donors or from patients de-

clared dead following the irreversible cessation of respiratory and cardiac function (DeVita et al., 1993; IOM, 1997b). Organs removed after death suffered considerable ischemic damage that compromised transplantation outcomes.

The concept of determining death by neurological criteria was introduced in the late 1960s (Report of the Ad Hoc Committee,1968). These criteria have been incorporated into the Uniform Determination of Death Act (UDDA). According to this act, death can be determined by cardiopulmonary or neurological criteria: the permanent cessation of cardiopulmonary function or the irreversible loss of all brain function. Although challenges and reconsiderations continue to surface, the use of neurological criteria for death has gained wide medical, legal, ethical, and public acceptance in the United States (Bernat, 1998; IOM, 1997b; Olnick, 1991; Veatch, 1993).

Since the establishment and acceptance of neurological criteria for death, the majority of organs for transplantation in the United States have been obtained from patients who are declared dead by these criteria. After death has been declared, cardiopulmonary function is sustained artificially until the organs are removed. Mechanical ventilation and other forms of medical support are continued in order to maintain the circulation of oxygenated blood to the organs and to maintain organ viability for transplantation. Because of improved transplant outcomes, organ procurement after death by neurological criteria has virtually replaced organ procurement after death by cardiopulmonary criteria.

During the past decade, renewed interest in organ donation following death by cardiopulmonary criteria has developed for two main reasons. The first reason is patient and family interest in organ donation in cases where neurological criteria for death cannot be met, but the decision has been made to withdraw life-sustaining treatment (DeVita et al., 1993). The second reason is the potential for increasing the supply of organs for transplantation.

The patient who becomes a non-heart-beating organ donor cannot sustain life without continued medical intervention. When this medical intervention is stopped, cardiac and respiratory functions cease, death is declared, and organs are removed. The process must be carried out rapidly in order to remove organs before they become unsuitable for transplantation.

Non-heart-beating donor organ procurement may be controlled or uncontrolled. In uncontrolled non-heart-beating organ procurement, organs are removed after the patient suffers a sudden cardiopulmonary arrest. The patient may arrive at the hospital in arrest, may suffer an unanticipated arrest (Maastricht categories I and II), or may arrest after neurological criteria for death have been established (Maastricht category IV) (IOM, 1997, pp. 25, 42–43; Koostra, 1995). For the patient who arrives in arrest or for whom arrest is unanticipated, death is declared when resuscitation efforts fail to restore heart function. In these cases, issues of consent arise. The patient's wishes about donation may not be known, and there may be a delay while the family is located and informed of the patient's condition. Organ viability can be preserved in situ while efforts are

made to contact the family, but in order to do this, certain invasive procedures (e.g., the insertion of cannulae) must be performed without consent. As far as this study was able to determine, only one center in the United States preserves organs in situ in this situation, although it is more common in Europe (Alvarez et al., 1997, 1999; Ward et al., 1997). Under a program based on extensive community outreach and local legislation, this medical center takes measures to preserve organs in situ pending family contact and consent (Washington Hospital Center, Appendix F).

The situation is simpler for the patient who arrests unexpectedly after death has been declared by neurological criteria and cardiac function cannot be sustained. In this situation, organs are removed rapidly following an unanticipated arrest—thus, the term "uncontrolled"—but the issues of consent are less complex. The option of donation may have been considered; consent may have already been given, or consent can be obtained readily in order for donation to proceed on short notice.

In controlled non-heart-beating donation, a decision is made to discontinue life-sustaining medical intervention. This decision is made when treatment offers little if any prospect for recovery or the patient's wishes to forgo such treatment are known (Beauchamp and Childress, 1994, pp. 196–234; President's Commission, 1983; Weir, 1989). A separate decision is made to donate organs after death. Life-sustaining treatment is discontinued, although measures to maintain the quality of the organs (e.g., the placement of cannulae and the administration of fluids and medications) may be undertaken. Death is declared when cardiopulmonary function ceases. Organs are removed after death has been declared.

Non-heart-beating organ donation has been undertaken in Japan, where the concept of neurological death remains controversial, and in parts of Europe, as an additional source of organs for transplantation (Hoshinga et al., 1995; Koostra, 1995; Yong et al., 1998 ). At this time, less than 3% of organ donors in the United States are non-heart-beating donors (Yong et al., 1998). The number of OPOs that engage in non-heart-beating organ procurement is also quite small. Although half of the OPOs in the country have non-heart-beating donation protocols, the majority of non-heart-beating organ procurement in the United States is conducted by no more than a dozen active programs. These programs report that non-heart-beating donors account for anywhere from 6% to 30% of their total donors (Table 4-1).

## The Institute of Medicine Report: 1997

In 1997, the Department of Health and Human Services (DHHS) asked the IOM to conduct a study of non-heart-beating organ transplantation. DHHS requested a thorough study of the medical and ethical issues involved in this ap-

proach to organ donation, with particular attention to the rights and welfare of donors (IOM, 1997b, p. 73).

The IOM study concluded that "the recovery of organs from NHBDs [non-heart-beating donors] is an important, medically effective, and ethically acceptable approach to reducing the gap . . . between the demand for and the available supply of organs for transplantation" (IOM, 1997b, p. 1). The report made specific recommendations for non-heart-beating organ procurement:

1. written, locally approved non-heart-beating donor protocols;
2. public openness of non-heart-beating donor protocols;
3. case by case decisions about the use of anticoagulants and vasodilators;
4. family consent for premortem cannulation;
5. safeguards against conflict of interest between patient care and organ procurement;
6. determination of death (for controlled non-heart-beating donors) by cessation of cardiopulmonary function for at least five minutes by electrocardiographic and arterial pressure monitoring; and
7. donation arrangements that honor family wishes (e.g., to remain with the dying patient), and protect the family from financial liability for donation.

The 1997 report based these recommendations on underlying ethical considerations (pp. 50–64): avoiding harm or potential harm to the donor patient, supporting donor and family choice and consent (autonomy), and avoiding conflicts of interest between organ procurement and donor patient care. According to the 1997 report, non-heart-beating organ procurement protocols may vary in ways that reflect local variations in population, custom, and medical practice. However, consistency with underlying scientific and ethical standards for patient care is essential to sustain ethical practice and public trust (pp. 47–50).

## NON-HEART-BEATING DONOR PROTOCOLS: 1997–1999

The 1997 IOM study on non-heart-beating organ transplantation found considerable variation in the recovery of organs from non-heart-beating donors by different OPOs and medical centers. It found considerable variation among OPOs in the level of interest and involvement in non-heart-beating organ transplantation. Based on these findings, the 1997 report made specific recommendations for the development and content of non-heart-beating donor protocols.

Following the release of the 1997 IOM report, the Department of Health and Human Services (DHHS) requested that the IOM undertake a follow-up study designed to facilitate the development of OPO non-heart-beating donor protocols. This 1999 report covers the findings and recommendations of the follow-up study.

**TABLE 1-1** Organ Procurement Organization Protocols

| | 1997 | 1998 | Changes, 1997–1998 |
|---|---|---|---|
| **Approved protocols** | 27 | 28 | 1997: 2 protocols approved but on hold<br>1998: 19 protocols not revised (includes 1 reactivated without revision); 9 protocols revised (includes 1 revised and reactivated, and 1 new) |
| Draft protocols | 7 | 7 | 3 drafts unchanged, 2 drafts revised, 2 drafts introduced, 2 drafts canceled |
| No protocols | 29 | 28 | 1 new protocol approved |
| **TOTAL** | **63** | **63** | |

In preparing for the follow-up study, IOM staff assessed changes in non-heart-beating organ protocol development and content following the release of the 1997 IOM report. Tables 1-1 and 1-2 summarize their findings. Table 1-1 summarizes changes in the number of OPOs with non-heart-beating donor protocols between 1997 and 1998. Table 1-2 summarizes changes in protocol content between 1997 and 1998. Both tables are based on informal telephone contacts with OPOs in which they were asked for (1) a brief account of their involvement in non-heart-beating donation, and (2) a copy of their protocol.

### Protocol Development: 1997–1998

Between 1997 and 1998, the number of OPOs with approved non-heart-beating donor protocols increased from 25 to 28, the number of OPOs engaged in drafting or revising protocols decreased from 9 to 7, and the number of OPOs that did not engage in non-heart-beating donation, and did not have protocols, decreased from 29 to 28 (see Table 1-1).

Of 29 OPOs without protocols in 1997, 26 remained without protocols in 1998. Two drafts were initiated, but two others were dropped. Only one OPO developed an approved protocol between 1997 and 1998. The majority of OPOs that had no protocols in 1997 reported no protocols and no plans to develop them in 1998.

In addition, the level of non-heart-beating procurement activity changed little between 1997 and 1998. The OPOs most active in non-heart-beating organ procurement in 1997 continued to be most active in 1998. The remaining OPOs reported using their non-heart-beating donor protocols seldom or not at all during 1998.

The possibility of an association between non-heart-beating organ procurement activity and protocol revision was considered but not found. Among nine

OPOs that described themselves as "active" or "experienced" in non-heart-beating organ procurement, three revised their protocols between 1997 and 1998, and six did not.

## Protocol Content

In 1997, 25 OPOs provided approved non-heart-beating donor protocols for the IOM study, which found that these protocols varied greatly (IOM, 1997b). The protocols were found to be consistent in two main areas: (1) requiring an independent decision to withdraw life support prior to any discussion of organ donation and (2) requiring an independent declaration of death by a physician not associated with the OPO, procurement team, or transplant team. The protocols varied on criteria for declaring death, the administration and timing of medications and medical procedures, and management of the withdrawal of life support (p. 44).

Following the publication of the IOM report in 1997, a limited number of OPOs revised their non-heart-beating organ procurement protocols or developed new draft protocols. Nine OPOs revised their protocols in accordance with the report's recommendations (see Table 1-2). Although they represent too small a number for meaningful tabulation, two OPOs made similar revisions in draft protocols. These findings suggest that the influence of the 1997 IOM report was limited primarily to OPOs that are already interested or involved in non-heart-beating organ donation. For these OPOs, the report provided a resource for protocol development and revision. The variations that the IOM study found problematic in 1997 persist in the unrevised protocols, and the OPOs without protocols in 1997 have not developed them.

Revisions in protocol content between 1997 and 1998 reflect the recommendations of the 1997 IOM report in two main areas: (1) clinical guidelines and (2) family provisions.

### *Clinical Guidelines*

Clinical guidelines include the five-minute interval between the cessation of cardiopulmonary function and the declaration of death, and guidelines for administering medications and placing cannulae. Revised protocols are far more likely to follow the recommendations of the 1997 IOM report (Table 1-2).

Revisions in these areas suggest that OPOs are interested in greater clarity and consistency in the clinical management of non-heart-beating organ donors. The 1997 IOM report provided a set of specific recommendations for accomplishing this. The degree of consensus in these areas is discussed in Chapter 4.

### *Family Provisions*

The 1997 IOM report recommended that family opportunities for visiting and remaining with the patient be limited as little as possible by the donation

**TABLE 1-2** Non-Heart-Beating Donor Protocols: Consistency with Institute of Medicine Recommendations: 1997–1998

| | All Approved Protocols | | Revised Protocols | Unrevised Protocols |
|---|---|---|---|---|
| | 1997 ($n = 25$) | 1998 ($n = 28$) | 1998 ($n = 9$)[a] | 1998 ($n = 19$)[b] |
| Medications handled case by case | 0 | 6 (21%) | 6 (66%) | 0 |
| Consent for cannulation | 8 (32%) | 13 (46%) | 6 (66%) | 7 (37%) |
| More rigorous criteria for determination of death | 2 (8%) | 13 (36%) | 8 (88%) | 2 (10%) |
| Separate discussions (e.g., life support, donation) | 20 (80%) | 23 (82%) | 9 (100%) | 14 (74%) |
| Independent declaration of death | 25 (100%) | 28 (100%) | 9 (100%) | 19 (100%) |
| Family options | 13 (52%) | 15 (54%) | 4 (44%) | 11 (58%) |
| Financial protection | 8 (32%) | 10 (36%) | 3 (33%) | 7 (37%) |

[a]Includes one new protocol; one revised and reactivated.
[b]Includes one protocol reactivated without revisions.

process (IOM, 1997b, pp. 62–63). Revised and unrevised protocols show similar variation in their provisions for family involvement. Customarily, families visit in the intensive care unit (ICU) but not in the operating room (OR). Thus, the location in which life-sustaining treatment is withdrawn affects the family's option to be present.

Non-heart-beating organ donation requires a balance between the needs of families to remain with the patient and the demands of rapid organ recovery. Clearly, organ donation itself is an important family option and requires some adjustment in family contact at the end of life. However, there is room for two-way accommodation: accommodation by the family to the needs of organ procurement and accommodation of the organ procurement process to the needs of families.

Factors that influence family options for visiting, leave-taking, and attendance during death include hospital policies and procedures, family and staff preferences, and the demands of the organ procurement process, including the transfer of the patient from a patient care unit to the operating room and the pressure for rapid organ recovery. Priorities for patient and family care during donation are discussed in Chapter 3.

### Impediments to Non-Heart-Beating Donation

In addition to asking about changes in protocols between 1997 and 1998, IOM staff asked OPO contacts about perceived impediments to the development of non-heart-beating donor protocols in their organizations. Table 1-3 summarizes this information. The impediments mentioned are quite similar to the impediments or potential impediments identified in the 1997 IOM report (p. 35). These impediments represent local conditions and concerns that limit OPO involvement in non-heart-beating donation.

Factors that affect local acceptance of and participation in non-heart-beating donation are discussed in Chapters 2 and 3. These factors include the following:

- hospitals: lack of protocols, lack of "interest," physician and staff resistance;
- OPOs: limited financial and staff resources for training and outreach, limited technology and expertise;
- organs: concerns about organ quality, adequate organ supply without non-heart-beating donors, and
- ethics: medical interventions, termination of life-sustaining treatment, determination of death.

### Conclusion

Based on the information gathered by staff and summarized above, the current study was designed as a dissemination, communication and consensus ef-

fort, and as a contribution to further non-heart-beating donor protocol development.

Clinical innovation involves a message to be disseminated, a target audience, and the translation of the message into changes in practice (Lomas, 1993). Each of these factors must be identified and addressed in order for change to take place; each of them was considered in the design of this study and in the conclusions and recommendations of this report.

In this report, the message to be disseminated includes the need for non-heart-beating donor protocols, the emphasis on patient and family choices and concerns, and specific recommendations for protocol content. The target audience includes the OPOs, health care professionals, hospitals, and communities whose cooperation and participation are essential to non-heart-beating donation. The translation of the message into practice requires sufficient research, education, training, financing and follow-up to sustain the development and implementation of protocols. The following chapters report on the committees findings and recommendations for non-heart-beating donation practice and protocols.

**TABLE 1-3** Issues in Non-Heart-Beating Donor Organ Procurement: 1998 ($n$ = 63)

| Issues | No. of Responses | Specific Responses |
|---|---|---|
| Hospital factors | 19 | "Lack of interest" (not specified) (10)* |
| | | Resistance (not specified) (5) |
| | | Failure to approve protocols (3) |
| | | Rapid decisions to terminate life support (preceding discussions of organ donation) (1) |
| OPO factors | 14 | Limited resources (5) |
| | | Low priority (3) |
| | | Efforts directed toward required referral (4) |
| Organs | 10 | Adequate supply without non-heart-beating donors (2) |
| | | Poor organ quality (8) |
| Adverse publicity | 9 | Media and public misunderstandings and anxiety (9) |
| Ethics | 6 | Resistance to discontinuing life support (1) |
| | | Perceived association with physician aid-in-dying (1) |
| | | Medical interventions or determinations of death (3) |
| | | Ethics (not specified) (1) |

NOTE: OPO = organ procurement organization.

*"Lack of interest" (10) or "failure to approve protocols" may indicate "resistance."

# 2

# Non-Heart-Beating Donation and End-of-Life Care

**Recommendation 2: The decision to withdraw life-sustaining treatment should be made independently of and prior to any staff-initiated discussion of organ and tissue donation.** The decision should be based on the gravity of the patient's condition and on his or her wishes to stop burdensome treatment (or on guidance from a surrogate decision maker who represents or affirms the patient's wishes). **It should follow established hospital protocols for withdrawing support and providing terminal care.**

**Recommendation 3: As recommended in the 1997 IOM report, statistically valid, observational studies of patients after the cessation of cardiopulmonary function need to be undertaken by appropriate experts. These studies should address the following:**

- conditions under which cardiac autoresuscitation might occur and at what intervals;
- signs, symptoms, and testing technologies that could guide the determination of death by irreversible cardiopulmonary function, and
- assessment of various technological and clinical observations of the degree and permanence of loss of brain function in whole or in part following the cessation of cardiopulmonary function.

Such studies are needed in order to develop further consensus on the appropriate interval between the cessation of cardiopulmonary function and the declaration of death.

To maintain the support and trust of care providers, families and the general public, it is essential that the decisions, actions, and personnel involved in the withdrawal of life-sustaining treatment and the declaration of death be kept separate from the decisions, actions and personnel involved in the recovery of organs. Trust depends on the knowledge that the best care will be provided to all patients regardless of decisions about organ and tissue donation.

Organ transplantation has gained strong social, medical, and policy support. Public education and public policy measures emphasize the importance of organ donation in providing the life saving benefits of transplantation to organ recipients. The 1997 Institute of Medicine (IOM) report identified the potential for conflict of interest between patient care and organ recovery. One protection against such conflict of interest is the legal mandate of the Uniform Anatomical Gift Act (UAGA) that the person who declares death not be associated in any way with the organ procurement team (IOM, 1997b, pp. 55–57). All organ recovery protocols adhere to this mandate.

However, in an environment of support for donation, the potential for actual or perceived conflicts of interest between patient care and organ recovery is more complex. In non-heart-beating donation, medical treatment is modified in order to allow donation to proceed. These modifications include medications and procedures, and the process of withdrawing life-sustaining treatment and declaring death. The 1997 IOM report's recommendations in these areas are intended to prevent harm or potential harm to the patient while still making it possible for donation to take place, in conformity with patient and family wishes.

Empirical research should be undertaken to address concerns about the determination of death. The five-minute time interval between cardiopulmonary arrest and the declaration of death recommended in the 1997 IOM report is a considered judgment based on the available data and on expert interpretation of these data. The 1997 report recommended further study in this area that has not been pursued. Although end-of-life research is an ethically sensitive undertaking, simple, noninvasive observations and data collection can contribute to a greater understanding of terminal events, and greater certainty in the declaration of death.

In addition, further research is needed into the psychosocial and ethical impact that non-heart-beating donation may have on families, the community, and health care providers. The level of concern or misunderstanding about the determination of death, or about the possibility that the donor may not expire following the withdrawal of support, are not known. A qualitative study of nurses' responses to non-heart-beating donation suggests that these concerns need to be better understood (Wolf, 1994).

## TERMS AND CONCEPTS

When death is declared by neurological criteria, the patient commonly is described as "brain dead." Unfortunately, some confusion persists among the

public and among care providers about what constitutes brain death and whether it means that the person is "really" dead (Sullivan et al., 1999; Youngner et al., 1989; DeJong et al., 1998). In addition, the terminology of brain death and cardiac death may suggest that there are two kinds of death, rather than two ways of determining that death has occurred (Menikoff, 1998). The committee was concerned that the terminology of "cardiac death" and "brain death" might contribute to doubts or misunderstandings about whether and when death "really" takes place.

This report uses the terms "death established by neurological criteria" and "death established by cardiopulmonary criteria." It describes the organ and tissue donation process as "non-heart-beating donation," and the patient as a "non-heart-beating donor." Although these terms are more familiar to health care professionals than to the general public, the committee judged them to be more accurate than the simpler terminology of "brain death" and "cardiac death" for conveying when and how death is determined.

The distinction between death by cardiopulmonary criteria and death by neurological criteria affects the terminology for describing medical interventions to sustain cardiopulmonary functions. The person who is declared dead by neurological criteria prior to donation continues to receive mechanical ventilation, fluids, and medications. These measures do not constitute life support because death has already been established. Instead, these measures are sometimes described as "artificial" or "aggressive" support.

In non-heart-beating donation, the patient dies after artificial support measures have been withdrawn and breathing and heart function have ceased. Thus, the measures that maintain circulation and ventilation can appropriately be called "life-sustaining treatment." This term describes a practice that is not universally accepted, but it conveys the actual sequence of events: life-sustaining treatment is withdrawn, the patient dies, and organs and tissues are removed.

The committee recognized that terminology needs to be comprehensible to the general public and to those who are considering this donation option. They chose to use more technical terminology for this report, but recognized that it may be appropriate to modify this terminology according to the situation.

## WITHDRAWING LIFE-SUSTAINING TREATMENT

Decisions to withdraw life-sustaining treatment have received considerable attention in recent decades. Although such decisions are not accepted universally, the mainstream of American ethical, legal, and clinical opinion accepts the withdrawal of life-sustaining treatment based on the patient's clinical condition and wishes.

**The Decision to Withdraw Treatment**

In the field of bioethics there is a wide range of opinion about whether and when life-sustaining treatment can be withdrawn. At one end of the spectrum is the opinion that such treatment may never be stopped under any circumstances. Death may intervene but can never be assisted by withdrawing treatment. At the other end of the spectrum is the opinion that intentional killing by such means as lethal injection is justified when requested by the patient (Weir, 1989, pp. 227–278).

Mainstream opinion in bioethics falls in the middle ground between these two points. Mainstream opinion endorses the withdrawal of life sustaining treatment, with differences of opinion about what treatments may be discontinued under what conditions. Debates focus on the certainty or reliability of diagnosis and prognosis, the imminence of death, the degree of suffering, the degree of neurological impairment, the burdens and benefits of continued treatment, and the degree of certainty that the patient would not want further treatment.

Legally, the right to refuse unwanted medical intervention is based on the common law right to bodily integrity, the constitutional right to privacy, and court opinions upholding the right of competent persons to refuse medical treatment. Recent case decisions involve decisions to withdraw life-sustaining treatment made by third parties on behalf of those who lack decision-making capacity (Beauchamp and Childress, 1994, pp. 170–180; Emanuel, 1988; Weir and Gostin, 1990). In law and bioethics there is general consensus that the absence of capacity does not diminish the right to refuse medical intervention and therefore to have treatment withdrawn under the guidance of a designated decisionmaker. Variations among state laws affect the authority that a surrogate may exercise on the patient's behalf and the options for family/surrogate decision-making, but not the underlying ethical grounds for refusing treatment on another's behalf (Brody, 1995; IOM, 1997b).

Clinically, the withdrawal of life-sustaining treatment is based on an understanding of the patient's wishes and on as accurate an assessment as possible of the patient's condition and prospects for improvement. Treatment that offers diminishing prospects for restoring health or critical bodily functions is described sometimes as "futile" (Beauchamp and Childress, 1994, pp. 212–214). Clinicians seek a degree of certainty about both the burdens and benefits of treatment and the patient's wishes when the withdrawal of treatment is being considered. Given the uncertainty of "futility" assessments and differences in opinion about the burdens and benefits of treatment, not all clinicians and not all patients or families will make the same decisions. Ultimately, decisions to forgo life-sustaining treatment are judgments that can best be made according to the patient's own values about the burdens and benefits of treatment and the prospects for an acceptable outcome (Callahan, 1991). They rest on patient wishes, family input, and clinical judgment, independent of organ transplantation needs.

The decision to withdraw life-sustaining treatment, to allow the heart and breathing to stop, and not to attempt resuscitation, is consistent with end-of-life care, whether or not organ donation follows.

### The Decision to Donate Organs and Tissues

Controlled non-heart-beating donation cannot take place unless life-sustaining treatment is stopped. However, the decision to donate organs and tissues and the action of recovering organs and tissues after death are distinct and separate from the decision to stop life-sustaining treatment and the action of withdrawing such treatment. Two separate and distinct clinical teams are responsible for these two sets of decisions and actions. Conflict of interest prevents the organ donation team from being involved in the decision to stop treatment or in the process of withdrawing treatment.

In maintaining this clear distinction, the committee is aware that the roles and responsibilities of each team do, in fact, overlap. Both teams provide the families with information and support; both contribute to patient management decisions prior to donation. Close collaboration between the two teams leads to more consistent care for the patient and family, and to better transplant outcomes—a goal that patients and families share. However, the interests of the organ donation team must not influence the decision to withdraw life sustaining treatment.

Due to increasing public awareness of organ donation, families may raise the question of donation before a decision about continuing or withdrawing treatment has been made. Those who are providing care to a patient may need to respond to such inquiries. In these circumstances, the family's interest can be supported, and arrangements made to discuss donation options as soon as possible after treatment decisions have been made.

### Withdrawing Life-Sustaining Therapy

Non-heart-beating donation has raised concerns that measures taken to maintain organ viability will in some way harm the patient or hasten his or her death (IOM, 1997 p. 51). Such concerns were the basis for the 1997 IOM report's recommendations that consent be obtained and anesthesia or analgesia administered for procedures such as cannulation, and that medications such as phentolamine (a vasodilator) and heparin (an anticoagulant) not be administered routinely but on a case-by-case basis, based on the patient's condition. These measures are taken to maintain organ viability, not to benefit the patient; the recommendations ensure that these measures at least cause no harm (p. 52).

The process of withdrawing life-sustaining treatment raises similar concerns. Just as there are differences of opinion about withdrawing life sustaining treatment, there are differences of opinion about specific steps in the process of "terminal weaning" from ventilator support (Tasota and Hoffman, 1996). For example, mechanical ventilation may be stopped in order to stop unwanted and

burdensome treatment; sedatives and narcotics may be administered in order to provide palliative care at the end of life. Both of these have been questioned as measures that may unduly hasten the dying process, and they generated considerable discussion at the workshop.

This study finds the withdrawal of life support, including terminal weaning and palliative care, to be (1) an area in which opinions and practices reasonably may differ, as long as they support patient choice and comfort, and (2) an area that is managed by the patient care team, rather than the organ donation team. The separation between the patient care team and the organ donation team should be maintained as much as possible during the process of withdrawing life-sustaining treatment, as well as during the decision making process.

Extensive work on withdrawing treatment has been done in bioethics and in end-of-life care (Hastings Center, 1987; Weir, 1989; Emanuel, 1995; Lo, 1995; Moskowitz and Nelson, 1995; Solomon, 1995; Tasota and Hoffman, 1996; IOM, 1997b; Singer et al., 1999). This work provides the basis for excellent guidelines for withdrawing life-sustaining treatment, support for patient and family choices, psychosocial and spiritual support, bereavement support, palliative care and the relief of pain and suffering, respect for patient and family choices, assistance with financial needs, and help with caregiving.

Hospital policies and protocols should guide the withdrawal of life-sustaining treatment whether or not organ and tissue donation is to follow. Such policies and protocols provide a standard for end-of-life care that applies to donors and nondonors alike, and provide a mechanism for ensuring that the standard of care is maintained for both.

## DETERMINING DEATH

Controlled non-heart-beating donation takes place after life-sustaining treatment has been withdrawn, cardiopulmonary function has ceased, and death has been declared. The time between the withdrawal of treatment and cardiopulmonary arrest varies according to the patient's condition. During this time, breathing and circulation continue, but both oxygenation and perfusion of organs and tissues are diminished (warm ischemia). Occasionally, a patient does not expire after life sustaining treatment has been withdrawn. If death does not occur within a limited time, organ viability suffers. Most non-heart-beating donation protocols stipulate that if death does not occur within one hour organ recovery will not be carried out. Instead, the patient will remain in a patient care unit and will continue to receive palliative care until death occurs.

In most cases, cardiopulmonary function ceases and death is declared shortly after support has been withdrawn. The 1997 IOM study found that non-heart-beating donation protocols varied in their criteria for declaring death after the cessation of cardiopulmonary function. The report found that some protocols allowed the removal of organs immediately following cardiopulmonary arrest;

others stipulated waiting periods varying from two to ten minutes; others did not specify a precise time interval (IOM, 1997b, p. 58).

Once cardiopulmonary function has ceased, the internal organs are no longer perfused with oxygenated blood and begin to deteriorate rapidly. Optimum organ viability can be achieved by removing the organs rapidly or by preserving them in situ with cold preservative solutions. The need to maintain organ viability creates a strong incentive for an early determination of death. This incentive for the early determination of death places one of the greatest demands on non-heart-beating practice and protocols—the demand for clear and credible standards for determining death prior to organ recovery. The state of consensus on the determination of death prior to non-heart-beating donation is discussed in detail in Chapter 4.

Here, the empirical and conceptual issues involved in determining death by cardiopulmonary criteria are reviewed. This review is based on a commissioned paper prepared for the committee and presented for discussion at the workshop (Youngner, DeVita, and Arnold, in press). This paper, and the work of the committee on the issue of determining death, focus on the issues involved, and the work that remains to be done to resolve them. In concurrence with the 1997 IOM, the committee found that the interval of five minutes between the cessation of cardiopulmonary function and the declaration of death provided adequate assurance of the irreversible cessation of cardiopulmonary function, and satisfied the requirements of the Universal Determination of Death Act (UDDA). They reiterated the recommendation of the 1997 report that further study of this interval be undertaken to provide more clarity and certainty in this area.

## Empirical Grounds for Determining Death

Based on a review of the available data and expertise, the 1997 IOM study recommended that in controlled non-heart-beating organ donation (1) an interval of at least five minutes be allowed to elapse between cardiopulmonary arrest and the declaration of death and (2) this period of cardiopulmonary arrest be verified by electrocardiographic and arterial pressure monitoring. In the absence of empirical certainty that cardiopulmonary function ceases irreversibly within five minutes of arrest, the IOM report based this recommendation on expert judgment about the terminal physiology of the brain and the circulatory system (IOM, 1997b, p. 59). It recommended further study to evaluate the validity of the five-minute interval as an indication of irreversible cessation of cardiopulmonary function.

The empirical data available indicate that cardiopulmonary arrest becomes irreversible within a shorter time interval—60 seconds or less. However, these data are quite limited (Table 2-1). Further, these were studies of terminal cardiac electrical activity, not autoresuscitation. Thus, existing empirical data cannot confirm or disprove a specific interval at which the cessation of cardiopulmonary function becomes irreversible. The recommendation of a five-minute inter-

**TABLE 2-1** Autoresuscitation Following Cardiopulmonary Arrest

| Author | Year | No. in Study | Age | Time of Longest Asystole Preceding Recovery (seconds) | Comments |
|---|---|---|---|---|---|
| Robinson | 1912 | 7 | 9–37 | 30 | Electrical activity after death certified in all |
| Willius | 1924 | 4 | 29–58 | 11.4 | No autoresuscitation. No certification of death standard or time reported. Only four of six patients studied reported |
| Stroud | 1948 | 23 | 10–87 | No recovery after asystole | 20 had electrical activity by EKG after death was determined |
| Enselberg | 1952 | 43 | 8–80 | 65 | 22 had resuscitative measures (i.e., medications and a "thump" to chest [not CPR]) |
| Rodstein | 1970 | 31 | ≥73 | 60 | Mean duration of coordinated EKG activity after death; 4.8 minutes; maximum, 17 minutes |

NOTE: CPR = cardiopulmonary resuscitation; EKG = electrocardiograph.

val between cardiopulmonary arrest and the declaration of death is based on the acknowledged limitations of these data.

However, this recommendation has been criticized as not conservative enough. One critic argues that there is only one standard of death—the permanent loss of all brain function—with two methods for determining that this has occurred. Death can be established by neurological testing or by cardiopulmonary arrest of sufficient duration to bring about the death of the brain. According to this critic, the interval between cardiopulmonary arrest and the declaration of death should be seven minutes or longer (Menikoff, 1998).

However, there is no legal or historical basis for such a rigid requirement for declaring death by cardiopulmonary criteria. The UDDA specifies the irreversible loss of all brain function *or* the irreversible cessation of cardiopulmonary function, not both. The issue of declaring death by cardiopulmonary criteria involves empirical and conceptual clarity on the definitions of irreversibility (Potts et al., 1998).

Lack of certainty about the determination of death is a potential obstacle to non-heart-beating donation. However, no studies have been done to determine how significant a concern it may be and for whom: care providers, families and the general public, and/or ethicists.

At this time, the five-minute interval has gained acceptance among some, but not all, OPOs. Further study of the validity of this time interval, as recommended in the 1997 IOM report, has not been undertaken. Such study is needed to evaluate the level of uncertainty about the five-minute interval and its relevance for support of non-heart-beating donation (see Chapter 6).

### Conceptual Issues in Determining Death

In their commissioned paper and during the workshop discussion, Youngner, DeVita and Arnold identified the concept of irreversibility as a major conceptual issue in the determination of death by cardiopulmonary criteria. Conceptually, "irreversible" cessation of cardiopulmonary function can be interpreted to mean several things: (1) will not resume spontaneously; (2) cannot be restarted with resuscitation measures; (3) will not be restarted on morally justifiable grounds. Because non-heart-beating donation involves those who elect not to continue life sustaining treatment, the 1997 IOM study accepted that death occurs when cardiopulmonary function will not resume spontaneously, and will not be restarted artificially.

Critics have suggested that cardiopulmonary function is not irreversibly lost as long as it could conceivably be restored by vigorous resuscitation efforts (Menikoff, 1998). However, there are no legal or moral grounds for attempting to resuscitate someone who has elected to discontinue life-sustaining treatment. When life sustaining treatment has been withdrawn, when the heart and breathing have stopped, and when the passage of time has rendered the possibility of

autoresuscitation vanishingly small, there are strong ethical, legal and clinical grounds for concluding that death has occurred. This was the conclusion reached in the 1997 IOM report (pp. 58–59).

Further assessment of the irreversible loss of cardiopulmonary function is recommended at the beginning of this chapter. The committee concluded that simple, noninvasive observation following the withdrawal of life sustaining treatment from both donor and nondonor patients would provide valuable information about the cessation of cardiopulmonary function, and that such observation could be done (with consent) without intruding upon the dying person or the family. Similar observational assessment was recommended in the 1997 IOM report, but has not yet been done. In addition, more complex technological and clinical observations need to be conducted by the appropriate experts, in ways that protect patient and family welfare and privacy.

In arriving at these recommendations, the committee considered the work that has been done to set the standards for determining death by neurological criteria. The definition of the irreversible cessation of all brain function and its acceptance as a standard for determining death have been developed through extensive study and debate in medicine, ethics and law (Ad Hoc Committee of the Harvard Medical School, 1968). Debates, misunderstandings, and revisions continue to surface (Youngner et al., 1989; Olick, 1991; Veatch, 1993; Bernat, 1998), but the determination of death by neurological criteria has been widely accepted.

The determination of death by cardiopulmonary criteria has not been subjected to the same kind of scrutiny as the determination of death by neurological criteria. The vast majority of all deaths are declared in this manner, according to established medical practice and judgment. The committee determined that a reassessment or redefinition of death by cardiopulmonary criteria, on the scale of the work that has been done on death by neurological criteria, was beyond the scope and expertise of this study. The committee addressed the determination of death prior to non-heart-beating donation as a dissemination issue, and suggested following:

1. Consistency in the determination of death by cardiopulmonary criteria should remain a goal for non-heart-beating donation protocols. As suggested during the workshop, uncertainty and controversy may undermine family, provider, and public confidence in non-heart-beating donation. Empirical observations as recommended at the beginning of this chapter are needed to establish the empirical grounds for such consistency.
2. Tests to determine that brain function is entirely absent vary somewhat in timing, extent, and technological complexity. Assessments of the irreversible cessation of cardiopulmonary function vary somewhat as well. However, both methods for determining death are consistent with the Universal Determination

of Death Act (UDDA) and provide legal, clinical, and ethical grounds for determining that death has taken place before organ recovery begins.

3. The issue at stake in the determination of death is one of trust that the health care system will provide optimum end-of-life care regardless of the demands of organ procurement. Trust is a matter not only of facts and data, but also of attitudes and commitments. Trust depends on optimum end-of-life care for patients and families, donor and nondonor alike, as discussed in the following chapter.

# 3

# Patient- and Family-Centered Donation

**Recommendation 4: Like all care at the end of life, non-heart-beating organ and tissue donation should focus on the patient and the family.** As an option for some patients at the end of life, non-heart-beating donation should

- follow patient and family wishes as closely as possible
- meet family needs for information, support, and follow-up;
- recognize and respect patient and family social, economic and ethnic diversity; and
- follow clear mechanisms for identifying and covering all organ procurement costs.

## PATIENT AND FAMILY WISHES

The patient's family plays a critical role in the decision to donate. Family members represent the patient's wishes, make decisions based on both the patient's and their own values, and give consent for donation to proceed. In some cases, patients have made their wishes known by discussing donation with family and friends or by signing a donor card. In other cases, the patient's wishes are not known, and the family acts according to what it knows about the patient's values or according to the values of the family members involved in the decision.

Recent Health Care Financing Administration (HCFA) regulations require that hospitals report all deaths and impending deaths to the local organ procurement organization, and that a trained professional discuss organ and tissue donation options with the patient's family. These measures are intended to improve the identification of potential donors, and to offer the option of donation in a skilled and sensitive manner. They combine efforts to increase organ and tissue

donation with efforts to "encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors" (42 U.S.C. Sect. 482.45).

Many families are interested in the option to donate organs and tissues. The current practice of non-heart-beating organ procurement has been influenced by family requests for organ donation to take place after the withdrawal of life-sustaining treatment. Organ procurement organizations that engage in non-heart-beating organ procurement report that their efforts have been stimulated by family requests. This information has been reported in the literature as well (DeVita et al., 1993).

The committee placed a high priority on learning at first hand the feelings, attitudes and experiences of non-heart-beating donor and nondonor families. As far as the committee was able to determine, no studies have yet been published on non-heart-beating donor families. Minimal information is available on families who seek non-heart-beating donation, or families who decide against it. Published studies deal with the general characteristics of donor families (Bartucci, 1987; Batten and Prottas, 1987; Pearson et al., 1995), or donor and nondonor families (DeJong et al., 1998), in the more usual situation of death by neurological criteria.

The committee was unable to locate family members who declined non-heart-beating donation. In general, non-heart-beating donation is offered as an option only after the family has expressed interest in having donation take place. At this time, there is no readily accessible pool of families who have considered and declined this option.

One father whose son became a non-heart-beating donor declined to participate in the workshop. Strongly committed to organ and tissue donation and to the non-heart-beating option, he preferred to devote his efforts to raising public awareness of donation, rather than to the activities of this workshop. A legal review of in situ organ preservation and rapid organ recovery reports on his experiences with his son's donation (Braun and Drobny, 1998).

Two families who wished to donate a family member's organs and tissues but were unable to do so because of the lack of a protocol were willing to participate in the workshop. They wished to share their regret at being unable to donate, and to help make this option possible for other families. In one case, parents sought to donate their son's organs and tissues after he was struck by a car and critically injured. Their interest in donation was particularly acute since this was their only surviving child. A younger son had been killed two years earlier in a skiing accident.

> Paramedics responded to the scene where our son needed cardiopulmonary resuscitation (CPR) and ventilation. Within hours of getting him to the hospital, we were faced with several decisions. Tests revealed no blood flow to his brain

> due to massive swelling, and he was on a ventilator with several medications to keep his vital organs going.
>
> While we were waiting, we talked about organ donation. We did not have the opportunity with our younger son, and particularly because this was our only surviving child, we felt it would be important to have something good come out of this tragedy.

The conversation with the physicians turned to whether or not he would be a good candidate for organ donation. We talked about the need to establish that he would not breathe on his own for 10 seconds while off the ventilator.

> On Monday morning, a meeting was called to advise us that he was not meeting the criteria of the breathing test, and to help us understand what that meant: either to forget about donation and let him go, or to wait it out and try again.

Their son died shortly thereafter. The parents emphasized two points. First, although they left the hospital believing that their son's tissues would be used, they were told later that a metabolic condition (acetylcholinesterase deficiency) disqualified him as a tissue donor. The presence of this condition was known; its effect on organ and tissue donation was not. Had this been clarified sooner, the "false hope" of tissue donation could have been avoided. Second, organ donation could not take place because neither the hospital nor the organ procurement organization had experience with, or a protocol for, non-heart-beating organ donation. As the father stated:

> It is difficult for us to understand how we could allow our son to die with one set of criteria, but could not let someone else live because of another set of criteria.

In the second case, a mother donated her son's tissues in the aftermath of his suicide. As a former critical care nurse and a donation coordinator, she was personally and professionally committed to donation.

> I think the first thing that went through my mind about donation was exactly that assumption: Well, of course I should do this. I had talked with my children about it, and I knew that my son had a donor designation on his license, but at the same time, I also know the power that parents have over their children. My other children said, "Did he have a choice; would he have done that if he had not been your son?" I don't know, and that is troublesome, too, sometimes to think about.
>
> My biggest concern was that having worked on the inside of the field, that I wasn't sure what would be left with me in terms of how I would remember him:, would I lose the memories of him as my son, and would he always be a clinical picture in my mind. That was a big concern to me.

> But we did go ahead and we donated tissues, because he was not able to be an organ donor. But I thought in many ways that as important as tissue donation is, I wish we could have donated organs. I think under the circumstances, because of the care that was given to him immediately at the time and had the hospital had the protocol in place at the emergency department, we probably would have done that.

This mother emphasized how important it is not to make assumptions about what patients and families may or may not want, and how important it is for them to be able to trust the health care system and the care that is being provided to a family member.

> Death is the great equalizer; it doesn't matter who you are. When it happens you are at base level, and it takes a lot of energy to just think. The other thing I believe we should always consider is the issue of trust. I often think how hard it is for people who don't have an advocate close to them to get through the system—how much more difficult it must be for them, to be in a situation where death and donation are options.

In each of these cases, the parents followed their own feelings and values as well as their childrens' in coming to a decision about donation. In the first case, the parents learned only later that their son had signed a donor card; in the second case, the mother knew that her son had signed a donor card but had second thoughts about whether it represented his wishes accurately. In both cases, the loss of the option to donate organs was a source of deep regret to the families and compounded their feelings of loss.

Clearly, these two accounts do not predict how all families will think and feel when coming to a decision about organ and tissue donation. However, these accounts provide some insight into what families go through in a traumatic end-of-life situation and about their needs for accurate information and timely, sensitive support.

What do families want to know? One workshop presenter suggested that families seek answers to three basic questions:

1. Is my loved one really dead?
2. Will he or she feel any pain?
3. What do I have to do?

These broad but fundamental questions indicate the kind of information and reassurance that families seek when organ donation is being considered. They suggest a broad outline of the information and support that patient care and donation staff can offer to assist families in coming to a decision about donation.

## Meeting Family Needs for Information and Support

Decisions about organ donation are made in a crisis situation. Generally, the person who becomes an organ donor is a previously healthy person stricken by a sudden, unanticipated, life-threatening event. At a time when grief and shock make it difficult to comprehend what has happened, families must make complicated, difficult decisions, including a decision about organ and tissue donation (Batten and Protas, 1987; DeJong, et al., 1998; Riley and Coolican, 1999).

### *Patient and Family Support*

Sensitive, sustained interaction and support are essential elements in end-of-life care for all patients and families. Physicians, nurses, OPO staff, social workers, and clergy interact with and support patients and families during this time. Their sensitivity and skill can made a tremendous difference to patients and families. Planning and coordinating these interactions helps to meet patient and family needs with reliable, readily accessible support.

During organ and tissue donation, particular needs and concerns arise for families, and particular planning and coordination need to take place in order to address these needs and concerns adequately. The division or decoupling of organ donation from patient care creates an additional level of complexity. In order to avoid conflicts of interest, discussions about withdrawing life sustaining treatment must be kept separate from discussions about non-heart-beating donation. However, after these discussions have taken place and the decisions have been made, workshop participants suggested that involving both patient care and donation personnel in discussions with families can be particularly helpful in providing consistent information and support. Careful communication and coordination between the separate teams is needed to avoid interruptions or inconsistencies in information and support.

Workshop participants also suggested bereavement support and family advocacy as particularly valuable arrangements for supporting families during and after the death of a loved one. These services, staffed and funded by the OPO or the hospital, can provide an essential anchor for bereaved families. Most importantly, such services contribute to ongoing support and follow-up as the family continues to deal with its loss. Immediate support while the patient is in the hospital should carry over into referrals for ongoing support and counseling services after the patient has died and donation has been accomplished.

The OPO becomes involved with the family when the patient has been identified as a possible donor or when the family raises the question of donation. A trained professional approaches the family, explains the process of donation, and obtains consent. While recognizing the value of such a framework for ensuring that all families are offered the option of organ and tissue donation in a skilled manner, workshop participants viewed the consent process as a part of a

larger process of information, support and trust that should inform and support families regardless of their decision about donation.

Finally, workshop participants stressed that the arrangements for non-heart-beating donation should place as few impediments as possible in the way of family visiting and leave-taking. Generally, the family can be present when life sustaining treatment is withdrawn in the intensive care unit (ICU). After cardiac and respiratory functions have ceased, the patient must be moved to the operating room (OR) within minutes for organ removal. If cannulae are placed and cold perfusion of the organs is initiated, family visiting can continue for an hour or more. Alternatively, some programs have been able to arrange for life support to be withdrawn in the OR with the family present. The family leaves the OR immediately after death has been declared so that organ recovery may proceed.

Not all families wish to be present when life support is withdrawn. Not all require a prolonged period of visiting after death. However, the committee emphasized the need to make whatever arrangements are most comfortable for the family, and to avoid undue isolation and separation between the patient and the family at the end of life.

*Patient and Family Information*

Workshop participants engaged in extensive discussion about how best to provide patients and families with information about non-heart-beating organ donation and with consistent support during and after the donation process. Participants emphasized the need for close communication between hospital and OPO staff—to provide a clear understanding of what donation options can be offered, and how donation will proceed.

While conflict of interest concerns prevent the OPO staff from being involved in the decision to withdraw artificial support, early communication between the patient care team and the donation team (1) helps clarify what donation options are open to the patient and family, and (2) ensures that personnel will be available to talk with the family about donation as soon as possible after the decision to consider donation has been made.

Communication between the patient care and OPO teams helps to provide the family with complete and accurate information about the non-heart-beating donation process: what procedures will be carried out, and how and where the withdrawal of support will take place. Patient care and OPO staff are involved in different aspects of these arrangements, so the coordination of their efforts maintains quality care at the end of life.

Part the workshop discussion focused on the development of a family information brochure and how such a brochure might be used to support patient- and family-centered care during non-heart-beating organ and tissue donation.

Both the committee and the workshop participants endorsed the concept of such a brochure. It can serve as a valuable tool for families—providing consis-

tent, comprehensive, and readily accessible information at a time when it is difficult to absorb and retain such information. It can supplement personal interactions and discussions with donation coordinators and provide a point of reference during and after the donation process.

The committee and workshop participants discussed the content, audience, and possible uses for such a brochure, based on a draft brochure provided for review. Substantial agreement was achieved on six points to be considered before offering an informational brochure to families. The draft brochure was revised in response to these points and is included as a resource for hospitals and OPOs that may wish to develop their own educational materials (Appendix D).

1. The separation between the decision to withdraw support and the decision to donate should be maintained; the discussion of donation, accompanied by the brochure, should not precede the decision to stop treatment.
2. The sample brochure is intended specifically for families who have already made the decision to withdraw life-sustaining treatment and are considering organ and tissue donation. It does not cover the full range of options for end-of-life care and/or donation. Comprehensive information for families at the end of life will, of course, cover all of these options.
3. The brochure is not a substitute for personal contact and communication between the family and the donation team. The sample brochure is intended to serve as a supplement to personal discussions with families who are considering non-heart-beating donation.
4. Sensitivity to the family's feelings of loss and grief is essential to the content and language of the brochure. A patient- and family-centered brochure will focus on patient and family options and concerns, particularly on the option for family to be present during the withdrawal of support. The need for organs and tissues is an appropriate component of the brochure, not its main focus.
5. Any decision about organ and tissue donation should be guided by the instructions, wishes, and values of the dying person. By the time donation is considered, the patient usually is unable to make his or her wishes known. The family's role in acting according to wishes and values of the dying patient and the family must be emphasized.
6. The sample brochure should be distributed on a limited basis for focus group discussion and feedback involving donor families, donor organizations, care providers, donation professionals, and the public. Feedback should be obtained from hospitals and OPOs with varying levels of experience with non-heart-beating donation and from such specialty areas as critical care and neurology.

Other informational pamphlets and brochures have contributed to the development of this sample brochure on non-heart-beating donation and can contribute to future development and review. The committee reviewed brochures on rapid organ recovery, organ donation, bereavement, and brain death (Hartford Hospital, Northeast Organ Procurement Organization, National Kidney Foundation,

Washington Hospital Center). The donor family bill of rights, developed by the National Donor Family Council of the National Kidney Foundation (Appendix D) provided particularly helpful guidelines for providing information and support to donor families. Within a comprehensive, well-thought-out process, a family brochure can provide a valuable tool for families to refer to before, during, and after organ donation.

### Patient and Family Diversity

Family needs for information and support vary greatly. There are individual differences in the quantity and detail of information sought, the time required to reach a decision, in the need for emotional support, and the level of confidence in health care providers. In addition, ethnic, cultural, and economic differences can contribute to misunderstandings and doubts in the medical setting.

In general, health care providers represent the mainstream culture. Their language, explanations, attitudes and values assume a common perspective that some patients and families may not share. Workshop participants focused on three ways in which these differences may contribute to gaps in communication and understanding about organ donation.

First, those who have been marginalized in our society (minorities, people of color, and the poor) may lack faith in the health care system and the organ procurement process. A history of adverse or demeaning encounters with authorities and institutions can undermine trust and bring a high index of suspicion to encounters with health care providers (Blackhall et al., 1998). Scrupulous attention to and respect for the needs and concerns of the patient and family are prerequisites for patient- and family-centered care. In a situation of limited trust, such respect is fundamental to maintaining faith in and support for organ donation (Creecy and Wright, 1990; Schutte and Kappel, 1997).

Second, beliefs about illness, death, and the body may affect attitudes about organ donation. Although almost all mainstream religious denominations in the United States support organ and tissue donation, support for donation is not universal among all cultural and religious backgrounds. An example of this was provided at the workshop (Cook et al., 1999):

> Persons with a Native American cultural heritage comprise the dominant ethnic minority [in rural Montana] and tribal representatives have registered grave reservations about any procedures that infringe upon the dying process. Two hospice nurses who work with different populations [have found] that it is common for people to stay with the newly dead body of a loved one for some hours after death, until there comes a time when the survivors "just feel" that the dead one has actually "left" and it is appropriate to remove the body.

Although this is only one example, it illustrates how different experiences and beliefs can affect attitudes towards organ donation and appropriate care for the

dying. Respect for diverse beliefs requires sensitivity to situations where the discussion of organ and tissue donation may be troublesome to families. Sensitive efforts to ascertain interest in organ donation can identify patients and families for whom donation is not an option.

Finally, financial considerations may exert undue influence on decisions about treatment and donation. Workshop participants noted that that an estimated 43 million people in the United States lack health insurance: 16% of the population, or one in six people under the age of 65 (Carrasquillo et al, 1999; Findlay and Miller, 1999).

In addition, it has been found that socioeconomic status is a major factor in determining whether kidney patients are placed on a waiting list for transplantation (IOM, 1999, p. 37). In this context, workshop participants raised major concerns about the possible effect of their inability to pay for treatment on a family's decision to stop treatment or donate organs.

Published data on the relation between financial constraints and treatment decisions is very limited. A single report was found in the literature of a correlation between financial strain and a preference for comfort care over life-extending care (Covinsky et al., 1996). This study found that financial burden was one of several factors associated with a preference for comfort care. This preference was found to be associated as well with severity of illness, functional dependency, depression, anxiety, and pain.

While the evidence of an association between lack of financial resources and the decision to forgo treatment is limited, socioeconomic differences create severe inequities between those who have resources to pay for treatment and those who do not. Those who donate may be providing a benefit for others while they or their families lack adequate health care (Eggers, 1995; Schutte and Kappel, 1997; Alexander and Sehgal, 1998).

Other reasons for declining organ and tissue donation have been identified in the literature: dissatisfaction with the care provided, lack of knowledge of the patient's wishes, lack of sensitivity in the request for donation, concerns about brain death, perception of bias in the allocation of organs, and doubts about the efficacy of transplantation (Creecy and Wright, 1990; Franz et al., 1997; McNamara and Beasley, 1997; DeJong et al.,1998). These factors indicate that patient and family attitudes and preferences about donation vary widely. A patient and family centered approach to donation recognizes and responds to this range of concerns.

### Financial Arrangements

Workshop participants saw a need to identify clearly the costs of non-heart-beating donation and to ensure that families do not incur additional costs because of donation. Further study and clarification of payment issues is necessary.

When organ donation follows death by neurological criteria, the declaration of death marks the point at which the cost of care shifts from the hospital and the patient to the OPO. The costs of medical intervention after death become part of the cost of organ procurement and are paid when organs are placed for transplantation. Covered costs include lab tests, tissue typing, fluids, medications, and mechanical ventilation, as well as physician, intensive care unit (ICU), and operating room (OR) charges. Patient costs may be incurred if care is continued in the expectation of organ donation but treatment is stopped or the patient dies before the neurological criteria for death are met (Grossman et al., 1996).

In non-heart-beating donation, death is not declared until after support has been withdrawn. Thus, no "bright line" separates patient care costs from donation costs. First, a decision is made to withdraw life-sustaining treatment. Then for a period of time that can vary from a few hours to a day or more, the costs of intensive medical treatment continue to accumulate.

The 1997 Institute of Medicine (IOM) report recommended that families should not incur any costs for non-heart-beating donation that would not be incurred if donation did not take place (IOM, 1997b, p. 63). Above all, when the family is told that organ and tissue donation will not involve additional costs, this commitment must be met. Current mechanisms for covering the costs of organ and tissue recovery vary considerably among OPOs (IOM, 1999, p. 115). These costs must be examined thoroughly and modified as necessary for the non-heart-beating donor situation.

The committee identified five points for further consideration:

1. Mechanisms must be developed to define and meet the direct costs of donation-related patient care. The costs for intensive care are a gray area. The patient who becomes a non-heart-beating donor may incur additional ICU costs between the decision to stop treatment and the decision to donate. The patient who becomes a donor after death by neurological criteria incurs no costs after death has been declared, but incurs them during the period of testing required to establish that death has occurred.

2. The issue becomes even more complicated when a patient is evaluated as a potential donor but does not donate. When donation follows death by neurological criteria, the OPO covers the costs of patient care after death has been declared. However, one study of donation costs found that in a third of the cases reviewed, consent was given for donation but donation did not take place because neurological criteria for death were not met (Grossman et al., 1996). In these cases, charges for care were passed on to families and third party payers even though care was directed towards a goal of donation. Non-heart-beating donation makes it possible for death to be established and donation to proceed in such cases, but it highlights the need for clear guidelines for the point at which the OPO assumes the costs of patient care.

3. Indirect costs associated with non-heart-beating donation have to be considered as well. Required referral can be expected to increase the number of patient referrals and necessitate increased OPO resources for evaluating potential donors. Expanded donor criteria also contribute to the supply of organs as well as to the cost of organ recovery (Jacobbi et al., 1997). Concerns over these costs may deter some OPOs from participating in non-heart-beating donation.

4. Prospective payment and managed care have a strong impact on the way in which hospital costs are allocated and covered. Third-party payers have an interest in distinguishing patient care costs from donation costs and limiting their payment obligations to the costs of patient care. The current approach (described at the workshop) of opening a new billing account when the decision to donate has been made, billing donation-related costs to this account, and auditing the bills retrospectively may not be sufficient to resolve payment questions.

5. Further information is needed before specific recommendations can be made for paying the costs of non-heart-beating donation. Workshop participants suggested the value of a roundtable discussion among OPOs, hospitals, third-party payers (public and private), and federal agencies to review the costs of non-heart-beating donation, current payment arrangements, and possible modifications in reimbursement. Public and private reimbursement practices should not deter non-heart-beating donation.

## Conclusion

Organ and tissue donation is an important option in end-of-life care. Efforts to keep this option open demonstrate respect for both patient and family wishes. Clear, comprehensive, locally developed and public protocols provide a means for organ and tissue donation to be carried out when patients die after the withdrawal of life-sustaining treatment.

Donation provides clear benefits to those in need of transplantation. The desire to benefit those in need motivates many families to request or agree to donation. However, a patient- and family-centered approach to donation emphasizes that the benefit to others is made possible only through the commitment of patients and families to salvage some benefit out of profound loss.

In a patient- and family-centered approach to donation, the compassionate care of patients and families is paramount. Such an approach treats organ and tissue donation as one among several options at the end of life. It focuses on patient and family wishes and needs. By honoring patient and family needs, it supports both the willingness of patients and families to donate and the benefits of transplantation.

Neither a protocol nor a family brochure can address all of the needs and concerns of patients and families. These needs and concerns begin with the traumatic event that leads to donation; for the family, they extend through many years of living with loss.

4

# Non-Heart-Beating Donation Protocols: Content

**Recommendation 5: Efforts to develop voluntary consensus on non-heart-beating donation practices and protocols should be continued.** The 1997 Institute of Medicine (IOM) report recommended specific protocol provisions based on underlying clinical and ethical standards. Substantial agreement was achieved during this study (Chapter 4). However, some variations persist, and ongoing efforts towards consensus are needed.

This recommendation is based on the roundtable discussion on protocol content held during the study's dissemination workshop. In this discussion, six programs that recover organs from non-heart-beating donors compared their non-heart-beating donor protocols. These comparisons helped to highlight and account for areas of consensus and variation in protocol content.

Roundtable participants represented hospital and Organ Procurement Organization (OPO) programs with different levels of non-heart-beating donation experience and activity. In addition, the workshop was attended by more than 50 transplant professionals who contributed their own experiences and insights to the discussion. The roundtable provided an opportunity for open communication and comparison among programs.

There was strong consensus at the workshop about the need for locally developed, publicly accessible protocols and for a strong national climate supporting these local efforts. There was strong consensus also on the underlying ethical standards for non-heart-beating donation: avoiding harm, avoiding conflicts of interest, and respecting patient and family decisions. Differences in

protocol content represent differences in considered judgment about how to put these standards into practice.

## PROTOCOL CONTENT

Roundtable participants provided their protocols for discussion, and for inclusion in this report (Appendix F). Table 4-1 summarizes the content of these protocols in relation to four specific recommendations from the 1997 IOM report.

There are minor local variations in protocol provisions for medications and for family options during the withdrawal of support. These variations are based on the preferences and practices of hospitals, OPOs, and organ recovery and transplant surgeons.

There is substantial consensus on obtaining patient or family consent for premortem cannulation. There is one exception in this area. When a patient has died following failed resuscitation efforts, Washington Hospital Center places cannulae and begins in situ organ preservation to keep the option of donation open until the family can be contacted. This intervention for uncontrolled non-heart-beating donation was developed through a program of community outreach and oversight and is permitted by local legislation.

There is substantial consensus on allowing a five-minute interval to elapse between the cessation of cardiopulmonary function and the start of organ recovery. There are variations in the way this interval is specified in the protocols. The declaration of death always precedes organ recovery. If the declaring physician incorporates the five minute interval into the declaration of death, organ recovery follows immediately. If not, the organ recovery team waits five minutes after the declaration of death before proceeding with recovery.

The University of Pittsburgh declares death and begins organ recovery after two minutes of pulselessness, apnea, and unresponsiveness (Appendix F). This center finds the empirical data on autoresuscitation adequate to support a two-minute interval. This variation is based on considered judgment about clinically and ethically acceptable practice and on expert interpretation of the available data.

These variations suggest that even with a strong commitment to ethical practice and a reliance on the best clinical data available, there is room for significant differences of opinion on non-heart-beating donation practices.

Workshop participants recognized the value of consistency in key areas to avoid confusion and to maintain public, provider, and family trust in the donation system. The committee concurred with the 1997 IOM report in recommending that a five minute interval be allowed to elapse between the cessation of cardiopulmonary function and the declaration of death. However, full consensus was not achieved at the workshop. This is an area in which well-considered judgments continue to differ. As such, it is a decision point at which different options may be followed, but the grounds for selecting one option over another should be clearly specified.

**TABLE 4-1** Non-Heart-Beating Donor Protocols: Institute of Medicine Workshop, May 1999

| Program | Medications | Consent for Premortem Cannulation | Organ Recovery After Death | Location for Withdrawing Support |
|---|---|---|---|---|
| Gift of Life Donor Program<br>Philadelphia<br>71 cases, 1995–1998 (6.5%) | Heparin given routinely; phentolamine case by case | Yes | After 5 minutes of asystole | In the OR. The family may be present. |
| New England Organ Bank<br>Newton, MA<br>7 cases | Case-by-case<br>May be given following withdrawal of support | Yes or postmortem | After 5 minutes of asystole | ICU with cold perfusion in OR. |
| Ohio Valley Life Center<br>Cincinnati<br>33 cases, 1994–1998 (13%) | Case-by-case | Yes | After 5 minutes of pulselessness | ICU or OR |
| Shands Hospital<br>University of Florida<br>Gainesville<br>4 cases prior to protocol<br>1 case under new protocol<br>Controlled only | Case-by-case | Yes | 5 minutes after death is declared | ICU with cannulation or in OR. Family may be present in ICU, not in OR |

| | | | | |
|---|---|---|---|---|
| University of Pittsburgh<br>17 cases, 1993–1998 (20%)<br>Controlled only | Postmortem | Postmortem | 2 minutes of pulselessness, apnea, unresponsiveness | ICU, OR, or preop holding area |
| Washington Hospital Center<br>Washington, DC<br>26 cases, 1994–1998 (30%) | | Controlled: yes or postmortem<br>Uncontrolled: postmortem pending consent (per Community Oversight Committee and DC legislation) | Organ recovery a minimum of 5 minutes after death is declared | ICU or OR |

NOTE: ICU = intensive care unit; OR = operating room.

The following section identifies the major decision points in the donation process and the variations that are found at each of these points.

## DECISION POINTS

Table 4-2 identifies decision points along the path of non-heart-beating donation. This table highlights the points at which the decisions that are made have significant implications for patients and families. The recommendations are based on clinical and ethical standards for patient and family care. Variations from these recommendations call for careful consideration of the grounds for such variations, their impact on patients and families, and their implications for public trust in organ donation.

### The Patient Who Becomes a Non-Heart-Beating Donor

*Decision*

In most cases, the patient who becomes a non-heart-beating donor has suffered devastating neurological damage, most often from trauma or stroke. In rare cases, a conscious, paralyzed, ventilator-dependent person has requested non-heart-beating donation (Snyder and DeVita, 1993). These requests are rare, but workshop participants reported an occasional request of this kind.

*Recommendation*

The decision to withdraw life-sustaining treatment or to stop cardiopulmonary resuscitation should be made before the option of organ and tissue donation is discussed. These are patient, family, and patient care decisions, based on the legal, ethical, and clinical grounds outlined in Chapter 2. OPO protocols may specify the patients to whom these protocols apply; this supplements but does not alter prior decisions to stop support.

*Consensus and Variations*

Provider, family, and public confidence in non-heart-beating organ and tissue donation depends on confidence that the decision to stop aggressive treatment has been made appropriately, on its own grounds, independently of organ procurement interests. The patient, family, and patient care team should share this decision, with ethics consultation as appropriate.

As discussed in Chapter 2, there are limits to consensus on decisions to stop support. Similarly, there are limits to consensus on who may be a non-heart-beating donor. For example, opinion is divided on the option of non-heart-beating donation for the patient who is ventilator dependent but conscious and who wants to stop life-sustaining treatment.

**TABLE 4-2A** Decision Points: Controlled Non-Heart-Beating Donation

| Process Step | Decision Points | Recommendations | Other Comments |
|---|---|---|---|
| Clinical situation: Patient is neurologically devastated and ventilator dependent. A decision has been made to discontinue life-sustaining treatment | What is the basis for the decision to stop life-sustaining treatment?<br>Will this protocol apply to the patient who is ventilator dependent but alert (e.g., spinal cord injury, ALS)? | The decision to stop treatment should be made prior to any discussion of donation. It should be based on *patient and family choice* and on established clinical, ethical, and legal guidelines | The donation team should not be involved in making the decision to stop treatment or in setting criteria for this decision<br>The conscious, ventilator-dependent person represents a special case where experience and consensus are limited |
| Decision to donate | When will the option of donation be raised? | After the decision to discontinue support *or* when the family asks about donation. | Per HCFA guidelines, all deaths and impending deaths are referred to the local OPO. OPO staff may follow the case while a treatment decision is being made. Patient and family wishes are paramount |
| | Who will raise the option of donation? | A trained professional familiar with non-heart-beating donation | Per HCFA guidelines |
| | Who offers the option? | Trained professional | Per HCFA guidelines |

*Continued*

**TABLE 4-2A** *Continued*

| Process Step | Decision Points | Recommendations | Other Comments |
|---|---|---|---|
| Withdrawal of life-sustaining treatment | Location? | Flexibility per family wishes and needs | ICU, OR, preop holding area |
| | Process?<br>• Extubation?<br>• Sedatives or analgesics? | Determined by patient care team and hospital protocols | The withdrawal of support should be the same whether the patient will become a donor or not. Comfort measures should never be withheld |
| | Family presence? | Family preference | |
| Declaration of death | Who will declare death? | Attending M.D. or designee, not associated with donation | Uniform Anatomical Gift Act |
| | Criteria?<br>• What interval should pass between the cessation of cardiopulmonary function and the declaration of death?<br>• How should the cessation of cardiopulmonary function be verified? | Cessation of cardiac function for 5 minutes, confirmed by EKG, arterial pressure monitoring, and unresponsiveness. | Further study is recommended |
| Procedures | Will arterial cannulae be placed?<br>What diagnostic tests will be done? | Postmortem *or* with patient's or family's consent and full disclosure<br>Analgesia or local anesthesia, if indicated | Cannulation is an invasive procedure for which consent and pain management are required |

| | | | |
|---|---|---|---|
| Medications to maintain organ quality | What drugs and doses will be given?<br>Drug indications?<br>Explanation to family? | Case by case, with full disclosure | Further research to verify need for medications is advised |
| Organ recovery | Allowable warm ischemia time after death and prior to organ recovery? | Per OPO guidelines | Further research to establish effect of warm ischemia time on transplant outcomes is advised |
| | Procedures for handling organs including pumping (kidneys), placement, and sharing? | Per OPO guidelines | Further research to establish effect of organ handling on transplant outcomes is advised |
| Financial arrangements | What charges will be transferred from the hospital and family to the OPO? When? | No family financial liability for costs associated with donation<br>Development of standard guidelines | Examples: lab tests, biopsies, medications, procedures, ICU time, OR time |
| Family support | What resources will be provided for family support?<br>What arrangements will be made for family leave-taking? | Family support staff should have specific training and skill in traumatic bereavement support and thorough understanding of non-heart-beating donation | Clergy, social services, nursing—with adequate preparation<br>Family advocates<br>Bereavement counselors |

NOTE: ALS = amyotrophic lateral sclerosis.

**TABLE 4-2B** Decision Points: Uncontrolled Non-Heart-Beating Donation

| Process Step | Decision Points | Recommendations | Other Comments |
|---|---|---|---|
| Clinical situation: cardiopulmonary arrest<br>• Following death by neurological criteria (brain death)<br>• Unsuccessful resuscitation | • Proceed with donation?<br>• Offer donation to family? | • Rapid organ recovery may proceed with family consent<br>• Patient may be maintained pending family contact under carefully specified conditions | Rapid organ recovery in the patient who has been declared dead by neurological criteria and for whom consent to donate does not raise issues of conflict of interest, consent, or harm. Rapid organ recovery following failed resuscitation raises these issues, and may only proceed with careful foresight and program development. |
| Declaration of death | Criteria for declaring death. | Physician judgment per individual situation (IOM, 1997, p. 60)<br>The physician who declares death cannot be associated with the organ procurement team (by law) | Current uncontrolled practices include: 30 minutes of unsuccessful CPR; 10 minutes of absent heartbeat after CPR is stopped (IOM, 1997, p. 60) |

| | | | |
|---|---|---|---|
| Donation | When will the option of donation be offered? | In arrest following death by neurological criteria, trained requester should approach the family (if this has not already been done)<br>An institution that wishes to recover organs after failed resuscitation should have the following:<br>• Immediate access to a trained requester not associated with the patient care team<br>• Specific guidance for maintaining the patient pending family contact | Because of the need for rapid intervention and decision making in this situation, hospitals that carry out uncontrolled non-heart-beating donor procurement should establish mechanisms for request and referral<br>Patient wishes concerning donation (e.g., signed donor card) are relevant |
| Clinical management prior to organ donation | May organ preservation be undertaken (intravenous cannulation and cold perfusion)? | These measures are appropriate only within specific community, legal and institutional guidelines. | Maintaining the patient following failed resuscitation requires invasive procedures prior to consent<br>Careful consideration should be given to what procedures are permissible, and how long they may be continued |
| | Administration of drugs? | Case by case, with full disclosure | Further research to verify need for medications advised. |
| | Diagnostic tests? | Case by case, with full disclosure | |

*Continued*

**TABLE 4-2B** *Continued*

| Process Step | Decision Points | Recommendations | Other Comments |
|---|---|---|---|
| Organ recovery | Procedures for handling organs including preservation, placement and shipping. | Per OPO procedure | Further research to establish effect of organ handling on transplant outcomes is advised. |
| Financial arrangements | What charges will be transferred from hospital and family to OPO? When? | No family financial liability for costs associated with donation<br>Development of standard guidelines | Examples: lab tests, biopsies, medications, procedures, ICU time, OR time |
| Family support | What resources will be provided for family support?<br>What arrangements will be made for family leave-taking? | Family support staff should have specific training and skill in traumatic bereavement support and thorough understanding of non-heart-beating donation | Clergy, social services, nursing—with adequate preparation<br>Family advocates<br>Bereavement counselors (hospital or OPO) |

NOTE: CPR = cardiopulmonary resuscitation.

Consensus on this option was not attempted at the workshop. There are compelling legal and ethical grounds for the right of the conscious person to refuse life-sustaining treatment. However, experience with organ and tissue donation in this situation is too limited to provide a basis for general conclusions and guidelines. Individual cases must be approached with the primary focus on patient comfort and palliative care.

## The Decision to Donate

*Decisions*

Referring patients to the local OPO and approaching the family with the option of donation fall within Health Care Financing Administration (HCFA) guidelines for routine referral and trained request. The decision points involve how the referral and the approach to the family are handled and whether non-heart-beating donation will be offered or discussed only at patient or family request.

*Recommendation*

Both the timing and the content of interactions between the OPO and the family require the greatest possible sensitivity. Requesters should be trained to handle the option of non-heart-beating donation.

*Consensus and Variations*

As discussed in Chapter 1, routine referral and trained request create an opportunity for non-heart-beating donation. Variations in hospital and OPO resources for outreach education and training affect the way this option is developed and handled

Both hospitals and OPOs have a role in required request. Consistent, uninterrupted information and support for patients and families depends on cooperation between hospital and OPO staff. Trained requesters may be OPO staff or hospital staff not associated with the care of the patient.

## Withdrawing Life-Sustaining Treatment

*Decisions*

Decision points include the location where support will be withdrawn and the management of terminal care, including whether or not to extubate and to administer sedatives and analgesics.

*Recommendation*

The withdrawal of life-sustaining treatment, including terminal weaning from the ventilator, extubation, and the administration of sedatives and analge-

sics, should be determined by the patient care team according to established hospital protocols.

**The withdrawal of support and the provision of palliative care should be the same for both donors and nondonors. In particular, comfort measures should not be withheld because a person is going to be a donor.**

*Consensus and Variations*

Hospital protocols for withdrawing support and providing palliative care are prerequisites for non-heart-beating donation. Workshop participants reported that OPO, hospital, and physician experience in this area varies, and identified this as an area for further in-hospital education and development.

The University of Pittsburgh non-heart-beating donor program attaches its protocol for withdrawing support to its protocol for non-heart-beating organ and tissue donation. This ensures that the protocol for withdrawing support will be followed in all cases of non-heart-beating donation.

## Medications

*Decisions*

Medications administered to maintain organ viability include heparin (an anticoagulant) and phentolamine (a vasodilator). These medications do not provide any benefit to the donor patient. A decision must be made about what medications can be given without harm to the patient.

*Recommendation*

As recommended in the 1997 IOM report, case-by-case decisions should be made about the administration of medications. Their use may be contraindicated in cases of active bleeding or low blood pressure (IOM, 1997b, p. 52). These decisions should be guided by the medical team caring for the patient. The patient and family should be fully informed about the use of medications that do not directly benefit the patient.

*Consensus and Variations*

Two protocols allow heparin to be given routinely. Otherwise, all six protocols stipulate that medications will be given on a case-by-case basis or postmortem.

Although this is not universally agreed, many transplant professionals find that these medications contribute to organ viability, successful transplantation, and the acceptance of non-heart-beating donor organs by transplant physicians and surgeons. Thus, they make the option of non-heart-beating donation possible for patients and families.

Variations in the administration of medications are based on differences in clinical judgment among patient care physicians, transplant surgeons, and OPO staff. These judgments are based on clinical experience and on a limited number of empirical studies. More experience with non-heart-beating donation and further outcome studies are needed to provide a strong empirical basis for the use of medications. Pending such studies, a local variation in the use of medications is to be expected.

## Premortem Cannulation

### *Decisions*

In the process of non-heart-beating organ donation, some centers place large intravascular cannulae into the femoral vessels. These cannulae are placed before or after death. After death has been declared, they are used to drain blood and to replace it with cold preservation solution. In addition, cold preservation solution may be infused into the abdominal cavity through large catheters.

Preserving organs in this way allows the family to remain at the bedside for an hour or more after death. If this procedure is not done, organ recovery must begin immediately after death. Thus, decisions about cannulation affect family options for leave-taking.

### *Recommendation*

Although the insertion of cannulae does not harm the patient, it does not provide any benefit. It may cause discomfort that can be alleviated with analgesia, sedation or local anesthetic. Cannulation is an invasive procedure that may appear particularly so to a grieving family. Thus, the procedure should be explained to families and their consent obtained if cannulation is to take place prior to death.

### *Consensus and Variations*

There is strong consensus that all procedures and interventions should be explained to family members and that consent should be sought for invasive measures such as cannulation.

Among the workshop participants, all obtain family consent for premortem cannulation in controlled non-heart-beating donation; two postpone cannulation until after death.

As described at the beginning of the chapter, the rapid recovery program for uncontrolled donation at Washington Hospital Center is an exception. At this center, committee oversight and local legislation allow the placement of cannulae and the initiation of cold preservation following death and pending family contact.

There is evidence both of strong support for this option (Braun and Drobny, 1998) and of lingering individual and community concerns (Hunt, 1998). This variation requires considerable forethought and public scrutiny, as Washington Hospital's program illustrates.

## Declaring Death

*Decisions*

The physician who declares death cannot be associated with organ donation or transplantation. Decision points include the patient care physician who will declare death (attending, designee, anesthesiologist) and the time at which organ recovery may begin.

*Recommendation*

The 1997 IOM report recommends that an interval of five minutes elapse between the cessation of cardiopulmonary function and the declaration of death, and that the cessation of function be verified by electrocardiogram (EKG) and arterial pressure monitoring.

*Consensus and Variations*

Workshop participants agreed on the value of consistent criteria for declaring death. Most of their protocols specify a five minute interval between the cessation of cardiopulmonary function and the initiation of organ recovery. Rather than specifying criteria for declaring death, which they consider to be the responsibility of the declaring physician, three centers await the declaration of death and add in the five-minute interval if the declaring physician has not done so.

As discussed in Chapter 2 and in the section on protocol content above, full consensus on the five-minute time interval has not been established and depends on further study and dialogue.

## Organ Recovery

*Decisions*

Several decisions are made about organ handling: the length of warm ischemic time to allow; whether or not to perform in situ organ preservation or to "pump" the kidneys (i.e. to circulate cold preserving solution through the kid-

neys during storage and transport). United Network for Organ Sharing (UNOS) provides uniform standards on packaging and storage; other decisions are based on clinical judgment and empirical data (Hoffman et al., 1996).

*Recommendation*

Decisions about organ handling and preservation are the responsibility of the OPOs, with monitoring from UNOS. Tracking transplant outcomes according to methods of organ handling is a suggested research agenda.

*Consensus and Variations*

Most centers limit warm ischemia time to one hour; local practices for preservation and pumping may vary. More research is needed to establish the efficacy of organ preservation measures.

Ohio Valley Life Center allows three hours of warm ischemia time and does not find that this interval affects kidney transplants adversely (Appendix F). Variations among protocols presented at the workshop reflect the current state of knowledge on non-heart-beating organ viability.

## Family Options

*Decisions*

Decisions about where support is withdrawn and who may be in attendance affect family options for leave-taking and for being present at the time that death occurs. If cold perfusion cannulae are placed, the family may remain with the patient after death has occurred. If cannulae are not in place, organ recovery must take place immediately after death.

*Recommendation*

Non-heart-beating donation should affect family options as little as possible. Hospitals and OPOs should exercise maximum flexibility so that families may remain with the dying patient without forgoing the option of donation. Options should be explained clearly to family members when they are making the decision about non-heart-beating donation.

*Consensus and Variations*

All roundtable participants reported that they attempt to accommodate family wishes for leave-taking. Generally, cannulae are placed and cold perfusion is begun if support is withdrawn in the intensive care unit (ICU). One center withdraws support in the ICU and transfers the patient to the operating room (OR) immediately after death. The family may be present if support is withdrawn

without cannulae in place (in the ICU, OR, or preoperative holding area) but must leave the bedside immediately after death so that organ recovery can proceed.

This is an area in which local variation can be expected among hospitals and practitioners. Cooperation between the patient care and organ procurement teams can provide maximum flexibility for accommodating family wishes.

## Financial Arrangements

*Decision*

Arrangements for covering the costs of non-heart-beating organ must be arranged between the OPOs and hospitals, including what costs will be covered and when costs will be shifted from the hospital and the patient to the OPO.

*Recommendation*

The family should not bear any donation-related costs. Further study and guidelines are needed to identify and cover the costs associated with non-heart-beating donation. Full disclosure to the family should include the information that every effort will be made to identify and pay for donation related costs. The family should be provided with the means to contact the OPO with any billing questions.

*Consensus and Variations*

Each workshop participant has mechanisms for identifying and covering donation-related costs. These mechanisms rely primarily on case-by-case assessment and review. Each participant saw a need for establishing consistent guidelines for these costs.

Limited experience with non-heart-beating donation leads to variation as to when and how OPOs assume donation costs. The cost of ICU time and the cost of OR time until death is declared are gray areas. Some variation is to be expected pending common guidelines for covering non-heart-beating donation costs.

## Conclusion

This summary of decision points highlights the complexity involved in developing non-heart-beating donation practice and protocols, even when there is substantial agreement on underlying scientific and ethical standards. Table 4-2. serves as a decision pathway to guide protocol development. Hospitals and OPOs working on protocol development will find a range of options to consider at each point.

The recommendations from the 1997 IOM report, and the consensus and variations from the 1999 workshop are summarized in this chapter, and provide a range of options. Not every protocol will match every other protocol on every point. However, differences among protocols highlight points at which the grounds for variation should be thoroughly examined and explained.

The decision pathway involves both the patient care team and the donation team. Each team has separate but intersecting responsibilities regarding medications, procedures, arrangements for the family, withdrawing support and declaring death, and financial arrangements. Each decision point involves cooperation between the OPO and the hospital, to specify roles and responsibilities.

Workshop participants identified the central role of the OPO in facilitating the development of non-heart-beating organ donation activity. However, participants recognized that OPOs may find that they have few financial incentives and limited local support for developing this option. Hospital and physician support, adequate funding, and family requests encourage OPO efforts in this area.

Finally, the pathway suggests areas where full consensus has not been achieved at this time; where greater empirical certainty may alter protocol provisions; and where discussion, dialogue, and comparison have to continue.

Ongoing dialogue and consensus building can contribute to the further development and implementation of non-heart-beating donor protocols. These processes are discussed in the next chapter.

5

# Protocol Development and Implementation

**Recommendation 6: Adequate resources must be provided to sustain non-heart-beating organ and tissue donation. Adequate resources are required to cover (1) the costs of outreach, education and support for Organ Procurement Organizations OPOs, providers and the public, and (2) any increased costs associated with non-heart-beating organ and tissue recovery.** Adequate funding for education and outreach is needed to develop professional and public understanding of non-heart-beating donation and to prepare patient care providers and organ donation personnel to participate in non-heart-beating donation. Adequate data and reimbursement mechanisms are needed to cover the costs of patient care and organ recovery.

This recommendation is based on the findings from two roundtable discussions at the workshop. In the roundtable discussion on protocol development, six active non-heart-beating donation programs described the development of their protocols. In the roundtable discussion on implementation, six patient care and donation experts identified issues that need to be addressed in the implementation of non-heart-beating donor protocols. The suggestions in this chapter are based on the participants' professional experience and familiarity with the available data.

Roundtable participants identified several components of successful non-heart-beating protocol development and implementation:

- the participation of all concerned parties (medical specialists, nurses, families, and community representatives);

- drafting and revising protocols, and obtaining approval from various committees, boards, and professional and community groups;
- initial and ongoing education, training, and support for practitioners;
- community and media outreach and education; and
- ongoing oversight and review, and ongoing protocol revision.

Each of these steps places demands on hospital and OPO resources, requiring specific attention to how these resources will be made available.

## CONSTITUENTS

### Development

> Take as much time as you need. Put all the adversaries on the committee and they will talk to you in the same room. (J. Light)

> I didn't anticipate that I would have trouble on the surgical side. There is a transplant center in my region that doesn't have a dedicated transplant surgeon (i.e. someone whose practice is dedicated to transplant only); a vascular surgeon does the surgery in that locale. At three in the morning it's not going to be easy to get a person to come out, stand there either in the operating room or in the intensive care unit, and await yes or no that the patient is indeed declared dead. (F. Delmonico)

> Our biggest surprise was anesthesia. We really didn't expect the anesthesiologists to give us such a hard time as far as volunteering services to come in and pronounce death. (D. Cornell)

The patient who becomes a non-heart-beating donor comes under the care of physicians, nurses, and other hospital staff in the emergency room (ER), intensive care unit (ICU), and operating room (OR). Staff concerns about non-heart-beating donation arise when the process is not understood fully, or when the staff is not prepared fully for the new responsibilities involved. They arise also when staff members have unresolved ethical, legal or patient care concerns about the non-heart-beating donation process.

In many cases, practitioner concerns can be addressed through early participation in the protocol development process and through education that explains the process of non-heart-beating donation and identifies practitioner responsibilities. They can be addressed also through ongoing education and follow-up during each non-heart-beating donor case.

The challenge is identifying and involving all concerned parties. All of the programs encountered unanticipated resistance, each from different practitioners. Direct communication and education help to clear up misunderstandings and to resolve concerns and issues. Involving all of the concerned parties from start to finish can avert misunderstandings at the beginning of the process.

### Implementation

> Nurses in the appropriate roles and with the appropriate expertise must have a defined role in the development and establishment of these protocols. Registered nurses will provide an essential perspective and must be full participants in ethics committees and forums regarding non-heart-beating donation along with physicians, transplant coordinators, and other health care professionals, as well as the public. (P. Weiskittel)

> We really do support some kind of national standardized criteria for which patients fall in the box and which ones don't. We need recommendations that all OPOs and transplant centers participate in non-heart-beating donation. We would like to see the entire transplant community involved in this process even if the organs will not be used locally. (M. Reiner)

From the perspective of OPO and patient care practitioners, clear and consistent protocols provide a source of guidance for practice. Being involved in developing the protocols that they will be responsible for implementing helps practitioners to make the critical connection between protocol content and its applications in practice.

These comments point to the need for patient care and transplant professionals to be involved in non-heart-beating protocol development at both the national and the local level. At the local level, transplant coordinators and health care practitioners have the ultimate responsibility for implementing the protocols. Successful protocol development will draw on their familiarity with their practice settings and with particular needs and concerns of their communities. At the national level, professional organizations are a valuable resource for developing guidelines that meet professional practice standards and promote local consistency.

## PROTOCOL APPROVAL

### Development

> Our arduous approval process involved approval first by the ethics committee and then by the policy review committee, the hospital lawyers. Then it went to the medical executive committee, and then we brought it to a quarterly staff meeting; so not only did we get the medical leadership, we also took it to the medical staff for their approval. Then it went to a joint conference committee—that is, medical, administrative and board member leaders—and then finally we took it to the board. (M. DeVita)

The approval process is complex, multileveled, and prolonged. The time each program spent from initiating the idea of non-heart-beating donation to full approval varied from eight months to three years. This process requires the commitment of considerable paid staff and volunteer professional time. An OPO

or hospital that wishes to develop a protocol must be able to commit the staff time required to see it through this process.

### Implementation

> Looking at organizational considerations, I would propose that it would be good to cultivate advocates within institutions, as I sometimes think of myself. We can help. (J. Sullivan)

Although the participation and support of frontline practitioners is essential, there is a role for institutional advocates in moving new practices and protocols along. Protocol development and implementation require effective leadership. The involvement of OPO and hospital leaders and authorities can contribute significantly to the process. Administrators, board members and medical, surgical, and nursing directors can provide the leadership and support needed to facilitate protocol development and approval.

## EDUCATION, TRAINING AND SUPPORT

### Development

> The protocol needs the partnership of hospitals, health care professionals, and OPOs. It is not enough to go out and say, "Now we have a protocol." Now you have to go out and educate, educate, educate within the health care system and you cannot overlook any one group. I can tell you we overlooked one group, of operating room nurses. It didn't cause major problems but it is something that we had to go back and deal with, so I think you need to cast a broad net in your educational efforts. (D. Lewis)

> Not only were we educating the hospital community, but we were educating our [OPO] staff, as well as the transplant surgeons. It was important to us that if these surgeons were coming out to the hospital they understand the impact that it would have on operating room personnel. We also utilized their assistance in family meetings or operating room meetings, talking with the nursing staff and anesthesia personnel who were going to be involved. (J. Edwards)

Outreach, education, training and support must involve medical, OPO, and hospital practitioners, as well as a variety of educational strategies: nursing in-service, grand rounds, presentation at professional meetings. Education starts with the initial discussions of non-heart-beating donation, and continues through the entire process of development and implementation.

OPO staff must be prepared to address questions and concerns that arise when hospital personnel are unfamiliar with or have reservations about the non-heart-beating donation process. The large number of staff involved and the limited number of non-heart-beating donators provide little opportunity for direct

experience with non-heart-beating donation. Non-heart-beating donation may be unfamiliar in spite of substantial educational efforts.

Workshop participants noted that staff participation in non-heart-beating donation requires staff support as well as education and training. Non-heart-beating donation is a new and unfamiliar process for most hospitals. A meeting with the staff immediately following the process was recommended as an opportunity for staff to discuss questions and concerns that may arise during the process. In addition, staff may find ethics consultation a valuable resource when non-heart-beating donation is being considered. One OPO sends two donation coordinators on every non-heart-beating case: one to handle the donation and one to educate and support the staff and family.

Both formal and informal education and support efforts are time consuming and costly. The ability of a hospital or OPO to pursue non-heart-beating donation depends to a great extent on the personnel and funds available for education, training and support.

### Implementation

> Without adequate preparation and education of hospital staff, negative consequences for donation could develop. Appropriate resource material and personnel need to be available to nurses during the donation process. It is also an excellent opportunity for nurses to be involved in writing the resource materials and to facilitate when needed as experts in the process. (P. Wieskittel)

> Health care personnel have a difficult time understanding policies and protocols that surround organ donation in general, whether it is non-heart-beating or not. About 35% of the nurses in our area have two years of training or less, and the vast majority have been in their position for only one to five years.

> One rural provider said, "Sure, you just want to educate us until we come around to your point of view." (A. Cook)

Educational efforts must be tailored to the groups that they are intended to serve. The ethical and practical concerns and the information needed will vary somewhat among different nursing specialties and other groups. Each group should be involved in developing appropriate educational resources and programs. It is especially important to be sensitive to the diverse social, economic, and ethnic backgrounds of practitioners. These factors can affect practitioner perceptions and reactions, just as they affect the perceptions and reactions of the patients and their families. A mechanism for addressing this kind of diversity is to involve practitioners from diverse backgrounds in protocol development and implementation.

## PUBLIC OUTREACH

### Development

> I think the biggest surprise to me has been the level of buy-in from the public, the acceptance it has had, the level of it being okay in that we are doing the right thing and that if families want that option, they should have it. (D. Lewis)

> Somebody called up a local reporter and said we were doing funny things. They came in and we gave them the policy, showed them all the documentation, explained exactly what was happening, and it was funny, the cameras went down and the reporter said, "What is the big deal?" The TV report was, "No, they are not killing people and this is a good thing and you should be a donor." (M. DeVita)

Workshop participants agreed that public and media awareness of non-heart-beating donation contributes to its acceptance. Lack of openness and lack of information can lead to misrepresentations and misunderstandings. Several of the participants advocate active media outreach to keep organ and tissue donation in the public eye.

Public involvement in hospital ethics committees, OPO boards, and community oversight committees contributes also to public awareness and support for donation.

Most importantly, donor and nondonor families are the final judges of the donation system. Their experiences, and their reactions to the non-heart-beating donation process constitute the strongest measure of public acceptance.

### Implementation

> We have started talking with our rural health care providers about organ donation. First, it is very clear that prior to the most recent Health Care Financing Administration (HCFA) regulations, they had very limited involvement with this issue, but the required request and referral is changing that. There are very, very few formal mechanisms to mitigate any problems that develop. In our area of the country, most of our states have out-of-state OPOs so that there is a very limited presence.

> In some of our counties, 25 or 30 percent of the people are uninsured. With the uninsured or underinsured, there is sometimes a sense that they need to repay society for the health care that they can't afford and there is an expectation of the hospitals that they will donate. In a rural hospital with very narrow cost margins, it is obviously a considerable value if the final day of care is paid for and that has been somewhat problematic for some of our health care providers; they fear the risk of coercion. We have talked about the need for things like public forums to talk this issue out. As long as it is seen as a gift for the insured and the wealthy, there is going to be skepticism. (A. Cook)

Like educational efforts, community and media outreach must be tailored to the local situation. Interests and perceptions vary according to local conditions and prior experience (positive or negative) with the health care system or with organ and tissue donation. Active non-heart-beating donation programs point to family request as a primary reason for protocol development. Rather different strategies may be needed if no family or community interest in this approach to donation has been identified.

## OVERSIGHT AND REVIEW

### Development

> We invested about three years in a community oversight committee following a consensus conference, which guided the efforts and facilitated the discussion. Part and parcel of all of this effort was establishing a system of family advocates. (J. Light)

Mechanisms for ongoing oversight include community groups, ethics committees, professional bodies and public agencies. Assurance that such review is being conducted, and access to the findings, are important contributions to public and professional confidence in non-heart-beating donation.

Workshop participants suggested the need for an ongoing audit process for non-heart-beating donation, similar to the hospital quality assurance process. Developing such an audit process was beyond the scope of the current study but is suggested as an undertaking for professional groups.

### Implementation

> One of the hospitals I work with is planning a community forum. It is an experiment to see if we can bring the issue up and talk about it in a community forum, and maybe do a newspaper insert before, and try to look at it in a planned, controlled way. (A. Cook)

> The questions I have are outcome more than anything else. We are trying to be advocates for the donor family, for the recipients, the services that we offer. What are the positive outcomes that can occur for both these groups? (L. Jacobbi)

These comments suggest the need for two kinds of outcome review: (1) overview of the donation process and its adherence to recommendations and protocols, and (2) empirical review of the transplant outcomes, organ recovery costs, and discard rates associated with non-heart-beating donation. A formal review process can provide both kinds of review, as well as contribute to a growing body of outcome data available to other programs.

Workshop participants raised particular concerns about the outcome of non-heart-beating organ transplantation. The 1997 IOM report cited a number of

outcome studies that found comparable transplant outcomes for heart-beating and non-heart-beating donor organs (Alvarez-Rodrguez et al., 1995; Hoshinga et al., 1995; Nicholson et al., 1997) with the exception delayed kidney function following transplantation (Wijnen et al., 1995). Several subsequent studies confirm these findings (Alonso et al., 1997; Kievit et al., 1997; Valdes et al., 1997; Pokorny et al., 1997; Yong et al., 1998). However, small numbers and multiple confounding variables limit the conclusions that can be drawn from these studies, and lead some experts to conclude that further study is needed to establish how organ quality and organ handling affect outcomes for non-heart-beating transplantation (Butterworth et al., 1997; IOM, 1999, 78–87.)

## RESOURCES

### Development

> Problems we did not anticipate were the amount of resources it took. We are committed to providing additional staff, as well as getting back into the institution immediately because it is on the second and third day after the case has been completed that we are getting whispers down the line, and some of the negative impressions that people have. (J. Edwards)

Practice innovation, with its requisite training, education, and review, requires an adequate resource base. The successful development and implementation of non-heart-beating donation protocols requires the commitment of financial and staff resources to support the process.

At present, these resources are made available when an individual hospital or OPO places a high priority on non-heart-beating donation and commits the resources needed to bring it about. In order for non-heart-beating donation to be adopted more widely, sources of funding for program development must be identified, and any reimbursement barriers must be eliminated.

### Implementation

> If you don't have a local transplant center that is willing to use these organs, you probably are going to have a higher discard rate which means that the OPO will take on a larger financial burden and perhaps some accommodation can be made for this. (M. Reiner)

> Our agency is based on maximizing our donors. Everyone says don't worry about cost but we are stewards of a very dear resource. We have to think about the health care dollar. What is the discard rate that we are looking at? Where can we develop means of evaluating these organs so that we can assure that outcomes are the same from both populations of donors? (L. Jacobbi)

The actual costs of non-heart-beating donation are difficult to assess. Patient care costs must be factored in and compared to the costs of maintaining donors after death by neurological criteria. The costs of the education, outreach, and staff time required for the more complex donation process must be assessed. In addition, the costs of higher rates of organ discard and delayed organ function following transplantation must be factored in (Elwell et al., 1997). Cost considerations are a potential impediment to participation in non-heart-beating organ recovery. A sound empirical study of the costs of non-heart-beating organ recovery is urgently needed.

## Conclusion

The findings from this study and the workshop highlight the need for further research on many aspects of non-heart-beating organ and tissue donation. Chapter 6 discusses a research agenda and presents a paper commissioned by the committee. It identifies research priorities and suggests methodological approaches for research that addresses these priorities.

6

# A Research Agenda for Non-Heart-Beating Organ and Tissue Donation

**Recommendation 7: Data collection and research should be undertaken to evaluate the impact of non-heart-beating donation on families, care providers, and the public.** Further information on the burdens and benefits of this approach to donation needs to be gathered and assessed in a systematic, coordinated way. Further data are needed on (1) patient, family, provider, and public attitudes and concerns, (2) the costs of non-heart-beating donation, and (3) the outcomes from non-heart-beating transplantation. An ongoing, centralized data base of published studies would assist greatly in monitoring developments in non-heart-beating transplantation practices, costs and outcomes.

During the course of this study, it became apparent that many empirical questions about non-heart-beating organ donation and transplantation remain open. The committee identified several concerns that should be addressed through further data collection and research, and the systematic coordination and communication of findings.

## RESEARCH PRIORITIES

The questions that arose during the workshop and committee deliberations clustered around two main areas of concern: first, the impact of non-heart-beating organ donation on the patients who become donors and on their families; second, the impact of non-heart-beating organ transplantation on transplant outcomes. The committee and the workshop participants identified the following areas in which additional information is needed to guide further development in non-heart-beating organ donation and transplantation practice.

### Questions About Donation

1. What further data are necessary in order to develop consensus on the declaration of death following the withdrawal of life-sustaining treatment and the cessation of cardiopulmonary function?

2. How can these data be collected in ways that are scientifically reliable but noninvasive and sensitive to donor patients and their families?

3. How do families respond to non-heart-beating donation? Anecdotal evidence supports the conclusion that some patients and families pursue this option eagerly and are profoundly disappointed if it cannot take place. However, there are no studies that compare the experiences of non-heart-beating donor families with those who choose not to donate in this way or with those who donate following death by neurological criteria.

4. What impact do the withdrawal of life-sustaining treatment and rapid organ recovery have on family leave-taking and on subsequent coping with grief and loss?

### Questions About Transplantation

1. What impact will non-heart-beating organ donation have on the shortage of organs for transplantation? Suggestions that organs from non-heart-beating donors can increase the supply of organs by as much as 20% (D'Alessandro et al., 1995; Koogler and Costarino, 1998; Lewis and Valerius, 1999) are balanced by suggestions that non-heart-beating donation may compromise public trust and thus reduce overall donation rates (anecdotal). With a total of approximately 150 non-heart-beating donors comprising less than 1% of donors in the past two years, the actual impact on organ donation cannot yet be assessed.

2. How much more costly is the recovery of organs and tissues from non-heart-beating donors than the recovery of organs and tissues following death by neurological criteria (Jacobbi et al., 1997; Butterworth et al., 1997)? Why are the costs higher, and what might be done to offset these higher costs?

3. Are the data on the outcomes of transplantation with organs from non-heart-beating donors adequate to persuade Organ Procurement Organizations (OPOs) and transplant surgeons of the value of non-heart-beating donor organs? In spite of published reports of favorable outcomes following non-heart-beating organ transplantation (Yong et al., 1998), workshop participants reported continuing reluctance to use these organs due to concerns about quality and long-term transplantation outcomes. This reluctance stems from the limitations in the published data: small numbers and many confounding variables.

4. How do different ways of handling recovered organs affect organ viability and transplant outcomes? Surgeons and OPOs employ a number of methods to promote organ viability and good transplant outcomes. These methods include in situ cold preservation, the use of anticoagulants and vasodilators, and "pumping" kidneys following removal. As suggested during the workshop, these

interventions rely on clinical judgment and experience and on limited outcome studies. Experience with non-heart-beating organ transplantation is not yet extensive enough to allow for controlled trials of different organ-handling techniques and their impact on organ viability.

The committee identified two limitations to the data currently available on non-heart-beating organ transplantation. First, the studies involve small numbers of cases over limited periods of time. Second, the data have not been gathered into one easily accessible data base. Individual institutions or practitioners may not find the studies convincing enough, or readily accessible enough, to justify major innovations in practice.

The sponsor and the committee identified the need for a comprehensive strategy for evaluating the impact of non-heart-beating organ donation protocols. Designing such a strategy involves identifying the outcomes to be assessed, the variables to be measured in order to assess these outcomes, and the data to be collected in order to measure these variables. The committee commissioned an expert paper to propose a strategy for evaluating the outcomes of non-heart-beating organ transplantation practices and protocols. This paper is included in full in the following section as a resource for practitioners, institutions, government agencies, and other interested parties to use in designing future research on non-heart-beating organ transplantation.

## MAXIMIZING BENEFITS, MINIMIZING HARMS: A NATIONAL RESEARCH AGENDA TO ASSESS THE IMPACT OF NON-HEART-BEATING ORGAN DONATION

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### Introduction and Overview

This paper has been commissioned by the Institute of Medicine (IOM) Committee on Non-Heart-Beating Organ Transplantation to propose a method for evaluating the dissemination and effectiveness of the recommendations from the two IOM reports on this subject. As with any evaluation effort, the first step is to determine appropriate purposes for the inquiry. One primary purpose and two related, secondary purposes are as follows:

1. The primary purpose of such an evaluation is to assess the potential benefits and potential harms of non-heart-beating organ donation to four key stakeholder groups: *patients* (i.e., prospective non-heart-beating donors and recipients), donor *families*, the *health care system*, and *society* or more precisely to underlying normative values that American society and American medicine have traditionally identified as important.

2. A second, related purpose is to compare the ways in which locally developed non-heart-beating donor protocols are being implemented in practice, with respect to both the OPOs' and hospitals' stated ideals, as expressed in their local protocols, and to the recommendations contained in both this report and the 1997 IOM report (IOM, 1997b).

3. A third purpose is to identify barriers to the development of non-heart-beating donation protocols and to design and test interventions to enhance non-heart-beating donation in ways that minimize potential harms, while maximizing potential benefits, to donor families and to organ recipients.

These three purposes are fundamental to the arguments and recommendations made in this paper and define the scope of the evaluation suggestions that are presented.

To accomplish these purposes, this paper seeks to answer the following questions:

1. What are the potential harms and benefits of non-heart-beating organ donation to patients, families, the health care system, and society at large that can and ought to be monitored?

2. What is a feasible and effective research agenda for assessing the impact of non-heart-beating organ donation on these four key stakeholder groups? In other words, what key research questions ought to guide inquiry, and what kinds of empirical evidence would it be appropriate to collect in order to monitor the implementation and impact of local non-heart-beating donation policies?

3. Within each of the research priority areas identified, what are some recommended data collection strategies and related methodological considerations?

To answer the first question, a conceptual framework is presented in Table 6-1. This framework lays out an a priori set of potential harms and benefits. This framework is used to guide the development of a research agenda. Key research questions, data collection strategies, and special methodological considerations are described for each of three recommended research priorities:

1. *research on family perspectives* aimed at understanding the consequences for, and experiential realities of, families who have consented to non-heart-beating donation;

2. development of *a "profile" of institutional behaviors* to ascertain the extent to which local policies and IOM recommendations are being implemented in practice in health care settings; and

3. development and testing of *interventions* capable of enhancing non-heart-beating donation policies, so that potential family benefits may be maximized.

The final two sections of this paper describe the limitations of such a plan as well as the expected benefits.

## Potential Harms and Benefits and Their Implications for Evaluation Research

Table 6-1 presents a detailed list of *possible* harms and benefits of non-heart-beating donation for each of the four key stakeholder groups: (1) patients who may be prospective donors, (2) families, (3) the health care system, and (4) society. The list was derived deductively by reviewing harms and safeguards described in the 1997 IOM report (IOM, 1997b) and other published literature (e.g., Arnold, et al., 1995; Koogler and Costarino, 1998) and from the author's professional experience working to improve end-of-life care in U.S. hospitals (Solomon, 1995; Solomon et al., 1991). The list therefore represents an a priori set of possible harms and benefits that can and should be modified on the basis of empirical evidence. If the research proposed later in this chapter is conducted at OPOs and hospitals, it will create an opportunity to confirm or disconfirm these issues and to discover other themes that have not yet been raised.

Table 6-1 is organized by stakeholder group. The middle column, "Possible Mechanisms" suggests the ways in which potential harms might come about. Since the potential benefits are more straightforward, it is not necessary to list possible mechanisms for them.

In addition to looking in detail at stakeholder groups, it is helpful to identify major themes. The following sections describe five themes that evaluation efforts should seek to address.

### *Greater Patient and Family Choice, Enhanced Psychosocial Outcomes for Families, More Organs*

Protocols that allow non-heart-beating donation serve several purposes. Non-heart-beating donation is intended to uphold patient autonomy (in cases where patients have clearly indicated a wish to become organ donors and communicated this intention prior to losing their decision-making capacity) and to honor family requests to donate. Evaluation research should determine the extent to which patients and families initiate such requests on their own. In addition, after families have decided to withdraw treatment and allow their loved one to die, trained OPO requesters may approach the family to discuss non-heart-beating donation. Thus, data can and should be collected on the number of cases, by hospital and OPO, in which a trained requester has initiated a donation request to a family after the decision to terminate treatment was made and on the number of families consenting to such staff-initiated donation requests.

There may be positive psychosocial consequences for families that will be important to document. In traditional donation, where death was established by neurological criteria, families have reported that donation helped give meaning to their tragic, senseless loss (Bartucci, 1987; Coolican, 1994; Riley, 1999). It is

**TABLE 6-1** Potential Harms and Benefits to Key Stakeholder Groups

| | Potential Harms | Possible Mechanisms | Potential Benefits |
|---|---|---|---|
| Patients | Patients could be prematurely "objectified"( i.e., perceived as donors rather than as persons)<br>Death could be hastened | Interest in donation could unconsciously lead to premature determinations of futility<br>• Allowing questions about donation to arise before decision about withdrawal<br>• In case of uncontrolled donors, resuscitation efforts might stop prematurely<br>• Use of anticoagulants and vasodilators in certain patients | |
| | Having an invasive procedure done while still able to perceive it | Cannulation without analgesia in certain patients | |
| | Inadequate pain management and/or sedation | Clinician worries about medication might cause physiological abnormalities that compromise organ quality | |
| | Wishes to donate could be ignored | Protocols that do not allow non-heart-beating donations or discourage such donations | Patients' satisfaction that their wishes, if expressed, would be honored |
| | Patients could be "abandoned" by their caregiving team | Staff discomfort with death, dying, and/or organ donation | |

| | | | |
|---|---|---|---|
| Families | Frustration and anger if wishes to donate are not honored | Protocols that do not allow non-heart-beating donations or that discourage such donations | Satisfaction that wishes have been honored |
| | Guilt that they have overridden loved one's explicit advance directives, indicating the patient had a desire to donate | | Comfort in the knowledge that a loved one's gift has extended life for someone else |
| | Guilt if they feel that they have agreed to organ donation but are not sure it was the right thing to do or what the loved one would have wanted | • Psychological issues for individual family members within the family unit<br>• Inappropriate coercion on part of requesters | |
| | Guilt or depression if they feel they have hastened death in order to donate | | |
| | Misunderstanding or confusion about the differences between withdrawing treatment, assisting suicide, and euthanasia | | |
| | Inadequate opportunities to say farewell, disruption, sense of abandonment, or lack of closure | Need to remove deceased to operating room for organ retrieval | |
| | Possible negative impact on bereavement | | Possible positive impact on bereavement |
| | Financial burdens | If procedures that would have been forgone are instituted to maintain organ quality | |

*Continued*

**TABLE 6-1** *Continued*

| | Potential Harms | Possible Mechanisms | Potential Benefits |
|---|---|---|---|
| Families | Distrust of the health care system and of health care professionals | • If requests for organ donation are made at the same time as decisions to forgo treatment<br>• Failure to disclose all relevant information (i.e., that death is near)<br>• Failure to seek permission for premortem cannulation or other procedures | Sense of support and satisfaction with health care institution and health care professionals |
| Health Care System | Greater distrust between the public and the health care system | If requests for organ donation are made at the same time as decisions to forgo treatment | More trust |
| | Public backlash, resulting in fewer donations | | Greater pool of donors and more donations |
| | Costs might exceed benefits | • If non-heart-beating donor organs prove less viable<br>• If cost of maintaining life support is high<br>• If distrust leads to fewer donors | Positive cost–benefit analysis |
| Society | Slippery slope from request and consent to persuasion to coercion | | • Greater support of patient and family wishes to donate; enhanced autonomy<br>• Greater altruism |
| | Intentional or unintentional objectification of patients as potential donors rather than persons | | Greater respect for diversity of views about organ donation, including support for informed dissent |

reasonable to infer that families of non-heart-beating donors would also find psychological and spiritual comfort in their decision to donate. Evaluation research should seek to determine the impact of consent to non-heart-beating donation on the psychological well-being of the family.

Non-heart-beating donation protocols are a hoped-for means of increasing the national supply of organs from a large, untapped source of potential donors. Thus, evaluation research should focus on determining the extent to which non-heart-beating donation does, in fact, increase the supply of organs, and what the viability of these retrieved organs is, including the effect of their transplantation on the survivability of recipients.

### *Better End-of-Life Care*

There are also possible collateral benefits to the health care system of allowing non-heart-beating donation. To be effective, such protocols will have to involve training health care professionals in the communication skills necessary for conveying a grave prognosis and for supporting patients and families through the final phase of life. It will also be essential to enhance clinicians' understanding of what is, and is not, ethically and legally permissible regarding the use or withdrawal of life-sustaining medical interventions (Solomon, 1993). Otherwise, families will not be able to arrive at well-informed decisions about the use of life supports and may become confused or distrustful. If OPOs and hospitals take these educational challenges seriously, they should intensify their educational efforts to improve staff skills in communication and ethical analysis. Thus, a possible collateral benefit of non-heart-beating donation might be an increased capacity on the part of health care providers to support well-informed family decision making near the end of life. Evaluation tools could be developed to ascertain improvements in the clinical staff's comfort in discussing a grave prognosis with families, staff understanding of key ethical concepts necessary to help families make decisions about forgoing life support, and staff comfort discussing death, dying, and organ donation.

Finally, there may also be broad, societal benefits, such as the cultivation of greater altruism among the public and greater societal openness toward dying, death, and organ donation. For example, making non-heart-beating donation permissible and available might help patients, families, and health care professionals to see organ donation as one final decision on a *single continuum* of end-of-life care choices that all families should discuss and anticipate together.

### *Impact on the Public's Trust*

A major potential burden of moving to non-heart-beating donation is a possible erosion in public trust in the organ procurement system (Burdick, 1995). Distrust might arise if families or patients began to sense that less than every-

thing was done to ensure the patient's recovery. This concern pertains to all types of organ donation; therefore, there has been a longstanding commitment to maintaining separation between the clinical team that cares for the patient and the clinical team that manages organ procurement.

Ideally, this division of clinical teams maintains the separation between patient interests and organ procurement interests. In practice, however, this distinction is less clear, and there are ways in which conflicts of interest may emerge. For example, clinicians caring for patients are the ones who alert organ procurement organizations that their patients may be approaching brain death and may therefore be appropriate as potential donors. Secondly, there may be strong incentives in health care institutions specializing in transplantation that could privilege organ procurement interests over patient interests. Moreover, the general social context, both within health care institutions and among the general public, is highly supportive of organ donation and transplantation, which may exert conscious or unconscious pressures on patients and their families.

However, non-heart-beating donation complicates this picture even further. Determinations of "futility" and "hopelessness" are vaguer than the relatively "purer" and more clinically straightforward determination of "brain death" (Shaw, 1995). Therefore, all non-heart-beating donation policies insist that the decision to withdraw treatment must be made independently of and prior to the decision to donate. Health care professionals should not *initiate* discussion of the topic, until after patients or family members have decided to terminate treatment.[1] Of course, families may raise the question of organ donation at any time while in the midst of grappling with their loved one's grave condition, and if they do, health care professionals will have to respond—hopefully by validating family concerns and interests, yet helping them to see the importance of focusing first on deciding whether to continue or withdraw further life-sustaining treatments, based on their loved one's wishes and best interests.[2]

Thus, a key mandate of any evaluation effort must be to collect data on the extent to which the line was maintained between the decision to withdraw treatment and the decision to donate organs. However, as Shaw (1995, p. 103) points out, "The first time the issue of conflict of interest arises is not in contemplating the withdrawal of care, but in judging that the prospective donor's condition is 'hopeless.' " This issue is particularly problematic if physicians and nurses caring for a gravely ill patient know of a prospective recipient who is in dire need

[1]New York and Missouri have imposed a higher evidentiary standard than "best interests," requiring families to provide "clear and convincing evidence" of what their loved one would have wanted, before termination of life support is allowed

[2]Some protocols, such as the Pittsburgh Protocol, specifically prohibit health care professionals from ever initiating the topic—according to the Pittsburgh Protocol, non-heart-beating-donor is only permissible if families have raised the issue (see Arnold et al., 1995).

and could directly benefit from the apparently dying person's organs, or in hospitals where a large amount of transplant surgery takes place and there may be cultural and financial incentives that support strong prodonation attitudes among the staff. Thus, in addition to determining whether separation existed between the decision to withdraw treatment and the decision to donate organs, evaluation efforts should seek to confirm that the prognosis of hopelessness was in fact accurate, that the best possible care was given to such patients, and that the prospect of organ donation did not influence treatment decisions. These constructs are difficult to measure, but they are central to establishing public trust.

### *Impact on the Quality of the Dying Experience for Patients and Families*

In the case of organ procurement following death determined by neurological criteria, the declaration of brain death creates a sharp line between patient treatment and organ procurement. Patient treatment is pursued until a neurological determination of death has been made. Management of the donor then shifts to organ procurement, but any alterations in management do not adversely affect the patient because death has already occurred. Moreover, since such donors are being maintained by artificial means, the family has ample opportunity for leave-taking at their own pace in the intensive care unit before the donor is removed to the operating room, where artificial support will continue throughout the organ procurement process.

Quite the opposite case occurs in non-heart-beating donation. In organ donation following death established by cardiopulmonary criteria, medications and procedures necessary for maintaining organ quality may be administered before death without benefit to the patient. Also, in some circumstances, there might be an inclination to limit medications (morphine or sedatives) that could ease the dying process for fear these medications might create "physiological abnormalities that could jeopardize the functional quality of potential donor organs (Shaw, 1995, p. 106)." Furthermore, the time between withdrawal of life support and organ procurement must be minimized to avoid organ damage, with donors often going immediately to the operating room where life support can be discontinued and organ procurement initiated immediately. These alterations in patient management raise concerns about eroding the quality of the dying experience and, in particular, about diminishing the family's opportunity for farewells (Fox, 1995, IOM 1997b). Some commentators (Frader N., 1995; Koogler and Costarino, 1998) have also pointed out that removal of the patient to the operating room for termination of life support may be especially disturbing in pediatric cases, since families often request—and pediatric intensivists and critical care nurses usually offer—an opportunity for parents to hold their children as life support is withdrawn. In the case of non-heart-beating donation, families may have to choose between organ donation and holding their dying child.

In sum, then, there is an underlying irony. Non-heart-beating donors are, by definition, individuals who have chosen, or whose families have chosen, to forgo life-sustaining treatments, often because they want a lower-"tech" death and more opportunities for what the public and lay media have called "a good death." Yet, in non-heart-beating donating, the family's altruism may result in a more technologically invasive death than the family understands.

Several obligations follow from this fact. First, there are obligations to disclose how the patient's care will change as a result of the decision to donate. Many families will still make the choice to donate, but there is an ethical imperative to disclose the trade-off. Secondly, hospitals and OPOs should recognize this irony and strive to create the most family-supportive environment possible during the final hours and moments of their loved one's life. Special arrangements should be developed to enhance family privacy and leave-taking. Evaluation studies should document these innovations and study their impact on family satisfaction with the dying experience.

*Consequences for Families After the Death of Their Loved One*

Making the decision to withdraw life-sustaining treatments is undoubtedly a difficult one for families, yet there is virtually no research on how families cope with this responsibility. From anecdotal experience and personal testimonials, however, it seems that many patients are confused about the differences between withdrawing treatments and assisting suicide, and some families may feel guilt or remorse about not having done all that could be done. These feelings might be compounded if families worried retrospectively that they had been unduly influenced to terminate life support by pressures (either internally or externally imposed) to donate their loved one's organs. It is therefore important to develop ways to measure guilt, remorse, depression, and grief reactions among family members several months, or even years, after the death of their loved one.

Another key issue to explore, both with families directly and through review of hospital billing procedures, is the extent to which decisions to donate their loved one's organs may result in additional financial burdens for families. Grossman et al. (1996, p. 1831) found that the average terminal hospital stay for a donor who had been declared dead by neurological criteria was $33,997—of this amount, $17,385 was for care that one would consider "futile" for the patient but "necessary for improved organ procurement rates." Although these estimates were based on donors who had died by neurological criteria, there will surely also be costs for families opting for non-heart-beating-donation. OPOs may pay the costs associated with organ procurement, but they usually only begin to pay for costs incurred after the determination of death has been made by neurological criteria (Grossman et al., 1996). The situation may be exacerbated in the non-heart-beating donation scenario, where it may be even more difficult to determine when the family's responsibilities for costs should end and the OPO's begin. Empirical re-

search is essential to ensure that the altruistic decision to donate does not mean that families are paying a higher overall hospital bill than would otherwise have been the case if life supports were simply withdrawn or never instituted.

In the next section, a national research agenda is proposed that is capable of monitoring the extent to which these potential harms are being minimized, and the potential benefits maximized, in hospitals and OPOs employing non-heart-beating donation protocols.

### A Research Agenda in Three Parts

Box 6-1 presents eight research questions that ought to drive the evaluation research agenda. The first question, What impact, if any, has non-heart-beating

**BOX 6-1 Proposed Research Questions**

1. What impact, if any, has non-heart-beating donation had on the public's trust in physicians, hospitals, and the nation's organ procurement system?
2. What impact does non-heart-beating donation have on patient and family well-being?
3. To what extent has the IOM non-heart-beating donor protocol been adopted by OPOs and hospitals?
4. (a). What do OPOs and hospitals see as the barriers to adoption? (b). Are there principle-based objectives to adoption or simply logistical ones?
5. What impact does non-heart-beating donation have on health care professionals, both OPO requesters and hospital staff?
6. How effective has non-heart-beating donation been as a strategy for increasing the supply of organs?

   a. What number of organs have been retrieved from non-heart-beating donors? From donors whose death had been determined by neurological criteria during the same period of time?

   b. How does the viability of organs retrieved via non-heart-beating donation compare with organs retrieved from donors who have died from neurological criteria?

   c. What is the survivability of recipients of non-heart-beating donor organs?

7. Are there special enhancing interventions to improve the effect of non-heart-beating these protocols?
8. What are the costs involved in implementing non-heart-beating donor protocols and in procuring organs from non-heart-beating donors, as compared to the costs associated with organs procured from donors whose death was determined by neurological criteria?

donation had on the public's trust in physicians, hospitals, and the nation's organ procurement system? is a superordinate question, in the sense that the answers to it must be derived from answers to several of the following questions. For example, by learning about the impact of non-heart-beating donation on the well-being of patients and families (question 2), by studying the extent to which local non-heart-beating donor protocols safeguard conflicts of interest (question 3), and by ascertaining the total number of organs retrieved from both non-heart-beating donors and donors who have been declared dead by neurological criteria (question 6a) during the same time period, researchers and policy makers can infer whether non-heart-beating donation is being implemented in ways that have enhanced or diminished public trust and family willingness to donate.

Three main types of research activities would be capable of answering seven of these eight questions. (Although question 8, pertaining to costs, is an essential one, this paper does not address the mechanisms for evaluating costs, because the issue is complex and goes well beyond its scope) The three main research activities are the following:

1. conducting *research on family perspectives* aimed at understanding the consequences for, and experiential realities of, families who have consented to non-heart-beating donation;
2. developing a "*profile of institutional behaviors"* that would include a variety of measures capable of capturing the extent to which the 1997 IOM recommendations (IOM, 1997a) and local non-heart-beating donation policies are being implemented in practice in health care settings; and
3. developing and testing *interventions* capable of enhancing non-heart-beating donation policies so that potential benefits may be maximized.

Figure 6-1 is a pictorial representation of the relationship among these three research priorities. As the figure indicates, the agenda is "triangulated" in the sense that when taken together, all three basic types of research activities would provide significant information on the extent to which non-heart-beating donation protocols are, in fact, minimizing harms and maximizing benefits for all the key stakeholders, as well as data on how these protocols could be improved. In the remainder of this section, relevant measures, data collection methods, and special methodological considerations are proposed for each of these three research priorities.

### *Research on Family Perspectives*

The main reason for conducting research on family perspectives is to ascertain what the impacts of non-heart-beating donation protocols, and family decisions to donate or not, have been on patient and family well-being. Qualitative interviews will be an essential aspect of this research, because the goal is

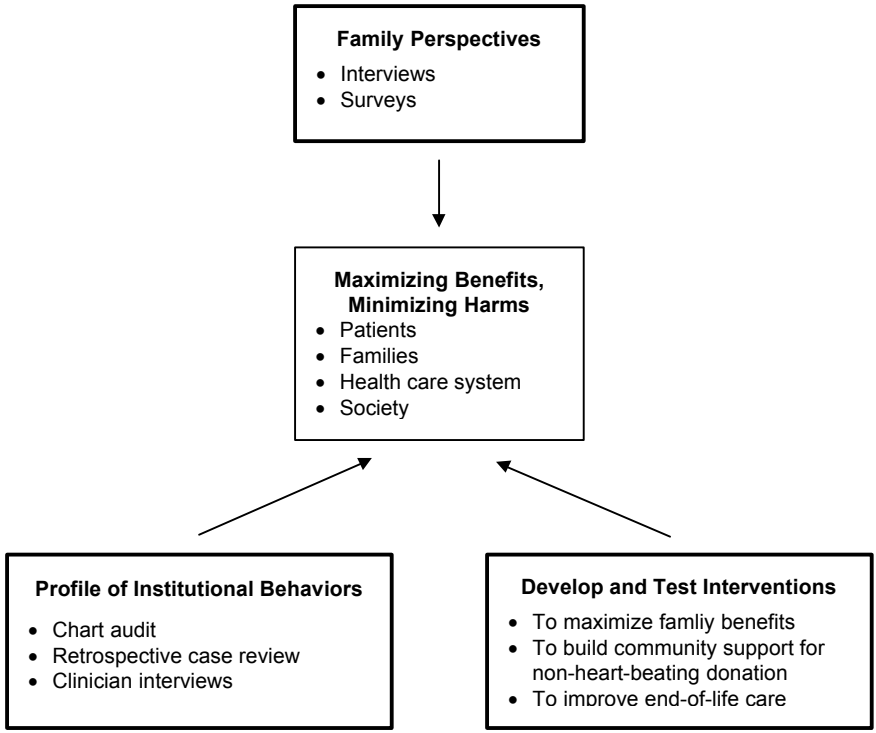


**FIGURE 6-1** National research agenda for assessing the impact of non-heart-beating organ donation.

to try to learn about a family's experience with their loved one's end-of-life care; the family's interpretation of events leading up to the donation request; and the meaning the family made of its decision, both during its deliberations and afterwards. However, surveys could be used to confirm qualitative findings in a larger, national sample of families, after prior qualitative studies had been conducted.

Timing for the interviews and/or surveys is important. Many hospitals conduct bereavement calls to families several weeks or months after the death of a loved one. It might be possible to "piggyback" questions onto these interviews. Prior research on how to optimize the donation request process (DeJong et al. 1998; Franz et al., 1997) found that it was feasible and effective to contact the families of donors who had been declared dead by neurological criteria six months after the death of their loved ones. Closed-ended questions asked via telephone interview yielded important information about how to improve the donation request process.

**BOX 6-2 Types of Family Data to Collect**

1. Evidence of family involvement in decision making and in setting goals of care.
2. Family knowledge of the patient's wishes and/or reasons for withdrawal of life support.
3. Evidence of separation between decision to forgo life support and decision to donate.
4. Satisfaction with the donation request process.
5. Satisfaction with patient and family care near death (e.g., adequate pain management, opportunities for leave-taking).
6. Retrospective satisfaction with donation decision.
7. Psychosocial consequences (e.g., grief, guilt, depression).
8. Financial burdens associated with the terminal hospital stay.

Ideally, surveys and interviews with family members must collect data from both families who have consented to donate and those who have not. This design in the sampling plan is important, because otherwise it will be hard to tell to what extent any reported negative family consequences are a result of the donation decision itself or simply a consequence of inadequate care near the end of life.

Furthermore, collecting data on a broad and diverse family population is particularly important, because family perspectives vary greatly across different ethnic groups on a whole range of related issues, including death, dying, organ donation, and advance care planning (Ersek et al., 1998), as well as trust in the health care system (Dula, 1994) and attitudes toward health care decision making (Blackhall et al., 1995; Koenig, 1997; Solomon, 1997).

Box 6-2 presents eight issues that family interviews and/or surveys should explore. These include probing for (1) evidence that families were involved in decisions about the use of life support and in setting goals of care for their loved one; (2) the family's knowledge of the patient's wishes and/or reasons the family felt that withdrawal of life support was in the patient's best interest; (3) evidence of separation between the decision to forgo life support and the decision to donate; (4) satisfaction with the donation request process; (5) satisfaction with the care the family and loved one received, (e.g., optimal pain management, ample opportunities for family leave-taking); (6) retrospective satisfaction with whatever decision the family made; (7) specific psychosocial consequences, such as possible guilt, remorse, or evidence of abnormal grief reactions; and (8) financial burdens on the family.

*Developing Profiles of Institutional Behavior*

In addition to proposing ways to safeguard potential and perceived conflicts of interest, the 1997 IOM report (IOM, 1997a) recommended case-by-case analysis by an attending physician (who is not a member of the organ procurement team) to determine whether or not anticoagulants and vasodilators (used to enhance organ preservation) might safely be used in patients whose families have consented to non-heart-beating donation. The report also called for family consent for premortem cannulation (insertion of a femoral arterial line for injection of preserving fluids postmortem). Rather than having to withdraw treatment in the operating room, away from families, premortem insertion of these cannulae makes it possible for life support to be withdrawn in the intensive care unit, where families can say their farewells. However, cannulation is an invasive procedure, and in a conscious person, insertion of the cannulae is painful and requires analgesia. The report also recommended a uniform method for determining death in controlled non-heart-beating donation (cessation of cardiopulmonary function for at least five minutes as measured by electrocardiographic and arterial pressure monitoring).

A combination of three different data collection strategies would result in a summarizable profile of the extent to which OPOs and hospitals have moved in these directions. *Chart reviews* could be done to determine evidence of family involvement in decision making and in setting goals of care. Data should be collected on the severity of the prognosis and the reasons that patients (if conscious) and their families felt life support was no longer appropriate. If good documentation practices have been instituted, the chart should also provide evidence of (1) a separate discussions of the decision to forgo treatment and the decision to donate; (2) whether an attending physician, unrelated to the organ procurement team, analyzed the suitability of anticoagulants and vasodilators for the patient and whether these were ordered (for a random, subsample of charts, there could also be an expert review to determine whether anticoagulants and vasodilators were ordered in cases where they should have been contraindicated); and (3 ) whether family consent was sought prior to premortem cannulation.

Unfortunately, data from charts are often incomplete and sometimes unreliable, so other ways to document compliance with these recommendations may have to be developed.

As part of an exit interview or at the end of the family interviews, families could be asked whether key items, such as premortem cannulation, had been explained to them and whether their consent had been sought for that procedure. Family responses could be compared to results on an identical checklist, which a health care professional on the clinical team would be expected to fill out for all non-heart-beating donors. In this way, it would be possible to compare clinicians' views of what they have communicated to families with families' views

of what they were told. Negative findings from the families may indicate either that the health care team failed to disclose these issues or that families failed to "hear" them; in either case, knowing that the communication failed is important for improving disclosure and consent procedures in the future.

*Retrospective case review* is another method that hospitals and OPOs could use to monitor compliance with their own non-heart-beating donor protocols and/or the recommendations of the 1997 IOM report. McNamara et al. (1999) have found this to be an effective method for monitoring compliance with protocols for neurological determination of death. Case review of non-heart-beating donations would make even more sense because of the potential conflicts of interest that one wants to monitor. Derived from the quality assurance movement, retrospective review, performed on a routine schedule, allows staff to follow the "path" that individual cases have taken in order to better understand where there may have been "glitches" in the system and to improve case management so it can come more directly in line with the recommended protocol. For the purposes outlined here, it would be wise for reviews to be done on a subsample of all cases in which patients meet some explicit criteria of grave prognosis (perhaps a certain number of hours or days on ventilatory support), not just on a subsample of cases in which discussions about the withdrawal of life support have been initiated. Including this broad a net is important because one of the findings might be that in many cases, a grave prognosis, which *should* have triggered discussions about life support, never did result in conversations with patients (if they were capacitated) or with their families.

*Clinician interviews* should also be an integral part of the data collection strategies used to create a profile of institutional behaviors. In particular, intensivists and critical care nurses are key informants, whose views will be essential for understanding how non-heart-beating donation is working. Box 6-3 presents examples of seven issues that these interviews should explore: (1) clinicians' perceptions of whether, and to what degree, families are involved in decision making and setting goals of care (which can be used in connection with a similar question that is asked of families); (2) perceptions of whether separation of the decision to forgo life support and the decision to donate has been maintained, and what barriers and importance (or lack thereof) clinicians see in maintaining this separation; (3) clinicians' own satisfaction with the donation request process; (4) clinicians' perceptions of families' satisfaction with the donation request process; (5) clinicians' satisfaction with the quality of the dying experience for patients and families; (6) clinicians' perception or experience of conflicts of interest; and (7) concerns of conscience that clinicians may have regarding any aspect of the non-heart-beating donation or procurement process.

**BOX 6-3 Types of Clinician Data to Collect**

1. Perceptions of whether, and to what degree, families are involved in decision making and setting goals of care
2. Perceptions of whether the decision to forgo life support is handled separately from the decision to donate; perceived barriers to maintaining this separation and perspectives on the importance of maintaining it
3. Clinicians' own satisfaction with the donation request process
4. Clinicians' perceptions of the family's satisfaction with the donation request process
5. Clinicians' satisfaction with the quality of the dying experience for non-heart-beating patients and their families
6. Clinicians' perceptions of, and experience with, conflicts of interest
7. Concerns of conscience that clinicians may have regarding any aspect of the non-heart-beating donation or procurement process.

*Developing and Testing Interventions to Maximize Family Benefits and Improve Non-Heart-Beating Donor Protocols*

This category of research covers a broad range of possible intervention studies that could conceivably be undertaken. The research could focus on building community support for non-heart-beating protocols or on designing innovations to improve family experiences with non-heart-beating donation. For example, some institutions might want to explore ways to enhance family leave-taking and thereby address donor family concerns about high tech death. Special rituals or compromises in the timing of removal to the operating room might be explored and their impact on families (and organ viability) documented. Other institutions might want to explore ways to integrate their protocols with efforts to improve end-of-life care more generally for all patients in the intensive care unit (ICU). For example, as part of their involvement in the Decisions Near the End of Life program, Dowdy et al. (1998) increased attendings' willingness to hold end-of-life conversations with families, generated greater documentation of the family's values and preferences in the medical record, and decreased resource utilization in the ICU, when they established an institutional routine requiring a conversation about goals of care whenever any patient in the hospital's ICU had been on a ventilator for 96 hours or more. The goal was to ensure that the attending would speak with the family (or patient, if he or she was able) about the understanding of the patient's prognosis and then develop a mutually agreed upon goal for care that could include either continued ventilatory support, terminal weaning, or a variety of intermediate trials of treatment. The point was not to advocate any particular substantive decision, but simply to ensure that a conversation took place, that families were apprised of the kinds of issues

they were likely to face in the coming days, and that caregivers were made aware of family values and preferences. Interventions that build on these findings, and simultaneously take new non-heart-beating donation protocols into account, might enhance end-of-life care and increase organ donation as well.

## Methodological Challenges

It is important to recognize that even if one conducts research on families (both consenting and nonconsenting) that have been approached with a donation request, there may be other families of potential non-heart-beating donors who were not approached and therefore will not fall within the group of people being studied. Since the clinical criteria for neurological determination of death are straightforward and usually recorded in the medical chart, death record reviews routinely done by OPOs, clearly establish which patients who had been declared dead by neurological criteria were candidates for donation and whether their families were approached, as they should have been. In the case of non-heart-beating donation, it remains an open question as to whether medical charts are a good means of identifying prospective candidates. Although the Health Care Financing Administration (HCFA) guidelines for routine referral and trained request are intended to notify the local OPO of all deaths and impending deaths, prognostic indicators are not yet well established, and providers may not always record (or sometimes even hold) end-of-life discussions about patient or family wishes to terminate treatment (Solomon, 1991). As a result, non-heart-beating donation researchers may be able to interview or survey only those families that were approached with a donation request, and it may therefore prove difficult to determine whether there are systematic biases in which families are approached with such requests.

It is important to determine these biases for a number of reasons. For example, Guadagnoli et al. (1999) found that the odds of the family of a white patient who had been declared dead by neurological criteria being approached for donation were nearly twice the odds that the family of an African-American patient would be approached. However, in other circumstances the opposite may be true: families of patients who are seen as socially undesirable or families of patients from ethnic groups that are different from those of their health care providers may be disproportionately approached. This may be particularly true for non-heart-beating donors. This may explain why some protocols, prior to the 1997 Institute of Medicine (IOM) report (IOM, 19997a) prohibited non-heart-beating donation unless it was explicitly requested by family members, not initiated by staff. Without being able to identify the universe of potential non-heart-beating donors, it will be extremely difficult to determine whether there are systematic biases in terms of who is being approached to provide a non-heart-beating donation.

### Significance and Benefits of This Plan

To date, most of the empirical research in the field of organ donation has focused on identifying public attitudes to organ donation (Franz et al., 1995) and trying to understand how to improve the donation request process (e.g., DeJong et al., 1998; Franz et al., 1997; Gortmaker et al., 1998; McNamara and Beasley, 1997; Siminoff et al., 1995) and thereby enhance family consent rates. The purpose of the research being proposed here is very different. The primary goal of this evaluation plan is not to increase donation rates, but rather to inform families, policy makers, ethicists, health care organizations, OPOs, the transplant community, and the general public about the trustworthiness of non-heart-beating donation protocols. Thus, the intent of this research is neutral: to uncover potential harms and benefits for patients and their families, so that protocols can be implemented with confidence or be redesigned to address problems.

If this research agenda were adopted, individual health care institutions and OPOs would be able to (1) assess the degree to which their practices are in line with their own local policies and with the guidelines of both this and the 1997 IOM report; (2) monitor the impact of their policies on families; and (3) make improvements in their approach to non-heart-beating organ donation on the basis of empirical data.

Moreover, if a number of OPOs and health care institutions around the country agreed to collect the same kinds of data, it might be possible to (1) assess the extent of compliance nationally and regionally with the recommendations of these IOM reports, and (2) compare the impact of different kinds of policies on family well-being. Although the recommendations call for some degree of national uniformity on key points, by asking OPOs and hospitals to develop their own local protocols, there is a clear recognition that protocols will differ in various regions of the country. While diversity in certain aspects of these local protocols is to be expected and perhaps even encouraged, common agreement on the outcomes to be measured and the development and use of shared research tools would help create a national laboratory for cross-institution and cross-regional comparisons. Although numerous separate research studies can and should emerge from this plan, it would be wise to begin a national dialogue about what is worth measuring and how to go about doing so in coordinated ways that can yield the most powerful results for the broadest set of stakeholders.

### Conclusion

The recommendations of this report address the study goals of (1) familiarizing relevant parties with the 1997 IOM report; (2) identifying obstacles to implementing its recommendations; (3) facilitating the development of organ procurement practices consistent with its principles and recommendations. Based on the input from the workshop, the committee recommends the development

and implementation of non-heart-beating donation protocols. This report provides guidelines for developing and implementing non-heart-beating donation protocols. These guidelines are based on the findings and recommendations of the 1997 IOM report and on the consensus and variations identified during the 1999 workshop.

In the course of the study and the workshop, the committee identified strong reasons for making the option of non-heart-beating donation available to all patients and families who want it. The committee recognized, however, that there are impediments and potential impediments to the acceptance of non-heart-beating by health care providers, organ procurement and transplant professionals, and the public. To the extent possible within this study, the committee sought strategies for addressing these impediments. It found that further research is needed to resolve many of the questions about non-heart-beating donation and transplantation that were identified during the study and at the workshop.

Dr. Solomon's paper has been included in full because it highlights the many areas where further research is needed to evaluate the best approaches to non-heart-beating organ donation, procurement and transplantation. Active non-heart-beating donation programs have established protocols that satisfy the underlying ethical concerns of promoting benefit and avoiding harm, respecting patient and family choice and well-being, and avoiding conflicts of interest. Active programs have developed strategies for meeting patient and family needs at the end of life. Non-heart-beating donation under such protocols as these has great potential for providing options to patients and families, and for contributing to future developments in organ procurement and transplantation.

The findings and recommendations of this report will be disseminated to OPOs and transplant centers, to physician specialty groups, and to transplant and health care professional associations. The report is intended to serve as a resource for those who are involved in non-heart-beating donation or in program initiation and protocol development. It is intended also to provide information on the current state of knowledge about non-heart-beating donation and transplantation for those who are concerned about potential impediments. Further understanding of the benefits and impacts of non-heart-beating organ donation relies on further experience and research as outlined in this report.

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# APPENDIX A

# Statement of Task

**NON-HEART-BEATING TRANSPLANTATION II:**
**THE SCIENTIFIC AND ETHICAL BASIS OF PRACTICE**
**AND PROTOCOLS**

**Major Unit:** IOM
**Division, Office or Board:** Health Care Services
**Subject Committee:** Non-Heart-Beating Organ Transplantation II:
The Scientific and Ethical Basis for Practice and Protocol
**Staff Officer Name:** Ellen Agard

**Statement of Task:**

This project follows on the Institute of Medicine's report, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement* (1997). For this project, the Steering Committee will engage in a process of communication and consultation to 1) familiarize all relevant parties with the 1997 IOM report, 2) to identify obstacles to implementing its recommendations, and 3) to facilitate the development of organ procurement practices consistent with the principles and recommendations articulated in the IOM report. The committee also may recommend further research or additional activities in support of the goals of this project.

The Steering Committee will include experts in law, medicine, and ethics. Additional expertise will incorporated through the participation of key groups and organizations involved in organ transplantation. The Steering Committee and project staff will consult with experts, and with those directly engaged in non-heart-beating organ transplantation, in order to identify participants for a national workshop. The national workshop will provide a forum for sharing information and promoting communication among interested parties and representatives of key groups, and for discussing any outstanding problems identified in non-heart-beating organ transplantation. A primary goal of this workshop will

be to encourage participation by all OPOs in the development of voluntary protocols and practices consistent with the principles in the 1997 IOM report.

A report of the proceedings and recommendations from the national workshop will be prepared and disseminated to project participants, federal and state agencies concerned with transplantation policy, OPOs, transplant coordinators, and relevant health care providers.

**Sponsor(s):** Department of Health and Human Services
**Date of Statement:** 01/07/99, editorial revisions
**Date of Previous Statement:** 07/14/98

# APPENDIX B

# Workshop Agenda

**NON-HEART-BEATING TRANSPLANTATION II:
THE SCIENTIFIC AND ETHICAL BASIS FOR PRACTICE
AND PROTOCOLS**

Washington, D.C., May 24–25, 1999

**Monday, May 24, 1999**

**Introduction**
Introduction to the Committee
Introduction to the Study
Institute of Medicine Study, 1997
OPO NHBD protocols 1997–1998

**Policy Context**
Lynn Rothberg-Wegman, Deputy Director, Division of Transplantation
Health Resources and Services Administration (HRSA)

**Clinical Context: Decisions to Forgo Artificial Support**
Brief review of legal/ethical basis for decisions to forgo treatment

**End of Life Care and Organ Donation: The Patient and Family**
Family member experiences
Short presentation; questions and answers
Bob and Nancy Curran
Peggy Schaeffer

**Roundtable I. Protocol Content**

Brief presentation by each program, comparing specific protocol provisions and rationale.

Washington Hospital Center, Jimmy Light, M.D.
University of Pittsburgh, Michael DeVita, M.D.

University of Florida/SHANDS, Danielle Cornell, R.N., B.S.N., C.P.T.C.
New England Organ Bank, Francis Delmonico, M.D.
Gift of Life Donor Program, John Edwards, R.N., C.P.T.C.
Ohio Valley LifeCenter, David Lewis, R.N., B.S.N.

**Building Consensus on Protocol Content**
Committee questions
Public comments

**Roundtable II. Protocol Development**

Brief overview of each program's experiences in developing a protocol for non-heart-beating organ donation.

Washington Hospital Center, Jimmy Light, M.D.
University of Pittsburgh, Michael DeVita, M.D.
University of Florida/SHANDS, Danielle Cornell, R.N., B.S.N., C.P.T.C.
New England Organ Bank, Francis Delmonico, M.D.
Gift of Life Donor Program, John Edwards, R.N., B.S.N., C.P.T.C.
Ohio Valley Life Center, David Lewis, R.N., B.S.N.

**Steps in Protocol Development**
Committee questions
Public comments

**Roundtable III: Protocol Implementation**

Transplant Coordinators
Mark Reiner, , P.A., CPTC, University of Florida OPO
North American Transplant Coordinators Association (NATCO)

Transplant Recipients
Patricia Weiskittel, R.N., M.S.N., American Nephrology Nurses' Association

Critical Care Nursing
Jacqueline Sullivan, R.N., Ph.D., Neurosurgery Intensive Care Clinical Nurse Specialist

Rural Hospitals
Anne Freeman Cook, M.P.A., High Mountains High Plains Bioethics Project

Outcomes

Louise Jaccobi, C.P.T.C., Louisiana Organ Procurement Agency

Discussion of implementing a non-heart-beating organ procurement program and carrying out non-heart-beating organ procurement protocols: resources, outreach, education, follow-up.

**Discussion: Issues in Implementation**
Committee questions.
Public comments

**Public Comment**

**Tuesday, May 25**

**Issues in Dissemination and Research: Declaring Death**
Commissioned Paper: Stuart Youngner, M.D., Robert Arnold, M.D., and Michael DeVita, M.D.
Committee questions

**Issues in Dissemination and Research: Evaluation**
Commissioned paper: M. Solomon, Ph.D.
Committee questions

**The Donor Family**
A family-centered approach
Family information pamphlet: review and discussion

**Public Comments**

# APPENDIX C

# Workshop Participants

## ROUNDTABLES I AND II: PROTOCOL CONTENT AND DEVELOPMENT

**Danielle Cornell,** R.N., B.S.N., C.P.T.C., University of Florida/SHANDS (hospital-based OPO), Gainesville.

As a hospital-based organ procurement organization (OPO), SHANDS has just developed a protocol for its home hospital in Gainesville, based on the protocol used by its satellite office in Jacksonville. It started with meetings between a development team and physicians (intensive care, surgery, anesthesiology). Protocol development took two and half years from idea to implementation, with ten months from first draft to approval. The approval process included legal, ethics, policy and procedure, and executive committees. In-services and grand rounds have been provided for operating room staff, surgery and anesthesia. Education is in progress for intensive care staff, social services, neurosurgery, the medical examiner, and the media.

**Francis Delmonico,** M.D., New England Organ Bank (independent OPO) Newton, Mass.

The NEOB started protocol development with a medical group and the OPO Board of Trustees. Its protocols have been submitted to New England state transplantation advisory boards, hospital associations, clergy, and the media. Protocol development took one year. It has addressed concerns among local surgeons about the ethics of non-heart-beating donation, and about physician staffing for organ recovery.

**Michael DeVita,** M.D., University of Pittsburgh (hospital program)

The University of Pittsburgh initiated non-heart-beating organ donation in response to patient and family requests, and initiated protocol development in response to staff and physician concerns about the withdrawal of support and the determination of death. Protocol development took 18 months of weekly meetings of both an ethics group, which dealt with the ethical issues of patient care at the end of life, and a procedural group, which set standards for withdrawing support, determining death, and auditing compliance. The protocol was approved by nursing, anesthesia, critical care, and medical personnel, and by a joint committee of hospital administrators, physicians, and board members. It was shared with ethics leaders and with the media, and published along with a series of articles in a special issue of the *Kennedy Institute of Ethics Journal* (Vol. 3, June 1993).

**John Edwards,** R.N., C.P.T.C., Gift of Life Donor Program (independent OPO) Philadelphia

Gift of Life developed its protocol (a draft it provides for local hospitals to follow or to use in developing their own protocols) in response to patient and family requests and in response to early referrals resulting from Pennsylvania's routine referral legislation (passed in 1994). This OPO has found that non-heart-beating donation requires greater resources than anticipated for hospital outreach and education, including two coordinators for each donation. Gift of Life has found it particularly helpful to meet with hospital administrative and medical leaders and to attend protocol review meetings held by hospital committees.

**David Lewis,** R.N., B.S.N., Ohio Valley Life Center (independent OPO), Cincinnati

Ohio Valley Life Center developed its protocol in response to family requests. In preparation for protocol development, it conducted qualitative interviews with eight families who were unable to donate because of the lack of a protocol. The protocol was developed and is overseen by an advisory board consisting of clergy, social services, physician specialists, nurses, hospital administrators, and family members. Development took eight months. Lewis emphasized the need for cooperation among OPOs, hospitals and practitioners, good media relations, and protocol revision as needed.

**Jimmy Light,** M.D., Washington Hospital Center (hospital program), Washington, D.C.

Washington Hospital Center developed its program in response to a high incidence of trauma deaths combined with a high need for kidney transplantation within the local community. A working group presented the idea to the hospital and then to the community in the form of a consensus conference, out of which a community oversight board was established. The process took two years. During

this time, the oversight board met monthly, and media outreach, community education, and surveys were conducted. The District of Columbia passed legislation in 1994 that allows the insertion of cannulae and the initiation of cold preservation of organs prior to family consent under limited conditions. Washington Hospital Center is particularly committed to a program of family advocates.

## ROUNDTABLE III: PROTOCOL IMPLEMENTATION

**Mark Reiner,** P.A., C.P.T.C., University of Florida OPO, North American Transplant Coordinators Association (NATCO)

Transplant coordinators are OPO field personnel who act as liaisons with referring hospitals, transplant centers, and families. NATCO is the professional organization that represents these coordinators. NATCO has four areas of concern: (1) the need for national, standardized criteria for non-heart-beating organ donation, including the definition of suitable donors; (2) the need for education and training for practitioners; (3) the need for national standardized criteria for recovering and accepting these organs; and (4) the need to account for the impact on OPO performance of increased costs and discard rates associated with non-heart-beating organ recovery.

**Patricia Weiskittel,** R.N., M.S.N., American Nephrology Nurses' Association (ANNA)

ANNA is the professional organization for nurses who work in dialysis units and with hospitalized patients with end-stage renal disease. These nurses take care of kidney recipients both before and after transplantation and thus can play a significant role in developing and implementing non-heart-beating organ donation, including the development of national standardized criteria that ensure nursing input; education, training, and guidance for nurses; participation in ethics committees and forums; and the identification of nursing concerns and educational needs.

**Jacqueline Sullivan,** R.N., Ph.D., Neurosurgery Intensive Care Clinical Nurse Specialist, Thomas Jefferson University Hospital, Philadelphia

Critical care nurses are strategically involved in non-heart-beating organ donation. Critical care nursing priorities include consensus and consistency in protocols, and nursing education and preparation. Lessons from donation following death by neurological criteria can be transferred to non-heart-beating donation, particularly in the areas of decoupling, standards for declaring death, and family education and support. Collaboration between OPOs and hospitals is essential.

**Anne Freeman Cook,** M.P.A., High Mountains High Plains Bioethics Project

A number of donation concerns arise in rural, low-income, medically underserved areas. These include limited educational and ethics resources; limited expe-

rience and training for referral and donation; limited understanding of the issues involved in conflict of interest, informed consent, and diversity; and a medically underserved population with limited trust in the health care system. Thus, there is considerable need for decoupling, patient and family advocacy, hospital and community education, and increased access to health care resources.

**Louise Jacobbi,** C.P.T.C., Louisiana Organ Procurement Agency

The Louisiana OPO has not undertaken non-heart-beating donation because of several unresolved concerns: resources for OPO and hospital education; staff time; equipment; and limited outcome data. There is an urgent need for follow-up studies on costs, organ discard rates, transplant outcomes, impact on OPO and hospital staff, and effect on family consent. It is difficult to move forward when local transplant centers do not want to use non-heart-beating donor organs, when the OPO is concerned about costs, when the organ discard rate is higher, and when adequate follow-up data are not yet available.

APPENDIX D

# Bill of Rights for Donor Families
# National Kidney Foundation

Reprinted courtesy of the National Kidney Foundation.

# *Bill of Rights*

## *For Donor Families*

*This document is intended to represent the rights and legitimate expectations of families of loved ones who die and who are or may be considered potential organ and/or tissue donors. This document is also intended to serve as a guide for services that are or should be offered to such families.*

*The term "family" identifies legal next-of-kin but is also intended to embrace other individuals who may have a significant relationship with a potential or actual organ and/or tissue donor, whether through biological, matrimonial or affectional ties.*

*The term "donor family" identifies family members who may be or have already been approached to give consent for organ and/or tissue donation from the body of a loved one after death has occurred.*

*This document does not address the situation of living persons who are contemplating or have consented to organ and/or tissue donation during their lifetime.*

**Donor families have the right:**

▲ 1. To a full and careful explanation about what has happened to their loved one, his or her current status, and his or her prognosis.

▲ 2. To be full partners with the health care team in the decision-making process about the care and support given to their loved one and to themselves.

▲ 3 To a full and careful explanation about the (impending) death of their loved one, with appropriate reference to the concept of cardiac and/or brain death and the basis upon which it has been or will be determined that that concept applies to their loved one.

▲ 4. To opportunities to be alone with their loved one during his or her care and after his or her death occurs. This should include offering the family an opportunity to see, touch, hold, or participate in the care of their loved one, as appropriate.

▲ 5 To be cared for in a manner that is sensitive to the family's needs and capacities by specially-trained individuals.

▲ 6. To have an opportunity to make organ and/or tissue donation decisions on behalf of themselves and of their loved one who has died. This opportunity is to be included in the normal continuum of care by the health care provider after death has been determined and the family has had sufficient time to acknowledge that death has occurred.

▲ 7. To receive information in a manner that is suited to the family's needs and capacities about the need for organ and tissue donation, the conditions and processes of organ and/or tissue donation, and the implications of organ and/or tissue donation for later events, such as funeral arrangements, viewing of the body, and related practices.

▲ 8. To be provided with time, privacy, freedom from coercion, confidentiality, and (if desired) the services of an appropriate support person (e.g., clergyperson) and other resources (e.g., a second medical opinion, advice from significant others, or the services of an interpreter for those who speak another language) which are essential to optimal care for the family and to enable family members to make an informed and free decision about donation.

▲ 9. To have their decisions about organ and/or tissue donation accepted and respected.

▲ 10. To have opportunities to spend time alone with their loved one before and/or after the process of removing donated organs and/or tissues, and to say their "goodbyes" in a manner that is appropriate to the present and future needs of the family consistent with their cultural and religious identity (e.g., a lock of hair )

▲ 11. To be assured that their loved one will be treated with respect throughout the process of removing donated organs and/or tissues.

▲ 12. To receive timely information that is suited to the family's needs and capacities about which organs and/or tissues were or were not removed, and why.

▲ 13. To receive timely information regarding how any donated organs and/or tissues were used, and, if desired, to be given an opportunity to exchange anonymous communications with individual recipients and/or recipient family members. Upon request, donor families should also be given accurate updates on the condition of the recipients.

▲ 14. To be assured that the donor family will not be burdened with any expenses arising from organ and/or tissue donation, and to be given assistance in resolving any charges that might erroneously be addressed to the family.

▲ 15. To receive ongoing bereavement follow-up support for a reasonable period of time. Such support might take the form of: the name, address, and telephone number of a knowledgeable and sensitive person with whom they can discuss the entire experience; an opportunity to evaluate their experience through a quality assurance survey; free copies of literature about organ and/or tissue donation; free copies of literature about bereavement, grief, and mourning; opportunities for contact with another donor family; opportunities to take part in a donor or bereavement support group; and/or the services of a skilled and sensitive support person.

**All explanations mentioned in this document should be provided by a knowledgeable and sensitive person in a private, face-to-face conversation whenever possible in a manner suited to the family's needs. Also, these explanations may need to be repeated or supplemented in more than one interchange.**

**This document has been officially endorsed by the following organizations:**

- **North American Transplant Coordinators Organization**
- **Division of Transplantation, Human Resources & Services Administration**
- **American Association of Critical-Care Nurses**
- **American Heart Association**
- **American Society of Transplant Physicians**

**This document was prepared by Charles A. Corr, Ph.D., Lucy G. Nile, M.A. and the members of the National Donor Family Council of the National Kidney Foundation**

*Margaret B. Coolican, R.N., M.S.*
*(Chairperson & donor family)*
*William Bennett, M.D. (donor family)*
*Vicky Crosier (donor family)*
*Kenneth J. Doka, Ph.D.*
*Jayne M. Miller (donor family)*
*Kenneth Moritsugu, M.D., M.P.H. (donor family)*
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*Cynthia Rodriguez (donor family)*

**National Kidney Foundation, Inc.**
**30 East 33rd Street**
**New York, NY 10016**
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**Item # 06-13**

# APPENDIX E

# Sample Family Information Brochure

## WHAT YOU SHOULD KNOW ABOUT DONATING ORGANS AND TISSUES: AN OPTION FR FAMILY MEMBERS

### How This Brochure Can Help

The death of a loved one is a deeply sad and painful time for you and your family. During this time, you face many difficult decisions. One is whether to donate the organs and tissues of your loved one, in keeping with your understanding of his or her wishes.

There are many options for providing care and comfort at the end of life. This brochure is written for families who are considering donating their loved one's organs and tissues after life-sustaining treatments are stopped. The information is intended to help you decide whether this is the right option for you and your loved one. The brochure can be used as a reminder of discussions about donation, which may have taken place at a time when it is difficult for you to remember the information.

Please know that:

- The decision to stop life-sustaining treatment should be made before organ and tissue donation is discussed.
- You will not be pressured to have this discussion.
- Whether or not you donate your loved one's organs and tissues, your family member will continue to receive the best care that the hospital staff can provide.

### Becoming an Organ Donor

Organ donation takes place only after life-sustaining treatment has been stopped, when the heartbeat and breathing have ceased, and death has been declared. Death is declared:

- when brain function is lost; or
- when the heart and breathing have irreversibly stopped.

Because of the emotional stress involved, making a decision about donating organs and tissues can be very hard. Your loss may be made easier by knowing that you are following the wishes of your loved one. He or she may have talked with you about organ and tissue donation, or may have signed a donor card.

If you do not know your loved one's wishes exactly, you will need to make the best decision that you can from what you know about your loved one's values and your own.

Families who donate organs and tissues gain comfort from knowing that the death of someone dear to them will help others, and that their loved one will leave a legacy by saving the life of someone who needs and organ or tissue transplant.

## What Will Happen

*Discussing Organ and Tissue Donation*

A physician or donation coordinator may discuss the option to donate your loved one's organs and tissues after he or she dies. Your approval and written consent are required for organ and tissue donation.

You will be asked questions about your family member's medical and social history. These questions must be asked in case there are medical reasons why your loved one's organs and tissues cannot be used for transplantation.

Each hospital follows set rules (called protocols) for organ and tissue donation. While the rules may differ slightly from hospital to hospital, they are written to guide the care given to your loved one. You should be able to see a copy of the protocol that your hospital follows. The protocol describes the process of preparing your loved one for organ and tissue donation.

*Keeping the Organs and Tissues Healthy for Transplantation*

The success of a transplant depends on many factors. A very important one is how well organs and tissues are maintained until they are removed.

To keep organs and tissues healthy, certain procedures may be done before life-sustaining support is withdrawn or after death has been declared. These procedures are not part of the medical care of your loved one, and include:

- *Blood and* other *lab tests* done to make sure your loved one meets the medical criteria for donation.
- *A tube called a catheter or cannula* inserted into a large blood vessel. This tube carries fluids that help to preserve the organs after death has occurred.
- *Medication*. Certain drugs help increase the blood supply to organs. Heparin is a drug that stops the blood from clotting. Phentolamine is a drug that

helps the blood vessels to expand (dilate). Decisions to use these drugs are made on a case-by-case basis.

*Removing the Organs and Tissues*

You may want to be with your loved one when life-sustaining support is removed and he or she dies. You can arrange this with the medical team caring for your family member. Organs and tissues are removed quickly after death has occurred.

The medical team focuses entirely on caring for your loved one. The doctor responsible for preserving and removing the organs will not be the same as the doctor who takes care of you loved one or the doctor who declares death.

Death usually occurs soon after life-sustaining support is stopped, though sometimes it may take a few hours. If this happens, the organs and tissues may not remain healthy enough for transplantation.

## Questions Family Members Often Ask

*Who will discuss organ and tissue donation with our family?*

In some cases, your doctor will give you information about donation. If you are interested, the doctor will ask a donation coordinator to discuss the process with you. If you know that your family member wants to be an organ and tissue donor, you can bring up the issue yourself with the nurse or doctor caring for your loved one.

*At what point will treatment be stopped?*

The decision to stop treatment will be made only when you and the medical team agree that it can no longer help your loved one, in keeping with your loved one's wishes.

*What organs will be removed?*

The "solid" organs—the kidneys and liver—are the most often removed from a patient whose heart has stopped. Bones, corneas, heart valves, skin, and tissues also may be removed.

*Will the drugs needed for donation make my family member die sooner than if he or she hadn't agreed to be an organ donor?*

Drugs are given to maintain the flow of blood to organs and tissues, not to hasten death. These drugs preserve the organs and tissues and increase the chances that they can be successfully transplanted. The physician caring for your

family member will decide what medications will be used. These will be avoided if they could worsen your loved one's condition.

*Will my loved one feel pain?*

No. Pain management medication is used for procedures that might hurt, such as inserting tubes. Organs and tissues are removed only after death occurs.We want to have an open-casket funeral. Will donation prevent this?

No. The incisions made to remove the organs and tissues are closed, like any surgical incision, and can be covered by clothing.

*Will organ donation increase my family member's medical costs?*

No. Costs associated with the donation process are paid by the organ procurement agency. If you should have questions about a bill, contact the organization that recovered your loved one's organs and tissues.

*This is a very difficult decision for me to make now. Who can I speak to about this?*

The death of a loved on is a devastating loss. No one can lessen this loss or feel your grief in the same way as you do, but help is available. You can get support from the nurse or doctor caring for your loved one; from the hospital's chaplain, grief counselor, or patient advocate; and from the donation coordinator. Your religious leader, family physician, relatives, and friends also can help you in this time of need.

**A Checklist for Family Members**

- Do you feel you have enough information to make a decision to go ahead with having your loved one be an organ and tissue donor?
- Is the medical care of your family member being handled separately from organ and tissue donation arrangements?
- Do you know that drugs will be given and why?
- Have you discussed the hospital's protocol that explains the steps in organ and tissue donation?
- Do you know what organs and tissues will be removed?
- Have you given your written permission for organ and tissue donation?

**Information about Organ Transplantation**

About 20,000 organ transplants are done each year in the United States. If your loved one's organs are donated, this gift of life will help one of 60,000 people on a waiting list for an organ transplant.

For more information, visit the U.S. Department of Health and Human Services (DHHS) Web site at **www.organdonor.gov,** or write to the Division of Transplantation, Health Resources and Services Administration, DHHS, Parklawn Building, Room 4-81, 5600 Fishers Lane, Rockville, MD 20857.

This brochure is based on information in *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement* and *Non-Heart-Beating Transplantation: Practice and Protocols*, reports of the Institute of Medicine. The Institute of Medicine, a part of the National Academy of Sciences, serves as an advisor to the federal government on issues of medical care.

APPENDIX F

# Non-Heart-Beating Donation Protocols

## LIFECENTER

### Non-Heartbeating Donor Protocol

There are many instances in which families want the opportunity to donate their loved ones organs, but do not wish to prolong the process by awaiting the onset of brain death, or cannot because criteria for formal brain death declaration might never be met prior to cardiac death. Organ donation from patients that are cardiac dead will provide the opportunity to increase the donor pool and most importantly assure that every opportunity is taken to carry out the wishes of the donor family.

I. Referral

A. Donor hospitals are encouraged to contact LifeCenter before terminating ventilator or vasopressor support on a patient.

B. Criteria: Between 2 and less than 65 years of age; no history of HIV infection, malignant cancer outside of the brain, renal failure, or does not meet any High Risk donor exclusion criteria as defined by the Center for Disease Control (addendum 1). The patient must be on a ventilator.

II. Consent Process

A. A hospital staff member will contact LifeCenter to inform the agency that a patient exists who is potentially eligible to be a non-heartbeating organ donor. LifeCenter will only become actively involved in a potential NHBD case after a decision has been made to terminate support.

B. The attending physician or his designee will discuss termination of support on medical grounds with the family of the patient. If the family agrees, a DO NOT RESUSCITATE (DNR) order will be documented in the chart.

C. A LifeCenter representative will discuss the possibility of procurement with the attending physician or his designee. This is to ensure that the physician agrees with termination of support on medical grounds.

D. LifeCenter will discuss organ/tissue donation with the family (next-of-kin). The complete donation process and the process for pronouncing death will be explained. The LifeCenter coordinator will obtain informed, written consent for organ and/or tissue donation, from the next of kin, as per the Uniform Anatomical Gift Act.

E. If there is high probability that the patient will not have spontaneous respirations upon terminating support, the LifeCenter coordinator will discuss the option of termination in the operating room with the family.

F. If the patient is a "coroner's case" the LifeCenter representative will contact the appropriate coroners office and obtain clearance for organ/tissue donation.

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Provided courtesy of Ohio Valley LifeCenter, Cincinnati.

G. The family will be given the opportunity to spend time with the patient prior to discontinuation of support.

H. Attention should be given to patient comfort measures.

I. The family will be given the option to see the deceased patient after organ and/or tissue recovery surgery has been completed.

III. Determining Death

A. Before termination of support, it should be clear that the patient does not meet brain death criteria.

B. LifeCenter will utilize the accepted method of terminating support as determined by the attending physician and/or hospital.

C. The attending physician or his designee will pronounce death.

D. LifeCenter will wait for five (5) minutes of pulselessness before proceeding with donation.

IV. Donor Management (Laboratory work will only be started after signed family consent is obtained and with a physicians order)

A. **Evaluation**—Lab and diagnostic tests to be done for kidneys and liver:

Kidneys: electrolytes, glucose, PT/PTT, ABO, ABG, CBC, BUN, creatinine, urinalysis, chest x-ray, blood, urine, and sputum cultures.

Liver: LFT's, total and direct bilirubin.

B. Stat serology tests should be done, after family consent is obtained. LifeCenter coordinator is responsible for arranging transportation to the serology lab.

C. Blood specimens for tissue typing should be drawn at the same time as serology labs are drawn.

D. Abnormal parameters to be treated (see LifeCenter *Donor Management Protocol)*.

1. Electrolyte abnormalities—change IV solutions, rates, and adjust additives.
2. ABG abnormalities—alter ventilator settings
3. Low hematocrit
4. Coagulopathy—warm patient to 37 degrees, give FFP
5. Low urine output—give fluids, mannitol, or lasix

V. Preparing Patient and Operating Room for Organ Recovery.

A. Per LifeCenter *Donor Management Protocol*, the patient will be given IV fluids, medications, blood products, etc. to prepare the patient for organ donation.

B. All preparation related to equipment and supply set-up needed for surgical removal of the organs will be completed prior to withdrawing support.

C. The organ recovery surgeon will be in the donor hospital and available prior to withdrawing support.

D. The attending physician or his/her designee will order for and orchestrate the termination of support.

E. The LifeCenter coordinator will be responsible for determining and documenting the warm ischemic time of each organ. The warm ischemic time will be calculated from the time that no pulses are detectable until the organs have been initially flushed and cooled.

VI. Death Declared

Once death has been declared:

A. Under no circumstances will chest compression's be performed after death has been declared.

B. If not already in the operating room, the patient will be moved quickly to the operating room.

C. A vertical, midline incision will be made and the abdomen entered.

D. Lymph nodes and portions of the spleen will be removed for use in tissue typing.

E. If consent has been obtained from the family, tissues will be recovered in the morgue.

VII. If the patient continues to breathe and has a sustained pulse and blood pressure for more than two-three hours, the donation process will be stopped.

The family will be informed of the time limit during the consent process. If the time limit expires, the family will be notified. The care of the patient will remain in the control of the attending physician.

VIII. All costs from the time that the family gives permission for donation until the donation occurs, or the patient is no longer a candidate for donation, will be the responsibility of LifeCenter. Also, LifeCenter will pay for any lab tests or medications that are ordered by the attending physician to assess organ suitability or prepare the patient for organ recovery.

VIIII. Organ allocation and distribution will take place according to federal guidelines established through the United Network for Organ Sharing (UNOS).

ADOPTED: May 1, 1996
REVISED: March 7, 1997
October 7, 1997
January 6, 1998
January 13, 1998
February 23, 1999

GIFT of LIFE
DONOR PROGRAM

## SAMPLE HOSPITAL POLICY AND PROCEDURE
## NON HEART-BEATING ORGAN DONATION

**PURPOSE**

Patients or their surrogates can decide to forego life-sustaining treatment. Furthermore, all patients have the right to elect organ donation in the event of death. [ Hospital Name] believes that it is ethically appropriate to consider organ procurement following cardiac death. This policy is for non-heart-beating organ donation (NHBD) which has been defined as organ recovery from patients who are pronounced dead on the basis of irreversible cessation of circulatory and respiratory functions. It is intended to provide patients and/or families with an additional option of donation that complies with patient or authorized family directives after a patient or other authorized family member has chosen to remove life support.

**CRITERIA**

Appropriate candidates for non heart-beating donation (NHBD) shall be limited to those patients who meet the following criteria:

a. The patient has a non-recoverable illness or injury that has caused neurologic devastation and/or other system failure resulting in ventilator dependency.

b. The family in conjunction with the medical staff has decided to withdraw life support.

c. In the opinion of the health care team, cardiorespiratory death will likely occur within 1 hour following withdrawal of life support. The Gift of Life Donor Program (GLDP) coordinator will assist in this determination.

**PROCEDURE**

1. Refer Patient to Gift of Life Donor Program (1-800-KIDNEY-1)

   GLDP will be notified by (e.g. primary RN) of all patients who meet the above criteria. A GLDP Coordinator will travel to the hospital immediately to assist the health care team in determining suitability for NHBD.

2. Evaluation of Suitability

   On arrival, the GLDP Coordinator with knowledge of attending physician will conduct additional screening and assist in coordinating an appropriately timed discussion with the patient's attorney-in-fact or legal next-of-kin, as applicable, about the option of organ, tissue and eye donation.

Provided courtesy of Gift of Life Donor Program, Philadelphia, PA.

**GIFT OF LIFE DONOR PROGRAM**

Provided courtesy of Gift of Life Donor Program, Philadelphia.

3. Family Consent

A GLDP Coordinator, following the family's decision to withdraw support, will present donation options to the family. Families need to be fully informed, regarding donation options and organ recovery procedures, as well as provided with the opportunity to attend the withdrawal of support and the death of their loved one. Additionally, families should be informed about the administration of Heparin. If the family elects to donate, a consent form (attachment 1) will be completed. In addition, consent will be obtained for any other surgical procedure or medical intervention performed for the purpose of organ donation prior to the determination of death [i.e. lymph node recovery (for tissue typing), femoral cannula placement (for organ preservation)].

4. Patient Management

To facilitate vital organ recovery, the patient must be maintained on a ventilator and hemodynamically supported for organ perfusion until the withdrawal of support. The transplant coordinators will work in conjunction with the hospital medical staff to request medical consultations and laboratory studies to determine the suitability of the organs for transplantation. If case falls under the jurisdiction of the coroner/medical examiner it will be the responsibility of the GLDP coordinator to contact the appropriate person(s) to arrange for organ/tissue recovery.

Standard care and comfort measures may be administered prior to the withdrawal of support at the discretion of the attending physician or his/her designee. In addition Heparin (300u/kg) will be administered at this time.

5. Withdrawal of Support

Method 1
After suitability has been determined and consent obtained, a transplant team is notified and assembled. When the transplant team has arrived at the hospital, the patient is transferred to the operating room while being mechanically ventilated and monitored. The surgical recovery team will prepare and drape in a sterile fashion. Once the body is prepared and all necessary recovery equipment and preservation solutions are in place, the surgical recovery team will leave the room. Removal of life support may then proceed. Following pronouncement of death by the attending physician or his/her designee surgical recovery of organs will commence.

Method 2
Withdrawal may occur in an area other than the operating room. When this occurs cannulas may be placed in the femoral vessels prior to withdrawal of support. Prior to their insertion a separate surgical consent will be obtained from the family. These cannulas will be used for administration of organ preservation solution following determination of death. After cannula placement, withdrawal of life support may proceed. Following pronouncement of death, organ preservation will be initiated. Subsequently the patient will be transferred into the operating room for the surgical recovery of organs.

6. Pronouncement of Death

Death will be pronounced by the attending physician or his/her designee. The physician certifying death may not be involved as part of a transplant or procurement team.

The patient will be pronounced dead after 5 minutes of asystole as measured by electrical activity and arterial pulse monitoring. The physician will record the date and time of death in the medical record and if applicable complete the death certificate. If the patient does not arrest within the designated time frame, the patient will be returned to a designated room where comfort care measures will be maintained.

7. Costs

GLDP will be responsible for all costs related to the evaluation and recovery of organs and tissues for transplantation.

**SHANDS at the University of Florida Donation Protocols**
**Department of Nursing and Patient Services**

**Memorandum Number: Pm02-20.01**
**Category : Medicolegal**
**Review Responsibility: Legal Services**

**SUBJECT: DONATION AFTER CARDIAC DEATH (Non-Heart Beating Donors Only)**

**PURPOSE:** To provide the option of organ donation to the families of patients who do not meet the criteria for brain death, but for whom a decision to withdraw life support has been made.

**POLICY STATEMENT:** Whenever a competent patient or an incompetent patient's next-of-kin or surrogate/proxy has, in consultation with the attending physician, made the decision to withdraw ventilator support from a patient, a referral shall be made to the Organ Procurement Organization (OPO) prior to disconnection from the ventilator and/or initiation of the terminal wean.

**SPECIAL INSTRUCTIONS:**

A. The decision to withdraw life support must be made in accordance with the procedures set forth in PM02-17 ("Withholding or Withdrawing Life-Prolonging Treatments or Measures").

B. The OPO shall make the determination of medical suitability for donation.

1. The patient's attending physician shall be responsible for the referral, however, the attending, resident, charge nurse, staff nurse or social work may make the call to the 800 number (1-800-535-4483). The consideration of and the discussion between the physician and the family regarding a terminal wean and/or disconnection from the ventilator should take place prior to, and independent from any consideration of and discussion relating to the possibility of organ donation.

2. The patient's attending physician shall not be associated with or employed by an OPO, nor shall he/she be affiliated with the Organ Procurement Team or Transplant Team.

*Continued*

**SHANDS at the University of Florida Donation Protocols** *Continued*

**SPECIAL INSTRUCTIONS** *Continued*

C. Medical suitability/unsuitability of the potential donor

1. Should the patient be deemed medically unsuitable for donation:

a. The routine referral form shall be completed showing the specific reasons, and placed in the patients medical record by the OPO or other Designated Requester, as defined in PM02-20.

b. The OPO will be responsible for contacting the attending physician or his/her designee so that a terminal wean/disconnection from the ventilator may proceed.

2. Should the OPO find that the patient is potentially medically suitable for organ donation, then the OPO shall consult the attending physician or his/her designee and any other staff necessary in order to determine whether a request exemption applies (as defined in PM02-20). If not, then the OPO or designated requester, in consultation with the attending physician or his/her designee, shall approach the next of kin to request donation

a. Should the next of kin decline the option to donate, the OPO shall complete the routine referral form and place it in the patient's medical record.

b. Should the next of kin agree to donation:

i. A written consent form shall be included in the patient's medical record (see PM02-20, Appendix B).

ii. The OPO or hospital staff under the direction thereof, may perform any and all tasks to evaluate the patient as a potential donor.

iii. All additional expenses incurred in the procedures to preserve the donor's organs or tissues shall be paid by the OPO.

D. Medical Management and Recovery of the Organ Donor

1. The critical care attending, primary care attending physician, and/or the attending anesthesiologist shall continue full responsibility for the patient until such time as the patient's death is pronounced.

2. Comfort measures shall be taken to reduce or eliminate patient discomfort (including discomfort from the insertion of a cold perfusion catheter) and shall continue until such time as the patient's death is pronounced.

3. If the family requests to be at the patient's bedside when the withdraw takes place, and with the patient's next of kin or patient healthcare surrogate's consent, a cold perfusion catheter may be inserted to aide in the viability of organs. Perfusion will not be initiated until five (5) minutes after death has been declared.

a. The OPO will be responsible for obtaining an informed consent using the hospital's procedures consent form.

4. When a cold perfusion catheter is in place, the terminal wean may take place in the operating room or the ICU. Should the terminal wean take place in the ICU, then family members may be present.

a. Should the family choose to be present during withdraw and the death of their loved one, and consent was not obtained for a cold perfusion catheter, then the OPO must refuse this patient as a potential organ donor.

5. Perfusion shall not begin until five (5) minutes after death has been pronounced by the Critical Care Medicine, Primary, or Anesthesiology Attending Physician.

6. Removal of organs shall take place only in the operating room.

7. No incision, for the purpose of removing organs, may be made until five (5) minutes after death is pronounced.

8. Death shall be pronounced when the patient meets cardiopulmonary death criteria.

E. For the purposes of pronouncing death prior to the recovery of organs from non-heart beating donors pursuant to this policy, the following shall be confirmed in order to declare death:

1. Confirm correct EKG lead placement, AND
2. Confirm a pulse of zero (0) via the arterial catheter or EKG AND
3. Confirm a zero (0) blood pressure via arterial catheter or NIBP monitor AND
4. Confirm the patient is apneic, AND
5. Confirm the patient is unresponsive to verbal stimuli.

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Provided courtesy of SHANDS at the University of Florida, Gainesville.

# NON-HEART-BEATING DONOR GUIDELINES AND PROCEDURES OF THE NEW ENGLAND ORGAN BANK

## Background

### *The Concept of Death*

Most deaths are declared by an absence of cardiorespiratory function. However, as a simple and unifying concept, all deaths occur when there is permanent loss of the entire brain function. Thus, if there is no circulation to the brain for a sustained period, the hypoxic injury to the brain is irreversible. The absence of a heart beat during that period can be simultaneously used to declare death by a traditional criterion of death, but also as a sign that there is insufficient blood flow to the brain. All patients who satisfy the cardiorespiratory criteria of death will also satisfy the criteria of brain death, if there is no restoration of heart beat. Conversely, the loss of the entire brain function (which involves both cerebral and brain stem activity) does not permit the restoration of heart beat.

A loss of brain stem function is detected by an absence of spontaneous respiration (in the presence of hypercarbia). The consequence of permanent and irreparable loss of the entire brain function is death.

### *Brain Death and Organ Donation*

Ninety-nine percent of organ donors in the United States are declared dead by brain death criteria (UNOS, Richmond,VA). Thus, the importance of the brain death formulation in the process of organ donation cannot be underestimated.

The American Academy of Neurology (AAN) definition of brain death is "an irreversible loss of the clinical function of the brain, including the brain stem."

The three cardinal findings of brain death are: coma or unresponsiveness from a known cause, absence of brain stem reflexes (pupil, ocular, corneal, pharyngeal, and tracheal) and apnea. Confirmatory laboratory testing of brain death may include either an electroencephalogram, contrast or isotope angiography, isotope scanning, or transcranial doppler ultrasonography (1). Although these tests are not mandatory for the diagnosis of brain death in adults, they are recommended in children (2).

### *Non-Heart-Beating Organ Donation*

Prior to the establishment of the brain death diagnosis in 1968, organs were only recovered for transplantation after a patient was declared dead by the absence of heart beat and respiratory activity. Since then however, the number of organs obtained from non-heart-beating donors (NHBD) has been limited, be-

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Provided courtesy of the New England Organ Bank, Newton, Mass.

cause the absence of cardiorespiratory function adversely affects the suitability of organs for successful transplantation, and because of the ethical complexities surrounding the NHBD process. Brain dead donors (versus NHBD) are ideal because organ function is interrupted under controlled conditions which minimize ischemia.

The NEOB experience with NHBD in the last several years has been the successful transplantation of 6 kidneys from 4 NHBD donors at the Massachusetts General Hospital. Nationally, an Association of Organ Procurement Organization survey of 42 member OPOs recovering organs from 4002 cadaver donors in 1997, revealed 51 (1.2%) were NHBD. The rate of transplantation following recovery was 78% for kidneys (98 recovered: 76 transplanted); and 53% for livers (17 recovered: 9 transplanted).

However, as a significant shortage of cadaver organs for transplantation has persisted, many have proposed that the opportunity of recovering organs from NHBD be reconsidered more broadly. With the advent of health care proxies, advance directives, and a societal reluctance for extraordinary measures of medical treatment for the terminally ill, end-of-life decisions are being made in response to patients' known or presumed choice in the circumstance of such injury or illness. Clinical conditions have become recognized in which non-survivable brain injury may be determined, without fulfilling the criteria of brain death. As with the diagnosis of brain death, the cause of the irreparable brain injury must be determined. With the family's approval (and often at their request), a joint decision with the physician may be made to withdraw life-sustaining support as appropriate care for the dying patient. This practice has become common and it has evolved to a public acceptance, irrespective of organ donation. Some of these patients from whom life support is withdrawn may be acceptable organ donors after death. At the conclusion of all care rendering decisions, the opportunity for organ donation may also provide the family an important consolation at the time of bereavement. Therefore, in certain instances regarding withdrawal of life support, consideration of organ donation has also become appropriate.

**The Institute of Medicine (IOM) Report**

In June, 1997, the NEOB Board of Trustees placed a moratorium on the establishment of an NHBD protocol by the NEOB: "It was voted that NEOB not be involved in any further efforts to expand NHBD in the region, pending the results of the IOM committee's report. It was noted, however, that the two hospitals with current NHBD protocols were free to continue to implement them, and NEOB would assist in the recovery of any such donors as we have in the past."

In July, 1997, a Committee on Medical and Ethical Issues in Maintaining the Viability of Organs for Transplantation was convened by John Potts, M.D.

of the Institute of Medicine of the National Academy of Sciences. The ethical aspects of many NHBD protocols were examined.

The IOM subsequently issued a supportive review affirming the following:

- that NHBD is medically effective and ethically proper;
- that organ donors must be dead before organs are recovered;
- that NHBD should not be an entree to euthanasia (3).

*The NEOB Board of Trustees subsequently approved the widespread implementation of the NHBD protocol throughout the New England Region.*

## References

1. Wijdicks EF. Determining brain death in adults. Neurology 1995;45:1003–1011.
2. Mejia RE, Pollack MM. Variability in brain death determination practices in children. JAMA 1995;274:550–553.
3. Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement. Institute of Medicine, National Academy of Sciences. National Academy Press, Washington, D.C. 1997.

## NEOB Objectives by NHBD

The findings of the IOM are now favorable for the NEOB to develop guidelines for the NHBD process.

Thus, the following NHBD protocol is provided as a model approach consistent with the specific recommendations of the IOM.

The NEOB objectives are:

- to encourage a consistent practice of NHBD in accordance with the IOM report, in hospitals which refer organ donors to the NEOB;
- to maximize public confidence in the ethical basis of NHBD;
- to increase the number of organs available for transplantation.

Because the controversy surrounding NHBD necessitated a review process by the IOM, the NEOB would urge that each medical center present this protocol to its Institutional Ethics Committee, or Institutional Review Board, and to its appropriate Intensive Care Physicians for approval.

We also wish to stress that the process can only be initiated when the family and primary care physician have made a decision to withdraw terminal care, that is entirely independent of organ donation.

We recognize that NHBD will entail a distinct process of informed consent that is explicit regarding procedure. An informed consent must be obtained that alerts the donor family and the ICU staff of the possibility that the patient may not die within one hour of the withdrawal of life support, in which case organ recovery will not be attempted. Furthermore, we fully anticipate that the NEOB will undertake an extensive education of NEOB staff , transplant center staff, and the staff of all hospitals where an NHBD protocol is developed.

**Sequential Time Points of NHBD Process**

- Decision and consent by patient, family, or surrogate + primary care physician to withdraw life support.
- Separate discussion with family about organ donation by NEOB.
- Consent to donate organs after declaration of death—will also include consent for:
  - premortem femoral cannulation,
  - administration of heparin (required),
  - administration of morphine (requested and permitted as per PCP)
- Withdrawal of life support: (extubation from ventilator) administration of phentolamine (permitted)
- Determination of asystole (as determined by the PCP)
- 5-minute interval
- Declaration of death (by the PCP not associated with the transplant service)
- Commence infusion of preservation fluids: (through femoral cannula) (node recovery for tissue typing permitted)
- Organ recovery

**NEOB Model Protocol for NHBD (Elements for Center Review)**

A. Suitable patient who could be considered for NHBD
B. Opportunity for pre-mortem cannulation
C. Administration of medical agents
D. Conflict of interest safeguards
E. Request of Medical Examiner's permission for donation
F. Determination of death
G. Location of patient where death is determined.

- Issue item for further discussion: prognostication of death after the withdrawal of care.

H. Allocation of organs
I. Center education

J. Procedure prior to declaration of death
K. Procedure following asystole

**NEOB Model Protocol for NHBD**

A. The Suitable Dying Patient to Consider NHBD:

- Patient age 1 to 55 years.
- In those clinical situations in which patient, family, or other patient surrogate, and the responsible care physician decide to withdraw care from a patient who is dependent upon life support for survival,
- and when brain death criteria are not fulfilled because of either detectable cortical activity or persistent brain stem function by detectable intact brain stem reflexes or spontaneous respiratory effort, and when the decision to discontinue life support fulfills hospital established criteria to withdraw life supporting care,
- and a do not resuscitate order has been written,
- and the patient has otherwise suitable organ function: liver function tests satisfactory, creatinine <2.0 mg %,
- the patient will be considered for NHBD.

B. Opportunity for Pre-mortem Cannulation:
Femoral cannulation for the installation of preservation fluids:

- after decision to withdraw care and consent to donate
- before the heart stops
- before the patient is declared dead.

The IOM report is quite specific in this regard (page 53):

- "Cannulation does not hasten death, and it is important in preparing for rapid initiation of organ preservation and enhancing the chances of obtaining quality donor organs and the best graft results for recipients."
- "Cannulation is invasive, and, in a conscious person, painful."
- "The report finds that cannulation is acceptable in controlled NHBDs after a decision to donate is made and beginning just before withdrawal of life support or at anytime thereafter, but it recommends that consent always be explicitly required and that local anesthesia be used if needed."

The placement of a femoral venous cannula for exsanguination is optional to the discretion of the recovery surgeon.

C. Sedation, Anticoagulants, and Vasodilators:

a. administration of morphine at the time of femoral cannulation: morphine is not objectionable if the intent is to benefit the dying patient by easing any discomfort at the time of death, even if the morphine may hasten the death through the unintended effect of suppressing breathing.

b. administration of heparin at the time of femoral cannulation: is required.

c. administration of regitine or phentolamine:

the IOM report in this regard is as follows (page 52):

- "Although prescription of these drugs during organ procurement is deemed useful and is undoubtedly safe in the majority of instances . . . a blanket policy cannot be recommended because of possible untoward effects in some donor patients."
- "Physicians responsible for the care of individual donors should be able to make a clinical judgment on the advisability of using either heparin or phentolamine or both without hastening death."
- "Protocols should note that donor families should be specifically informed on these matters."

The administration of phentolamine should be carefully considered by each center only after the withdrawal of life support, before the patient's heart stops, and before the patient is declared dead, and only if the patient's family has given specific informed consent to its administration.

D. Conflict of Interest Safeguards:

The IOM report provides the following (page 55):

- "These safeguards require separating major decisions and discussions in patient care (withdrawal of life support, discontinuing CPR, and declaration of death) from major decisions and discussions in organ donation and transplantation (obtaining consent for donation and other transplant-related procedures and involvement in the actual process of organ retrieval)."
- "Such safeguards include scrupulous separation of patient care personnel from procurement and transplant personnel"

Thus, the NEOB process stipulates the following:

1. The physician who declares the patient dead must not be directly associated with the transplant team, or simultaneously involved in the care of an inpatient allograft recipient.

2. The physician who declares the patient dead must not be an anesthetist whose responsibility of care takes place in the operating room at the time of organ recovery.

E. Medical Examiner Approval:

No organ recovery will occur unless the Medical Examiner is notified and permission is granted, as is the NEOB policy for all organ donors.

However, since the donor may not be dead when the ME is notified, the ME will be alerted to the circumstance of NHBD.

Thus, the intention of withdrawal of life support etc. must be reviewed with the ME, as a condition of the ME approval for organ recovery after death.

F. Determination of Death:

The IOM report provides the following (page 59):

- "The definition of cardiopulmonary death is irreversible cessation of circulatory and respiratory functions. Clarification of the meaning of irreversibility and of the determination of death must rest on expert medical opinion."
- ". . . an interval of at least 5 minutes [must] elapse after complete cessation of circulatory function . . . before death is pronounced and organ perfusion or removal begins."
- "A patient may be declared dead after the withdrawal of terminal care if 5 minutes elapsed from the determination by the physician that the heart has stopped and that circulation has ceased."

(Attesting that circulation has stopped )

- "The accepted medical detection standards include electrocardiographic changes consistent with absent heart function by electronic monitoring and zero pulse pressure as determined by monitoring through an arterial catheter."
- ". . . decisions otherwise regarding the declaration of death are the responsibility of the primary care physician."

G. Location of Patient as Death is Determined:

Options: Intensive care unit or operating room

The advantage of initiating recovery in the ICU is to verify by public observation that no organ donor recovery procedure is begun until the necessary 5 minute interval has elapsed, after the patient is declared dead.

The disadvantage of bringing the patient to the operating room is the dilemma which arises if the patient does not die within an hour of the withdrawal of care.

The advantage of initiating recovery measures in the operating room is to minimize the warm ischemia time before the organs can be recovered.

The decision to pronounce death in either the ICU or the operating room may be influenced by the ability to prognosticate the cessation of breathing after the ventilator has been withdrawn. Inspiratory force on respiratory mechanics has been suggested as an approach to determine whether the patient will stop breathing after the ventilator is discontinued.

Unless a reliable prognostication regarding death can be forecast consistently, the NHBD process is hampered by the inability to predict a successful organ recovery.

Thus, personnel and resources could be delivered to the operating room with little prediction of death within one hour of life support withdrawal, and require the return of the patient to the ICU from the operating room.

H. Allocation of Organs:

The NEOB supports the immediate transplantation of organs recovered from NHBD, because of the emphasis of averting ischemic injury to organs already compromised by their recovery from an NHBD.

Thus, the NEOB supports the following UNOS Region 1 approach that would enable:

For livers:

- the transplant surgeon responsible for the patient who is allocated the liver by the standard UNOS rules will recover the liver for that patient, irrespective of the NHBD donor location.

For kidneys:

- When the NHBD donor is hospitalized at a transplant center: the transplant center surgeon responsible for the recovery of NHBD kidneys will receive a priority of performing the transplant of these kidneys to patients at that center.
- When the NHBD donor is at a non-transplant center: the transplant center surgeon identified as responsible for the recovery of kidneys (as previously defined by the current NEOB Policy, July 15, 1997) will receive a priority of performing the transplant of these kidneys for patients under the care of that transplant center.

NEOB Model Protocol for NHBD if initiated in the ICU:

Following decision to withdraw life support and consent to donate given (also following approval from the medical examiner):

1. Obtain Instrument Tray and Supplies from OR Instrument Room (1 cannulation kit, 1 cannulation tray, 1 bag sterile supplies, 1 bag non-sterile supplies.). Notify OR Staff of Impending Donor
   **To Be Done By:** *Transplant Staff*

2. Obtain: One set of clean stick blood cultures
   1 purple top (5 ml) + 1 red top (10 ml) (for Serology Testing)
   6 yellow top (10 ml) (for NEOB Tissue Typing)
   **To Be Done By:** *Request by ICU Staff*

3. Place Chilled 6 L. UW + 4 L. LR Solutions into ICU Refrigerator
   Notify NEOB Tissue Typing Staff of Impending Donor (tel. 617 732 5872)
   **To Be Done By:** *Donation Coordinator*

4. Place Ice Cooler and Ice in ICU (but not at the bedside, to avoid discomfort to family)
   **To Be Done By:** *Donation Coordinator*

5. Mix Additives to UW Solution per Liter:
   PCN 200,000 units
   Decadron 16 mg
   Regular Insulin 40 units
   Mix Heparin Solution:
   50,000 units in 250 ml saline (to infuse separately before UW in that line)
   **To Be Done By:** *Donation Coordinator*

6. Insure Adequate Wall Suction Apparatus at Bedside (sterile tonsil tip in instrument tray)
   **To Be Done By:** *Donation Coordinator*

7. Obtain 2 Portable IV Poles at Bedside
   **To Be Done By:** *Donation Coordinator*

NEOB Model Protocol for NHBD:

Following the Consent to Donate, Before Withdrawal of Care:

1. Notify the OR, and NEOB Technical Staff, via page, of Impending Travel
   **To Be Done By:** *Donation Coordinator*

2. Obtain Blood Samples:
   NEOB Tissue Typing:
   2 red top (10 ml)

2 green top (10 ml)
Tissue Donor:
2 tiger top (10 ml)
1 yellow top (10 ml) for PCR testing
**To Be Done By:** *Request by ICU Staff*

3. Place Ice Cooler, UW, + LR at Bedside
**To Be Done By:** *Donation Coordinator*

4. At Bedside: Shave/Prep Groin + Abdomen
**To Be Done By:** *Transplant Staff*

5. Femoral Artery and Vein Dissection
**To Be Done By:** *Transplant Staff*

6. Cannulate Femoral Artery with Organ Procurement Catheter or 22 Fr Baxter Fogarty Occlusion Catheter (60 cc sterile saline [250 cc bottle] to balloon) pump tourniquet around femoral artery
**To Be Done By:** *Transplant Staff*

7.

| | |
|---|---|
| Cannulate Femoral Vein (Argyle chest tube) | *Transplant Staff* |
| Extubate Patient | *Primary Care Physician* |
| Heparinize: (30,000 units to the central venous line) | *Donation Coordinator* |
| Determine Asystole | *Primary Care Physician* |
| Declaration of Death | *Primary Care Physician* |

After Declaration of Death:

1. Infuse 4 L. of UW Solution (+Heparin Solution) through femoral artery cannula at 1 meter hydrostatic pressure, raise level if needed or apply pressure bags
**To Be Done By:** *Donation Coordinator*
2. Exsanguinate femoral vein fluid into urimeter bags change bags at barrel connector
**To Be Done By:** *Donation Coordinator*

3. Insert Peritoneal (dialysis) Catheters x 2 (inflow and outflow)
**To Be Done By:** *Transplant Staff*

4. Initiate Iced LR Peritoneal Lavage: (2 L. q 15 minutes)
**To Be Done By:** *Donation Coordinator*

5. Proceed to the Operating Room for removal of liver and kidneys as soon as possible.
   **To Be Done By:** *Transplant Staff*

*All supplies and equipment to accompany patient to OR.

## UNIVERSITY OF PITTSBURGH MEDICAL CENTER PRESBYTERIAN, POLICY AND PROCEDURE MANUAL

**SUBJECT:** Non-Heartbeating Organ Donation
**DATE:** February 3, 1999

### I. POLICY

It is the policy of the UPMC Presbyterian (UPMCP) to strive to provide an ethically justifiable and auditable policy that respects the rig s of patients to have life support removed -and to donate organs if they wish to do so. The UPMCP presently has a policy regarding guidelines on life-sustaining treatment (Policy No. 4007). Patients or their surrogates can decide to forgo life-sustaining treatment, and the guidelines authorize comfort measures for patients wishing to forgo such treatment. Furthermore, all patients have the right to elect organ donation in the event of their death. For the last 20 years, the great majority of organ donors have been persons declared dead by brain death criteria. However, donation by persons who die from cardiac or respiratory failure is legal and was a commonly accepted practice before brain death criteria were established. The UPMCP believes that it is ethically appropriate to consider organ procurement from non-heartbeating donors. For correlating Western Psychiatric Institute and Clinic (WPIC) policy, see "Advance Directives" policy in the WPIC policy manual.

### II. MANAGEMENT OF TERMINALLY ILL PATIENTS WHO MAY BECOME ORGAN DONORS AFTER DEATH

A. Principles

1. Decisions concerning the treatment and management of patients (including but not limited to the decision to withdraw mechanical support and/or medications) must be made separately from and prior to discussions of organ donation. This means that appropriate candidates for withdrawal of life support shall be identified independently of donor status. Consideration of organ donation shall occur only after a decision has been made by the patient, surrogate, or family and physicians that the patient be assigned the status of "comfort measures only" as indicated in UPMCP policy Guidelines on LifeSustaining Treatment. (Policy No. 4007). Organ donation may be an important option for the patient and/or patient surrogate. However, harm can result if the issue of donation is inappropriately raised.

Consequently, health care professionals familiar with the concerns of the patient's family must use their judgement to determine whether to recommend a

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Provided courtesy of University of Pittsburgh Medical Center Health System.

discussion of organ donation when the issue is not raised by the patient or patient surrogate. The health care team-should consult with a representative of the Center for Organ Recovery and Education (CORE) to determine suitability for organ, tissue and eye donation, consistent with UPMCP Policy 5060, Organ and Tissue Donation.

2. It is the health care professional's primary responsibility to optimize the patient's care. The process of removing-life support shall be done primarily to promote patient comfort and respect patient autonomy. It is an important objective of this policy that the interest in procuring organs does not interfere with optimal patient management.

3. Appropriate candidates for organ donation shall be limited to those patients on life-sustaining treatment in whom withdrawal of that therapy is likely to result in death within a few hours (e.g. patients who are respirator or intra-aortic balloon dependent).

4. Interventions intended to preserve organ function but which may cause discomfort to the patient or hasten death are prohibited.

5. This policy explicitly prohibits any intervention whose intention is to shorten the patient's life except when forgoing life support.

6. Utmost attention and caution shall be taken to protect the dignity and rights of donors.

7. Health care professionals shall not be recruited to participate in the procedures described below if such participation is against their personal, ethical, or religious beliefs.

8. In this policy, the term "surrogate" decision maker is defined as specified in UPMCP policy Patient Consent (Policy No. 4011).

B. Procedures

1. The detailed discussion of organ donation shall be deferred until after the decision to withdraw life support has been reached. An agreement between the patient or patient surrogate and the attending physician at the patient is assigned the status of "comfort measures only" (as described in the Guidelines on Life-Sustaining Treatment (Policy No. 4007)) is required for the patient to be considered an organ donor according to this policy. The discussions with the patient or patient surrogate, leading to the decision to withdraw all life-sustaining therapy, must be appropriately documented in the medical record.

2. After it has been decided to withdraw life support, and if a discussion of the option of organ donation has not been initiated by the patient or patient surrogate, the health care professionals caring for the patient should decide whether it is appropriate to recommend such a discussion. The health care team should consult with a representative of CORE to determine suitability for organ, tissue and eye donation, consistent with UPMCP Policy 5060, Organ and Tissue Do-

nation. If CORE is not called for organ donation prior to withdrawal of life support, H will always be called for possible cornea and tissue donation in agreement with the required referral law and UPMCP policy (Policy No. 5060).

3. Organ procurement may proceed only if the patient or patient surrogate agrees to organ procurement upon death of the patient and signs the appropriate consent form. Consent for donation can be withdrawn at any time. No pressure or coercion shall be used to maintain consent.

4. Patients who are not competent and are without surrogates shall not be considered for organ donation.

5. Organ procurement may proceed only if, prior to signing the appropriate consent form, the patient or patient surrogate has met with a member of the Ethics Consultation Service. At that meeting, the ethics consultant should review the decisions to have life support withdrawn and become an organ donor. The ethics consultant will write a summary of the discussion with the patient or patient surrogate in the patient's medical record.

6. If any member- of the health care team perceives an ethical problem, he or she is encouraged to request a full ethics consultation.

7. The administrator-on-duty (AOD) shall be notified that organ procurement from a non-heartbeating donor is being contemplated.

8. Appropriate support will be provided for the patient, surrogate, or family by the health care professionals. Discussion should take place with the family regarding whether they wish to be present at the moment of the patient's death. If organ donation is agreed to-, health care providers should also discuss with the family their wishes regarding seeing the patient after organs have been procured. Pastoral care of the patient, surrogate, or family shall be provided in the Intensive Care Unit (ICU) by clergy, if requested.

9. The patient's attending physician(s) must agree with the proposed procedure and note this in the chart. He or she may be present in the Operating Room (OR) if he or she desires.

10. The responsible OR anesthesiologist or his or her designee (e.g., anesthesiologist in charge or on call) will be informed of planned terminal management in the OR and the possibility of organ procurement.

11. Once the patient or patient surrogate has expressed intent to donate organs, the patient's attending physicians) or his or her designee must inform the ICU gatekeeper of the request or organ procurement from a non-heartbeating donor. The ICU gatekeeper[1] will see that the management of the donor patient is in accordance with this policy. These activities shall involve an ICU staff physician (preferably the patient's ICU staff physician) under the authority designated for this purpose, who fit the criteria in Section II, part B, paragraph 13.

[1]ICU physician with responsibility for ICU bed allocation.

12. The responsibilities of the ICU physician withdrawing support include the following:

a. Review of the informed consent procedure to ensure that it has included discussion with the patient or patient surrogate of the following:

- the UPMCP's current policies regarding patients for whom the goal of care is comfort measures only;
- the process of removal of life-sustaining therapy;
- the process of organ procurement from non-heartbeating donors;
- that withdrawal of life-sustaining therapy will he completed in the operating room;
- that a femoral arterial catheter will be required;
- that while death is expected during or shortly after
- discontinuation of life support, removal of support may not always 1M to death of the patient in a very short time;
- that organs will not be procured until after the patient is declared dead;
- based on the medical judgment of the transplant surgeon, that organs designated for donation ma not be procured if certain problems occur (e.g. , due to ischemic injury);
- that death will be certified in accordance with existing Pennsylvania law; and
- that consent can be withdrawn at any time without cost or prejudice.

The physician withdrawing life support is also responsible for answering any questions the patient may have.

b. Deciding when to initiate transfer of the patient to the OR.

c. Managing the patient's care with the assistance of an ICU nurse in the OR or holding area.

d. Informing the surgeon when it is acceptable to start surgical preparation of the patient's skin (see below).

e. Certifying death. The physician certifying death must not be involved either in procuring organs or the care of any of the transplant recipients. Completion of the death certificate and death summary in the medical record are the responsibility of the primary clinical service.

f. Filling out and signing the Non-Heartbeating Organ Donor record (Form 2013-2255-1293) jointly with the ICU nurse.

13. The following criteria shall be used for selecting the supervising ICU staff physicians:

a. The physician must attend in an ICU.

b. The physician must have familiarity with the guidelines on life-sustaining treatment and the policy for removal of life-sustaining support in potential non-heartbeating organ donors.

c. The physician must have personal experience with termination of life support, and specifically with removal of life support from patients who have been designated "comfort measures only."

d. The physician shall have no clinical responsibilities on a transplantation service.

e. No physician who receives direct funding from a grant involving the transplantation team shall be involved in the management of donors in the OR.

f. Physicians shall be designated by the chairman of the ICU Committee and/or a UPMCP appointed credentialing committee.

g. ICU physicians who have an other basis for conflicts of interest in individual cases shall decline or not be asked to participate in withdrawal of life support and certification of death.

14. The surgical staff responsible for organ procurement shall in no way participate in the weaning process or in the donor's care. It is preferable that the operating team not be resent in the OR until certification of death except for skin preparation and draping as in procedure 18.

15. OR anesthesiologists who later might be involved in the management of recipients of the donated organs shall not participate in the weaning-process or other forms of the donor's medical management. During transport to and terminal management, all equipment (e.g., for assisted ventilation and monitoring) and drugs (e.g., sedatives and narcotics shall be brought from the ICU. Technical support, including oxygen, compressed air, and suction equipment may be provided by the anesthesiology staff.

16. If narcotics and sedatives are administered, these drugs must be titrated to the patient's need for provision of comfort. The administration of clinically appropriate medications in appropriate doses to prevent discomfort is acceptable, with titration of medication predicated on signs compatible with distress. Interventions intended to preserve organ function but which may cause discomfort to the patient or hasten death are prohibited.

17. If organ ischemia is prolonged (e.g., beyond two hours), it may not be possible to utilize organs designated for donation, and procurement may not be performed. The decision to cancel organ procurement because of prolonged ischemia rests with the responsible transplantation surgeon. Under these circumstances, the designated ICU physician may also decide to return the patient to the ICU.

18. No organs may he procured until death has been certified. To keep warm ischemia time to a minimum, all other appropriate preparations for the procurement operation may take place prior to death but never before the patient

has become totally unconscious and unresponsive to noxious or painful stimuli. Skin preparation and draping may be performed by the staff of the Pittsburgh Transplant Foundation.

19. For certification of death, the prompt and accurate diagnosis of cardiac arrest is extremely important. Procurement of organs cannot begin until the patient meets the cardiopulmonary criteria for death, that is, the irreversible cessation of cardiopulmonary function. The irreversible cessation of cardiac function is "recognized by persistent cessation of functions during an appropriate period of observation."[2]

Because of obvious concerns regarding conflict of interest, the criteria to be used in this policy are therefore more stringent than the standard clinical practice for declaring death in other patients who are designated "comfort measures only" but who are not candidates for organ donation. Clinical definitions of cardiac arrest, such as the absence of a palpable pulse in a large artery (i.e., the carotid, femoral, or brachial artery), do not suffice for this application. The absence of a clinically palpable pulse does not necessarily mean cessation of mechanical activity of the heart.

The diagnosis of death by traditional cardiopulmonary criteria requires confirmation of correct EKG lead placement and of absent pulse via a femoral arterial catheter. The pulse pressure must be zero, or by definition the heart is beating. In addition to pulselessness (as defined here), the patient must be apneic and unresponsive to verbal stimuli. Given the above, any one of the following electrocardiographic criteria will be sufficient for certification of death:

- 2 minutes of ventricular fibrillation,
- 2 minutes of electrical asystole (i.e., no complexes, agonal baseline drift only),
- 2 minutes of electromechanical dissociation.

20. Immediately after certification of death, organ procurement is to proceed following CORE protocol.

21. The procedure for organ procurement, cleaning of the body, and transfer to the morgue is to be conducted with respect and sensitivity to the deceased and his or her surrogate. This is the responsibility of the CORE.

[2]Report of the medical consultants on the diagnosis of death to the President's commission for the study of ethical problems in medicine and biomedical and behavioral research. Guidelines for the determination of death in the President's commission for the study of ethical problems in medicine and biomedical and behavioral research. Defining Death: medical, legal and ethical issues in the determination of death. 1981:162.

22. Procured organs from non-heartbeating donors shall be distributed in accordance with current UPMCP policies and United Network for Organ Sharing (UNOS) requirements.

23. Donor patients will not be charged for the costs of organ procurement (e.g., the use of the OR, special personnel, or medications used in the OR).

24. At least initially, cases will be reviewed by a committee composed of the chair person of the Medical Ethics Committee or designee, the director of OR Nursing Services or designee, and the chief of Anesthesiology at Presbyterian University Hospital or designee. A member of the Committee on Oversight of Organ Transplantation, reviewers external to the hospital, will be invited to observe these case reviews and the entire Committee on Oversight of Organ Transplantation will receive the conclusions of these reviews at least quarterly. The responsible ethics consultant, ICU physician withdrawing life support, ICU nurse, and transplant surgeon or designee will be expected to provide a verbal or written report in whatever detail appropriate. The physician withdrawing support and the ICU nurse will both sign the records indicating clinical observations and medications administered The purpose of this review is to:

a. assure that the above principles are adhered to;
b. assure that the above procedures are complied with;
c. identify problems and complications, potential or actual, and recommend changes toward their solution;
d. protect the interests of the donor, recipients, the UPMCP, and involved health care workers; and
e. assess the effect of these procedures on the family's grief process and determine whether changes could be made to improve the process for them.

## III. PATIENTS UNDERGOING "BRAIN DEATH PROTOCOL" WHO ARE PRONOUNCED DEAD USING CARDIAC CRITERIA

A. Individuals who are in the process of having death declared using neurologic criteria may become non-heartbeating organ donors if:

1. adequate consent has been obtained from the patient or patient surrogate; and/or
2. the patient has been pronounced dead by a physician not on the transplant team using accepted cardiac criteria.

B. Consent must specify the following:

1. The patient will be dead before any interventions for organ preservation are instituted.

2. The specific interventions (such as catheter placement, chest compressions, or heparin[3]) which are used to promote the preservation of organs in non-heartbeating organ donation.

C. The patient or patient's surrogate should understand that he or she may consent to organ donation and refuse any specific interventions which enhance non-heartbeating organ donation.

In these instances the patient may still be a donor only if the transplant team agrees to procure organs after death is declared using cardiopulmonary criteria without the use of the specified interventions.

D. The transplant team is not obligated to procure organs they feel are not viable.

SIGNED: Gail A. Wolf
Vice President, Clinical Operations
ORIGINAL: March 3, 1993
REVIEW MONTH: February
Policy Review Committee: February 3, 1999
Medical Ethics Committee: January 12, 1999
Medical Executive Committee: February 10, 1999
PRECEDE: April 1, 1998
SPONSOR: Chair, Medical Ethics Committee

[3]Chest compressions may be provided for circulation of heparin if consent has been obtained. If chest compressions are performed, ventilation should not be provided because it is not necessary for circulation of heparin, and may result in unexpected cardiac resuscitation.

(ATTACHMENT)

**GUIDELINES FOR REMOVAL OF LIFE-SUSTAINING SUPPORT IN TERMINALLY ILL PATIENTS WHO MAY BECOME ORGAN DONORS AFTER DEATH**

I. GOALS:

1.1 Humane removal of life support.

1.2 Provision of comfort for all dying patients, without direct intention to cause death.

1.3 Promote quality of care.

1.4 Achieve accountability.

*Attachment continues on next page.*

II. SPECIFIC GUIDELINES AND CORRESPONDING RATIONALE:

| GUIDELINES | | RATIONALE | |
|---|---|---|---|
| 2.1 | Patients will receive comforting medication only for demonstrated need, e.g., this could either be PRN medications or a fixed dose of narcotics for documented signs compatible with pain or other discomfort. | | |
| 2.2 | Although a drug is given with the primary intent of assuring patient comfort, it is recognized that the drug may have a secondary (unintentional) effect of hastening death. The justification must be noted in the patient's record. | | |
| 2.3 | No physician may purposefully deliver or order administration of any medication with the primary intent of hastening or causing death, since this is strictly prohibited by law. | | |
| 2.4 | All patients who manifest objective-evidence of stress or discomfort will be given comforting medication, unless there is proof that the patient cannot interpret these sensations. | 2.4 | There will be conscious patients who clearly can sense discomfort (e.g., patients with amyotrophic lateral sclerosis), and those who clearly cannot (e.g., cortical death). Clearly all patients who express discomfort discomfort should be treated. However, there is a continuous spectrum between those patients who clearly cannot sense discomfort and those who clearly can. Therefore, in order that no patient will suffer discomfort, all patients in whom cortical death has not been confirmed must be treated for objective evidence of discomfort. Examples of |

| | | |
|---|---|---|
| | | objective evidence compatible with discomfort include (but are not limited to) tachycardia, tachypnea, gasping or use of accessory respiratory muscles. |
| 2.5 | The ICU staff physician will titrate dosing of medication. | 2.5 Each patient is an individual and his or her response to therapy is not reliably predictable. Some patients will be sensitive, others tolerant. |
| 2.6 | The ICU staff physician will adjust the removal of all life support in a sequence and rate that best serves the patient. | 2.6 By decreasing the ventilator (or other life support) setting only when the patient is comfortable, it is less likely that the patient will have distress at the next lower ventilator setting. The timing and size of the decrement can be varied, but the patient shall be evaluated for distress prior to proceeding to the next level of support. |
| 2.7 | Neuromuscular blockade must be documented to have worn off or been reversed prior to initiating removal of mechanical ventilation. | 2.7 See Rationale 2.8. |
| 2.8 | Prior to initiating weaning, the ICU physician will verify that the patient is not receiving substantially more medication than needed to provide comfort. Continuous, stable infusions of narcotics or sedatives are not contraindicated if one of the following criteria are met:<br>1) Spontaneous ventilation. | 2.8 When more drugs may have been given than is required to maintain comfort, the concern is that when life support is withdrawn, the high levels of drugs rather than the underlying condition will be the cause of the patient's death. This concern may be relieved by the criteria listed:<br>1) Patients who have spontaneous ventilation are by definition not prevented from breathing; weaning may begin if there is no discomfort. |

*Continued*

| | GUIDELINES (*continued*) | | RATIONALE (*continued*) |
|---|---|---|---|
| 2.8 | 2) Signs of discomfort. | 2.8 | 2) Patients may be apneic from narcotics but still manifest discomfort or cognition. Patients who are uncomfortable shall be made comfortable even if a secondary effect is suppression of ventilation) from Guidelines on Life-Sustaining Treatment, Policy No. 4007). |
| | 3) Recovery of cognition (awareness). | | 3) Recovery of cognition adequately indicates reversal of sedation. |
| | 4) No evidence of sedating drugs by toxicology analysis. | | 4) Sedating drugs are not the cause of unresponsiveness. |
| | | | The requirement for at least one of the above criteria to be satisfied may result in a patient manifesting some minimal sign of discomfort before receiving additional comfort medication. |
| 2.9 | Patients who have received general anesthesia will not have ventilatory support removed until the anesthetic drugs have worn off or been reversed sufficiently to meet any of the following criteria:<br>1) Spontaneous breathing present,<br>2) Patient shows signs of discomfort,<br>3) No evidence of sedating drugs by toxicology analysis, and/or<br>4) Recovery of cognition (awareness) observed. | | |

| | | |
|---|---|---|
| 2.10 | The weaning process shall be documented, using the Non-Heartbeating Organ Donor Record (Form 2013-2755-04937). This shall include clinical signs justifying medications and clinical notes including time of loss or consciousness, apnea, etc. | 2.10 By making the entire schedule PRN, with objective criteria for each step and physician and nursing documentation, the process may be audited retrospectively to determine that only as much medication as necessary was given to the patient. |
| 2.11 | This weaning procedure will be used for any patient during withdrawal of mechanical life support, regardless of the patient's cognitive state at the initiation of the weaning process. | 2.11 The desire of a conscious patient for sedation may influence drug administration in that awareness of condition may be a form of discomfort. Therefore, a loss of awareness, as judged by clinical responses, may be provided at the patient's request. Profound sedation or narcosis may be provided only if required for comfort, because of the concerns expressed above (see 2.8). Because life support is withdrawn and comforting medications given according to patient need, progression of the weaning is titrated. |
| 2.12 | In case of accidental extubation, the patient will usually not be reintubated. The physician may elect to reintubate to manage precipitous signs of discomfort (either subjective or objective evidence (see above)) which are not readily relieved by titrating medication. | |

III. SAMPLE ORDERS AND SPECIFIC RATIONALE:

This section is for illustrative purposes only, and does not impose specific orders upon the attending physician.

| | WRITTEN ORDER | RATIONALE FOR ORDER |
|---|---|---|
| 3.1 | Premedication (e.g., diazepam, IV); may continue stable infusions of hypnotics/narcotics. | Anxiolytic, amnestic but not an apnea-inducing dose. Maintain current comfort medication. |
| 3.2 | Infusions of vasoactive drugs and other pharmacologic or mechanical life support that do not contribute to patient comfort may be discontinued. | Withdrawal of life support has been decided by the attending physician and the patient. Comfort measures only has been decided by the attending physician and the patient (or surrogate). Comfort measures only are provided in accordance with the guidelines on Life-Sustaining Treatment (Policy No. 4007). |
| 3.3 | For a spontaneous breathing rate below 24 per minute and no distress, decrease respiratory support (ventilator rate, tidal volume, $FiO_2$ or PEEP). | Ventilator weaning occurs only if no distress is present. No additional sedation is given because it is not needed. |
| 3.4 | For signs of discomfort (e.g., respiratory rate above 24 per minute, tachycardia, tachypnea, gasping or use of accessory respiratory muscles) give narcotics or sedation (e.g., morphine IV). | Weaning is on hold and sedation is given because of evidence of distress. |
| 3.5 | When ventilatory support is stopped, remove ventilator. Patient may be extubated. | Weaning completed. |
| 3.6 | Continue order 3.4 PRN after the ventilator has been removed and patient has been extubated. | Provides for continued patient comfort after weaning has been completed. |

# WASHINGTON HOSPITAL CENTER: PROTOCOL FOR THE RAPID ORGAN RECOVERY PROGRAM, TRANSPLANTATION SERVICES

## Overview

The single greatest factor limiting the number of renal transplants performed today is the size of the donor pool. The number of patients awaiting renal transplantation today is greater than ever, but the size of the donor pool has failed to increase to meet this demand, and in fact, has shrunk slightly in the last several years. We have proven that kidneys can be recovered from the NHBD and through utilization of unique pulsatile preservation methods verify viability of these organs prior to transplantation. Work in Europe suggests that, addition of the Non-Heart-Beating Donor (NHBD) to the pool could increase the number of available kidneys by at least 20%.

In the fall of 1993, under the sponsorship of the Medlantic Research Institute, we hosted a Consensus Conference on the Asystolic Trauma Donor. Expert panels addressed medical, legal, ethical, social, and community concerns raised by our proposed protocol for recovering organs from victims of fatal trauma in the MedSTAR. The conferees concurred with protocol implementation with a variety of recommendations.

We have implemented those recommendations and have undertaken the recovery of kidneys from the NHBD for transplantation. Successful kidney recovery has taken place. Steps have been taken to meet the recommended requirements for community education. However, a variety of research initiatives must continue to explore consent issues, community attitudes, experimental aspects of organ recovery, training and education. Our goal is to assure that the option of organ donation is available to all potential donor families, successfully recover transplantable organs and recover costs.

## Design and Methods

### *Oversight*

This protocol is subject to the oversight of an advisory committee, as recommended by the consensus conference participants. This committee is composed of community members who have an interest in seeing that the program is sensitive to community needs and concerns. The Community Oversight Committee is comprised of nurses, physicians, morticians, clergy, legal services representatives, D.C. Government officials, educators, and local transplant groups. The advisory committee is currently chaired by the Director of the Office of Decedent Affairs and reports directly to the office of Community Affairs of the

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Provided courtesy of Washington Hospital Center, Washington, D.C.

Medlantic Healthcare Group. This advisory committee meets at least on a quarterly basis and began in December 1993. All policies, protocols, and practices will be available for review by the Community Oversight Committee.

There will also be regular reports submitted to the IRB for continuing review. Although the Rapid Organ Recovery Program does not constitute a research program, we are requesting the same consideration under the existing internal review mechanisms. We feel that because of the nature of the program and the community that we serve, the internal review board must be kept apprised of the program's progression and offer advice or direction as the board deems appropriate.

*Donor Criteria*

Potential Non-Heart-Beating cadaveric organ donors will include all patients pronounced cardiac dead in MedSTAR, an ICU or the Emergency Department at Washington Hospital Center. The potential donors will be limited to the following criteria of acceptability:

- Patients should generally not be over 60 years of age or younger than 18 years of age (<18 with next-of-kin consent). Exceptions will be made on a case by case basis.
- Patients D3 = have a known time of death.
- Patients *must not* have active, untreated systemic bacterial sepsis at the time of death.
- Patients *must not* have documented positive testing for HIV, HBsAg, or HTLV1.
- Patients *must not* have cancer except primary brain tumors, lip/skin cancers, in-situ carcinomas.
- Patients *must not* be among those classified high risk by the CDC, including homosexual/bisexual males, current I.V. drug abusers, or patients with hemophilia/coagulation disorders.

The identity of the patient *must* be known. In those cases where the identity of the patient is unknown, the Family Advocate will make an assessment of the known circumstance of death that will include discussions with the involved law enforcement agency. Line placement pursuant to the provisions of the Anatomical Gift Amendment Act of 1996 will not occur unless a high probability of patient and next-of-kin identification and notification can be accomplished within four hours after the known time of death.

*ICU Donor Protocol* (*controlled donors*)

There are several avenues to obtain organs from non-heart-beating donors in the Intensive Care Units. Any patient over 60 years old from whom withdrawal of support is anticipated and who is expected to suffer a cardiac death shortly after withdrawal (<48 hours) should be considered a potential donor. When such patients seem medically suitable according to the criteria in this document, a member of the primary or critical care team should notify the ODA. After the approval of the responsible intensivist the ODA will contact the Medical Examinees Office (if necessary) and WRTC to evaluate the patient. The WRTC coordinator will discuss the potential of organ acceptability with the intensivist. The patient's attending along with the critical care team will discuss withdrawal of support with the family or person responsible for the patient's health care decisions. If organs seem acceptable a member of the primary or critical care team will introduce the family to the WRTC coordinator who is generally the individual who will discuss the option of organ donation along with the ODA Family Advocate. The family member or other person responsible for the patient's healthcare decisions may then elect to have organs donated. If consent for organ donation has been obtained, the primary medical team and critical care team will notify the ODA of the impending withdrawal of support. The ODA will communicate with the ROR team and WRTC to coordinate their efforts with the primary or critical care team which will direct the withdrawal process. If the patient dies during or after the withdrawal of support the ROR line placement and preservation protocol will be instituted. A patient will remain in the ICU during this time unless it is determined that the OR, MedSTAR or the PACU is the preferred setting.

To accomplish preservation, abdominal cooling lines will be inserted. Next the femoral artery and vein will be accessed and a catheter inserted within the 60 minute time allowance. The kidneys will be flushed with a perfusion solution designed to limit the amount of ischemic damage which the kidneys will sustain. Once cooled, the donor can be maintained up to four hours until an operating room is available and a standard operative recovery can be performed.

*Fatal Trauma Victim Protocol* (*uncontrolled donors*)

The second method for recovering organs from non-heart-beating donors is applicable to patients in MedSTAR or the Emergency Department who suffer uncontrolled cardiac arrest In this situation it is imperative that the respective unit physicians pronounce death prior to any intervention from the Transplantation Services Department and that there be a clear delineation of the time of death versus the initiation of organ preservation protocols. Based on recommendations made by the attendees of the "Trauma Victims as Organ Donors; Con-

sensus Conference," numerous steps have been taken to educate the community about this program.

Since appropriate steps have been taken, and with concurrence from the Community Oversight Committee, it has been determined that line placement for the purpose of preserving the option of donation for the next-of-kin is both legal (Anatomical Gift Amendment Act of 1996) and appropriate in the event that the family is not present. If the family is present, the Family Advocate must obtain consent prior to the placement of the cold preservation lines. It has been documented that most of the potential ROR cases will arrive in MedSTAR without family present and this constraint has jeopardize the success of the ROR Program. However, data has been accumulated to show how families will respond to the placement of preservation lines.

When a potential donor is identified, the Trauma Fellow, Trauma team leader (R4), trauma nurse, or designee in MedSTAR shall page the in house Family Advocate through the in-house MedSTAR emergency page system. MedSTAR staff may participate in the ROR Protocol only in a support role to the line placement team. This type of support may include locating supplies and movement of the decedent to a more suitable location for line placement. They may not participate in direct hands-on donor preservation line placement.

*Placement/Transfer of Potential Rapid Organ Donors*

Potential ROR donors shall be cared for in MedSTAR, an ICU or the PACU until organ recovery occurs. Under no circumstance should these patients be transferred to a floor to await ROR unless specific arrangements are made between the ICU medical staff and the Nursing Supervisor covering the ICU.

*Consent*

A majority of deaths in MedSTAR or an ICU may fall under the jurisdiction of the Medical Examiner for the District of Columbia. The Family Advocate shall assist with notification and must obtain consent from the M.E.'s office prior to initiation of any procedure, should this death fall under their jurisdiction. Regardless of the next-of-kin's wishes, the Medical Examiner has the right to object to donation of any organs or tissues, if such removal would have a potential impact on the determination of cause and manner of death. *Under no circumstances will any procedure be initiated without the Medical Examiner's approval*. Once the Medical Examiner has agreed to allow intervention, the Family Advocate will immediately page the Line Placement Team.

The Family Advocate shall be responsible for responding to the MedSTAR unit immediately and determining whether a decedent is a possible Rapid Organ Recovery candidate. Tile determination will be made in consultation with the attending physician/intensivist. The Family Advocate will then immediately

page the Line Placement Team A search in conjunction with local authorities will be instituted if a family member cannot be located. The Family Advocate is responsible for offering the option of organ/tissue donation to the decedent's next-of-kin. The consent will be obtained utilizing the standard Uniform Donor Form according to WHC Standard Practice # 583.20 and ODA SOP#C.300. Additionally, the decedent's medical/social history must be obtained from the legal next-of-kin and documented utilizing the standard WRTC Medical History Form.

A Line Placement Team will be available in-house 24 hours a day to respond to preservation calls. If deemed necessary, the team member will draw 10 cc's of blood and run a STAT viral screening. Should the potential donor show positive, efforts for organ preservation will be discontinued. Negative test results will continue the procedure. Two 10cc red top tubes and one lavender top tube of blood will be drawn and labeled. One red top tube will be held for the project coordinator to be sent for virology testing and the second sent by MedSTAR/ICU staff to the stat lab for ABO determination, BUN, Creatinine and Electrolyte levels. The lavender top will also be sent by MedSTAR staff for CBC evaluation. Aerobic and Anaerobic blood cultures will also be drawn and sent. The bladder will then be catheterized and a specimen sent for stat urinalysis and urine culture. An additional 3 red top tubes of blood must also be drawn for the Medical Examiners Office along with as many PVC test tubes of urine as possible. All tubes must be labeled with the donor's name, social security number (if available), medical record number, and the date and time of death. A visual image will be recorded at the medical examiner's request. WRTC will be advised as soon as possible as to the whereabouts of the blood samples. The WRTC Coordinator will notify the central donor lab so that arrangements can be made for the transport of the samples to that lab and serological testing can be initiated.

*Line Placement Technique*

A cooling blanket should be placed under or over the donor and set at the lowest possible setting. This is used as an adjunct to core cooling the donor. Supplies for the cannulation and flushing procedure will be provided by the Line Placement Team. A member of the Line Placement Team place the abdominal lavage lines and cannulate the femoral artery and vein in the following manner:

1. PERITONEAL LAVAGE:

Two small incisions in the abdomen shall be made to insert the in-flow and outflow peritoneal lavage trocars. A sterile disposable trocar, Auto Suture, Surgiport, 1–1.5 mm, provided in the onsite donor kit) is then placed through the abdomen into the peritoneum, preferably in the patients right upper quadrant, to facilitate infusion of peritoneal lavage. An second modified trocar (with holes in

it) and pool suction cannula should be placed in a similar fashion into the left lower quadrant directed towards the pouch of Douglas for outflow. Cold 0.9% Saline solution is infused until abdominal distention is noted (usually 4 liters). This tubing will be connected to a sterile submersion pump. This ravage should be run continuously until stopped by the Transplant Recovery Surgeon. Documentation must be maintained according to Standard Operating Procedures regarding the amount, type and flow rates of fluid used in the lavage on the NHBD/MedSTAR Flow Sheet.

2. PERFUSION CATHETER:

A femoral cut-down is performed. The femoral artery is isolated and controlled with a 0 Silk ligature. An arteriotomy is performed and a Porges Multiple Organ Recovery Balloon Catheter passed to the level of the xiphoid process and inflated with approximately 15cc of 50% hypaque solution. The Porges Catheter is placed in the femoral artery for the purpose of infusing the perfusate. The infusion tubing should be connected to the mixed perfusate I.V. solution and primed to expel any air in the line. The arterial access catheter is then connected to the primed infusion tubing. The tubing may be secured to the patient with a 0 Silk suture. The occlusion balloon is also inflated. *IN SITU FLUSH SHOULD BEGIN NOW*.

The flush solution shall consist of several liters of Viaspan solution, each augmented with:

4 mg Stelazine
40 units insulin
16 mg dexamethasone
20,000 units heparin

3. EFFLUENT CANNULA:

In the same cut-down site utilized for placement of the perfusion catheter, the femoral vein is isolated and controlled with a 0 Silk ligature. A venotomy is performed and a marked 22 or 26 fr. Foley Catheter is inserted to the marking to allow venting for the perfusate solution. This 30cc balloon is to be inflated with approximately 20–30 cc of 50% hypaque catheter must be pulled taut to set the balloon at the femoral bifurcation. The catheter be secured with a 2-0 Silk ligature. The distal end of the venous catheter is connected in a sterile fashion to a 2000 cc urine collection bag. Drainage %*All be accomplished by gravity only, and riot with the assistance of suction.

ALL SUPPLIES NECESSARY FOR CANNULATION AND PERFUSION ARE SUPPLIED IN THE ON-SITE RAPID ORGAN RECOVERY CART

These solutions shall be maintained at 4°C until the time of infusion. (Refrigerated until the patient is included as a candidate for donation and then placed in the provided igloo cooler on ice.) Pre-mixed solutions shall be stored in the refrigerator located in MedSTAR and should be used only if there is no time to mix them in the lab under sterile conditions. To allow for optimal kidney flush and preservation, the solutions should be infused at 70 mm Hg of pressure.

The infusion pressure may be approximated by raising the I.V. pole and/or by providing pressure bags as an adjunct. The Line Placement Team will monitor of the flush solutions for continued inflow and outflow. Flow characteristics and other parameters to be measured are found on the ROR/MedSTAR Flow Sheet.

*Organ Recovery*

Organ recovery will not be initiated without consent of the legal next of kin, consistent with current practice. Once preservation attempts are completed, consent for organ/tissue retrieval is obtained, and the recovery surgeon and the WRTC coordinator are present, the body of the donor will be removed from either the MedSTAR unit or the ICU unit. It should be noted that this process will not be delayed if the WRTC Coordinator is not present when the recovery surgeon is ready to proceed with the recovery. The recovery will be performed using standard technique. Efforts to topically cool the kidneys by peritoneal lavage will be discontinued at the request of the surgeon.

1. The body will be prepped from the neck to the pubis and draped in the usual fashion.
2. A midline incision is made from the sternal notch (sternal saw required) to the symphysis pubis with bilateral supra umbilical transverse extensions through the skin, subcutaneous layer, fascia, and muscle. Hemostasis is obtained using the electrocautery.
3. The right colon and small bowel mesentery are then reflected to expose the retro peritoneum from the aortic bifurcation to the renal veins. The abdominal organs will be visually inspected. If upon inspection the organs they appear well flushed and cool to the touch, a hepatectomy, pancreatectomy and/or a bilateral en-bloc nephrectomy (as approved by the M.E. and family consent), will be performed as described below. The abdominal cavity and kidneys are then packed with iced saline slush.
4. The kidney, renal vessels, and ureter are carefully dissected with Metzenbaum scissors, DeBakey forceps, and Dean hemostatic forceps. One method of resection of en bloc resection, involves the removal of sections of the inferior vena cava and aorta with both kidneys in continuity. An incision is made along the route of the small bowel mesentery up to the esophageal hiatus. The entire gastrointestinal tract, spleen, and inferior portion of the pancreas are mobilized by dividing the celiac axis and the superior mesenteric artery, exposing the en-

tire retroperitoneal region. The inferior vena cava and aorta are clamped below the renal vessels with vascular clamps, and the vessels are divided.

Lumbar tributaries are secured with metal clips and are divided. The kidneys and ureters are freed from their surrounding soft tissues. The ureters are divided distally at the pelvic brim. The suprarenal aorta and inferior vena cava are clamped and divided superior to the diaphragm. The vessels and kidneys are severed from the surgical field, and the aorta and vena cava are ligated.

5. After removal of the kidneys, the kidneys are moved to the back table and are placed in a container of cold saline solution and surrounded by saline slush where they are immediately flushed with cold (8°C) Viaspan solution. Careful inspection, dissection and measurement are carried out on the back table. Cultures of the abdominal fluid, the ureter tips and the organs and the basin containing sterile slush will be obtained and sent to the microbiology laboratory. A wedge biopsy will be obtained of the liver as well as each kidney and sent to surgical pathology for both a frozen and permanent section.

6. The kidneys are then placed in the hypothermic pulsatile perfusion machine for transport to the MRI/HUH OPL for monitoring and evaluation.

7. While kidney perfusion is begun, the abdominal lymph nodes and spleen are removed for use in tissue typing.

8. The incision is closed with heavy running suture.

A video tape may be made at the request of the Medical Examiner of the initial incision and the recovery physician will verbally note any pertinent observations. This tape will be labeled with donor name and date and will be sent to the Medical Examinees Office. Finally, any other tissues donated (e.g., corneas, heart valves, skin, bone, etc.) by the next-of-kin will be procured by the appropriate tissue agencies. All relevant parameters and interventions will be recorded. The WRTC on site coordinator will observe the surgical recovery and record the anatomy of the kidneys. Photos of the recovered organs will be taken for documentation purposes.

*Kidney Preservation*

The kidneys will be placed on a hypothermic pulsatile perfusion machine in the Operating Room where they will then be transported to the Medlantic Research Institute/Howard University Hospital Organ Preservation Lab for perfusion and evaluation. The kidneys will be perfused with a modified commercially available solution used in standard ex-vivo kidney perfusion. Appropriate parameters for kidney function and status such as temperature, flow rates, ph and perfusion pressures will be measured and recorded over the next four to six hours, to determine organ viability as well as suitability for transplantation. Patient history prior to injury, hemodynamic parameters prior to death, warm ischemic time, cannulation and flush characteristics, biopsy and perfusion characteristics will be used to

determine the viability of the kidneys and to assess the potential suitability for transplant. Once the kidneys have been deemed suitable for transplantation by the MRI/HUH Organ Preservation Lab Co-Medical Directors and the WRTC Medical Director through a conference call initiated by the MRI/HUH Organ Preservation Lab staff, the WRTC Coordinator will be notified so that recipients may be located and the kidneys placed as per UNOS Standards. Placement will not take place until the kidneys are on pump for a minimum of 6 hours. In the event that one or both of the MRI/HUH Co-Medical Directors are unavailable for consultation, the organ recovery surgeon will be responsible for organ suitability evaluation and communications with the WRTC Medical Director.

Kidney preservation will be performed according the MRI/HUH Organ Preservation Lab's Standard Operating Procedures, under licensure from the District of Columbia Department of Consumer and Regulatory Affairs. Post perfusion photos of the kidneys will be taken for documentation purposes.

## Community Education

One of the most important factors in the success of the Rapid Organ Recovery Program is effective community education. The primary concern of the participants of the 1993 Consensus Conference was that of community education and awareness of the Rapid Organ Recovery Program. To this end, the Office of Decedent Affairs has planned and conducted more than 30 educational presentations. Media coverage of the program has been extensive. The Community Oversight Committee designed a survey which has also been utilized to assess public attitudes toward the Rapid Organ Recovery Program. Presentations have been made to key D.C. City Council Members as well as the mayor, all expressing support for the program. A program brochure will be made available to potential donor families and the community at large. The brochure has been developed through the efforts of the community oversight committee.

## Facilities and Equipment

The placement of preservation lines will take place within the Washington Hospital Center. Potential donors will remain in MedSTAR/ICU until Operating Room time is coordinated. All necessary line placement equipment and supplies were purchased previously and are available. Organ recovery will take place in the WHC operating room. Kidneys will be placed in the Medlantic Organ Preservation Lab's MOX perfusion pump while in the OR and transported to the MRI/HUH Organ Preservation Lab for preservation and evaluation. The MRI/HUH OPL is fully equipped and ready to perfuse and evaluate ROR organs. No additional equipment will be necessary.

**Collaborators/Consultants**

These costs are reimbursable and are outlined in the WRTC billing agreement when organs are recovered and transplanted.

## Conclusion

The recovery of organs from this donor source will clearly be a major advance in increasing the supply of available organs for transplantation. It has been shown that the recently deceased cadaver is a medically acceptable source of organs for transplantation. By utilizing this donor source both the number of patients waiting for cadaveric transplantation, and the time these individuals must wait for such a transplant will be reduced. Further, a wider pool of potential matches for those patients with uncommon HLA antigens will be available. In addition, more patients and bereaved families will now have the unique opportunity to gain solace from organ donation.

We have, in the past year, shown that kidneys recovered from this donor source can be successfully recovered and transplanted by our program. Major steps have been taken to insure compliance with the recommendations made by the participants of the Consensus Conference. We have spent the past year crawling and it is now time to walk. Several other transplant centers are exploring the possibility of utilizing kidneys from non-heart-beating donors. However, only a handful of transplant centers in the U.S. have actually recovered and transplanted kidneys from this donor population.

All charges incurred in the evaluation and procurement of these kidneys for transplant will be paid through an agreement with WRTC either through standard billing mechanisms or direct WRTC billing from the Medlantic Research Institute Transplant Research Center.