

Donation After Cardiac Death: Analysis and Recommendations from the New York State Task Force on Life & the Law

Introduction

The scarcity of organs for transplantation, an ongoing crisis, has inspired many initiatives to increase supply. Within this context, donation after cardiac death (DCD) is receiving considerable attention. Of note, the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) required all hospitals to develop policies for DCD, effective January, 2007.¹ Similarly, the United Network for Organ Sharing (UNOS) proposed new bylaw amendments requiring all transplant centers and Organ Procurement Organizations (OPOs) to develop DCD policies by January 1, 2007.² In response to these initiatives, hospitals in New York and around the country are creating DCD policies. To assist in the development of consistent and appropriate policies for DCD, a 2005 national conference of transplant professionals, bioethicists and others reviewed issues related to DCD and formulated consensus guidelines.³

However, even as DCD gained acceptance, it has engendered controversy. Some practitioners express reservations about the ethical propriety of various aspects of DCD. As a result, individual facilities invest considerable time and effort to devise policies that address the interests and concerns of patients, families, and practitioners. Many facilities request guidance in crafting appropriate and consistent guidelines that address both ethical questions and specific issues within New York law.

This Task Force report provides ethical and clinical guidance for facilities in New York that are drafting and/or reviewing policies for DCD. It reviews the history of DCD, describes the DCD process, analyzes areas of legal and ethical tension within the practice of DCD, and attempts to resolve those tensions. The document includes specific recommendations for clarifying legal and ethical issues related to DCD in New York.

History of Donation After Cardiac Death

Nobel Laureate Dr. Joseph Murray performed the first human organ transplant at Peter Bent Brigham Hospital in 1954. In this transplantation, Ronald Herrick donated a kidney to his identical twin, Richard, who lived for another 8 years post-transplant. Transplantation might have remained a novelty if it could only serve identical twins, one with a failing organ and another with a spare and healthy organ. Shortly after Murray's initial success, however, physicians sought to expand the applicability of transplantation both by overcoming the hurdle of organ rejection and by identifying additional sources of organs.

Transplantation pioneers began to use organs from live donors other than identical twins, as well as from recently deceased patients. Daunting technical difficulties emerged, regarding both immune suppression and organ viability, as the donor pool expanded beyond living identical twins. Yet less than a decade after Murray's ground-breaking effort, Dr. Thomas Starzl and others reported a series of 12 renal transplants using various methods to decrease rejection and increase organ function; 10 organs came from live donors and 2 from deceased donors.⁴ Among the recipients from living donors, 9 patients survived; both recipients of organs from deceased donors died. Of note, all deceased donors during those early years met

cardiopulmonary criteria for death, the only standard then in existence. Early experiments using donation after cardiac death proceeded without ethical reservation. However, transplantation of organs from these early donors after cardiac death produced disappointing results. Transplant pioneers met with greater success through the emerging practice of donation after brain death.

Determination of Death: In 1968, the Ad Hoc Committee of Harvard Medical School established the standard for brain death, defined as “the irreversible cessation of all brain function.”⁵ The clinical indicators of brain death include coma, lack of brainstem reflexes, and apnea. The Ad Hoc report prompted legislatures around the country to clarify the legal status of brain death. New York State relied upon case law to confirm the legal validity of brain death.⁶ New York’s Department of Health produced voluntary guidelines for the assessment of brain death, most recently revised in 2005.⁷ In contrast to neurologic criteria for death, the cardiopulmonary criteria are the irreversible cessation of heart and lung function. Patients who meet either cardiopulmonary or brain death criteria are legally dead; both sets of criteria are valid ways to document the same state.

Brain death is a function of modern technology. In brain death, all aspects of brain function have failed, including the brain apparatus that maintains breathing; without a ventilator a brain dead person’s lungs do not function and the person will meet cardiopulmonary criteria for death. When brain dead persons are attached to ventilators, continued oxygenation may temporarily preserve the viability of organs. In contrast, patients who meet cardiopulmonary criteria for death lack heartbeats and respiration; by definition their organs are not supported by ventilators and receive neither blood flow nor oxygenation.

Prior to the introduction of the Harvard Brain Death criteria, organs were recovered only from living donors or individuals meeting traditional cardiopulmonary criteria for death. Following the establishment and acceptance of the neurological criteria for death, donation after brain death became far more common in the U.S. than donation after cardiopulmonary death. Organs from brain dead donors suffered less trauma and produced better outcomes than those from donors after cardiac death. Moreover, brain death standards permitted the recovery of organs, including hearts, which are difficult to obtain via donation after cardiac death due to their great sensitivity to ischemia. Importantly, it was the technical superiority of the recovered organs that drove the move away from donation after cardiac death and toward brain death, rather than ethical reservations about DCD.

Institute of Medicine Reports: In 1997, the Department of Health and Human Services (HHS) requested that the Institute of Medicine (IOM) review ethical and technical aspects of DCD (then known as “non-heart beating organ donation”). Both health policy and transplantation experts were alarmed at the shortage of organs for transplant, and hoped to increase supply. In addition, controversial information emerged regarding the practice and meaning of DCD. Specifically, a bioethicist in Ohio learned of a proposed DCD protocol at the Cleveland Clinic and was convinced that the process involved euthanasia to obtain organs.⁸ Rather than review her concerns with officials at the Cleveland Clinic, she met with the local district attorney and also appeared on the television show *60 Minutes*; this controversy occurred just prior to HHS’ request to IOM to assess ethical and clinical aspects of DCD.

Far from condemning DCD, the IOM produced two separate reports, in 1997 and 2000, that define and support the process.⁹ The 1997 report notes that the contemporary practice of DCD depends upon appropriate policies for and acceptance of the withdrawal of life-sustaining treatments such as mechanical ventilation. The report describes the increased attention to DCD

in the 1990's at leading transplant centers such as those at the University of Wisconsin at Madison and Pittsburgh. The report also includes a review of all known DCD policies at the time of publication. The protocols varied in significant ways as facilities worked to resolve tensions surrounding this end-of-life procedure. These same issues concern facilities that are currently devising DCD protocols. Policies vary regarding the permissibility and timing of specific interventions, including the use of medications, including heparin, the insertion of cannulae into donors before death, and the period of time elapsed between cardiac arrest, declaration of death, and organ retrieval.

The 2000 IOM report was commissioned by HHS to provide guidance for organ procurement organizations (OPOs) in developing appropriate procedures for DCD. IOM staff reviewed and analyzed changes in protocols since the publication of the 1997 report, and noted impediments to DCD.

Institute of Medicine Report: Recommendations
<ul style="list-style-type: none"> ● All Organ Procurement Organizations (OPOs) should explore DCD in cooperation with local hospitals, health care professionals, and communities. A protocol must be in place in order for DCD to proceed. ● The decision to withdraw life-sustaining treatment should be made independently of and prior to any staff-initiated discussion of organ and tissue donation. ● Statistically valid observational studies of patients after the cessation of cardiopulmonary function need to be undertaken by appropriate experts. ● DCD should focus on the patient and the family. ● Efforts to develop voluntary consensus on DCD practices and protocols should be continued. ● Adequate resources must be provided to sustain DCD in order to cover the costs of outreach, education and support for OPOs, providers and the public, as well as any increased costs associated with DCD recovery.
Institute of Medicine Report: Obstacles to DCD Implementation
<ul style="list-style-type: none"> ● Hospitals: lack of protocols, lack of interest, physician resistance ● OPO: limited financial and staff resources for training and outreach, limited technology and expertise ● Organs: concerns about organ quality, adequate organ supply without DCD donors ● Ethics: medical interventions, termination of life-sustaining treatment, determination of death

Technological improvements led to an increased capacity to preserve organ viability in the context of DCD. Certain centers continued to perform DCD even as donation after brain death became more common; these centers helped improve techniques.¹⁰ In addition, the concept of brain death inspired substantial controversy in Japan, which did not adopt legal standards for brain death until 1997. Transplantation there relied upon live donation and DCD, contributing to the study and improvement of DCD techniques.¹¹

Current Developments in Transplantation and DCD

Demand for transplantable organs continues to grow at a rate that far outstrips supply. In part, transplantation is the victim of its own success. Continued advances in fighting organ rejection and preserving function in transplanted organs make transplant an attractive option.

Both survival and quality of life are improved for patients after renal transplantation, as opposed to those who continue with dialysis.¹² There are many causes for the growing number of patients with end stage organ disease; contributing factors include increased rates of obesity, diabetes, and hypertension leading to renal failure. High rates of hepatitis C, in addition to cirrhosis and other factors, contribute to liver failure.¹³ Medical advances, too, play a role. Many patients now survive life-threatening illnesses, such as heart attacks, yet do so with substantial chronic impairment. Significant resources have been devoted to promoting organ donation, and rates of donation are increasing as a result. However, wait lists continue to grow. Transplant advocates seek to maximize possible sources of organs, including those from brain dead donors with less than optimal, or extended criteria, organs.

Renewed focus on DCD forms part of a broader strategy to help resolve the shortage of organs for transplant. In recent years, the federal government has funded a series of large-scale projects called “Breakthrough Collaboratives” designed to support, improve, and expand various aspects of transplantation. Similarly, a number of public and private research institutions have directed considerable resources toward investigating new systems to promote donation. The Institute of Medicine’s publication, *Organ Donation: Opportunities for Action*, reviews various methods to increase the number of organs for transplantation from both live and deceased donors.¹⁴

DCD Candidates

Organs for donation, either via DCD or brain death, must function sufficiently well to benefit a potential recipient. Patients who are not suitable donors include many with cancer and systemic infectious disease, as these conditions present serious medical hazards to immunosuppressed recipients. Organ function decreases with age, and thus some older patients are not suitable donors. Irrespective of whether patients will meet neurologic or cardiopulmonary criteria for death, candidates for donation represent a minority of terminally ill patients.

Candidates specifically for DCD “include patients whose life-sustaining treatment is under consideration for withdrawal and who will likely die soon after the withdrawal/refusal of this treatment.”¹⁵ Conditions leading to DCD candidacy include irreversible brain injury, end-stage musculoskeletal disease and severe spinal cord injury.¹⁶ Other possible candidates include those who rely upon ventilators and other life-sustaining interventions, and who decide to withdraw treatment for reasons unrelated to organ donation. DCD candidates often closely approximate patients who meet brain death criteria, yet without fully meeting all prerequisites.

DCD Organs

Different organs tolerate different periods of reduced blood flow; therefore, technical challenges and success rates of DCD vary for different organs. For renal transplants, DCD organs currently provide comparable results to those from brain dead donors, and at times better results than from extended criteria donation (ECD) by brain dead donors.¹⁷ DCD liver transplants offer mixed results; some experts report “excellent” outcomes.¹⁸ However, others note the liver’s increased susceptibility to warm ischemic time, the period of low or absent blood flow prior to organ retrieval; prolonged warm ischemic time can result in decreased liver function.¹⁹ However, patients with end stage liver disease lack the option of a bridge therapy

like dialysis. Due to the shortage of organs, their choice is often between an imperfect liver and no liver, rather than between imperfect and optimal organs.²⁰ DCD lung transplantation is a new and evolving practice.²¹ DCD heart transplant remains rare due to the heart's extreme sensitivity to ischemia, but some experts anticipate the development of this practice.²²

Process of Donation After Cardiac Death

The complex process of DCD may vary in some particulars, but basic procedures are substantially the same; variants and related ethical issues are noted. In all cases, staff members who find DCD ethically objectionable are allowed to excuse themselves from participation in the procedure. The process of DCD includes these steps:

- Decision to withdraw treatment
- Assessment for DCD
- Withdrawal of treatment
- Pre-mortem interventions
- Cardiac arrest and organ retrieval

1. Decision to Withdraw Treatment. Advocates of DCD, including the IOM, insist upon a clear separation between the decision to withdraw life-sustaining treatment and the decision to donate organs. A patient who retains decision-making capacity could decide to terminate life-sustaining treatment and to subsequently donate organs through the process of DCD. In these cases where the patient personally provides informed consent for DCD, there are few ethically complex issues. However, first person consent is quite rare in the context of DCD. Far more commonly, a patient has suffered a profound loss of cognitive capacity and others must make the decision on behalf of the patient. If the patient appointed a proxy while still capable, the proxy can determine whether withdrawal of treatment honors the patient's previously expressed wishes or best interests. If the patient has not appointed a proxy, New York law requires that a surrogate decision-maker rely upon "clear and convincing evidence" of the patient's wishes in order to terminate life-sustaining treatment.²³

The option of donation is not raised in advance of the decision to withdraw treatment for fear that this might inappropriately hasten withdrawal. In some cases, family members raise the issue of donation; in these situations the family is encouraged to make the decision about withdrawal of treatment first and then decide about donation. After the decision to withdraw treatment, the hospital contacts the OPO, and then organ donation representatives review the patient's clinical condition to see if donation after cardiac death is possible (medical factors such as systemic infection and advanced age preclude organ donation). If the patient is a potential candidate, the donor coordinator will then approach the family to discuss donation. Seeking consent for DCD includes an explanation of the process and an opportunity for the family to ask questions. The family must understand that a number of factors may prevent DCD, including failure to reach cardiac arrest within a specified period after respirator removal.

2. Assessment for DCD: If the patient or authorized surrogate decision-maker wishes to pursue the option of DCD, the organ donation representative will further assess the patient. A critical factor in determining suitability is the expected duration of respiration and heartbeat after the ventilator is withdrawn. Some patients do not breathe at all without assisted ventilation, and cardiac arrest ensues rapidly. Other patients will continue respiratory efforts for a prolonged period; this degree of respiration may be insufficient to sustain life but can delay cardiac arrest

for hours or days. Organs deteriorate after a prolonged period of low blood flow and/or low oxygenation; an extended period of relative ischemia or hypoxia will render organs unusable.

Assessment of DCD potential requires a trial of weaning from the ventilator to measure the patient's capacity for spontaneous breathing, the inspiratory force of such efforts, and their efficacy in maintaining oxygen saturation in the blood. Such an assessment of respiratory capacity is neither inappropriate nor uncommon when withdrawal of the ventilator is planned. Often, the assessment clarifies whether withdrawal is appropriate and how the process will unfold, even for patients who are not potential donors. However, since trial weaning could destabilize a ventilator-dependent patient, the surrogate decision-maker should give explicit consent for this procedure as part of the DCD process.

Researchers from the University of Wisconsin have devised an assessment tool that estimates the duration of time between removal of the ventilator and cardiac arrest.²⁴ This tool assigns points for various measures, including the patient's rate of spontaneous respirations, age, and dependence upon medications to support blood pressure. If the assessment indicates that cardiac arrest will occur within one to two hours after cessation of treatment, the patient is deemed a suitable candidate for DCD. Not all facilities rely upon the Wisconsin assessment tool; some doubt its predictive reliability while others worry that it may inappropriately increase risk for patients since supplemental oxygen is not used during the assessment. Some facilities assess respiratory capacity by the same protocol that is used in the assessment of brain death.

3. *Withdrawal of Treatment:* Whenever withdrawal of life-sustaining treatment is planned, a patient must have an order not to resuscitate (DNR). Without such an order, physicians attending the dying patient would face a paradoxical obligation to reinsert the ventilator tube and provide other interventions as well. With a DNR order in place, in contrast, health professionals must not attempt any resuscitative interventions because consent is explicitly denied in the order. A DNR order is needed for the process of withdrawing treatment that precedes and forms part of the DCD process.

Patients who are candidates for DCD are generally transferred to the operating room (OR) for withdrawal of treatment. Some facilities permit the patient to remain in the intensive care unit until cardiac arrest, in an effort to ease barriers to DCD both for families and staff.²⁵ However, transfer of the patient after cardiac arrest may result in delays that cause deterioration of the organs and undermine the intent to donate. In some facilities the family may accompany the patient in the OR during the cessation of life-sustaining treatment and while awaiting cardiac arrest. The family must agree to leave the OR immediately after arrest or donation cannot occur.

Hospital policies vary as to which physician should take responsibility for the withdrawal of the ventilator. Often the patient's attending physician performs this task. In some cases the anesthesiologist in the OR supervises withdrawal of the ventilator, though some anesthesiologists raise ethical objections to this practice.²⁶

If a patient meets eligibility criteria and begins the process for withdrawal with the intent to donate, yet does not progress to cardiac arrest within the designated time limit (usually one hour), then the patient will not become a donor and will return to the intensive care unit or other suitable ward for comfort measures and appropriate care. Patients would not at that point be re-intubated, unless in the unusual circumstance of a specific request from the surrogate decision-maker. This eventuality would need to be discussed with the family as part of the consent process for DCD.

4. *Pre-mortem Interventions.* Various interventions may increase organ viability; interventions after the death of the donor generally do not pose ethical problems. Individual

clinicians and facilities reach different conclusions about the ethical propriety of interventions before the patient's death that are intended to benefit the organ recipient. Hospital policies vary considerably as to which interventions are permitted. Some facilities, consistent with the advice of the IOM reports, permit the pre-mortem installation of catheters in the patient's leg; these can be used to rapidly instill cooling and preserving fluids after the patient's demise. Other facilities permit the use of a range of medications, including those that may lower the patient's blood pressure, or heparin, which helps prevent the formation of blood clots. Issues related to pre-mortem interventions are discussed in the Legal and Ethical Issues section of this report.

5. Cardiac Arrest and Organ Retrieval: Once the ventilator and other life-sustaining treatments are withdrawn, the patient receives palliative care according to the facility's policy. Pain medication or other measures comfort the dying patient; this period may last up to two hours depending on local protocol. Once respiration stops completely, cardiac arrest must be documented. For the purposes of DCD, cardiac arrest is determined by 1) the absence of a palpable pulse; and 2) electrocardiographic changes such as pulseless electrical activity that indicate the absence of heart function. After the determination of cardiac arrest, clinicians must wait a prescribed period, from two to ten minutes, depending on the local protocol. This waiting period is intended to guarantee that the patient's heart is no longer capable of spontaneously resuming contractions. The appropriate duration of this waiting period has received much discussion. After cardiopulmonary arrest and the subsequent waiting period, the physician declares the patient dead by cardiopulmonary criteria. A different set of physicians, not responsible for declaring death, will then proceed with organ retrieval.

LEGAL AND ETHICAL ISSUES

Several legal and ethical issues arise in relation to DCD; many are associated with aspects of surrogate consent. (Issues related to the determination of death also arise and will be discussed subsequently.) Patients who retain decision-making capacity have a clearly established right to request that life-sustaining therapies be withdrawn or withheld. Similarly, patients with capacity may consent to donate organs after their demise, including through DCD. There are relatively few legal or ethical problems related to DCD for patients with decision-making capacity, although even these patients may not request measures that actively hasten death. However, patients with decision-making capacity who are potential DCD candidates are rare; most potential DCD candidates have lost decision-making capacity and someone else must act on their behalf.

I. Surrogate Consent for DCD

Laws governing surrogate consent for various health-related matters in New York are complex and often conflict with one another; New York's legal standard for surrogate healthcare decision-making has been described by scholars as "unworkable."²⁷ Different, often contradictory, laws govern surrogate decisions in the following circumstances: 1) orders not to resuscitate; 2) health care decisions made by appointed agents; 3) health care decisions made when no appointed surrogate exists; and 4) organ donation. The DCD process may require consent under a number of these laws. This complex regulatory thicket may assign competing authority to different persons making different decisions during the process of DCD. Actual instances of conflict are not common since many patients either have only one person to speak on their behalf, or all concerned parties are in agreement.

DCD includes multiple procedures, both pre- and post-mortem. Ethically relevant aspects of the surrogate consent process exist for each of these elements of DCD:

- Orders not to resuscitate
- Decisions to withdraw life-sustaining treatment
 - By designated health care agents
 - Without a designated surrogate
- Pre-mortem procedures
- Organ donation

Orders Not to Resuscitate: A DNR order must be part of the process of DCD; life-sustaining treatment will be withdrawn, allowing the patient to expire without efforts at resuscitation. New York Public Health Law section 2965 governs consent to an order not to resuscitate (DNR order), including consent by a surrogate. Except when an adult patient consented to a DNR order before losing decision-making capacity, clinicians must obtain surrogate consent before issuing such an order. If neither the patient nor a designated health care agent can provide consent, a person from the following list, chosen in order of priority listed, has the authority to consent to a DNR order on behalf of the patient:

- a person appointed by a court to manage the personal affairs of an adult who is incompetent, developmentally disabled, or mentally retarded;²⁸
- the spouse;
- a son or daughter 18 or older;

- a parent;
- a sibling 18 or older;
- a close friend.

New York law also provides for the issuance of a DNR order by a physician on behalf of the patient when no one from the above list is available, and when other specific conditions are met.²⁹

Withdrawal of Life-sustaining Treatment via Health Care Agents: Under New York law, a patient's authorized health care agent can make decisions regarding health care, including withdrawal of life-sustaining treatment, in accordance with the patient's known wishes, or in the patient's best interests if his/her wishes are not known.³⁰

Withdrawal of life-sustaining treatment without a designated surrogate: Most patients in New York have not appointed a health care agent; when such patients lose decision-making capacity, New York case law requires "clear and convincing" evidence of the patient's wishes in order to withhold or withdraw life-sustaining treatment. This unusually high standard of evidence puts New York in a tiny minority among the states, and serves as a barrier to health care decision-making in a wide range of contexts. For more than a decade, efforts to address this gap in New York law have focused on passage of the Family Health Care Decisions Act. However, New York has not succeeded in passing the Act, despite widespread support from a broad range of professional and civic groups. Without the Act, New York lacks a mechanism for making reasoned decisions for that majority of incapacitated patients who have neither appointed an agent nor spoken in sufficient detail about the circumstances of their demise to satisfy the legal standard. There is no established hierarchy among family members and friends who might wish to help make decisions for their loved one, and no mechanism for acting in the patient's best interest, in the absence of specific commentary from the patient on end of life treatment.³¹

Pre-mortem DCD procedures: A number of different pre-mortem procedures are included in DCD protocols; considerable variability exists among DCD policies about the use of pre-mortem procedures. These procedures potentially include: 1) the insertion of large intravenous catheters or cannulae to facilitate the post-mortem administration of fluids that preserve organs; 2) medications that increase organ viability by increasing vasodilation; and 3) medications that increase organ viability by preventing clotting.

Some question the right of health care agents to make decisions about pre-mortem interventions that form part of the DCD process. This argument focuses primarily on the specific language regarding the definition of health care in New York's proxy statute. The proxy law defines a "health care agent" as an adult to whom a patient delegates the "authority to make health care decisions."³² A "health care decision" is defined as "any decision to consent or refuse to consent to health care."³³ "Health care," in turn, is defined in the law as "any treatment, service, or procedure to diagnose or treat an individual's physical or mental condition."³⁴ Thus, this argument holds that decisions about interventions to promote organ viability are not intended to help diagnose or treat the patient, and are therefore not health care decisions. (Proxies clearly can and do provide consent for the same interventions, such as the use of heparin, at other points in the patient's treatment.) If correct, the argument that pre-mortem decisions related to DCD are not health care decisions would effectively prevent DCD in New York; it would mean that not even the health care proxy could consent to pre-mortem interventions that promote organ viability. Of note, this argument does not have an impact on DCD discussions in other states or nationally.

Moreover, others argue that this line of reasoning ignores important aspects of both health care and surrogate decision-making. Patients appoint health care agents because they know that not all potential decisions can be foreseen, and so can neither be discussed with loved ones nor included in a document such as a living will. This problem particularly affects novel interventions and practices, including DCD, that were not known options at the time the advance directive was written. The core function of a health care agent is to uphold the patient's preferences and values in making future health care decisions. In appointing a proxy, patients indicate that they trust this person to define their best interests and uphold them. A restrictive reading of the definition of "health care" countermands the specific intent of the patient in appointing a proxy, and thus stands in opposition to the intent of the law. New York's proxy law was explicitly designed to provide robust decision-making powers for the health care agent, as its legislative history makes clear. For example, the Task Force's influential 1987 report, *Life-Sustaining Treatment: Making Decisions and Appointing a Health Care Agent*, notes that the appointment of an agent "enhances the individual's ability to direct health care matters in accordance with personal concerns, values, and life goals."³⁵

In addition to the question of whether decisions relevant to DCD constitute health care decisions, one might question whether such decisions are made in the patient's best interest, as the agent is instructed to act when the patient's wishes are unknown. A definition of best interest that includes promoting the patient's values and goals will lead to the inclusion of decisions related to DCD within the purview of the health care agent.

Pre-mortem Catheterization: The issue of the patient's best interest overlaps with that of consent to pre-mortem interventions, especially when such procedures might pose a risk to patients. We analyze the ethical issues related to three proposed pre-mortem procedures: the insertion of additional catheters, the administration of anticoagulants and/or the administration of vasodilating medications. Large-bore catheters, or cannulae, are sometimes inserted in advance of the patient's demise into major vessels such as leg veins in order to rapidly supply cooling and preserving fluids upon the patient's death; these fluids help preserve organ viability. The insertion of a catheter in an alert patient could be painful; analgesia is generally used if there is any possibility that a patient could feel pain during this procedure. The 1997 IOM report found that this procedure is ethically appropriate but that family members should provide explicit consent for it. Some major transplant centers follow this policy. Nonetheless, even if pain is controlled, some view pre-mortem insertion of a cannula as an unacceptable burden on the dying patient. In addition, this procedure is not considered essential for organ preservation. Various facilities in New York that permit DCD do not include pre-mortem cannulation in their protocol.

Vasodilators and Anticoagulants: Different medications can promote organ viability, for instance by preventing clots or increasing vasodilation. As noted in the 1997 IOM report, protocols at that time varied widely, with some prohibiting either type of medication, some permitting both, some permitting their use pre-mortem, but others only permitting administration after cardiac arrest or after declaration of death.³⁶ Medication that dilates vessels can help preserve organ viability but may also lower the patient's blood pressure and hasten demise. Facilities vary regarding the permissibility of pre-mortem administration of vasodilators in their protocol. No expert consensus exists currently as to the technical necessity of pre-mortem use of vasodilating medication.

In contrast, experts agree that heparin is a critical component of DCD. Transplant professionals at a national consensus conference stated that, "the administration of heparin at the time of withdrawal of life-sustaining treatment is the current standard of care and a key

component of best practice.”³⁷ Many transplant surgeons fear that organs without heparin will not function and therefore will not accept DCD organs unless heparin has been administered. Thus, elimination of heparin from DCD protocols might render the process unworkable. However, not every successful DCD donation includes the pre-mortem use of heparin.³⁸

Questions about the use and timing of heparin can present a barrier to the adoption of DCD policies, as clinicians worry that this medication may actively speed the demise of the patient. In response, transplant physicians note a lack of supporting data to show that heparin hastens death. Indeed, most intensive care patients are already treated with heparin as part of their medical care. Moreover, it is the patient and/or surrogate’s decision to withdraw life-sustaining treatment that permits the underlying pathology to cause death; death is neither an unexpected nor an unwanted outcome in this process. However, all agree that active hastening death is not the goal.

Third-party consent to organ donation: New York law authorizes third-party consent for organ donation by next of kin and others. New York’s Anatomical Gift Act designates the following priority list of individuals who can consent to donation of a deceased individual’s organs, assuming the deceased never expressed contrary wishes:

- Spouse
- Child (18 or over)
- Parent
- Sibling (18 or over)
- Legal guardian
- Person authorized to dispose of the body

A health care agent can consent to organ donation only if he/she also fits one of the above categories. As the proposed DCD protocol of one New York hospital cautions, “The Health Care Proxy is not authorized to give consent unless THAT INDIVIDUAL APPEARS IN THE LIST ABOVE.” (emphasis in original). Though the Anatomical Gift Act authorizes consent for donation, it clearly does not authorize the donation surrogate to consent to withdrawal of treatment.³⁹

Potential conflicts in surrogate decision-making: As noted above, the health care proxy is not listed among those who can consent to organ donation; this omission derives from the fact that the donation law preceded the existence of the proxy legislation. Further, the surrogate priority list for organ donation differs from the priority list for DNR orders, creating additional potential for conflict in surrogate decision-making for the DCD process. New York’s statutes and standards for surrogate end-of-life decisions present a series of conflicting priority lists and procedures. Irrespective of the creation of DCD policies, harmonization of these standards would improve the decision-making process for these vulnerable patients.

The Task Force encourages New York State to develop legislation that will harmonize priority lists for statutes related to end-of-life decision-making. These statutes include, but are not limited to:

- i. Health Care Proxy Law (Public Health Law Article 29-C)
- ii. Anatomical Gift Law (Public Health Law Article 43)
- iii. DNR Law (Public Health Law Article 29-B)

II. Determination of death

The determination of appropriate intervals between cardiopulmonary arrest, declaration of death, and organ retrieval within the DCD process has been a topic of vigorous debate. Variations in facility policies were noted in the IOM report, as well as in the transplant literature. The briefest interval between arrest and declaration was one minute; other facilities waited as long as ten minutes. After death is declared, organ retrieval proceeds without delay. The challenge is to find the duration that best guarantees that cardiorespiratory function cannot resume, while still preserving organ viability. Both the IOM and the National Conference report recommended five minutes as an appropriate pause.

Dead donor rule. The transplant community supports a general principle known as the dead donor rule, which dictates that patients must be declared dead before their organs are removed. In the DCD context, the phrase “donation after cardiac death” itself explicitly states a timeline: death, then donation.⁴⁰

While some theoreticians have debated the wisdom of this principle, the dead donor rule is unequivocally reflected in New York law, which states that an anatomical gift “take[s] effect upon death.”⁴¹ Like any cadaveric donation, a DCD organ would be an anatomical gift, and therefore subject to this statutory form of the dead donor rule.

Legal definition of death. Under New York law, a person is defined as dead when they meet either one of two sets of criteria: “(1) irreversible cessation of circulatory and respiratory functions; or (2) irreversible cessation of all functions of the entire brain, including the brain stem.”⁴² It is the first of those two standards that characterizes the DCD donor.

The Anatomical Gift law also reflects these two methods of determining death:

When a donor is determined dead based on irreversible cessation of circulatory and respiratory functions, the time of death shall be certified by a physician.... In all other cases the time of death shall be certified by the physician who attends the donor at his death and one other physician....⁴³

Although the law provides a legal definition of cardiopulmonary death—“irreversible cessation of circulatory and respiratory functions”—neither statute nor regulation defines “irreversible” or specifies the moment when irreversible cessation occurs.

Isolating this precise moment is rarely important. In DCD, however, timing is crucial, as clinicians must adhere to the dead donor rule while recognizing the time-limited viability of organs. As the first IOM report states, “A little more time can make the diagnosis [of death] obvious, but, in donors, may result in organs of poor or unstable quality.”⁴⁴ Scholars such as Jerry Menikoff are concerned that DCD may thus create an incentive to “‘rush’ the process of declaring death.”⁴⁵

As described in the 2000 IOM report, “irreversible” can have one of several meanings: “(1) will not resume spontaneously; (2) cannot be started with resuscitation measures; (3) will not be restarted on morally justifiable grounds.”⁴⁶ IOM, like the transplant community, chose a hybrid definition, selecting the first and third meanings above and leaving aside the second. They conclude that “death occurs when cardiopulmonary function will not resume spontaneously and will not be restarted artificially.”⁴⁷ This definition does not include the troubling second possible meaning, that heart and lung function simply cannot be restarted, including by medical intervention. This aspect of the definition is left aside because it may not be literally true in at

least some cases of DCD. We have limited data on the outside limit of time after which a heart could resume function with vigorous intervention. Moreover, when DCD lungs are removed from the donor, the cessation of pulmonary function is reversed. The same would apply in the case of cardiac function for DCD donors, though substantial technical barriers to cardiac DCD exist.

This problem of defining the moment of death applies not only in the case of DCD, but also with all instances of the planned and consensual withdrawal of life support. The patient is declared dead when heart and lung function cease. No attempts will be made to restart such function, because permission for resuscitation is explicitly denied in the DNR order. Thus, all declarations of death for DNR patients define “irreversible” to mean that cardiopulmonary function will not spontaneously resume, and that physicians are not permitted to attempt resuscitation.

Menikoff calls the IOM definition “moral” irreversibility.⁴⁸ An opposing definition would be “scientific” irreversibility, whereby “cardiopulmonary function is not *irreversibly* lost as long as it could conceivably be restored by vigorous resuscitation efforts.”⁴⁹ As noted, medical evidence is inconclusive regarding the maximum time without blood flow and oxygen that might still permit resuscitation. Attempts to rely upon the second definition could invalidate the 5-minute threshold as a marker for the dead donor rule.

Expert consensus currently supports use of the 5-minute waiting period between arrest and declaration of death; the Task Force also supports a 5-minute interval. This standard derives from a review of available evidence by IOM, and has been reiterated in guidance issued by UNOS as well as by organizations of transplant professionals.⁵⁰

III. Task Force Recommendations

After this thorough review of existing literature and analysis of relevant laws and regulations, the Task Force crafted the following set of recommendations to assist facilities in New York State in developing DCD policies. These recommendations provide ethical guidance in an effort to assure that policies are consistent and appropriate.

1. Surrogate consent for DCD

- Hospital DCD policies should clarify that health care agents are authorized to consent to pre-mortem DCD procedures, to the extent that these procedures are consistent with the patient’s known wishes and/or best interests, as understood by the health care proxy.

2. Pre-mortem treatment

- Hospital policies should support the use of heparin, but should not currently support the insertion of additional catheters pre-mortem, or the addition of medications solely for the purpose of vasodilation to promote organ preservation.

3. Declaration of Death

- Hospital policies should support the imposition of a 5-minute waiting period between cardiopulmonary arrest and the declaration of death in DCD protocols.

Conclusion

The current practice of DCD constitutes the reemergence of a practice from the earliest days of transplantation, yet with attention to contemporary standards of end-of-life care. Both the Joint Commission and UNOS required that facilities have DCD policies by January 2007. This Task Force document analyzes challenging issues within the process of DCD, and presents recommendations to address legal and ethical tensions. As DCD becomes more common in New York, NYS DOH and health care facilities may wish to collaborate in collecting data that will help identify best practices regarding consent, pre-mortem interventions, declaration of death, and the medical and other impact on patients, their families and providers. The Task Force hopes that these recommendations will permit hospitals to include DCD among the options that support patient preference in end-of-life care.

¹ JCAHOnline, "Revised organ procurement and donation standard," June 2006. Website:

http://www.jointcommission.org/Library/JCAHOnline/jo_06_06.htm, accessed October 30, 2006.

² "Highlights of the June Board Meeting," *UNOS Update*, July-August, 2006: 3.

³ J. L. Bernat, A. M. D'Alessandro, T. P. Port, et al., "Report of a National Conference on Donation After Cardiac Death," *American Journal Transplantation*, 2006; 6:281-291.

⁴ T. Starzl, T. Marchioro, R. Brittain, et al. "Problems in Renal Homotransplantation," *Journal of the American Medical Association*, 1964,187(10):734-740.

⁵ Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Practice and Protocols*, National Academies Press, 2000, 25.

⁶ New York State Task Force on Life & the Law, *The Determination of Death*, NYS DOH, 1986.

⁷ New York State Department of Health, "Guidelines for Determining Brain Death," NYS DOH, 2005.

⁸ G. Kolata, "Controversy erupts over organ removal," *The New York Times*, April 13, 1997.

⁹ IOM, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*, National Academies Press, 1997. IOM, *Non-Heart-Beating Organ Transplantation: Practice and Protocols*, National Academies Press, 2000.

¹⁰ 1997 IOM report, 23.

¹¹ M. Nishikido, M. Noguchi, S. Koga, et al., "Kidney Transplantation from non-heart-beating donors: analysis of organ procurement and outcome," *Transplant Proceedings* 2004;36(7):1888-90.

¹² R. A. Wolfe, V. B. Ashby, E. L. Milford, et al., "Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant," *New England Journal of Medicine*, 1999;341:1725.

¹³ R. Stribling, N. Sussman, J.M. Vierling, "Treatment of Hepatitis C Infection," *Gastroenterologic Clinics of North America* 2006;35(2):463-86.

¹⁴ Institute of Medicine, Committee on Increasing Rates of Organ Donation, J.F. Childress and C.T. Liverman, *Organ Donation: Opportunities for Action*; National Academies Press, 2005 (prepublication).

¹⁵ Bernat, 282.

¹⁶ Bernat, 282.

¹⁷ Bernat, 285.

¹⁸ L. Olson, J. Kisthard, J. Fung, et al., "Livers transplanted from Donors after cardiac death occurring in the ICU or the operating room have excellent outcomes," *Transplantation Proceedings* 2005;37:1188-1193.

¹⁹ Bernat, 284. P. Abt, M. Crawford, N. Desai, et al., "Liver Transplantation from controlled non-heart beating donors increase incidence of biliary complications," *Transplantation* 2003; 75(10):1659.

²⁰ New York State Department of Health Workgroup, "Workgroup on Expanded Criteria Organs for Liver Transplantation," *Liver Transplantation*, 2005; 11(10):1184-92.

²¹ G. I. Snell, T. Oto, B. Levvey, et al, "Evaluation of techniques for lung transplantation following donation after cardiac death," *Annals of Thoracic Surgery*, 2006;81(6):2014-9.

²² Bernat, 285.

²³ Decisions regarding administration of artificial nutrition and hydration may be made only if the patient's wishes are known or can be ascertained. § 2982(2). New York State law permits a formally designated proxy to make surrogate decisions for patients who lack capacity based on the patient's wishes, if known, or best interests in other cases. A significant gap in New York law, making it highly unusual among the states, requires non-designated surrogate decision-makers to rely upon "clear and convincing" evidence of a patient's wishes. Thus, for patients without formal advance directives, or designated proxy deciders, or this high level of evidence, decisions to withdraw treatment are problematic. The majority of patients in New York today lack proxies and sufficient evidence of their wishes. The proposed Family Health Care Decisions Act would resolve this significant problem but has failed to pass in the New York State Legislature.

²⁴ J. Lewis, J. Peltier, H. Nelson, et al., "Development of the University of Wisconsin donation after cardiac death evaluation tool," *Progress in Transplant* 2003:13:265-73.

²⁵ Olson.

²⁶ G. A. Van Norman, "Another Matter of Life and Death: What every anesthesiologist should know about the ethical, legal and policy implications of the Non-Heart-beating cadaver organ donor," *Anesthesiology*, 2003; 98(3):763-73.

²⁷ T. Miller, T. Powell, J. Arras, et al., "Panel Discussion: Current Work of the Task Force—The Family Health Care Decisions Act and Directed Live Organ Donation," *NYSBA Health Law Journal* 2005:10(3):24-36.

²⁸ Specifically, the statute defines this person of first priority as: "a committee of the person or a guardian appointed pursuant to article seventeen-A of the surrogate court's procedure act." In addition, this provision of the DNR law "shall not be construed to require the appointment of a committee of the person or guardian for the purpose of making the resuscitation decision."

²⁹ Public Health Law § 2966.

³⁰ Decisions regarding administration of artificial nutrition and hydration may be made only if the patient's wishes are known or can be ascertained. § 2982(2).

³¹ See Miller, "Panel Discussion."

³² Public Health Law § 2980(5)

³³ § 2980(6).

³⁴ § 2980(4).

³⁵ NYS Task Force on Life & the Law, *Life Sustaining Treatment: Making Decisions and Appointing a Health Care Agent*, NYS DOH, 1987, p 90.

³⁶ 1997 IOM report.

³⁷ Bernat, National Conference, 283.

³⁸ Olson, 1190.

³⁹ Such an individual might provide clear and convincing evidence of the patient's wishes not to receive life-sustaining treatment, but that would be separate from their authority to consent to an anatomical gift.

⁴⁰ This chronology is not explicitly suggested in the DCD synonym "non-heart-beating organ transplantation."

⁴¹ PHL § 4301(a).

⁴² 10 N.Y.C.R.R. § 400.16.

⁴³ PHL § 4306(2). The law specifies that a physician certifying death under either criteria cannot participate in "the procedure to remove or transplant" an organ.

⁴⁴ 1997 IOM report, 57.

⁴⁵ J. Menikoff, "The Importance of Being Dead: Non-Heart-Beating Organ Donation," *Issues in Law and Medicine* 2002:18:3-20. Menikoff writes: "The desire to maximize the utility of the donated organs means that there is a pressure to minimize the time between the cessation of cardiac function and removal of the organs." Menikoff, 13.

⁴⁶ 2000 IOM report, 24.

⁴⁷ 2000 IOM report, 24 (citing 1997 IOM report).

⁴⁸ J. Menikoff, *Law and Bioethics*, Georgetown University Press, 2001, 464.

⁴⁹ 2000 IOM report, 24 (citing Menikoff).

⁵⁰ 2000 IOM report; Bernat, 28

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