The Report of a National Conference on Donation after Cardiac Death

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On April 7-8, 2005, a national conference on organ donation after cardiac death (DCD) was convened in Philadelphia, PA, to address the increasing experience of DCD and to affirm the ethical propriety of transplanting organs from such donors. The professional affiliation of participants included the American Medical Association (AMA), the Society of Critical Care Medicine (SCCM), the American Association of Critical Care Nurses (AACN), the American Society of Anesthesiologists (ASA), the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the American Society of Transplant Surgeons (ASTS), the American Society of Transplantation (AST), the Association of Organ Procurement Organizations (AOPO), the Scientific Registry of Transplant Recipients (SRTR), Eurotransplant, the North American Transplant Coordinators Organization (NATCO), the National Association of Medical Examiners (NAME), the United Network for Organ Sharing (UNOS) contractor of the Organ Procurement Transplant Network (OPTN), the Division of Transplantation of the Department of Health and Human Services (DOT), Centers for Medicare and Medicaid Services (CMS), the National Kidney Foundation (NKF) and the World Health Organization (WHO). The neuroscience community was represented by renowned physicians from the Neurocritical Care Society. Distinguished bioethicists from the medical and lay community participated as well.

The Institute of Medicine (IOM), the SCCM, and the JCAHO have concluded that DCD is an ethically proper approach of recovering organs from a deceased patient for the purpose of transplantation (1-4). The Canadian Council of Donation and Transplantation has recently convened a forum in Vancouver, British Columbia whose report promotes “patient-care based principles for providing the option of donation within a sound ethical framework” and supports donation after cardiocirculatory death (5).

The aim of the national conference held in Philadelphia was to expand the practice of DCD in the current continuum of quality end-of-life care. When the withdrawal of life support has been consensually decided by the attending physician and patient, or by the attending physician and family member or surrogate (particularly in the hospital setting of the intensive care unit), a routine opportunity for DCD should now be available to all families for consideration and to honor deceased donor wishes. The message derived from the conference was to convey a societal responsibility that regularly enables organ
transplantation from deceased donors, determined to be dead either by circulatory or brain criteria.

Six working groups of conference participants were assembled to address specific DCD issues and fulfill the conference objectives: 1) determining death by a cardiopulmonary criterion, 2) assessing medical criteria to predict DCD candidacy following the withdrawal of life support, 3) protocols for successful DCD organ recovery and subsequent transplantation, 4) initiating DCD in donation service areas (DSA), 5) the allocation of DCD organs for transplantation, 6) the media, public perceptions, and DCD.

**Work Group 1: Determining Death by a Cardiopulmonary Criterion.**

The ethical axiom of organ donation is adherence to the dead donor rule: the retrieval of organs for transplantation should not cause the death of a donor (6).

A prospective organ donor’s death may be determined by either circulatory or brain criteria as prescribed by the President’s Commission provided in their proposed death statute, the Uniform Determination of Death Act, which stated that an individual satisfying *either* the cardiopulmonary or neurologic criteria is dead (donation after brain death DBD) (7). The circulatory criterion of death (used in DCD) is employed when the donor does not fulfill brain death tests, ventilatory support is not used or has been withdrawn, and circulation and respiration have ceased.

In clinical situations that fulfill either brain death criteria or the circulatory criterion of death, the President’s Commission stipulated that the diagnosis of death requires the determination of both *cessation of functions* and *irreversibility*. The circulatory criterion of death, used for the determination of death in DCD patients and most other hospitalized patients, provides that a person with irreversible cessation of circulatory and respiratory functions is dead.

The Work Group participants defined the terms *cessation of functions* and *irreversibility*.

1. **Cessation** of functions is recognized by an appropriate clinical examination that reveals the absence of responsiveness, heart sounds, pulse, and respiratory effort. In applying the circulatory criterion of death in non-DCD circumstances, clinical examination alone may be sufficient to determine cessation of circulatory and respiratory functions. But the urgent time constraints of DCD may require more
definitive proof of cessation of these functions by the use of confirmatory tests. Confirmatory tests (for example intra-arterial monitoring or Doppler study) should be determined by hospital protocol to assure family and the hospital professional staff that the patient is dead.

The 1997 IOM report suggested that “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” (1). Work Group 1 participants found that electrocardiograph silence is not required for the determination of death, because the criterion determining death is the absence of circulation. However, if ECG silence is determined, it may be used as a confirmatory test for absent circulation because ECG silence is sufficient to show absence of circulation.

2. Irreversibility is recognized by persistent cessation of function during an appropriate period of observation. The 2000 IOM report noted that “irreversible” cessation of cardiopulmonary function “can be interpreted to mean several things: (1) cardiopulmonary function will not resume spontaneously; (2) cannot be restarted with resuscitation measures; (3) will not be restarted on morally justifiable grounds” (2).

Using a cardiopulmonary criterion, DCD donor death occurs when respiration and circulation have ceased and cardiopulmonary function will not resume spontaneously. This meaning of “irreversibility” also has been called the “permanent” cessation of respiration and circulation because if the current data show that auto-resuscitation (spontaneous resumption of circulation) cannot occur and there will be no attempt at artificial resuscitation, respiration and circulation have permanently ceased.

In clinical situations where death is expected: once respiration and circulation cease (irrespective of electrical cardiac activity), the period of observation necessary to determine that circulation will not recur spontaneously (autoresuscitation) may be only a few minutes. In analyzing current data on auto-resuscitation, the relevant event is cessation of circulation; it is not cessation of electrical activity. When life sustaining therapy is withdrawn, based on the limited data available, spontaneous circulation does not return after 2 minutes of cessation of circulation.
The Terminology of DCD:

The term donation after cardiac death (DCD) clearly indicates that death precedes donation. Death determination in the DCD patient mandates the use of a cardiopulmonary criterion to prove the absence of circulation. In *Defining Death* (1981) the President’s Commission stated: “The accepted standard for determining death has been the permanent absence of respiration and circulation.” In DCD patients, respiration usually ceases prior to circulation. But if not, respiration ceases almost immediately, once circulation ceases. Therefore, the criterion of death set forth in this report is consistent with the President’s Commission recommendations. While institutional protocols for death determination may vary in the duration used to determine that cessation of circulation is permanent, they must be consistent with the criterion that circulation will not resume spontaneously.

**Period of circulatory cessation observed to determine death:**

The Work Group participants were aware of the Organ Procurement Organization (OPO) survey conducted for the DCD conference that determined 92% (47) of all OPOs use a 5 minute interval from asystole to the declaration of death, consistent with the IOM recommendations. Nevertheless, there are 4 OPOs that use an interval of 2 minutes (3 OPOs) and 4 minutes (1 OPO). The Society of Critical Care Medicine (SCCM) concluded that “at least 2 minutes of observation is required, and more than 5 minutes is not recommended.” (3). The IOM and SCCM recommendations were expert judgments. Subsequent studies have not been conducted to provide a statistically valid basis for determining the minimum duration of observation that should occur to rule out the possibility of autoresuscitation of circulation. Until additional data are available, the Work Group participants concluded that there may be variation in the time interval of observing the absence of circulation that a physician might use to certify death. The Work Group supported the wording of the SCCM that for DCD “at least 2 minutes of observation is required, and more than 5 minutes is not recommended” (3). Once death is determined using recommended criteria, organ donation may proceed without further required delay.

In addition, Work Group participants recommended that appropriate agencies of HHS fund observational studies on the frequency of auto-resuscitation in DCD patients and other patients dying after withdrawal of life-sustaining therapy. However, the cardiopulmonary
criterion of death (irreversible cessation of circulatory and respiratory function) applies to all patients who lose circulation, regardless of organ donor status.

The importance of this work group’s deliberations was to affirm the ethical propriety of DCD as not violating the dead donor rule and to assure the community that there is no future plan to do so. Whether individual hospitals use the IOM or SCCM recommendations to determine a cessation of circulation (and respiration) to prove permanence, the loss of circulation is not auto-reversible in either of these approaches. Thus, DCD occurs after the declaration of death. Finally, Work Group participants recommended that each institution establish specific tests for death determination, in a written policy. This policy will set a standard for that institution that can be both followed explicitly and audited (both pro- and retrospectively).

**Work Group 2: Assessing Medical Criteria to Predict DCD Candidacy Following the Withdrawal of Life Support.**

Quality end-of-life care for a potential organ donor (as with any individual whose treatment is being withdrawn) is the absolute priority of care and must not be compromised by the donation process. However, quality end-of-life care for dying patients includes an obligation to inform them or their family members of the option of organ donation. Standard formats for living wills and advance health care directives should include consideration of organ donation. The decision for withdrawal/withholding of life sustaining treatment should be made with the patient or family surrogate before the discussion of organ donation with the patient and/or family begins. This decision to withdraw or withhold treatments should be made on its own merit, with the patient’s physician having established the futility of any further treatment, and not for the purpose of organ donation.

Decisions regarding the suitability of a donor should be made by the OPO in consultation with the patient’s health care providers. The conditions that may lead to consideration of DCD eligibility include: irreversible brain injury, end-stage musculoskeletal disease, and high spinal cord injury. Potential candidates for DCD include patients whose life sustaining treatment is under consideration for withdrawal, and who would likely die soon after the withdrawal/refusal of this treatment. In the Intensive Care Unit, this clinical scenario has been referred to as Controlled DCD (versus Uncontrolled DCD which occurs when patients unexpectedly suffer cardiac arrest from which the patient does not survive).
The time limit to cardiac death that enables DCD following withdrawal/withholding of treatment is determined in conjunction with the OPO. Each institution should have a policy and procedure that specifies a defined interval of time when efforts to proceed with DCD should cease and designates a hospital location where the patient may be moved for the continuation of end of life care. Once the decision is made to withdraw support in medical examiner/coroner cases the medical examiner (or coroner) should be notified as early as possible.

The administration of sedatives and opioids should be the same as that which is customary for all end-of-life care and should treat patient discomfort and/or the appearance of discomfort. Neuromuscular blocking agents should not be initiated in the process of withdrawal/withholding of life sustaining care. After the decision to withdraw life sustaining therapies has been made, if the physicians determine that brain death might occur imminently then families should be counseled about the options after both brain death and cardiac death. The decision whether and when to proceed with a DCD protocol versus a brain death protocol must be arrived at through discussion among the family, the OPO and the health care team. Once consent for DCD is obtained the health care team should proceed in a timely fashion to not delay the organ donation process.

**Medications and interventions not relevant to withdrawal of treatment prior to the declaration of death in a DCD patient:**

After the decision to withdraw life sustaining therapy has been made (but before the process has begun) special transplant related medications (such as vasodilators, anticoagulants and anti-oxidants) may be administered or interventions may occur. The administration of these medications or the intervention of premortem vessel cannulation require specific informed consent that addresses the potential risks of hastening death and the potential benefit of improving the opportunity for successful transplantation. Since the primary physician will need to give signature approval, OPOs must confer with the hospital medical staff on all proposed medications, blood draws and procedures, prior to the patient’s death.

The intent of transplant related pre-recovery medications is to improve post-transplant organ function, although it is possible that the death process may be unintentionally accelerated. However, these medications are not given to accelerate the dying process. It is
important to assess as accurately as possible the true risks of the administration of such medications and not speculated risks. Finally, it should be recognized that the ultimate goal of the dying patient or their surrogate, is for organ donation to be accomplished. When organ donation is desired, a good outcome fosters the patient’s and surrogates interests. Therefore, interventions that enhance improved outcomes from transplant serve the interests of dying patients and their surrogates.

Some DCD protocols employ pre-mortem cannulation of large arteries and veins (before the cessation of circulation occurs) to facilitate post mortem infusion of organ preservation solutions as a method of rapidly introducing preservation fluid to a potential donor. Individual institutions may approve this type of intervention (vessel cannulation) as a method of rapidly introducing preservation fluid to a potential donor, after circulation ceases and death is pronounced. As suggested by the IOM, informed consent of the patient or family is necessary for any pre-mortem intervention (1).

The principle of double effect:

The principle of double effect permits the performance of a good act despite the possibility that an unintended and undesirable side effect or outcome may result (especially in a situation devoid of another suitable option). The principle of double effect is invoked in DCD circumstances by enabling the good of becoming an organ donor (after the withdrawal of life sustaining treatment and after the declaration of death) despite the theoretical and unintended effect of hastening (the inevitable) death by the administration of pre-recovery medications (such as heparin or vasodilators). The intent and wishes of the potential donor or the family are to donate organs after death. The principle of double effect sustains the good act of organ donation. Moreover, the organ recovery process does not cause the death; thus, the dead donor rule is also maintained.

Criteria that Predict Cardiac Death after Withdrawal of Treatment:

Evidence based clinical judgment should be used to assess whether cardiac death will likely occur within a time period allowing successful DCD. The University of Wisconsin has developed an algorithm for the assessment of the potential DCD donor. A score is computed based upon the patients age, BMI, O2 saturation, method of intubation (endotracheal versus tracheostomy), level of spontaneous respiration, and the requirement for vasopressors, all of
which indicate the likelihood of death within one hour after extubation (8) (Table 2). UNOS has also developed criteria that can be helpful in identifying potential DCD (Table 3).

**Work group 3: Protocols of DCD organ recovery and successful transplantation.**

The goals of this work group were to evaluate the various surgical techniques employed for DCD organ recovery, the acceptable limits of warm (WIT) and cold (CIT) ischemic time for each organ transplanted from DCD, and the effect that pre recovery administration of agents might have on the ischemia-reperfusion injury experienced after transplantation. These protocols were considered in both controlled and uncontrolled DCD situations as defined by the Maastricht classification system (9). The Maastricht classification system groups potential donors into four categories: dead on arrival to the hospital and not resuscitated (category I); unsuccessful resuscitation (category II); withdrawal of life support (category III); and cardiac arrest while brain dead (category IV) (9). The controlled circumstance of DCD is represented by category III.

**Warm ischemic time: controlled.**

The interval of time between extubation (as the definitive withdrawal of treatment) until the initiation of cold perfusion is the most commonly used definition of WIT; however, WIT definitions still vary among centers recovering DCD organs. Thus, work group participants concluded that a more descriptive definition of what occurs after withdrawal of treatment is necessary. They proposed that the definition of WIT be described into two phases:

*Withdrawal Phase (Phase I):* the time interval from withdrawal of ventilatory support to cardiopulmonary cessation (this phase includes the extubation at the time of discontinuation of life-support);

*Acirculatory Phase (Phase II):* the time interval from cessation of circulation to the initiation of cold perfusion. This phase includes the waiting period from the absence of circulation to the declaration of death (typically 2 - 5 minutes). Thus, the declaration of death occurs at the end of this phase.

The work group participants recommended that the OPTN modify data submission requirements to differentiate Phase I from Phase II. Data that should be collected minute-by-minute during these two phases include systolic, diastolic, and mean arterial blood pressure, O₂ Saturation, and urine output. Collection of data in this fashion will enable analysis to
delineate the duration and impact of hypoperfusion after withdrawal of life support (but prior to declaration of cardiac death). Prior to the availability of this newly collected data, a retrospective study merging current known hemodynamic data from OPO’s with SRTR data regarding corresponding recipient outcomes was also recommended.

**Warm ischemic time: uncontrolled.**

The time course of WIT in an uncontrolled donor circumstance in which there has been no intended withdrawal of treatment is more difficult to define, but it may be considered in three phases as proposed by this work group:

- **Preresuscitative:** the time interval from cardiac arrest until resuscitation. The work group participants acknowledged that the acceptable time interval that would still enable successful recovery of DCD organs for transplantation is unknown and imprecise.
- **Resuscitative:** the time interval from institution of CPR until declaration of death
- **Postresuscitative:** the time interval after the conclusion of resuscitative efforts that coincides with the determination of death. For Maastricht Category II donors (unsuccessful resuscitation), the recommend waiting period was not specified by IOM. For Category IV donors (cardiac death in a brain-dead donor), no waiting period is required.

The work group participants recommended collection of data from each of these phases. The development of precise time frames of data collection will be essential to the correlation of these Phase I and II DCD events with successful DCD transplantation.

**Acceptable Duration of WIT for the successful transplantation of organs:**

Current reports from the literature (utilizing the definition of WIT as the interval of time between extubation until the initiation of cold perfusion) suggest that the WIT for successful liver transplantation should not exceed 30 minutes, or 60 minutes for kidney and pancreas transplantation (Table 1) (10). These generally accepted guidelines referable to WIT assume that the mean arterial pressure has fallen to < 60mm Hg within minutes after the withdrawal of treatment. For livers, WIT of > 30 minutes may increase the risk of post-transplant biliary stricture (10).

**Cold Ischemia Time:**

Cold ischemia time (CIT) extends from the initiation of the organ’s cold preservation of the recovered organs to restoration of warm circulation after transplantation. For DCD, CIT may begin at the onset of cold perfusion in situ, i.e. before organ recovery. The interval
period of liver allograft vessel anastomoses (after the liver is removed from cold storage) until reperfusion of blood is established (the anastomosis time) is an additional period of WIT. The reasonable limits of WIT and CIT have yet to be established by precise data. There is variability by accepting surgeon/center and by donor and recipient characteristics. Intuitively shorter CIT and WIT are better. For kidney transplantation, the CIT should be less than 24 hours; for pancreas transplantation less than 18 hours and for liver transplantation less than 8 hours (Table 1).

As there is a paucity of data to make a proper decision regarding the acceptance of organs with variable CITs and WITs, information should be obtained to characterize the influence of these variables. For example, current evidence suggests that lungs may have better tolerance to long warm and cold ischemia times than other donor organs (11).

**Pre-recovery administration of agents:**

The pre-recovery administration of pharmacologic agents may be effective in minimizing ischemia/reperfusion injury and improving organ function after DCD transplantation. There is an emerging body of subclinical/molecular evidence supporting the use of pre-procurement treatments, which appear to help via their effect on the vascular endothelium of the transplanted organ (12). However, there is an insufficient clinical experience to make a definitive conclusion. Local practices vary and may dominate considerations in the development of protocols.

The administration of heparin at the time of the withdrawal of life sustaining treatment is the current standard of care and a key component of best practice. The long term survival of the transplanted organ may be at risk if thrombi impede circulation to the organ after reperfusion. The omission of heparin could negatively impact organ recovery and hinder the distribution of recovered organs (as most centers require the use of heparin in DCD).

The use of heparin has been considered controversial on the basis of theoretical concerns that it may hasten the death of the donor. The Work Group participants addressed this issue by noting that there is no evidence that heparin would cause sufficient bleeding after the withdrawal of treatment to be the cause of death. It should not be overlooked that the event of demise is the withdrawal of life support that affects the loss of circulation and respiration (and not the use of the heparin).
The appropriate timing of the administration of anticoagulants and vasodilators during the DCD process is unresolved. Flushing organs with anticoagulants/vasodilators after procurement may be as effective as pre-procurement administration. Thrombolytics may be of value after the declaration of death but there is little data to answer this question.

Vasodilators such as phentolamine (Regitine) and anti-oxidants such as steroids, vitamin E, N-acetylcysteine, and agents such as mannitol may be administered per local protocols of DCD, but their necessity for successful transplantation is not established.

Work Group 3 participants made several specific points regarding the administration of medications prior to the determination of death:

1. The intent of pre-recovery medications is to improve post-recovery organ function which is consistent with the intent and wishes of the family to donate quality organs;
2. Informed consent regarding any pre-mortem interventions is necessary;
3. It is important to assess as accurately as possible the true risk of interventions, and not unsubstantiated risks.

**Cold storage solutions and pulsatile perfusion:**

The pulsatile preservation of DCD kidneys remains a controversial area in kidney transplantation that necessitates the development of controlled trials to establish its efficacy. Data presented by the SRTR appeared to suggest that there is no benefit of pulsatile preservation in preventing delayed graft function (DGF) of DCD kidneys (Table 4). If true, this would be an important finding as DGF appears to have a negative impact on survival (Table 5). Nevertheless, there may be a value of pulsatile preservation that reveals perfusion characteristics that brings security in accepting DCD organs for transplantation.

For cold storage, the optimal preservation solution (UW, HTK and others) has yet to be established. Since the type of preservation solution has only recently been added to the SRTR data base; no information was available for the conference participants to consider.

For non DCD transplantation the literature suggests that for short-term preservation (< 12 hours) there is little evidence of difference between pulsatile preservation and cold storage. For long-term preservation (> 12 hours), UW may be advantageous. With regard to DCD liver transplantation, studies are needed to determine the impact of the preservation solution on the development of biliary strictures (thought to be secondary to ischemia).
The technical aspects of organ recovery from DCD donors were presented during the conference, but are not summarized here. The retrieval of thoracic organs that requires the reintubation of the DCD donor following the declaration of death was addressed at the special thoracic session May 12, 2005 devoted to the recovery of lungs from DCD.

**Thoracic Subcommittee Report:**

Recommendations of a thoracic subcommittee, which met separately in May, 2005 are reported here. Since securing transplant center acceptance of lungs from DCD donors may be more challenging, additional time may be required by the OPO to achieve this objective, and should be supported by the abdominal transplant groups. Since aspiration is a frequent problem in potential lung donors (possibly exacerbated in the DCD situation), a nasogastric tube should be placed in all potential DCD lung donors. Likewise, a bronchoscopy prior to withdrawal of support and extubation is necessary to adequately assess suitability for DCD lung donation. Once death occurs, it is important to re-intubate and ventilate the lungs before surgical excision. Venting of the vena cava should preferentially occur in the abdomen or via femoral or vena caval cannulae and not in the thoracic cavity. As in all cases of abdominal and thoracic recoveries, the surgical teams should discuss the conduct of the surgical procedure.

As regards heart transplantation, several lines of clinical and experimental evidence predict that the interval of warm ischemia encountered with DCD protocols would result in myocardial injury that could be reversible with coronary reperfusion. Limited anecdotal evidence in humans supports the feasibility of cardiac transplantation following DCD including the first successful heart transplant. Ongoing research involving optimization of the reperfusate and reperfusion technique may enhance immediate functional recovery. Based on the growing numbers of successful non-cardiac solid organ retrievals following DCD, and the ongoing shortage of cardiac donors especially in the pediatric arena, protocols to develop and optimize heart transplantation following DCD for pediatric and adult recipients should be initiated and supported.

**Work group 4: Initiating and Increasing DCD in Donation Service Areas.**

DCD requires an integration of the best practices from “three estates” of the medical community (the donor hospital, the OPO, and the transplant center) to achieve an ethically proper end of life care and the successful recovery and transplantation of DCD organs. The
objectives of this work group were to determine the obstacles to best practice and identify action strategies to address such barriers so that DCD could be initiated in DSAs where DCD recovery doesn’t occur currently and expand it where DCD recovery is not very extensive. The 20 DSAs (of 58 CMS designated service areas) that accomplished more than 5 DCD in 2004 were cited (Table 6).

The work group participants reviewed data from an OPO survey that suggested a variety of impediments to DCD that included a concern for a negative public perception, the absence of an OPO or donor hospital policy on DCD, the lack of transplant center surgeon support to recover DCD organs, and the lack of sufficient resources to accomplish DCD.

Thus, the Work Group 4 participants proposed specific actions to agencies and organizations that could be used to successfully eliminate barriers to DCD:

- **AOPO**
  - Establish a DCD mentorship program in a more direct manner than its current Technical Assistance Program (TAP)
  - Add DCD component to OPO accreditation standards
  - Work with ASTS, AST, UNOS to develop 24/7 phone consult service
  - Conduct financial analysis of DCD cost effectiveness on DSAs

- **HHS Secretary’s Advisory Committee on Organ Transplantation (ACOT)**
  - Support the development of studies assessing the frequency of auto-resuscitation in DCD patients and other patients dying after withdrawal of life-sustaining therapy
  - Recommend standardized data and reporting parameters for potential DCDs to the OPTN for inclusion in the Scientific Registry for Transplant Recipients
  - Recommend that the OPTN modify data submission standards to capture Phase I and Phase II data with a minute-by-minute collection of data to assess systolic, diastolic, and mean arterial blood pressure, the measurement of $O_2$ saturation, and urine output;
  - Provide guidance on issues of informed consent.
  - Conduct regional hearings regarding DCD barriers in service areas where prevalence of DCD recoveries is zero or small.
• OPOs
  – Designate an in-house ‘expert champion’ to lead DCD program.
  – Assign a dedicated contractual or ‘in house’ FTE as a 24/7 DCD qualified organ recovery surgeon.
  – Standardize data and reporting parameters for potential DCDs
  – Integrate DCD into the OPO’s ‘Hospital Business Plan.’ Develop relationships with DCD experienced OPOs to assist with DCD program development
  – Utilize real-time consultative relationship with experienced OPOs
  – Develop practical workshops on DCD to foster skills of donation coordinators, Hospital Development coordinators, and recovery staff.
  – Utilize the role of the in-house coordinator to maximize DCD
• OPTN/UNOS
  – Revise transplant center membership criteria to require DCD protocols
  – Revise OPO membership criteria to require DCD policies and protocols
  – Establish organ specific sub-committees on DCD to address organ specific suitability criteria and allocation policies
  – Conduct financial analysis of long term impact of DCD organ use on transplant centers
  – Use regional meetings as venue for DCD discussion and education
• NATCO
  – Maintain and promote NATCO DCD Resource Council list serve
  – Expand DCD in all NATCO education programs; i.e. Introductory Course, Hospital Development Course, Annual Meeting and Transplant Institute
• ASTS / AST
  Establish joint committee to increase DCD recovery and utilization;
  Sponsor evidence based symposia on DCD and develop practice guidelines
  Revise fellowship training to include experience with DCD recovery
• JCAHO
  – Revise accreditation standards to require hospitals to implement DCD protocols
  – Treat lack of a DCD protocol as a requirement for improvement
• SRTR
  – Provide annual DCD report with regional profiles, new developments, and data.
• CMS
  – Regulations governing donation, utilization and reimbursement should be revised to reflect the unique characteristics of DCD procurement and transplantation.
• HRSA
  – Presentation on proceedings of the May 2005 meeting of the Organ Donation Breakthrough Collaborative National Learning Congress in Pittsburgh
  – Accord high priority to DCD as special focus for the Collaborative’s ‘knowledge management system’
  – Collaborative Leadership Coordinating Council
    • LCC members should each develop a statement of support for DCD policy with the goal of gaining constituent endorsement.
• Donor Hospitals
  – Evaluate (or re-evaluate) clinical triggers to ensure that DCD donors are identified and referred in a timely manner
  – Assure practices that routinely offer families the opportunity for DCD
  – Address DCD in the larger context of quality end of life care
  – Assure ongoing DCD education and interaction with key clinical and administrative personnel and for all members of each hospital community.
• Transplant Centers:
  – Establish multidisciplinary committee to review DCD practices and data
  – Formalize relationship with OPO to assure availability of experienced DCD procurement team with 24 hour / 7 day coverage
  – Develop standardized terminology in order to facilitate communication and data tracking
  – Establish organ specific acceptance criteria.
The impact of DCD upon the occurrence of DBD (donation after brain death) organ recovery and transplantation:

A difference in how the increasing incidence of DCD in the U.S. is affecting the number of DBDs was compared to that of the Netherlands. Unlike the Netherlands, which experienced a 21% decrease in DBDs (159 -> 126) during the most recent 5 year period in which there was a 129% increase in DCD (41 -> 94) (13), the U.S. has increased its total DBD while at the same time accelerating DCD organ recovery.

The 16 DSAs accounting for 80% of the nation’s DCD in 2004 demonstrated a 49.3% increase in DCD while at the same time increasing standard criteria donors (SCD) by 9.4% and expanded criteria donors (ECD) by 3.8%. OPOs experiencing these increases offer the following insights about how implementation of DCD protocols positively impacts the number of donations after brain death:

- Appropriate clinical triggers can permit timely notification by hospitals of all eligible donors, both DCDs and DBDs;
- Timely notification of potential DCDs permits dialogue between OPO and hospital staff regarding the likelihood that eligible DCD donors may progress to brain death and thereby permit donation of a greater number of thoracic organs;
- Timely discussion between OPO and hospital staff can prevent premature discontinuation of life support thereby maintaining the option of DBD;
- Preventing premature discontinuation of life support preserves the option of both DBD and DCD and permits informed discussion with next-of-kin and other family members regarding their donation preferences.

Because SRTR data show the number of DCDs is positively correlated with the number of DBDs, it is essential that all DSAs commit to testing and implementing protocols that will maximize every type of donation opportunity (DBD and DCD) and promote recovery of the highest possible number of transplantable organ.

**Work group 5: Allocation of DCD Organs for Transplantation.**

The Work Group assignment was to consider strategies of DCD organ allocation that would provide equitable access for DCD organs, while sustaining incentives for DCD recovery. This work group also considered the economic impact of DCD upon the transplant center’s interest to accept DCD organs, noting that the rate of delayed graft function (DGF) is
almost doubled for DCD (40.1%) (not ECD characteristics) versus non-DCD SCD kidneys (21.2%) (Figure 1) and the yield of organs from DCD is clearly less that SCD but slightly better than that achieved by ECD (Figure 2).

However, despite the higher incidence of DGF associated with transplantation of DCD kidneys, it appears that the outcomes of DCD and DBD kidney transplantation are comparable at one and three years (Figure 3). DGF status was captured in the SRTR/OPTN database for all but 454 of the 41,218 DBD and 27 of the 1,635 DCD deceased donor kidney transplants performed between Jan 1, 2000 and December 30, 2004. Among those transplants for which DGF status was known, the frequency of DGF increased progressively across donor categories with transplants from 21.2% of DBD non-ECD (SCD), 33.3% of DBD that met the ECD definition (ECD), 40.1 percent of DCD that did not meet the ECD definition (ECD), and 55.2% of DCD that met ECD criteria (DCD/ECD) reported to have suffered DGF (Figure 1).

Among kidney transplants from deceased donors that did not meet the ECD definition, overall adjusted one-year and three-year allograft survivals were 90 and 80% for SCD, and 89 and 80% for DCD recipients, respectively (Table 5). Among transplants from donors that met the ECD definition, overall one-year and three-year adjusted allograft survivals for ECD transplants were 83 and 71%, and for DCD/ECD kidneys were 81 and 70%, respectively (Table 5).

As shown in Table 5, allograft survival at one and three years, closely parallel ECD status for both DGF and non-DGF deceased donor kidney transplants. Among transplants with DGF, overall adjusted one-year and three-year allograft survivals were 80 and 68% for SCD, and 83 and 69% for DCD recipients, respectively. Whereas among transplants from donors that both met the ECD definition and had DGF, overall one-year and three-year adjusted allograft survivals for ECD transplants were 72 and 58%, and for DCD/ECD kidneys were 76 and 55%, respectively.

The SRTR analysis of OPTN outcome data were important references of the allocation considerations of the working group (Figure 3 and 4). Given current donor and candidate acceptance criteria, allograft survival for similar subgroups (with or without ECD status, with or without DGF) of DCD and DBD kidney are demonstrated to be comparable.
**Allocation Incentives and Disincentives:**

No allocation incentives exist for lung, liver, and pancreas recipients of DCD organs. However, OPOs are not required to include kidneys recovered from DCD in the same process (the payback process) for returning a kidney to the general national pool of organs in exchange for a transplant center in the OPO’s DSA having received a zero antigen mismatched kidney from another OPO. They are exempt from the national zero antigen mismatch sharing policy and required to be allocated to zero antigen mismatched patients locally, and are otherwise allocated by a local, regional and national distribution. Allocation policy should hasten the process (organ placement) by which OPOs obtain transplant center acceptance for a DCD organ and work to increase DCD recovery and reduce discards. To counter the disincentive to recover DCD, work group participants recommended that DCD not be used in calculating outcomes for OPTN or CMS reports of center performance. Ten to thirty percent of potential DCD offers do no come to fruition because upon the withdrawal of life support the potential donor does not die in a time period that enables the successful recovery of organs. There is also inconsistent OPO remuneration to surgeons who may spend long hours of travel and time engaged in the attempted recovery of DCD organs from these “dry runs”. Such financial issues must be addressed.

**Allocation Issues: Liver**

Work Group 5 participants recommended that the OPTN require centers to list candidates who would be willing to accept DCD liver offers. Given the higher risk of graft failure for DCD livers when compared to the current outcome of SCD livers (Figure 4), candidates should be counseled regarding the risk of DCD organ acceptance with informed consent at time of listing (see below). The impact of DCD on outcomes (OR=1.85) may influence recipient selection. The hazard ratio of death following transplantation exceeds the risk of death waiting on the list for candidates at certain MELD scores (14).

The Work Group participants recommend that DCD donor liver placement follow the current allocation algorithm with distribution stratified by local recovery and allocation followed by regional offers. Parallel offers (back up offers) should be made to expedite placement. Consideration should be given to minimizing cold ischemic time, avoiding technically challenging recipient operative situations and assuring the availability of having a back-up recipient within the accepting center.
Allocation Issues: Kidney

With current data showing equivalency in graft and patient survivals of DCD and DBD primary kidney transplants despite higher DGF rates in DCD organs, (Figure 3 and Table 5), Work Group participants were reluctant to recommend changes in the current DCD allocation policy. The number of potential DCD kidneys available (and current data) do not seem to justify a separate allocation system as with ECD. DCD kidneys with ECD characteristics could be allocated as ECD in the separate ECD allocation system.

Work Group participants recommended that centers list candidates who would accept DCD offers. Offers would be made to local and regional centers by the standard OPTN computer match program and then by an accelerated placement process to aggressive DCD centers (also by OPTN computer match program). In the near future the development of a simultaneous broadcast or ‘blast’ offer may be initiated by the OPTN to facilitate accelerated placement (possibly in 12 - 15 months).

Allocation Issues Pancreas:

Work Group participants recommended that the current OPTN pancreas allocation algorithm be followed with local DSA priority given for combined kidney pancreas candidates or pancreas alone candidates who have been listed as accepting of a DCD pancreas. Successful pancreas transplantation has been reported from DCD at the University of Wisconsin (15).

Finding Recovery Surgeons:

The issue of finding a local recovery team and transplant center, especially for a kidney only DCD donor was discussed. Work Group participants concluded that centers should identify themselves as DCD recovery centers and as further recovery stratification, note their willingness to fly a recovery surgeon within and/or outside of its region.

If there is no local center available to recover DCD organs, the OPTN computer match run should be followed regionally. The accepting regional program must be willing to procure to receive the DCD organs. For DCD kidney only donors, the regional center could recover and retain one kidney for its patient. The other kidney is offered locally to a willing center. If there is no accepting local center, then the second kidney will be offered through the UNOS Organ Center according to the OPTN computer match program.
Work Group participants recommended that these proposals be incorporated into the allocation policies forthcoming from the OPTN/UNOS Kidney Allocation Review Subcommittee (KARS). KARS is to consider whether the elimination of HLA matching for DCD donor kidney placement could expedite placement and reduce cold ischemia time.

**Recipient Informed Consent:**

Workgroup participants considered the information that should be shared with a potential transplant recipient of a DCD organ to achieve informed consent. This aspect of the deliberations was controversial. Some of the participants’ recommended full disclosure of the donor circumstances of death because the outcome especially for DCD liver allograft recipients (Figure 4) might be less than achieved by transplantation of DBD organs. The process of informed consent should be done in phases, with a discussion of the current characteristics of the deceased donor pool at the outset of a patient listing (16). This initial consent discussion should include the transplantation of organs from donors with varying degrees of risk of failure when compared to an ideal donor. Final consent should be obtained at the time of the proposed transplantation when the physicians have a more precise assessment of the risks associated with undergoing a DCD (or ECD) transplant versus the risk of waiting for the next available donor (considering the candidates’ severity of disease and mortality risk at the time of the offer).

**Work group 6: The Media, Public Perceptions, and DCD.**

The work group participants are to disseminate this submitted conference report in an informative but not promotional manner. The expansion of DCD reflects advances in the practice of medicine. Families who want their loved ones to be an organ and tissue donor should no longer be excluded from the opportunity of donation nor should they have to bear a responsibility of raising the DCD option to the medical care team.

The work group participants are to assemble comprehensive information for different audiences: 1) transplant community, 2) other professional disciplines, and 3) the press and the general public. The message to be conveyed about DCD is provided by the following:

- DCD honors donor wishes in the continuum of quality end of life care;
- DCD can provide comfort and support to donor families;
- DCD saves lives.
Conclusions:

The National Conference on DCD has affirmed DCD as an ethically acceptable practice of end of life care, and capable of increasing the number of deceased donor organs. Accordingly, efforts should be made to ensure that all hospitals in the United States have a DCD policy. Conference participants acknowledged that DCD has been controversial in some media reports and for some health care professionals. However, much of the controversy has been fostered by misinformation about the timing of death, the risks of pre-mortem administration of medicines, and the quality of transplant outcome. Therefore, programs that adopt DCD policies should be committed to educating not only the media and general public of their local community but also their professional staff.

Acknowledgement:

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Finally, we wish to acknowledge our gratitude to the following staff of the SRTR for responding to the data requests: Dawn Zinsser, M.S.; Valarie Ashby, M.S.; Joshua McGown, M.S.; Laura Christensen, M.S.; Nathan Goodrich, M.S. and Sarah Miller.
Table 1. Desirable warm and cold ischemia times for transplantation of DCD organs.

<table>
<thead>
<tr>
<th></th>
<th>Kidney (Donors &lt; 60)</th>
<th>Liver</th>
<th>Pancreas</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WIT:</strong></td>
<td>1 hour</td>
<td>30 minutes</td>
<td>1 hour</td>
</tr>
<tr>
<td><strong>CIT:</strong></td>
<td>&lt;24 hours</td>
<td>&lt;8 hours</td>
<td>&lt;18 hours</td>
</tr>
<tr>
<td></td>
<td>if possible</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2. The University of Wisconsin criteria for predicting asystole following withdrawal of life support.

### UW Donation After Cardiac Death (DCD) Evaluation Tool

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Assigned Points</th>
<th>Pt. Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Spontaneous Respiration after 10 min.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rate &gt;12</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Rate &lt;12</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>TV &gt;200 cc</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>TV &lt;200 cc</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>NIF &gt; 20</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>NIF &lt;20</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>No Spontaneous Respirations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 25</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>25-29</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>&gt; 30</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Vasopressors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Vasopressors</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Single Vasopressor</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Multiple Vasopressors</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Patient Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-30</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>31-50</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>&gt; 50</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Intubation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endotracheal tube</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Tracheostomy</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Oxygenation After 10 minutes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O2 Sat &gt;90%</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>O2 Sat 80-89%</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>O2 Sat &lt;79%</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Final Score</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Extubation</td>
<td>Time of Extubation</td>
<td></td>
</tr>
<tr>
<td>Date of Expiration</td>
<td>Time of Expiration</td>
<td></td>
</tr>
<tr>
<td><strong>Total Time</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Scoring**

- 8-12 High Risk for continuing to breath after extubation
- 13-18 Moderate risk for continuing to breath after extubation
- 19-24 Low risk for continuing to breath after extubation
Table 3: UNOS Criteria for identifying potential DCD patients

- Apnea
- RR<8
- RR>30 during trial off mechanical ventilation
- LVAD
- RVAD
- V-A ECMO
- Pacemaker with unassisted rhythm<30
- PEEP≥10 and SaO2≤92%
- FiO2≥0.5 and SaO2≤92%
- V-V ECMO
- Norepinephrine, epinephrine, or phenylephrine ≥0.2 g/kg/min
- Dopamine ≥15 g/kg/min
- IABP 1:1 OR dobutamine or dopamine ≥10 g/kg/min and CI ≤2.2L/min/M^2
- IABP 1:1 and CI≤1.5L/min/M^2

Table 4.

<table>
<thead>
<tr>
<th>DCD and Pumping Type</th>
<th>% DGF</th>
<th>OR*</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-DCD, Not Pumped</td>
<td>23.9</td>
<td>1.00</td>
<td>Ref</td>
</tr>
<tr>
<td>Non-DCD, Pumped</td>
<td>17.0</td>
<td>0.54</td>
<td>&lt;0.0001</td>
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<tr>
<td>DCD, Not Pumped</td>
<td>42.3</td>
<td>2.52</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>DCD, Pumped</td>
<td>40.2</td>
<td>2.04</td>
<td>&lt;0.0001</td>
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</table>

*p=0.15

*Adjusted for recipient age, sex, race, PRA, ESRD cause, years of ESRD, HLA mismatch, year of transplant, previous transplant, transfusions and donor age, sex, race, hypertension, diabetes, cause of death, creatinine, cold ischemia time

SRTR
Table 5.

<table>
<thead>
<tr>
<th>Donor Type</th>
<th>N</th>
<th>% DGF</th>
<th>One-Year Survival %</th>
<th>Three-Year Survival %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>No DGF</td>
<td>DGF</td>
</tr>
<tr>
<td>SCD</td>
<td>29,862</td>
<td>21%</td>
<td>93%</td>
<td>80%</td>
</tr>
<tr>
<td>ECD (no DCD)</td>
<td>5,424</td>
<td>33%</td>
<td>88%</td>
<td>72%</td>
</tr>
<tr>
<td>DCD (no ECD)</td>
<td>1,120</td>
<td>40%</td>
<td>93%</td>
<td>83%</td>
</tr>
<tr>
<td>DCD+ ECD</td>
<td>136</td>
<td>55%</td>
<td>85%</td>
<td>76%</td>
</tr>
</tbody>
</table>

*Adjusted for recipient age, sex, race, PRA, ESRD cause, years of transplant, previous transplant, transfusions and donor sex, race, ESRD, HLA mismatch, year of e, diabetes, cold ischemia time slide

*No patients in this group after Day 313, as shown in previous slide

Table 6.

<table>
<thead>
<tr>
<th>OPO</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gift of Life</td>
<td>47</td>
<td>(12%)</td>
</tr>
<tr>
<td>NEOB</td>
<td>38</td>
<td>(19%)</td>
</tr>
<tr>
<td>Gift of Hope</td>
<td>36</td>
<td>(12%)</td>
</tr>
<tr>
<td>Life Center NW</td>
<td>33</td>
<td>(19%)</td>
</tr>
<tr>
<td>Midwest</td>
<td>28</td>
<td>(18%)</td>
</tr>
<tr>
<td>UW</td>
<td>27</td>
<td>(20%)</td>
</tr>
<tr>
<td>Lifequest</td>
<td>18</td>
<td>(17%)</td>
</tr>
<tr>
<td>Michigan</td>
<td>14</td>
<td>(5%)</td>
</tr>
<tr>
<td>CORE</td>
<td>14</td>
<td>(9%)</td>
</tr>
<tr>
<td>WRTC</td>
<td>12</td>
<td>(10%)</td>
</tr>
<tr>
<td>NYFL</td>
<td>11</td>
<td>(21%)</td>
</tr>
<tr>
<td>TRC MD</td>
<td>10</td>
<td>(10%)</td>
</tr>
<tr>
<td>Louisiana</td>
<td>8</td>
<td>(5%)</td>
</tr>
<tr>
<td>MTA</td>
<td>8</td>
<td>(7%)</td>
</tr>
<tr>
<td>Onelegacy</td>
<td>7</td>
<td>(2%)</td>
</tr>
<tr>
<td>Carolina</td>
<td>7</td>
<td>(5%)</td>
</tr>
<tr>
<td>Golden State</td>
<td>7</td>
<td>(15%)</td>
</tr>
<tr>
<td>NYODN</td>
<td>6</td>
<td>(2%)</td>
</tr>
<tr>
<td>NJTO</td>
<td>6</td>
<td>(4%)</td>
</tr>
<tr>
<td>Iowa</td>
<td>6</td>
<td>(15%)</td>
</tr>
</tbody>
</table>

Source: AOPO annual survey
Figure 1.

Delayed Graft Function (DGF) for DCD vs. Non - DCD Kidneys (w/ and w/o ECD), 2000 -2004

There were 454/41,218 non-DCD and 271,835 DCD kidneys with missing DGF information.

Figure 2.

Organs Recovered Per Donor 1995 - 2004
Figure 3.

Adjusted* Graft Survival for DCD vs. non-DCD Kidney Transplants, 2000-2004

Adjusted HR = 1.85
P<0.0001

Adjusted* Liver Graft Survival
(1/1/2000 - 10/31/2003)

Adjusted HR = 1.68
P<0.0001

Figure 4.
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