

**OPTN/UNOS Organ Procurement Organization (OPO) Committee
to the Board of Directors
November 14-15, 2011
Atlanta, GA**

Summary

I. Action Items for Board Consideration

- The Board is asked to approve modifications to Attachment III to Appendix B of the OPTN Bylaws (Model Elements for Controlled DCD), Appendix B to the OPTN Bylaws (Criteria for OPO, Transplant Hospital and Histocompatibility Laboratory Membership, I - Organ Procurement Organizations, and II - Transplant Hospitals), Policies 2.7 and 2.8 (Removal of Non-renal Organs), 3.5.3.3 (Sharing), 3.5.5 (Payback Requirements), 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years), 6.4.2 (Developmental protocols in International Organ Exchange), and 6.4.3 (Ad Hoc Organ Exchange). The proposed modifications strengthen the language by making them requirements, update terminology (i.e. cardiac to circulatory), and require a time-out as opposed to recommending one. (Item 1, Page 3)
- The Board is asked to approve modifications to Policies 5.4.3 (Vessels) and 5.10.2 (Vessel Storage) that require the vessel container to be labeled and clarifies language regarding the placement of the OPTN distributed label. (Item 2, Page 12)

II. Other Significant Items

- The Committee distributed proposed modifications for public comment to change the term “consent” to “authorization” throughout OPTN Policy when used in reference to deceased donation. (Item 6, Page 16)
- The Committee distributed for public comment proposed modifications to Policy 5.1.3 (Mechanical Preservation Machine) and 5.3 (External Labeling Requirements) that will align deceased donor shipping policy with that of living donor shipping policy, eliminate the ability to use an alternate label for preservation machines, and require the OPTN distributed standardized label. (Item 6, Page 16)
- The Committee distributed proposed modifications to Policy 7.0 (Reporting Definitions) for public comment that will make the Imminent and Eligible death data collection more consistent. Modifications include organ specific criteria that will exclude a patient from being reported as an eligible death, the addition of weight and BMI limits, and the elimination of multi-system organ failure as an exclusionary criterion. (Item 6, Page 16)
- The Committee is preparing a survey of OPOs regarding current practices in uncontrolled DCD (u-DCD) and is considering policy development (similar to the DCD Model Elements) to provide guidance to OPOs and transplant centers. (Item 9, Page 19)
- The Committee will work with the Living Donor Committee to develop a Living Donor transport label. (Item 11, Page 20)

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OPTN/UNOS Organ Procurement Organization (OPO) Committee
Report to the Board of Directors
November 14-15, 2011
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Lori Brigham MBA, Chair
Richard Pietroski MS, CPTC, Vice Chair

This report details the OPO Committee's deliberations during its face-to-face meeting on September 14, 2011, and Committee conference call/Live Meeting on June 20, 2011. Additionally, the uncontrolled DCD (u-DCD) donor, Labeling, and Imminent and Eligible Death Definition Subcommittees have met by conference call/Live Meeting.

1. **DCD Model Elements.** In 2009, the Board of Directors charged the OPO and Organ Availability Committees with the goal of reviewing DCD policies to ensure that they were consistent with current practice. The Committees formed a joint Work Group and identified two areas that needed to be updated and clarified: 1) policy and bylaws and 2) definitions affecting DCD data reporting. Their work was ultimately approved by both Committees.

The Work Group determined that existing policies regarding DCD were comprehensive; however, the DCD Model Elements were out of date and did not reflect current practice. The OPTN Bylaws require that OPOs and transplant centers incorporate the DCD Model Elements into their DCD policies. The Committees recommended specific changes to update terminology such as changing the terms "Model Elements" to "Requirements." Additionally, the Committees agreed that the title "Donation after Cardiac Death" does not accurately reflect the Uniform Determination of Death Act's (UDDA) definition of death, which states:

"An individual who has sustained either 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead." (Uniform Determination of Death Act, 12 uniform laws annotated 589 (West 1993 and West Suppl. 1997))

To be consistent and to reflect the intent of the UDDA, the Committees proposed that the name "Donation after Cardiac Death" (DCD) be changed to "Donation after Circulatory Death" (DCD). This change is particularly important because the heart is not dead (nor are other organs) when the heart stops, but when circulation and oxygenation to the tissues are irreversibly stopped. Organizations such as the Society of Critical Care Medicine (SCCM) use this terminology. The OPO Committee and OAC unanimously supported this change.

The name "Donation after Cardiac Death" appears in seven policies and bylaws: Attachment III to Appendix B of the OPTN Bylaws (Model Elements for Controlled DCD), Appendix B to the OPTN Bylaws (Criteria for OPO, Transplant Hospital and Histocompatibility Laboratory Membership - I - Organ Procurement Organizations and II - Transplant hospitals), Policies 2.7 and 2.8 (Removal of non-renal organs), 3.5.3.3 (Sharing), 3.5.5 (Payback Requirements), 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years), 6.4.2 (Developmental protocols in International Organ Exchange), and 6.4.3 (Ad Hoc Organ Exchange).

If approved, the terms "cardiac" will be changed to "circulatory" and "Model Elements" will be changed to "requirements" in each of those policies and Bylaws to ensure consistency. The phrase "withdraw life sustaining measures" was changed to "withdraw life sustaining medical

treatment/support,” to reflect current language used by the community, the Society of Critical Care Medicine, and CMS.

While rare, DCD donation may occur in patients who do not have a neurological injury, but who suffer from a disease that renders them ventilator dependent (i.e. amyotrophic lateral sclerosis). As such, the term “disease” was included in the language that describes suitable candidate conditions. This change will be more specific in allowing these candidates to grant first person consent for donation and make these Model Elements more consistent with current practice. Terms like “heparin” and “regitine” were changed to “anticoagulant and /or vasodilator administration” as this new language is less prescriptive and more flexible in the event that there are newer or more appropriate medications to be used.

The Committee also added language that reflects the CMS requirements that OPOs have a written agreement with participating hospitals. These changes are consistent with CMS expectations and make the Model Elements more complete and inclusive.

The Model Elements currently require an assessment to determine whether death is likely to occur (after withdrawal of life sustaining medical treatment/support) within a timeframe necessary for organ donation. This language was deleted because there is no industry standard that allows for a true assessment of the likelihood of death within a specific period. Each hospital establishes its own timeframe for organ acceptability.

In 2009, there were 920 DCD cases reported in the United States. This number represents an 8.5% increase in the number of DCD cases reported nationwide compared to 2008, and indicates improved understanding of donor hospital willingness to develop DCD policies; OPOs to facilitate DCD protocols; and transplant centers to accept DCD organs to treat end-stage organ failure. Furthermore, with some of the more successful OPOs achieving up to 32% of their donor base as DCD donors, there exists a significant gap in unrealized donor potential that can be better captured by using more complete and up-to-date DCD Model Elements.

The proposed changes were distributed for public comment in the Spring, 2011. On June 20, 2011, the Committee reviewed and responded to public comments; there was strong support for this proposal (**Exhibit A – Briefing Paper**). The Committee voted in favor of the changes to the bylaws and policies and recommended that they be submitted for Board approval with a vote of 14-0-0.

****RESOLVED, that modifications to Appendix B to the OPTN Bylaws (Criteria for OPO, Transplant Hospital and Histocompatibility Laboratory Membership - I - Organ Procurement Organizations and II - Transplant hospitals), Attachment III to Appendix B of the OPTN Bylaws (Model Elements for Controlled DCD), and Policies 2.7 and 2.8 (Removal of non-renal organs), 3.5.3.3 (Sharing), 3.5.5 (Payback Requirements), 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years), 6.4.2 (Developmental protocols in International Organ Exchange), and 6.4.3 (Ad Hoc Organ Exchange), shall be modified as set forth below, effective pending notice to the membership:**

The following Bylaw proposal may appear different than what the reader is accustomed to seeing. Because of the large number of changes that were made (editorial and substantial content changes), much of the Bylaw would be crossed out making the proposal difficult to read and understand. In the new proposed language below, only those changes that are substantial content changes are either ~~crossed out~~ if the language was eliminated or underlined if there is substantial new content added. Additionally, a “crosswalk” and original policy language that is

crossed out can be found in (Exhibit B). This document will assist the reader in identifying where changes occur and where content can be found if moved.

Attachment III to Appendix B of the OPTN Bylaws
~~Model Elements~~ Requirements for Controlled
Donation after ~~Cardiac~~ Circulatory Death ~~Recovery~~-(DCD) Protocols

Introduction: Donation after ~~Cardiac~~ Circulatory Death (DCD) describes the organ recovery process that may occur when a death is defined as the irreversible cessation of circulatory and respiratory functions. Death is declared in accordance with hospital policy and applicable state and local statutes or regulation. A DCD donor may also be called a non-heartbeating or asystolic donor. The Institute of Medicine, along with the transplant community, recognizes DCD as an ethical and viable option for patients and families making end-of-life decisions.

These ~~guidelines~~ requirements will help OPOs and transplant centers develop the necessary DCD protocols and may be helpful in analyzing existing protocols for process improvement. These ~~guidelines~~ requirements do not address local practices, cultural and resource issues, and therefore should not be the only resource consulted when developing DCD protocols. DCD protocols should continue to be developed through collaboration between OPOs and transplant centers. OPTN members that experience difficulty in adopting a DCD protocol may consult with the joint OPO Committee/MPSC working group for assistance.

A. Agreement

The OPO must have a written agreement with hospitals that participate in DCD recovery. The participating hospital must be a Medicare and Medicaid participating hospital or a Critical Access Hospital as certified by Medicare. The participating hospital must also have a ventilator and a functional operating room.

B. Protocols

OPOs, in consultation with their affiliated transplant centers shall establish protocols that define the roles and responsibilities of the OPO and transplant centers for the evaluation and management of potential DCD donors, organ recovery and organ placement in compliance with OPTN policy.

C. Candidate Evaluation

~~Before evaluating a patient as a DCD candidate, the hospital's primary healthcare team and the legal next of kin must have decided to withdraw ventilated support or other life-sustaining treatment and that decision must be documented in the patient's chart.~~ A potential DCD donor should ~~then~~ be evaluated by the primary healthcare team and the local OPO to determine if the candidate meets the following criteria:

1. A patient, ~~from age newborn to the Donation Service Area's (DSA) defined upper age limit,~~ with a permanent and irreversible neurological injury (i.e. upper spinal cord injury), or permanent and irreversible disease (i.e. end-stage musculoskeletal or pulmonary disease) that results in necessary life-sustaining medical treatment or ventilated support ~~but who does not fulfill the neurologic criteria for death,~~ may be a suitable candidate for DCD.

2. A patient with end-stage musculoskeletal disease, pulmonary disease or upper spinal cord injury may also be a suitable DCD candidate.
5. ~~An assessment should be made as to whether death is likely to occur (after the withdraw life sustaining measures) within a time frame that allows for organ donation.~~

The OPO may also consult with the OPO Medical Director and the Transplant Center team that may be considering the organs for transplantation.

D. Consent/Authorization

~~For the purpose of obtaining consent and authorization for a DCD recovery, “legal next of kin” can include any of the following:~~ Consent and authorization for a DCD recovery can be obtained from any of the following:

1. the patient who consents to be an organ donor candidate;
2. the next of kin as defined by state or local law; ~~or or the Uniform Anatomical Gift Act~~
3. the designated health care agent

The legal next of kin may consent to procedures or drug administration to prepare the patient for a DCD recovery. Some examples of procedures or drugs may include, but are not limited to, femoral line placement, lymph node excision, ECMO circuit cannulation, bronchoscopy, anticoagulants, and vasodilators.

A medical examiner or coroner must give clearance, when applicable.

Create a plan for patient care in the event that death does not occur within the established time period after the withdrawal of life-sustaining medical treatment or ventilated support. This plan should include provisions for ~~continued~~ end of life care and the immediate notification of the patient’s next of kin.

E. Withdrawal of Life Sustaining Medical Treatment/Support Measures/Patient Management

Before withdrawing life-sustaining medical treatment or ventilated support, the OPO is required to conduct a timeout to:

1. Verify the patient’s identification.
2. Determine the process and location for withdrawing life-sustaining treatment or ventilated support. Items to be considered may include ETT removal or termination of blood pressure management medications.
3. Review the roles and responsibilities of the primary patient care team, the OPO team, and the organ recovery team.
4. Review the plan for patient care in the event that death does not occur within the established time period after the withdrawal of life-sustaining medical treatment or ventilated support.

No member of the Transplant Center surgical team may be present for the withdrawal of life-sustaining medical treatment or ventilated support.

No member of the Organ Recovery team or OPO staff may guide or administer palliative care or declare death.

F. Pronouncement of Death

The patient care provider who is authorized to declare death must not be a member of the OPO or the surgical recovery team. Circulatory Death is death defined as the irreversible cessation of circulatory and respiratory functions. Death is declared in accordance with hospital policy and applicable state and local statutes or regulation.

Pronouncement of death can only be made after a sufficient time period has passed, as defined by hospital policy.

G. Organ Recovery

The surgical recovery of organs may not be initiated until the patient is declared dead.

~~A. Financial Considerations~~

- ~~1. OPO policy to ensure no donation related charges are passed to the donor family.~~

Resources:

Maastricht Classification – Definition of Controlled DCD Donors

DCD donors are grouped by the Maastricht classification (1995; amended 2003).

- | | |
|------------|--|
| I | Dead on arrival to hospital |
| II | Unsuccessful resuscitation |
| III | Awaiting cardiac arrest – In-patient (withdrawal of support) |
| IV | Cardiac arrest after brain-stem death |
| V | Cardiac arrest in a hospital inpatient |

Controlled DCD donors would include those outlined in Maastricht criteria III.

Sources:

- President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death* (Washington: Government Printing Office, 1981), p. 73.
- Uniform Determination of Death Act. 12 Uniform Laws Annotated 320 (1990 Supp). Uniform Determination of Death Act, 12 uniform laws annotated 589 (West 1993 and West Suppl. 1997)

~~How is irreversibility defined?~~

~~From the Report of a National Conference on Donation after Cardiac Death.
Am J Transplant. 2006 Feb; 6 (2):281-91.~~

~~*Irreversibility* is recognized by persistent cessation of function during an appropriate period of observation. Based on 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.~~

~~If data show that auto-resuscitation (spontaneous resumption of circulation) cannot occur and if there is no attempt at artificial resuscitation, it can be concluded that respiration and circulation have ceased permanently.~~

~~In clinical situations in which 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 (auto-resuscitation) may be only a few minutes. Current data on auto-resuscitation indicate that the relevant event is cessation of circulation, not cessation of electrical activity.~~

~~When life-sustaining therapy is withdrawn, based on the limited data available (presented by Michael DeVita at the National Conference), spontaneous circulation does not return after 2 minutes of cessation of circulation.~~

~~How is the permanent absence of circulation determined?~~

~~From the Report of a National Conference on Donation after Cardiac Death.~~

~~*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. However, the urgent time constraints of DCD may require more definitive proof of cessation of these functions by the use of confirmatory tests.~~

~~Confirmatory tests (e.g. intra-arterial monitoring or Doppler study) should be performed in accordance with the hospital protocol to assure the family and the hospital professional staff that the patient is dead.~~

~~* Other Important Determination of Death Resources~~**

~~Recommendations for non-heart-beating organ donation, A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine, Critical Care Medicine, 2001 Vol. 29, No. 9, pp. 1826-1831.~~

- ~~1. Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement, Institute of Medicine, December 1997.~~
- ~~2. Non-Heart-Beating Organ Transplantation: Practice and Protocols, Institute of Medicine, 2000.~~

~~*Below is the policy language for those OPTN and UNOS Policies and Bylaws that will also need to be changed to be consistent with the changes proposed to the Model Elements. Only the section that includes information on DCD is included here to eliminate the need to have entire policies listed when only a small portion of the policy requires a change.*~~

APPENDIX B TO BYLAWS OPTN/UNOS

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

Donation after ~~Cardiac~~ Circulatory Death: OPOs must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. OPO DCD recovery protocols must address the requirements ~~d-model elements~~ set forth in Attachment III.

II. Transplant Hospitals.

Donation after ~~Cardiac~~ Circulatory Death. Transplant hospitals must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. Transplant Hospital DCD recovery protocols must address the requirements ~~d-model elements~~ set forth in Attachment III.

POLICY 2.0

MINIMUM PROCURMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)

Policy 2.7 and 2.8

2.7 REMOVAL OF NON-RENAL ORGANS. When a non-renal organ is offered for transplantation, the recipient center procurement team must be given the option of removing the non-renal organ unless extenuating circumstances dictate otherwise. This policy also applies to non-renal organs from controlled donation after ~~cardiac~~ circulatory death (DCD) donors.

2.7.1 Multiple Abdominal Organ Procurement. It is expected that all authorized organs should be procured from a donor if each organ is transplantable and/or recipients are identified for each organ. The OPO will document the specific reason for non-recovery of an authorized organ. Cooperation between all organ recovery teams is required.

2.8 In order to recover organs from a DCD donor, an OPO must follow an established protocol that contains the ~~standards of the DCD Model Elements~~ Requirements for Controlled Donation after ~~Cardiac~~ Circulatory Death ~~Recovery~~-(DCD) Protocols as adopted in the OPTN Bylaws, Appendix B, Attachment III.

POLICY 3.0

ALLOCATION OF DECEASED KIDNEYS

3.5.3.3 Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after ~~Cardiac~~ Circulatory Death donors¹ if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after ~~Cardiac~~ Circulatory Death donors¹, if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch who has agreed to be

transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a candidate with a zero antigen mismatch does not have the implicit right to choose between the two kidneys.

The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a candidate with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all candidates for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after ~~Cardiac~~ Circulatory Death donors, if there is any candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to regional and then national pediatric or sensitized adult candidates (CPRA>20%) in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

¹For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after ~~Cardiac~~ Circulatory Death donors shall be defined as follows: (1) A controlled Donation after ~~Cardiac~~ Circulatory Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after ~~Cardiac~~ Circulatory Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after ~~Cardiac~~ Circulatory Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.5 Payback Requirements. Except as otherwise provided in Policy 3.5.3.5 (Sharing of Zero Antigen Mismatched Kidneys - Time Limit), ~~3.8.1.6.1 (Sharing of Zero Antigen Mismatch Pancreata - Time Limit)~~, ~~3.8.3.4 Organ Offer Limit~~, 3.5.5.2 (Exception for Prior Living Organ Donors), and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged Less than 35 Years), when a kidney is shared pursuant to: (i) the zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a candidate with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after ~~Cardiac~~ Circulatory Death donor¹, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after ~~Cardiac~~ Circulatory

Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

¹For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after ~~Cardiac~~ Cardiac Circulatory Death donors shall be defined as follows: (1) A controlled Donation after ~~Cardiac~~ Cardiac Circulatory Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after ~~Cardiac~~ Cardiac Circulatory Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after ~~Cardiac~~ Cardiac Circulatory Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.11.5.1 Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years. Kidneys from donors aged less than 35 years that are not shared mandatorily for 0 HLA mismatching, for renal/non-renal organ allocation, or locally for prior living organ donors pursuant to Policy 3.5.11.6 (Donation Status) shall be offered first for transplant candidates who are less than 18 years of age at listing irrespective of the number of points assigned to the candidate relative to candidates 18 years old and older, with the exception of candidates assigned 4 points for PRA levels of 80% or greater under Policy 3.5.11.3 (Panel Reactive Antibody) who otherwise rank higher than all other listed candidates based upon total points assigned under policy. When multiple pediatric transplant candidates are eligible for organ offers under this policy, organs shall be allocated for these candidates in descending point sequence with the candidate having the highest number of points receiving the highest priority. For purposes of assigning allocation priority among pediatric candidates for kidneys from donors aged less than 35 years under this Policy 3.5.11.5.1, one additional point shall be assigned for candidates who are less than 11 years old; only in the case of candidates who are zero antigen mismatched with Donation after ~~Cardiac~~ Cardiac Circulatory Death donor kidneys allocated regionally or nationally, four (rather than one) additional points shall be assigned for candidates who are less than 11 years old and three additional points shall be assigned for candidates who are 11 years old or older but less than 18 years old. The priority assigned for pediatric candidates under this policy does not supercede obligations to share kidneys as a result of a zero antigen mismatch pursuant to Policies 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys) and 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).

POLICY 6.0

TRANSPLANTATION OF NON-RESIDENT ALIENS

6.4 EXPORTATION AND IMPORTATION OF ORGANS-DEVELOPMENTAL STATUS. International exchange of organs for transplantation is technically feasible but remains an uncommon procedure. The OPTN regards international sharing of organs to be in an early phase of development.

6.4.1 Exportation. [No Change]

6.4.2 Developmental Protocols in International Organ Exchange. After prior approval by the OPTN, members may enter into formal organ exchange arrangements, each not to exceed two years in duration, with a foreign transplant program or programs. Negotiations with foreign transplant programs or foreign agencies which include importing organs must be approved by the Ad Hoc International Relations Committee. Importation of organs is defined in Policy 6.4.5 (Importation). Proposed protocols must be submitted to the OPTN describing the basis for such arrangements, expected benefits to both foreign and domestic participants, credentials of the foreign source, number and type of organs anticipated to be involved, and plans for allocation procedures and reporting of results. Proposed protocols must include a requirement for the donor organization to submit documentation certifying the informed consent of the donor or his or her legal representative. Proposed protocols must also include a requirement for the donor organization to submit documentation certifying that the donor has met the brain death or donation after ~~cardiac~~ cardiac circulatory death (DCD) protocols that are in compliance with recognized U.S. standards for domestic organ procurement. Proposed protocols must include a requirement for the donor organization to submit documentation of the donor's ABO. Proposed protocols will be reviewed by the Ad Hoc International Relations Committee, which will then make recommendations to the Board of Directors.

6.4.3 Ad Hoc Organ Exchange. Except as provided for in approved international exchange protocols, all offers of organs for human transplantation from foreign sources must be made to the Organ Center. If a member is contacted by a foreign source with an organ offer, that member must notify the Organ Center of that offer. No more than six exchanges by any member with any foreign program(s) will be allowed on an ad hoc basis. Additional exchanges must be made as part of an international organ exchange protocol approved by the Ad Hoc International Relations Committee and Board of Directors.

Imports of organs from foreign sources on an ad hoc basis must meet the requirements for importing organs and allocation of those organs under organ exchange protocols found in Policy 6.4.2.1. Additionally, organs imported by OPOs must include documentation certifying that the donor has met brain death or donation after ~~cardiac~~ cardiac circulatory death (DCD) protocols that are in compliance with recognized standards for domestic organ procurement. Organs imported by OPOs must include documentation from the donor organization certifying the informed consent of the donor or his or her legal representative. Organs imported by OPOs must include documentation from the donor organization verifying the donor's ABO.

- 2. Vessel Labeling.** This proposed policy modification will clarify that the container used for vessel storage must be properly labeled. In January 2011, the Committee introduced a new labeling system to enhance consistency throughout the OPTN and to eliminate errors. The policy stated that the interior label distributed by the OPTN contractor was required for vessel storage; however, the vessel container itself did not require a label when stored. Additional policy language required vessels to be placed in a triple sterile barrier, one of which is the rigid container, and labeled with the OPTN distributed label. The Committee also understood that transplant centers were storing vessels without the triple sterile barrier and agreed that policy clarification was needed.

The Committee members recognize the importance of a consistent and standardized packaging and labeling practice, and the original intent for the proposed changes was to make the labeling requirements for vessels storage consistent with those when transporting vessels. As such, the Committee agreed that labeling the container for vessel storage was not necessary because the OPTN contractor distributed label, affixed to the outermost barrier of the triple sterile barrier, was required.

Although this proposal garnered regional and public support, the Ad Hoc Disease Transmission Committee and the Operations and Safety Committee strongly opposed the lack of a label directly on the container as they agreed it was a patient safety issue. As such, this proposed change was eliminated and the language clarified that a container label is required in addition to the OPTN contractor distributed label on the outermost barrier.

Policy also assigns responsibility to the OPO to complete all packaging and labeling in the donor operating room. Language has also been updated to include the “PHS Guidelines.

After reviewing the public comment responses, (**Exhibit C – Briefing Paper**) the Committee agreed that a label should be required for the vessel container when stored. At the June 20, 2011, meeting, the Committee modified the wording to clarify language as demonstrated in the double underlines in the proposed policy. The Committee also recommended the development of an electronic vessel label that would fit a storage container and have all of the needed policy requirements. Members agreed that this label could be downloaded from the OPTN or UNOS websites or provided electronically, and then printed on labels.

The Committee voted to amend the proposed language described and recommend the revised proposal to the Board for approval. The Committee approved this resolution with vote of 13-0-0.

****RESOLVED**, that Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials) be modified as set forth below, effective pending notice to the membership:

Policy or Bylaw Proposal

5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS. [NO CHANGE]

5.1- 5.3 [No Change]

5.4 INTERNAL LABELING REQUIREMENTS

5.4.1 – 5.4.2 [No Change]

5.4.3 Vessels

Both ~~the~~ the vessels container and outer sterile barrier must be labeled with the standardized vessel labels distributed by the OPTN contractor. The information must contain the: recovery date, ABO, all serology-infectious disease testing results, container contents, and the UNOS Donor ID. If the donor is in a “high risk” group as defined by the ~~Centers for Disease Control and Prevention (CDC), US Public Health Service (PHS) guidance~~¹, the label must indicate that the vessels are from a donor who meets the ~~CDC~~ (PHS) criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state “for use in organ transplantation only.” If packaged separately from the

organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label must be affixed to the outermost barrier and container.

5.5 – 5.9 [No Change]

5.10 VESSEL RECOVERY, TRANSPLANT, AND STORAGE

The intent of this policy is to permit:

- vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant); and
- vessel recovery and storage for use in a subsequent solid organ transplant from a donor with a different UNOS Donor ID (for example, when the vessel(s) and the liver or pancreas allograft are being transplanted from different donors with different numbers).

5.10.1 Vessel recovery and transplant [No Change]

5.10.2 Vessel storage

The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (e.g. subsequent positive serology testing, monitor inventory of stored vascular conduits). This person must monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container and must be protected by a triple sterile barrier, one of which must be the rigid container, labeled with the recovery date, ABO, serology infectious disease results, container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be ~~attached~~ affixed to the outer most sterile barrier bag and information on the label must include ~~all of the above information and all serology testing results~~ the: recovery date, ABO, all serology infectious disease results, container contents, and the UNOS Donor ID. If the donor is in a “high risk”¹ group as defined by the Centers for Disease Control and Prevention (CDC) US Public Health Service (PHS) guidance¹, the label must indicate that the vessels are from a donor who meets the CDC(PHS) criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state for use in organ transplantation only. If removed from the triple sterile barrier, the transplant center must re-label the vessels prior to storage.

- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

5.11 TRANSPORTATION RESPONSIBILITY [No Change]

3. **Data Review.** At the September 14, 2011, meeting, UNOS Research staff provided a summary of donation-related data for the first half of 2011, and compared those data with those from the first half of 2010. (Exhibit D)
- Data demonstrate an increase of 23 (0.6%) deceased donors recovered; however, the number of organs recovered and organs transplanted (OTPD) has decreased by 21 (0.2%). The number of OTPD was 3.10 in 2010 and 3.08 in 2011.
 - The number of Standard Criteria Donors (SCD) has increased by 15 (0.6%), however, there were 72 fewer SCD organs transplanted. The number of OTPD was 3.79 in 2010 compared to 3.74 in 2011).
 - There were 73 (7.6%) fewer Extended Criteria Donors (ECD) and 124 fewer ECD organs transplanted in 2011. The number of OTPD increased slightly from 1.83 in 2010 to 1.84 in 2011.
 - There were 81 (17.3%) more Donation after Cardiac Death (DCD) donors in 2011 and there were 175 more organs transplanted from DCD donors. The DCD OTPD increased from 1.97 to 2.00. Thirteen DSAs demonstrated a decrease in DCD donation; however, twenty-eight DSAs demonstrated increases in DCD donation that ranged from a 7.1% to 700% increase. These DCD data are representative of 54 DSAs that had at least one DCD donor in the both years.
4. **Organ Yield Calculator.** At the September 14, 2011, SRTR staff provided a demonstration of the new “yield calculator” that will assist OPOs in identifying an individual OPO’s “observed” vs. “expected” organ yield. The calculator considers donor characteristics, such as disease factors, life style factors, and demographics and determines how many organs should be recovered from a donor with those characteristics. The models include both organ specific and aggregate data. The MPSC is developing flagging methodologies to help OPOs identify performance improvement needs for quality improvement.

The “expected” yield number is calculated in models based on donor characteristics using a 2-year cohort. Although the models are not auto-populated from DonorNet[®], data can be moved into the system retrospectively so OPOs can evaluate past performance as well. Committee members discussed the possibility of performing a prospective analysis. One Committee member suggested that OPOs might limit the amount of time dedicated to a donor based on data that might show a low projected yield. Members recognized that there are some factors that cannot be controlled. The SRTR will place the calculator on the secure site when completed.

Data for the calculator tool is for the OPO’s use and is not required by policy. The models use the data already collected from the Deceased Donor Record (DDR). If an OPO recovers no

transplantable organs from a donor, the OPO is penalized on its observed vs. expected ratio. Based on the current data collection, if you recover at least one organ for the purpose of or with the intent to transplant, then the OPO classifies that person as a donor. Therefore, the data do not demonstrate the number of donors that had no organs transplanted. These data would be relevant to OPOs and of interest to the Committee. The Committee requested data that show how many donors had no organs transplanted out of the total number of donors, and that these data be broken down into ECD, DCD and SCD donors.

5. **HRSA Update.** Robert W. Walsh, HRSA Public Health Analyst, provided a brief update on the HRSA role in the OPTN. HRSA provides oversight of the OPTN to ensure that the OPTN is compliant with the requirements of the contract, NOTA, and the Final Rule. Additionally, HRSA staff serves as ex-officio members on committees, the Board of Directors, and acts as liaisons between the OPTN and HRSA.

6. **Items Distributed for Public Comment September 15, 2011.**

- A. *Consent vs. Authorization.* The Committee distributed proposed modifications for public comment to change the term “consent” to “authorization” throughout OPTN Policy when used in reference to deceased donation. The affected policies are: 2.0 (Minimum Procurement Standards for an organ Procurement Organization), 3.3 (Acceptance Criteria), 3.5 (Allocation of Deceased Kidneys), 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels, and Tissue Typing Materials), 6.0 (Transplantation of Non-Resident Aliens), and 7.0 (Data Submission Requirements), and Attachment III to Appendix B of the OPTN Bylaws (Model Elements for Controlled Donation after Cardiac Death Protocols).
- B. *Alternate Label for Perfusion Machines.* The Committee distributed for public comment proposed modifications to Policy 5.1.3 (Mechanical Preservation Machine) and 5.3 (External Labeling Requirements) that will align deceased donor shipping policy with that of living donor shipping policy, eliminate the ability to use an alternate label for preservation machines, and require the OPTN contractor distributed standardized label.
- C. *Imminent and Eligible (I & E) Death Data Collection.* The Committee proposed changes to the imminent and eligible (I & E) death definitions to make data collection more consistent. It has been determined that the data are inconsistent due to several factors:
- 1) The definitions are being interpreted differently throughout the country (i.e. multi system organ failure); and
 - 2) Some state laws or hospital protocols require two (sometimes more) brain death exams while others only require one. This is particularly important to the data collection because when two exams are required, and only one is completed, the patient is not reported as an imminent or an eligible death.

The definitions classify a death as either “eligible,” “imminent,” or “neither.”

The Committee has proposed significant changes to the definition:

- Add minimum weight to the definition that would
 - Exclude patients less than 5 kg or
 - Include patients that weighted 5 kg or greater
- Add Maximum Body Mass Index (BMI)
 - Include patients with a BMI of 50 kg/m² or less
- **Include a list of organ specific exclusionary criteria**
- **Remove multi-system organ failure as an exclusionary criterion**

The changes are for reporting purposes only and are not designed to screen donors or be used for allocation. The following demonstrates the organ specific exclusionary criteria:

The kidney would be deemed suitable for transplant unless the donor has one of the following:

- Polycystic kidney disease
- Glomerulosclerosis $\geq 30\%$
- Chronic Renal Failure
- No urine output ≥ 24 hours
- **No candidates on the list/exhausted the list

The Liver would be deemed suitable unless the donor has one of the following:

- Cirrhosis
- Direct Bilirubin/Total Bilirubin $\geq 15\text{mg/dl}$ over 24 hours with no trauma or transfusion
- Portal hypertension
- Macrosteotosis $\geq 60\%$ or bridging fibrosis \geq stage III
- Fulminant hepatic failure
- Terminal AST/ALT > 5000 U/L
- **No candidates on the list/exhausted the list

The heart would be deemed suitable for transplant unless the donor has one of the following:

- History of Coronary Artery Bypass Graft (CABG)
- History of coronary stent/intervention
- Current or past medical history of myocardial infarction (MI)
- Severe vessel diagnosis as supported by cardiac catheterization (i.e. $>50\%$ occlusion or 2+ vessel disease)
- Acute myocarditis and/or endocarditis
- Heart failure due to cardiomyopathy
- Internal defibrillator or pacemaker
- Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
- Serial echo results showing severe global hypokinesis
- Myxoma
- Congenital defects (whether surgically corrected or not)
- **No candidates on the list/exhausted the list

The lung would be deemed suitable for transplant unless the donor has one of the following:

- Diagnosed COPD (emphysema)
- Terminal P/F <250
- Asthma (with daily Rx) in which COD due to asthma
- Pulmonary Fibrosis
- Previous lobectomy
- Multiple blebs documented on Computed Axial Tomography (CAT) Scan
- Pneumonia as indicated on Computed Tomography (CT), Xray, bronchoscopy, or cultures

- Diagnosed tumor
- Bilateral severe pulmonary contusions as per CT
- **No candidates on the list/exhausted the list

Based on these screening criteria, if the donor has at least one organ that is transplantable, the death is classified as an imminent or eligible death.

The Committee discussed the criterion, “No candidates on the list/exhausted the list,” that appears on each organ specific list and agreed that a death should not be reported as an imminent or eligible death when the OPO evaluates the organ and has no one to accept the offer. So in order to define “exhausting the list, the Subcommittee recommended the following:

A death is not considered eligible in the following situations:

- If a potential donor has no suitable organ or if the OPO has exhausted the list, if either a match run has been run and all centers and patients on the list have declined the organ preoperatively or
- If the donor goes to the operating room with the intent to recover organs for transplant but upon visualization of the organ, all surgical teams determine not to take an organ, and no organ is actually recovered based on visualization, then this death would not be considered an imminent or eligible death.
- If an OPO pursues a donor but stops the pursuit, it is not considered exhausting the list.
- If kidneys are recovered but biopsy results are not acceptable, and the intent was to transplant the organ, then this death would be considered an eligible death.
- When a donor is “consented but not recovered” and if the biopsy does not discount the organ but no one wants it, this death is considered an eligible death.

A death is not considered an eligible death if:

- the donor has no suitable organ, or;
- the list has been exhausted, or;
- all centers and patients on the list have declined the organ preoperatively, or;
- the donor goes to the operating room with the intent to recover organs for transplant but upon visualization of the organ, all surgical teams present determine not to take an organ, and no organ is actually recovered based on visualization.

At the June 20, 2011 conference call, the Committee made the following motion:

Motion: that the proposed policy change to the imminent and eligible death reporting definitions be distributed for public comment on September 15, 2011.

The motion was passed by a vote of 14-0-0.

The Subcommittee will consider various issues such as:

- Mechanical preservation pump issues or parameters.
- Different definitions of conversion rates be made consistent

7. **Effective Screening Work Group.** Ms. Brigham provided an update of the work of the Effective Screening Work Group. This group evolved from the Tiered Acceptance Work Group and worked under the premise that transplant centers would define the listing characteristics based on a multi-variable table (i.e. ECD, age, Hepatitis C) as to what type of organ the center would accept for an individual donor. Prior to completion of that work, UNOS implemented DonorNet[®] and the Work Group disbanded as they concluded that the electronic service would help to streamline allocation and eliminate the problem; however, this was not the case.

Often, in spite of the education provided, transplant centers do not use the criteria to manage the wait list. (i.e. if they do not want to transplant a DCD organ, they do not use the system to screen the DCD donor organ out). Another survey has been conducted to determine if this is effective. UNOS is making every effort to better utilize better recipient screening.

8. **UDHQ Form Update.** The Uniform Donor History Questionnaire (UDHQ) Stakeholder Review Group's goal is to reduce the complexity of the questionnaire and provide education to the users. The project began in 2006, and the Group was formed to create a uniform qualified history questionnaire. The HHS Advisory Committee on Blood Safety recognized and supported the Review Group. In December, 2010, the Review Group released a 52-question draft version and distributed it for public comment. When revising the survey, members considered the question order, screening redundancy, question length, the use of "he/she," educating historian regarding risk assessments, the child questionnaire (12 years of age and younger will have a separate questionnaire), and documentation. Once finalized, the Review Group will field-test the survey and provide national training courses.
9. **u-DCD Model Elements.** Mr. Pietroski, Vice-chair, provided an update of the uncontrolled DCD (u-DCD) subcommittee. The subcommittee is currently developing a survey to determine current practice and to identify whether or not the term "uncontrolled" appropriately describes the process, and is considering the need for u-DCD guidelines. The Committee agreed that the term "uncontrolled" denotes a chaotic or poorly managed process and that other terms (i.e. urgent, rapid, and critical) might better describe it. The Committee also agreed that using the Maastricht scale to describe u-DCD might help to stratify the data for reporting. The primary factor in u-DCD that is different from DCD is the speed with which it occurs, so "rapid" or "immediate" might better describe it. The Committee agreed that there must be consistency in how these u-DCD donors are reported.

Data show that on average, 20-40 donors per year, or 4% of all DCDs, were reported as "not controlled" DCDs. Members agreed that all DCD donors should be reported using the Maastricht system.

Currently, DCD donors are reported on the DDR, and it will take several years, possibly 5 years, to go through the OMB process and change the data collection on the DDR form. As such, this modification should be placed on the next OMB review and at present, guidance should be provided describing the Maastricht system of classification. The definition on the DDR could also be changed.

The Maastricht classification

- I Dead on arrival – uncontrolled
- II Unsuccessful resuscitation – uncontrolled
- III Withdrawal of support – awaiting cardiac arrest – controlled
- IV Cardiac arrest after brain death declaration – uncontrolled
- V Cardiac arrest as a hospital inpatient - uncontrolled

The Committee agreed that using the Maastricht scale in classifying DCD donors in the definition would be helpful, create more consistency in reporting, and yield meaningful data. The definition should also be changed in UNetSM.

Motion: That the definition of uncontrolled DCD be changed to: Uncontrolled DCD is the recovery of organs after a patient suffers a sudden cardiac arrest including brain dead donors and

those that meet Maastricht classification 1, 2, 4, and 5. Controlled DCD is classified as Maastricht 3.

The Committee supported the motion by a vote of 17-0-0.

The Committee discussed what to call u-DCD in the survey and determined that the community should weigh in on what it is currently termed.

Motion: That a question will be inserted into the survey asking the community for its opinion on an appropriate name for u-DCD while providing several options (i.e. rapid, urgent, immediate, arresting, and unplanned).

The Committee supported the motion by a vote of 17-0-0.

The u-DCD subcommittee will continue to consider u-DCD guidelines, model elements, or requirements that are similar to the controlled DCD.

10. Vessel Work Group. Ms. Brigham provided an update of the Vessel Work Group. The Work Group distributed for public comment an issue regarding the storage of Hepatitis positive vessels and recommended that the positive vessels not be stored. After public comment, there were comments regarding the need to store positive vessels. The Work Group reconsidered the proposal and revised it so that the positive vessels could be stored and provided only to the intended recipient. This proposal was sent for Board approval in June, 2011; however, the Board did not vote on this issue and asked the Work Group to further consider the issue. The Work Group agreed that there is a broader patient safety issue that needs to be addressed and that the positive vessels should only be transplanted into the intended recipient.

11. Labeling and Packaging of Living Donor Organs.

- The Living Donor Committee requested that a specific label for Living Donor organs be developed. Several components of the current labeling system seem inappropriate for Living Donors (i.e. OPO phone number and contact information). The subcommittee will work with the Living Donor Committee and draft a label.

Motion: That a specific label for Living Donor organs be designed and added to the current labeling system.

The Committee supported the motion by a vote of 17-0-0.

- The Committee received a request for clarification of the “R value” calculation for containers used in organ transport. Policy 5.0 requires that organs be placed in a container that has a temperature validated “R value” of 1.5. After investigation, it was determined that the industry does not allow ½ inch measurement, and the “R” value is dependent on the density of the foam. As such, the policy language should be updated.

The Committee considered changing policy to state that the container must maintain a given temperature; however, that would be impossible to monitor when organs are shipped and subjected to temperature extremes. It was suggested that the policy be changed to “manufacturer provided validation for the container” that the temperature be maintained within a range between 1 and 6 degrees C for a minimum of 12 hours.

Motion: In addition to the “R” value, the Committee agreed that, based on the manufacturer provided validation for a container, the subcommittee should consider a policy change that the temperature value be maintained with a given temperature range for a designated time.

The motion was passed by a vote of 17-0-0.

The Committee agreed that this issue should be considered by the subcommittee, and it will provide policy language regarding temperature and time. It was recommended that the subcommittee contact tissue and blood banks as they may have policy language regarding the temperature requirements for their shipping containers.

- An OPTN member requested clarification regarding the requirement to send a red top tube following organ recovery since ABO has been confirmed. The Committee agreed that there may be additional testing that the receiving center wishes to conduct (i.e. NAT, HTLV) and it may use the specimen for that testing.

Motion: That Policy 5.0 be modified: A red top tube for blood, ~~specifically for ABO confirmation,~~ must be sent.

The motion was passed by a vote of 17-0-0.

- The subcommittee will consider moving toward an electronic record as opposed to a paper chart when transporting organs.

12. Concerns from DEQ. The Department of Evaluation and Policy (DEQ) requested input from the Committee regarding the following issues.

- The DEQ has requested clarification for Policy 5.8.2 regarding the placement of the blood type on the red top tube that is provided for ABO confirmation. The policy states “may not...” and it is unclear as to whether it is a choice or required. It has been noted that, if you put a blood type on the label itself, that it violates policy for some labs. The Committee considered this issue and agreed that a policy language should be modified as, “red top tube must be sent.”
- The MPSC has requested that the Committee consider the use of Score Cards that are used for DEQ site visits and the need to establish thresholds for evaluation. Currently, transplant centers have specific thresholds that are used for performance improvement measures. When UNOS performs a site visit and considers the OPO’s compliance with policies, they score the OPOs compliance. To be more effective in identifying OPOs performance improvement needs, specific thresholds need to be established.

In the past, the DEQ has used a national average to rate OPOs on the scorecards. These thresholds not only pertain to labeling errors, but guide the entire site visit. The Committee agreed that there needs to be further clarification from MPSC and formed a subcommittee that will consider developing appropriate thresholds.

- The Operations and Safety Committee is seeking clarification or education regarding what an allowable and appropriate second identifier could be used for tissue typing materials and recommended the use of date of birth as a second identifier. The Committee noted that the date of birth is not always known.

Additionally, complaints have been received regarding the use of a unique identifier that has not been documented in the donor chart, resulting in the transplant center’s inability to validate it. The Committee agreed that there needs to be a policy in place requiring that the

unique identifier be documented in the donor record. The Committee considered whether there should be a standard that is used for the unique identifier that is allowed in policy.

The Committee agreed that a standard unique identifier is not necessary and that whatever identifier is used must be documented in the donor record. This is the responsibility of the host OPO. Each OPO, in its individual policies, has the unique ID that is used. There have been some issues that in the pre-recovery chart, the unique identifier is not present.

One of the issues may be that the donor data is not entered into DonorNet® until after the OPO has sent the tissue typing materials to a lab. In this case, there is no UNOS ID assigned as of yet. Therefore, the problem is twofold: 1) OPOs are not providing a 2nd identifier and 2) they are not documenting the second identifier in the donor chart. The Committee determined that developing a list of standardized unique identifiers will not correct the issue as it is a compliance issue. Out of 17 policy violations regarding labeling and packaging within the first 6 months of 2011, 7 were related to noncompliance with a unique identifier. Members agreed that these are policy violations, and do not require policy modification to specify what the unique identifiers should be.

Motion: That policy 5.0 be changed to read the “locally assigned unique identifier” must be documented in the donor record.

The motion was approved by a vote of 16-0-0.

- 13. Donor Information Sharing Task Force.** A Task Force was formed to address various issues concerning the sharing of recipient and donor information. Task Force members reviewed the HIPAA regulations and exceptions as well as current practices, policies and protocols among OPOs and transplant centers. The Task Force is finalizing Guidelines for sharing of information and there will be a live video webcast about this information on October 5, 2011.

Some members opined that the “guidelines” should be “requirements” and that the language should be stronger. It was suggested that once the guidelines are implemented, it may be prudent to pursue policy changes.

- 14. Testing of Qualified Specimens.** OPTN members have requested clarification regarding new generations of serology testing, the obligation of the OPO for donor culture reporting. For example, all OPOs have protocols regarding how frequently cultures must be checked but there are some concerns that some cultures may have growth but it is not determined outside of the 24, 48 hour and 7 day check. The Committee suggests a subcommittee be formed to work with the Operations and Safety Committee.
- 15. Allocation of Livers for Hepatocytes.** Dr. Olthoff, Liver Committee chair, requested that the OPO Committee consider the allocation of hepatocytes (Policy 3.6.1.0 Liver Allocation). The Liver Committee has received concerns about OPOs not exhausting the hepatocytes list prior to assigning the liver for research. The Committee identified the problem as the need for OPOs to exhaust the liver list, which would take many hours. Once an offer has been declined by all of the national 1A and aggressive centers, OPOs understand through experience that no one will accept the offer. At that point, based on the allocation algorithm, OPOs cannot skip to allocating hepatocytes, they stop allocation and send the liver for research.

The reality is that an OPO might spend up to 24 hours to make offers of the liver and still not exhaust the list. Additionally, OPOs are not reimbursed for hepatocytes as they would be for a full liver transplant. The Committee will send a letter to the Liver Committee describing the

logistical barriers to placement of the hepatocytes and seek guidance from the Liver Committee regarding how to overcome the barriers in the allocation of hepatocytes.

- 16. Ex Vivo Lung Preservation.** There are currently 2 FDA trials that are testing a device that can ventilate, intubate and perfuse lungs when recovered for transplant. The Committee felt that this presents new issues for the OPO community. The Thoracic Organ Transplantation Committee has requested input regarding the coding for lung disposition in the UNOS database, and how it might demonstrate that the organ has been recovered for research and not for transplantation. The Committee agreed that the organs that undergo this research protocol that are ultimately transplanted to save an individual's life, should be coded as "recovered for transplant."

Motion: Until it is FDA approved, there should be donor authorization for both research and transplant, and that the organ following transplantation be coded as "recovered for transplant." For those that are not transplanted, they are coded as "recovered with the intent to transplant but sent for research." Additionally, there should be authorization for both research and for lung transplantation for this procedure.

The motion was passed by a vote of 14-0-0.

The Committee also discussed how to allocate the organs that are placed on this preservation machine. The Committee agreed that if a match run is completed, and the lungs improve, there is no need to re-run the list. Based on lung function, the center will decline the offer based on all of the exclusions they use now (i.e. high risk, etc.) Under the study, there are very specific acceptance criteria. The center accepts them for a specific patient according to match run order, with the condition that they can be reconditioned. If the lungs pass, they may wish to move to a local back up. If centers participating in the study decline for all of their enrolled patients and go to another center, they may wish to use the organ for compassionate care. Current policy states that if a center is not going to transplant the intended patient, then the center must contact the OPO and reallocate. If this is done, UNOS must be notified.

- 17. Liver Biopsy Form.** – The OPTN Organ Availability Committee (OAC) asked for Committee input regarding a standardized Donor Liver Biopsy Form with some web based training for labs, transplant surgeons and fellows. Sandy Feng MD, OAC Chair, provided an overview of the development of the biopsy form. The OAC wishes to provide resources to pathologists for those that provide evaluation of liver biopsies.

The Committee agreed that the form was a dramatic improvement toward standardization; however, pathologists, particularly in small community hospitals, may not wish to use it or have difficulty using it. Additionally, the Committee agreed that this form should be recommended and not required.

Members agreed that the photo documentation would be very helpful to centers when considering offers and provide a valuable resource; however, education for pathologists will be essential. Members questioned whether there will be standardized photo techniques and recommendations as well as the technology for reading the photos.

The Committee will send a memo to the OAC with the following comments and suggestions:

- The form lacks renal or other organ opportunities.
- Recommend striking HIPAA language.
- One universal form for all organs would be ideal.
- The form does not distinguish between a permanent or frozen section.
- Guidelines for universal stain would be helpful.

- Possible indications for doing the biopsy.CPT codes and ICD-9 codes for pathologists
- Should this be completed at the bedside vs. intraoperative.
- Define the mild-moderate as 5%.
- Chronic hepatitis will rule out the liver for some OPOs.
- It should say chronic inflammation and remove the hepatitis.
- The Committee questioned why this type of photo documentation could not be expanded for other organs.

18. Future Dates for Conference Calls.

- October 11, 2012 at 3:00 pm Eastern Time
- October 25, 2012 at 2:00 pm Eastern Time
- November 29, 2012 at 3:00 pm Eastern Time

OPO COMMITTEE			
	MONTH	June	September
	DAY	18	14
	FORMAT (select)	Live Meeting/ Teleconference	In Person
NAME	COMMITTEE POSITION		
Lori Brigham MBA	Chair	X	X
Richard Pietroski MS, CPTC	Vice Chair	X	X
George Lipkowitz MD	Regional Rep.		
Susan Stuart RN, MPM	Regional Rep.	X	
Lynn Williams	Regional Rep.	X	
Patrick Giordano FACHE	Regional Rep.	X	
Lisa Stocks FNP, RN	Regional Rep.	X	X
Katherine Kickertz BSN, CPTC	Regional Rep.	X	X
Meg Rogers	Regional Rep.	X	X
Rob Linderer RN, BSN	Regional Rep.		X
Julie Mirkin MA, RN	Regional Rep.		X
Gordon Bowen MS	Regional Rep.	X	
Michael Marvin MD	Regional Rep.	X	
Esther Carmichael	At Large	X	X
Meredith Harrison	At Large	X	
Jeffrey Orłowski MS, CPTC	At Large		
Richard Padula RN	At Large	X	X
William Reitsma BSN	At Large	X	X
Sean Van Slyck BA,CPTC	At Large	X	X
Teresa Beigay DrPH	HRSA	X	X
Robert Walsh	HRSA	X	X
Monica Lin	HRSA		
David Zaun	SRTR Liaison		X
Ajay Israni	SRTR Liaison		X
Tabitha Leighton	SRTR Liaison		By Phone
Stacey Burson	Business Analyst	X	
John Rosendale	Support Staff	X	X
Franki Chabalewski RN, MS	Committee Liaison	X	X
Margaret Kearns	DEQ	X	By Phone
Tiffany Lord	DEQ	X	By phone
Sarah Herbert	DEQ		By Phone