

OPTN/UNOS Organ Procurement Organization (OPO) Committee
Report to the Board of Directors
June 25-26, 2012
Richmond, VA

Summary

I. Action Items for Board Consideration

- The Board is asked to approve modifications throughout the policies to change the term “Consent” to “Authorization.” (Item 1, Page 3)
- The Board is asked to approve modifications to Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels, and Tissue Typing Materials) to no longer permit the use of an alternate label for perfusion machines. (Item 2, Page 11)

II. Other Significant Items

- The Committee continues to work on proposed modifications to Policy 7.0 (Reporting Definitions) 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 15)
- The Committee reviewed modifications made to the Proposal to Modify DCD Model Elements. (Item 7, Page 16)
- The Committee is working with the Department of Evaluation and Quality to establish scorecard thresholds for site survey visits. (Item 11, Page 18)
- 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 13, Page 19)

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Lori Brigham MBA, Chair
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This report details the OPO Committee's deliberations during its face-to-face meeting on March 8, 2012, and Committee conference call/Live Meetings on November 29, 2011 and January 27, 2012.

- 1. Proposal to Change the Term "Consent" to "Authorization" Throughout Policy When Used in Reference to Organ Donation** During the past several years, the OPO community has become aware that the term "consent" for organ/tissue/eye donation is widely perceived by the general public and healthcare workers to have the same meaning as "informed consent." However, the medical concept of informed consent does not apply to the way anatomical gifts are made. The confusion arises because organ/tissue donation always takes place in a healthcare setting when the donor has been undergoing medical or surgical treatment, and the donor's family is dealing with an unexpected and often traumatic death. Statutes, regulations and courts define the medical concept of "informed consent" to mean that physicians must disclose and discuss with patients such things as their diagnosis, risks and benefits, and alternatives. Only after these issues have been discussed can an individual give informed consent for medical procedures or treatment.

By contrast, when an individual decides to become an organ, eye, or tissue donor, it is usually in a non-medical situation. This can happen when applying for a driver's license, joining a donor registry, or including wishes in an advance directive, will or some other signed document. OPOs have a responsibility to educate the public about organ, eye, and tissue donation. In places and situations where a person may decide to be a donor, OPOs should make sure information is available about the donation process. It is not respectful of the potential donor's decision or helpful to the donation process to view these types of decisions through the prism of medical "informed consent." If individuals have not made the decision to donate their organs, the process of requesting the anatomical gift takes place at a more intensely personal level and in a medical setting. OPOs are legally required to advise the persons who have the legal right to make the gift such as the patient's next-of-kin of the option to donate or not. Family members are asked to make a deceased donor "authorization" in contrast to "informed consent" decisions made by family sought by the healthcare team to medically treat an severely injured patient. Again, it is not helpful to the family or to the donation process to have the concept of medical informed consent applied to the donation decision, and nor does informed consent even apply to a deceased individual. The term "consent" does not accurately reflect the permission granted for steps taken that occur in the donation process. Another aspect to be considered for the organ donor "authorization" terminology change, are OPTN policies related to a true "informed consent" decision that one can make for living donation.

Therefore, the OPO community requested that the OPTN adopt changes to bring the terminology in all policies, bylaws, and publications into line with actual usage in the donation and transplantation community of practice. The OPO Committee reviewed all relevant policies and bylaws and made the necessary changes. Specific details about the proposal can be found in **Exhibit A**. The Resource Assessment and Impact Statement for this proposal are provided as **Exhibit B**.

The proposal was circulated for public comment in September 2011. Of these, 17 (60.71%) supported the proposal, 7 (25.00%) opposed the proposal, and 4 (14.29%) had no opinion. Of the 24 who responded with an opinion, 17 (70.83%) supported the proposal and 7 (29.17%) opposed the proposal. All OPTN Committees that voted on the proposal were in support. All eleven regions were

in support of the proposal as well. The Committee recommends the following for consideration by the Board:

***** RESOLVED, that the following policies and bylaws be amended, effective pending member notification.**

2.0 MINIMUM PROCUREMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)

In order to maximize the gift of donation and optimize recipient outcomes and safety, the Organ Procurement Organization (OPO) must comply with the following policies for minimum procurement standards.

2.1 HOST OPO. The OPO responding to an organ donor call from a hospital is the "Host OPO" for that particular donor. The Host OPO is responsible for identifying, evaluating and maintaining the donor, obtaining ~~consent~~ authorization for the removal of organs, complying with OPTN policy throughout the donation process, and organ allocation.

Additionally, the Host OPO is responsible for ensuring that donor tissue typing information is entered into UNetSM and that the approved OPTN automated organ allocation computer algorithm is executed for each donor organ.

The Host OPO shall make reasonable attempts to obtain a medical/behavioral history from individual(s) familiar with the donor.

The Host OPO is responsible for organ procurement quality including appropriate preservation, and packaging of the organs, and assurance that adequate tissue typing material is procured, divided, and packaged.

The Host OPO is responsible for written documentation of donor evaluation, donor maintenance, ~~consent~~ authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials).

2.2 – 2.3 [No Change].

2.4 OBTAINING ~~CONSENT~~AUTHORIZATION. The Host OPO must provide evidence of ~~consent~~ authorization for donation according to applicable legal authority.

2.5 – 2.9 [No Change].

3.3 ACCEPTANCE CRITERIA

3.3.1– 3.3.5 [No Change].

3.3.6 Center Acceptance of Organ Offers. If an organ is offered and accepted without conditions, the Host OPO and intended recipient's transplant center shall be bound by this transaction unless there is mutual agreement on an alternative allocation of the organ.

3.3.6.1 Exception for DCD Donor who Converts to Brain Death After an Organ Offer has been Made. When a DCD donor converts to brain death, the match system must be re-executed and organs must be allocated according to policies 3.5 - 3.11. Policy 3.6.5.1 does not apply when a DCD donor converts to brain death. Additionally, OPOs are encouraged to initiate allocation of organs that may have been ruled out due to the donor's DCD status (i.e. heart, lungs, pancreas).

3.3.6.1.1 The Host OPO may choose not to re-allocate organs from a DCD donor who converts to brain death in the following circumstances: 1) lack of donor family approval and ~~consent~~ authorization; 2) donor instability; or 3) other extraordinary circumstances. The Host OPO must document the reason for not re-allocating organs when a DCD donor converts to brain death and make this documentation available upon request.

3.5 ALLOCATION OF DECEASED KIDNEYS

3.5.1 – 3.5.3.2 [No Change].

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

3.5.3 – 3.5.4 5 [No Change].

3.5.5 Payback Requirements. Except as otherwise provided in Policy 3.5.3.5 (Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.3.4 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 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 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 Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written ~~consent~~ authorization for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before ~~consent~~ authorization for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until ~~consent~~ authorization can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is ~~consented~~ authorized for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.6 – 3.5.17 5 [No Change].

5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

5.1 – 5.4 [No Change].

5.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL

5.5.1 Documentation accompanying the organ

- Complete donor documentation must be sent in the container with each transported organ. This documentation must include:
 - ABO typing source documentation;
 - Infectious disease testing results;
 - Medical/Behavioral History form;
 - Donor Evaluation;
 - Complete record of the donor;
 - ~~Consent~~Authorization form; and
 - Organ quality information as noted in Policy 2.5
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
 - a location specifically designed for documentation, or
 - between the outer and inner containers.
- Whenever a deceased donor organ is transported, the Host OPO or the Transplant Center, as applicable, must include in the donor documentation the source documentation.

5.5.2 Documentation accompanying the vessel

If the vessels are not shipped in the same package as the organ, the same complete donor documentation, as described in Policy 2.5.6.1, must be included with the vessels.

5.6 - 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

- The ~~consent~~ authorization forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.
- The vessels cannot be used other than for the implantation or modification of a solid organ transplant.
- Vessels can be shared among transplant programs. If sharing occurs between transplant programs, the implanting program must submit to the OPTN a detailed explanation justifying the sharing. The justification will be reviewed by the Membership and Professional Standards Committee (MPSC). The

implanting transplant program must notify the OPTN of subsequent disposition of the vessel(s).

- If the transplant center stores vessels and subsequently uses the vessels for the intended recipient or another transplant recipient, the OPTN must be notified.
- If vascular conduits from donors with positive serology for hepatitis are subsequently used in other than the intended recipient, the implanting transplant center must provide a detailed explanation to the OPTN for the use of this conduit. The explanation will be reviewed by the MPSC.

5.10.2 – 5.11.3 [No Change].

6.0 TRANSPLANTATION OF NON-RESIDENT ALIENS

6.1 - 6.3 [No Change].

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. Exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

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~~ authorization 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 met brain death or donation after cardiac 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 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~~ authorization 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.

6.4 – 6.5 [No Change].

7.0 DATA SUBMISSION REQUIREMENTS

Members must submit data to the OPTN through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. All transplant data forms must be submitted through UNetSM, beginning January 1, 2003. All OPOs are responsible for submission of patient level data for all ~~consented~~ authorized donors, ~~consent~~ authorized but not recovered potential donors, imminent neurological and eligible deaths in its DSA. All OPOs are also responsible for submission of the total number of reported deaths by donor hospital. The OPO responsible for allocation of the donor organs will be responsible for submission of the Deceased Donor Feedback information, Deceased Donor Registration (DDR) Forms and Potential Transplant Recipient (PTR) Forms. Histocompatibility laboratories will be responsible for submission of the Donor and Recipient Histocompatibility forms for each donor and actual transplant recipient typed by the laboratory. Recipient transplant centers are responsible for submission of Recipient Feedback information, Living Donor Feedback information, Living Donor Registration Forms, Living Donor Follow-up Forms, Transplant Candidate Registration Forms, organ-specific Transplant Recipient Registration Forms, organ-specific Transplant Recipient Follow-up Forms, and Recipient Malignancy Forms for each recipient on the waiting list, transplanted or followed at the center.

7.1 – 7.9 [No Change].

9.0 RELEASE OF INFORMATION TO THE PUBLIC.

9.1 – 9.6.5 [No Change].

9.6.6 Updated OPO-specific donor procurement volumes, (using data validated by the member through UNetSM, including organ-specific ~~consent~~ authorization, procurement, and utilization volumes, by OPO; and numbers of donors by OPO, (using data validated by the member through UNetSM, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.

9.6.7 – 9.12 [No Change].

ATTACHMENT III TO APPENDIX B OF THE OPTN BYLAWS

Model Elements for Controlled DCD Recovery Protocols

~~A.~~ Suitable Candidate Selection [No Change].

~~B.~~ Consent Authorization/Approval

1. The legal next of kin may elect to ~~consent to~~ authorize procedures or drug administration for the purposes of organ donation (e.g. heparin, regitine, femoral line placement, lymph node excision, ECMO, and bronchoscopy). No donor related medications shall be administered or donation related procedures performed without ~~consent~~ authorization.
2. Clearance from medical examiner/coroner must be obtained when applicable.
3. There should be a plan for patient care if death does not occur within the established timeframe after the withdrawal of life sustaining measures. This plan should include logistics and provisions for continued end of life care, including immediate notification of the family.
4. For purposes of these model elements, “legal next of kin” shall also include the patient, a designated health care representative, legal next of kin, or appropriate surrogate.

~~C.~~ Withdrawal of Life Sustaining Measures/ Patient Management

1. A timeout is recommended prior to the initiation of the withdrawal of life sustaining measures. The intent of the timeout is to verify patient identification, roles and the respective roles and responsibilities of the patient care team, OPO staff, and organ recovery team personnel.
2. No member of the transplant team shall be present for the withdrawal of life-sustaining measures.
3. No member of the organ recovery team or OPO staff may participate in the guidance or administration of palliative care, or the declaration of death.
4. There must be a determination of the location and process for withdrawal of life sustaining measures (e.g. ETT removal, termination of blood pressure support medications) as a component of the patient management.
5. If applicable, placement of femoral cannulas and administration of pharmacologic agents (e.g. regitine, heparin) for the sole purpose of donor organ function must be detailed in the ~~consent~~ authorization process.

~~D.~~ Pronouncement of Death [No Change].

~~E.~~ Organ Recovery [No Change].

~~F.~~ Financial Considerations [No Change].

2. **Alternative Labels for Perfusion Machines** Current policy allows the use of an alternate label when OPOs transport an organ on a perfusion machine. OPOs create their own type of labels resulting in inconsistent labeling. The proposed policy modifications eliminate the use of alternate shipping labels on mechanical preservation machines and require OPOs to use a new standardized label that is part of the current color-coded labeling system distributed by the OPTN Contractor. This change would make labels for perfusion machines consistent with the labels used for all deceased and living donor organs that are transported outside of donor hospitals.

The OPO Committee implemented a new labeling system in January 2010 with the goal of making all organ transport labels consistent throughout the country. The Committee agreed that using an alternate label conflicted with this goal and could create a patient safety concern since OPTN members might not be familiar with each label and could complete them differently. The labels distributed by the OPTN Contractor are required by policy and, when properly completed, contain all of the required information about any given organ type. A new label will be developed for preservation machines that are consistent with the current OPTN color-coded labeling system. This label will be required by policy.

The Committee unanimously recommended striking the language in Policy 5.0 that permits the use of an alternate label. The Committee also recommended the development of two different-sized labels that would fit on or in a sleeve that would attach to the two types of preservation machines currently in use today. Specific details about the proposal can be found in **Exhibit C**. The Resource Assessment and Impact Statement for this proposal are provided as **Exhibit D**.

As of 1/12/2012, 21 responses have been submitted to UNOS regarding this policy proposal. Of these, 16 (76.19%) supported the proposal, 0 (0%) opposed the proposal, and 5 (23.81%) had no opinion. Of the 16 who responded with an opinion, 16 (100.00%) supported the proposal and 0 (0%) opposed the proposal. The comments were mostly in support of this proposal although one comment suggested one adhesive label and one that can be attached via zip tie. The comment agreed and noted that the current labels do have an eyelet for a zip tie. The Committee recommends the following for consideration by the Board:

***** RESOLVED, that Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels, and Tissue Typing Materials) shall be modified as set forth below, effective pending member notification.**

5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

The purpose of Policy 5.0 and its subsections is to:

- state requirements for packaging and labeling organs, tissue typing specimens, and vessels to prevent wastage (and/or to promote safe and efficient use);
- define terms and responsibilities related to packaging, labeling, and transporting organs, tissue typing specimens, and vessels; and
- state requirements for recovering, storing, and using vessels in solid organ recipients.

The responsibility for packaging and labeling deceased donor organs is assigned to the Host OPO. Transplant Center staff may not leave the operating room without allowing the OPO to package and label the organ in accordance with OPTN policy. The OPO must submit a report through the Patient Safety System when a Transplant Center fails to comply with this policy. The OPO will make all reasonable efforts to package and label the organ in a timely fashion. If

an organ is repackaged by a transplant center for transport, the Transplant Center will package, label and ship the organ in accordance with this policy and immediately notify the recovering OPO of the repackaging.

5.1 EXTERNAL PACKAGING SPECIFICATIONS

An external transport container is defined as a: disposable shipping box, cooler or mechanical preservation machine. The transplant center or OPO must use both internal and external transport containers to package a deceased donor organ that travels outside of the recovery facility where the organ is recovered.

5.1.1 – 5.1.2 [No Change]

5.1.3 Mechanical preservation machine

- Mechanical preservation machines are permitted for transporting an organ.
- The cassette containing the organ must be labeled with the organ type (i.e. left kidney, right kidney), ABO, and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with:
 - ⊖ the standardized external label distributed by the OPTN contractor, ~~or~~
 - ⊖ ~~an alternate label that contains all information included on the OPTN contractor standardized label.~~
- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous donor organ must be removed.

5.2 INTERNAL PACKAGING SPECIFICATIONS [No Change]

5.3 EXTERNAL LABELING REQUIREMENTS

When a disposable shipping box or cooler is used to transport a deceased donor organ, the Host OPO must use the standardized external label distributed by the OPTN contractor.

~~When a mechanical preservation machine is used, the OPO or Transplant Center, as applicable, may use an alternative label if the label contains all of the required information.~~

No further changes to Policy 5

3. **Data Review.** At the March 8, 2012, meeting, UNOS Research staff provided a summary of the data requested during the September 2011 meeting.

Donation-Related Data Review

The Committee requested regular updates on the progress that DSAs are making in the recovery of all types of donors as well as organs transplanted from these donors. The data requested included the regular update with the following additions: Include information about donors from whom no organs were transplanted and information that show the trends over time.

Highlights of the presentation:

- Data showed an increase of 2.3% (184 donors) over 2010 in deceased donors which is the biggest increase since 2006. The number of organs recovered increased by 1.6% (393 organs) and organs transplanted increased by 1.5% (380 organs), with 21 (0.2%) more

- organs transplanted over the previous year. The number of organs transplanted per donor was 3.07 in 2011 compared to 3.10 in 2010.
- The number of standard criteria donors (SCD) increased by 2.5% (126 donors). The number of SCD organs recovered increased by 1.1% (233 organs) and the number of SCD organs transplanted increased by 0.7% (143 organs) The number of SCD organs transplanted per donor was 3.71% compared to 3.77% in 2010.
 - Extended criteria donors (ECD) continue to decline in numbers which has been a trend over the last few years. There was a decrease of 2.9% (54 donors) in the number of ECDs over 2010. There was a decrease of 1.5% (76 organs) in the number of ECD organs recovered and a decrease of 1.9% (66 organs) in the number of ECD organs transplanted. The number of organs transplanted per donor increased from 1.85 in 2010 to 1.87 in 2011.
 - There were 11.9% (112 donors) more donation after circulatory death (DCD) donors in 2011. The number of DCD organs recovered increased by 10.1% (236 organs) and the number of DCD organs transplanted increased by 16.9% (303 organs). The number of organs transplanted per DCD donor increased from 1.91 to 2.00 in 2011.

Additional information about the results of the analysis can be found in **Exhibit E**.

The Committee requested more information about why there were no organs transplanted from 111 SCD donors and 443 overall deceased donors. This includes looking at the organ types and reasons why the organs were not transplanted.

Eligible and Imminent Neurological Death Data Review

In January 2008, the OPTN began collecting eligible and imminent neurological death data on an individual patient-level basis. The development of the eligible and imminent neurological death definition was a significant and lengthy project for the Committee and it continues to monitor and review the results of this data collection effort. This analysis provided an update on conversion rates by subgroup of donors and analyzed imminent neurological deaths compared to the eligible deaths by DSA. All analyses are based on data reported by the OPOs on the OPTN Deceased Donor Registration (DDR) form and the Death Notification Registration (DNR) form as of February 3, 2012. The time period of the analysis is January 1, 2008 through November 31, 2011.

It was noted that conversion is defined as an eligible death that became a donor that meets the eligible death criteria. It does not include donors that are beyond the eligible death definition for whatever reason. (e.g. over 70 years of age, DCD, or an eligible with some exclusion) It was also noted that a donor is defined as having one organ recovered for the purpose of transplantation, but not necessarily transplanted.

There was some concern about the number of imminent neurological deaths per 10 eligible deaths reported by OPOs. The minimum was 1.8 and the maximum was 35.7 for the period of December 1, 2010 to November 30, 2011. This was a slight change from the 1.1 and 44.3 for the period of January 1, 2008 to November 30, 2011. The Committee suggested contacting the OPOs that had the lower and higher numbers to investigate more about their practices for gathering, verifying, and reporting these data. It was noted that one explanation could be the change in the definition of eligible from all deaths and imminent deaths to just legally-declared brain dead. The Committee suggested a review of the decrease in numbers by DSA before and after the change to see if that provides an explanation for why so many donors that would have been in the eligible death definition are now in the imminent death definition. A suggestion was made to compare conversion rates to the eligibles and contact any DSA that is more than two standard deviations from the mean. It was noted by UNOS Research staff there are two resources for the data used for conversion rates. The death notification registration contains the eligible and the imminent death information and for those that become donors the source

of all data is the DDR. Additional information about the results of the analysis can be found in **Exhibit F**.

4. **OPO Metrics Webinar** There was a webinar held on December 13, 2011, that provided an overview of the OPO metrics and the OPO yield calculator available on the SRTR website. There were 114 registered attendees and a copy of the slides can be found in **Exhibit G**. The SRTR noted that one concern raised following the webinar was the lung PO2 terminal value that is used in the individual organ modeling. It is the opinion of some individuals that the value should be divided by the FiO2 value. The SRTR noted that their plan is to go ahead with the next release which is scheduled for July 2012 and continue to study the differences in the models. They will present those findings to the Committee at a future meeting. The SRTR noted that the next OPO report will not include any of the expected values in certain tables but will provide an idea of the numbers that will be included in the report. Along with the yield table, which has not been developed yet, the SRTR plans to include all patients and variables that are used in the modeling as a supplement to the calculator to help OPOs check their data. The Committee agreed that an update webinar might be helpful in the future as we move forward with this, especially when the MPSC starts reviewing the information and develops a flagging methodology.
5. **Flush Solution Recommendations** There was a member request to add flush solutions to the drop-down lists on the DDR so the information would not have to be entered as text fields. Currently, there are three flush solution questions for every recovered organ: initial flush, back table flush, and final flush/storage. There is one drop-down list for initial and final flush and one drop down list for back table flush. During the process of reviewing the solutions in the drop-down lists it was determined that it was a good time to make sure that the drop-down choices made sense and reflect current practices.

After considerable discussion, the Committee recommended the following changes:

- UW (keep UW as the generic term in the dropdown and add these to the definitions: Belzer Cold Storage, Viaspan, and SPS-1. New solutions of the same chemical composition can be added to the definitions in the future)
- Eurocollins
- Modified Collins
- ~~Cardioplege~~ (this is a process, delete and list solutions used to perform cardioplege)
- ~~Pulmoplege~~ (this is a process, delete and list solutions used to perform pulmoplege)
- ~~Saline~~
- Ringers
- Celsior
- HTK (keep HTK as the generic term in the dropdown and add Custodial to the definitions. New solutions of the same chemical composition can be added in the future)
- Perfadex
- No Flush
- Belzer MPS/KPS-1 (These machine preservation solutions have the same chemical composition. If new solutions of a different chemical composition become available they can be added as a different selection)
- Steen Solution (this machine preservation solution has a different chemical composition than Belzer MPS and KPS-1)
- Unknown
- Other, Specify

Additionally, the Committee recommended having separate dropdown selections for the initial flush, back table flush, and final flush/storage. UNOS Research staff noted that IT staff is still evaluating the effort required to make these changes.

6. Imminent and Eligible Death Definitions – Post-Public Comment Review The Committee distributed this proposal for public comment in September 2011. The purpose of the proposal was to make the data collection more consistent because the definitions are being interpreted differently throughout the country. Additionally, some state laws or hospital protocols require two or more brain death exams while others only require one. Following the public comment period, the Committee began reviewing comments and determined that additional changes needed to be made to the definitions. A subcommittee was formed to begin drafting revisions to the definitions. The Committee was reminded that the goal of the changes is to add objectivity in order to collect consistent data that was originally intended for the conversion rates. Some of the changes made to the original proposal include:

- There was some concern about the chronic renal failure listed under the kidney section. It was noted that there would have to be a diagnosis of chronic renal failure and the committee did not think adding “documented chronic renal failure” was necessary. The subcommittee also recommended adding “age 50-69 years with history of type-1 diabetes for > 20 years” to exclude a kidney donor from the eligible data definition.
- The subcommittee recommended changing the terminal AST/ALT from 5000 to 3000 u/l to exclude a liver donor from the eligible data definition. They also agreed that adding the phrase “and trending up” would be vague and difficult to define and apply. It was noted that the original number was selected by liver surgeons, however the data the Committee reviewed showed that there were very few livers transplanted from donors that had an AST/ALT of 5000 u/l. There was suggestion made that the Committee review data on liver donors with an AST/ALT of 3000 u/l in order to be prepared for any negative feedback during public comment.
- The subcommittee recommended 60 years of age or older to exclude heart donors from the eligible data definition based on the number of hearts that are transplanted from that age group. There was considerable discussion about heart donors that have additional co-morbidity factors so the subcommittee recommended adding “ ≥ 45 years of age with a history of ≥ 10 years of HTN or ≥ 10 years of type 1 diabetes.” Additionally, for lung donor the subcommittee added ≥ 60 years of age, asthma with the daily prescription, and asthma as a cause of death.
- There was considerable discussion about the issue of ruling out organ recovery in the operating room. The Committee agreed to leave the following language as it was originally drafted: “The donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplantation.”

The Committee will work to finalize modifications to the definitions and have several OPOs “pilot test” the proposed changes to the definitions to analyze the impact. It was noted by UNOS staff that when this proposal goes back out for public comment in the fall it will be rewritten in the new structure used for the policy rewrite project.

7. Proposal to Modify DCD (Donation after Cardiac Death) Model Elements The Committee briefly discussed the changes made to this proposal that was originally distributed for public comment in March-June of 2011. In November 2011, the Executive Committee requested that the OPO Committee review comments received from several organizations prior to the November Board meeting, revise the proposal if necessary, and resubmit it for public comment. The Committee made some minor modifications to the proposal language and will resubmit it for public comment in the March 2012.

8. **Rerunning the Match Run** The Committee reviewed a memo from the MPSC and DEQ requesting the formation of a joint working group to discuss the issue of rerunning the match run when there are changes in serology results. The Committee agreed that the ideal situation is to screen candidates off the match run in order to avoid wasting time and resources to place organs. The Committee initially thought this was a straightforward issue however after a brief discussion identified the following issues:

- It was noted that it depends on what type of serology results because only hepatitis B and hepatitis C candidates would be screened off subsequent match runs.
- If a candidate that has accepted an organ is screened off the subsequent match run then rescinding an offer would violate OPTN policy.
- Rerunning the match run should not be used as a way of communicating changes in serology results.

9. **DTAC/OPO Sharing Updated Donor Information Subcommittee Update** The Committee was provided with an update from the initial conference call of this subcommittee on February 10, 2012. The main focus was the reporting of culture results following organ recovery. This issue was initially discussed at the November board meeting and it was recommended that verbal communication be required to share updated donor information such as culture results. The subcommittee discussed the following variations in practice:

- Some OPOs use a centralized lab while some have the tests performed at the donor hospital.
- Some OPOs have automated reporting while others use manual follow up to obtain the results from wherever the tests are performed.
- There are variations in how results are reported to transplant centers and this becomes even more challenging with exported organs. The results might be reported to a coordinator, surgeon/physician, individual on call, or some random individual in the office that day. Results for exported organs are being reported to the accepting OPO instead of directly to the transplant center. UNOS staff pointed out that current policy requires direct notification to the recipient center, not the importing OPO.
- Some OPOs are reporting all results including the negatives while others are just reporting positive results.
- The method of reporting varies with most OPOs having a combination of the following: faxed results 2) verbal reporting 3) posting on DonorNet[®].

There was also concern about what to report as a potential disease transmission as opposed to routine reporting of results of cultures. Staff noted that a DTAC guidance document is available to help members. The patient safety contact list was suggested as a means for notifying transplant programs however most of the OPO members thought that was not the best way of reporting because the person on call for patient safety might not be the person you want to receive culture results. One member noted that the DonorNet[®] OPO console can be used to see who is currently on call. It will list the primary and secondary person that took the offer and the person that is currently on call. A suggestion was made to highlight the patient safety contact list and OPO console in a guidance document to help educate the OPO community rather than making a policy change. The guidance document could be developed with direction on local versus exported offers, including screen shots of the OPO console.

10. **Effective Screening Work Group** This project started out as the tiered acceptance project in 2007 soon after DonorNet[®] was implemented. This work group has recently been reviewing effective screening practices since DonorNet[®] was implemented and has developed some specific recommendations to share with the various committees. Some of the recommendations include:

- Impact analysis of targeted letters sent to liver programs
- Perform other analyses including ECD listing practices, impact of geography on acceptance practices, sequence number as a possible screening criterion
- Develop support for KDPI becoming a new donor acceptance parameter in new KAS
- “Screening opportunity” letters to programs that have consistent pattern of refusing all high KDPI import donors to encourage effective use of KDPI
- Provisional yes – consider eliminating it or changing it to work more effectively and monitor percentage of provisional yeses that become refusals in order to detect abuse.

The chair of the working group had requested the opportunity to present the recommendations to the OPO Committee and get their feedback about acceptance criteria. This includes working with the local transplant centers to make sure organizations are sharing information and to evaluate the impact of screening criteria within the local, regional, and national areas. Finally, if there is agreement that this should move forward then a project request will need to be submitted to the POC and Executive Committee for approval. The Committee agreed to schedule a conference call in May 2012 to review the recommendations.

11. Organ Tracking & Traceability Project The Executive Committee approved the Operations and Safety Committee (OSC) to begin evaluating a standardized donor code or identification system that could help with organ tracking and traceability. The Committee is currently reviewing one system that has been endorsed by the World Health Organization called ISBT 128. Many of the blood centers across the country have implemented this bar coding system. UNOS leadership, along with the leadership of some of the committees, are planning on doing site visits to some of the local blood centers to see how they have been able to implement that standard and track blood products once they are allocated from the donor and evaluate if it might be a system that could potentially work for organs. The OSC plans to form a multi-committee work group to discuss that system, the risks and benefits of a system like that, and what would be needed to implement something similar.

12. OPO Scorecard Threshold Subcommittee Report This subcommittee was formed in the fall of 2011 to address a request from the MPSC to help establish a threshold for scorecards used during site survey visits. During the initial conference call in December 2011 (Exhibit H) the subcommittee was provided with a general overview of the scorecard, the national averages, and a breakdown of individual OPO scores (OPO names were not included). The average scores were 96% for clinical and 78% for administrative. The clinical scores include donor evaluation, accuracy of infectious disease reporting, ABO verification, packaging and labeling, and critical data reporting such as time of death. The subcommittee had considerable discussion about the importance of accurate and timely serology reporting, especially for diseases like HIV and hepatitis. There was some concern about setting a single score threshold for all aspects of the clinical score. However, it was noted that there is a process in place where the MPSC is notified when there is an issue with one of the critical elements so the subcommittee agreed that setting the clinical score threshold at 95% would be reasonable based on the numbers that were reviewed. The Committee had the following concerns:

- The Committee had concerns about the data submission aspect of the scorecard. For example, an OPO can be delinquent for two years but as long as it gets the data submitted before the auditors arrive on-site it is fine. The converse is true as well, if an OPO does a great job of data submission for two years but overlook some data submissions prior to the site visit it will count against it. The Committee was concerned about this process because if policy requires that the DDR be completed within 30 days of the form generation date then that should be what the OPOs are evaluated on especially considering that the information on the DDR have an impact on expected graft survival rates.
- The Committee had some concerns about the definitions for data elements on the DDR. Examples include inotropes and blood products used for transfusions. It was noted by UNOS

- staff that the Transplant Coordinators Committee is working on definitions for forms and will be requesting input from the OPO Committee when they are ready to review the DDR.
- The Committee had concerns that transplant centers are not being scored on data submission like the OPOs.
 - The Committee had concerns about the sample size used during site visits. Using 10 random charts regardless of the number of donors the OPO had during a two year period did not seem fair.

Additional details about the subcommittee discussions can be found in **Exhibit I**. The subcommittee will send a request to the MPSC to allow the Committee to provide input on the process instead of just making recommendations about the scorecard thresholds. The subcommittee will continue to review and analyze the components of the scorecards and hopefully have some final recommendations for the Committee during its fall 2012 meeting.

13. Packaging and Labeling Subcommittee Update The subcommittee is continuing its work on addressing issues related to packaging and labeling. This includes evaluating the issue of r-values for shipping containers. There have also recently been some questions raised about when labels are required for shipping specimens. Current policy requires that OPOs use approved labels when shipping specimens “commercially” but there is confusion about what exactly that means. For example, if you are sending blood to a lab down the street using a courier does it require a UNOS label? The Committee discussed the intent of the policy and agreed it applies only to shipping specimens outside the local area. The Committee requested that the subcommittee review the policy language and make recommendations to provide clarification for the members. Additionally, there was a request that if any committee member has encountered issues with Policy 5 to please forward them to the subcommittee for review.

14. Uncontrolled DCD Survey This survey is intended to get a baseline on what is currently happening in the OPO and transplant community with regards to uncontrolled DCD. The Committee reviewed and modified a draft survey (**Exhibit J**) that will be distributed through the Association for Organ Procurement Organizations (AOPO).

15. Committee Project Process The Committee was provided with an overview of the committee project approval process. In November 2010, the Board of Directors endorsed a new planning process. By evaluating and prioritizing new projects at the early stage in their development, the Board will be able to make the best use of finite resources. Committees have been developing annual work plans for several years but what is new is the setting of priorities for committee work.

The review process begins when liaisons work with their committee leadership to complete project forms (new and ongoing) early in the calendar year. The Policy Oversight Committee reviews and scores every project during their spring meeting and makes recommendations to the Executive Committee. Finally, the Executive Committee reviews the projects during their June meeting and sets the priorities for the upcoming year which runs from July to June.

16. Evaluation Plan The Committee discussed some recent concerns that have come up following OPO site survey visits. There have been questions raised about how the policies and bylaws are interpreted by UNOS staff. It was noted that there is an evaluation plan located on the OPTN website that outlines how members can comply with each policy and how member compliance is monitored. However, when site surveyors are on-site there might be issues that come up regarding what types of documentation is required and where it should be located. The source documentation is there but it might be in a different location than what is expected from the site surveyors. The Committee used this as an example and agreed it would be beneficial to form a subcommittee to review the sections of the evaluation plan that deal specifically with OPOs. The Committee could then initiate dialogue

with the Department of Evaluation and Quality to possibly improve communications about what is expected during site visits.

- 17. Cannulation** The Committee discussed the recommendation to update the DDR field labels to reflect the initiation of core cooling. The original intent of the cannulation fields was not to get the date and time when the cannulation actually occurred, but the time at which the initiation of core cooling took place. It was noted that each field on the DDR has an edit range designed to prevent the entry of data that falls outside what is common practice in the field. The current edits list a minimum time of 15 minutes before withdrawal of life sustaining measures and a maximum time of 60 minutes after clamp date/time. After discussion, the Committee agreed that the minimum time should be the date/time of death since core cooling cannot be initiated until pronouncement of death. They also recommended changing the maximum time to 4 hours to allow for scenarios where core cooling is delayed for whatever reason.
- 18. Vascularized Composite Allografts (VCA) Federal Register Notice** During its January 27, 2012 conference call the Committee reviewed the federal register notice in order to provide input that will be included with the OPTN response to the federal register notice. The Committee's response:

The OPO Committee supports the concept of including vascularized composite allografts (VCAs) within the definition of organs under the authority of the OPTN. The Committee expressed concern about the impact on state first person authorization registries which may not be inclusive for VCA authorization. It is recommended that VCA authorization be required so individuals or family members can be informed and have the option of donating VCAs. It should not be implied that first person authorization to donate organs would include VCAs. This is an issue for the individual states to address, and there might be a need for a grace period to allow state first person authorization registries time to update their processes. Finally, the Committee acknowledged that OPOs will be impacted in the future as more details about procurement, allocation, member requirements, and data submission are developed.

OPO COMMITTEE

	MONTH	January	March
	DAY	27	8
	FORMAT	Live Meeting/ Teleconference	In Person
NAME	COMMITTEE POSITION		
Lori Brigham MBA	Chair	X	X
Richard Pietroski MS, CPTC	Vice Chair	X	X
Chris Curran	Regional Rep.	X	X
Susan Stuart RN, MPM	Regional Rep.	X	
Christy Corbitt, RN, CPTC	Regional Rep.	X	X
James A. Cutler, CPTC	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
Paul Nelson, MD	Regional Rep.	X	X
Cynthia Willis	Regional Rep.	X	X
Esther Carmichael	At Large	X	X
Meredith Harrison	At Large	X	
Jacqueline Honig, MD	At Large		X
Richard Padula RN	At Large	X	X
William Reitsma BSN	At Large	X	X
Sean Van Slyck BA,CPTC	At Large	X	
Teresa Beigay DrPH	HRSA	X	X
Robert Walsh	HRSA	X	X
David Zaun	SRTR Liaison		X
Ajay Israni, MD, MS	SRTR Liaison	X	Phone
Jon Snyder, PhD, MS	SRTR Liaison		Phone
Tabitha Leighton	SRTR Liaison	X	Phone
Robert Hunter	Committee Liaison	X	X
James Alcorn	Director of Policy		X
John Rosendale	Support Staff	X	X
Franki Chabalewski RN, MS	Committee Liaison	X	X
Margaret Kearns	DEQ	X	Phone
Tiffany Lord	DEQ	X	Phone
Sarah Herbert	DEQ		Phone
Kimberly Taylor	OSC Liaison		X