

**OPTN/UNOS Organ Procurement Organization Committee**  
**Report to the Board of Directors**  
**March 2-3, 2009**  
**Houston, Texas**

**Summary**

**I. Action Items for Board Consideration**

- The Board of Directors is asked to approve modifications to Policy 2.0 (Minimum Procurement Standards for an Organ Procurement Organization). These proposed changes would update terminology, clarify policy language that may place OPOs at risk for noncompliance, and eliminate or change policy language is inconsistent with current OPO practice. (Item 1, Page 3)
- The Board of Directors is asked to approve modifications to Policy 3.6.9.1 (Minimum Information for Liver Offers) to provide consistency with changes in Policy 2.0 regarding the removal of the GGT laboratory test from the required list of laboratory values for potential liver donors. (Item 1, Page 4)
- The Board of Directors is asked to approve the following programming changes to DonorNet<sup>®</sup>: display the name, date and time of the user who added the donor to DonorNet<sup>®</sup>, the name of the user who enters the donor's ABO and the name of the user who verifies the donor's ABO, as well as the date and time it was verified. (Item 2, Page 5)
- The Board of Directors is asked to approve programming changes to DonorNet<sup>®</sup> to the disposition codes for "technical reasons" so it will be applicable to any organ that is transplanted for technical reasons. Currently, OPOs can only apply this code when the pancreas is transplanted for technical reasons. (Item 2, Page 6)

**II. Other Significant Items**

- The OPTN began collecting Imminent and Eligible Death patient level data on January 1, 2008. The data show that confusion exists when applying the definitions resulting in inconsistent data reporting. The Committee sponsored two Live Meeting<sup>®</sup> training sessions to help members understand the definitions. (Item 4, Page 7)
- In a joint effort, the Committee conducted a NAT Survey to determine current OPO practice and identify the challenges OPOs face in conducting NAT on potential donors. (Item 6, Page 9)
- The new Organ Transport Labels produced by UNOS became mandatory October 1, 2008. Considerable follow up has been necessary. (Item 10, Page 12)
- The OPO Performance Metrics Joint Work Group has a preliminary model to evaluate OPO performance based on Organs Transplanted per Donor. (Item 11, Page 13)
- Policy 5.0 (Standardized Packaging, Labeling, and Transporting of Organs, Vessels, and Tissue Typing Materials) has been revised and distributed for Public Comment. (Item 12, Page 14)

- The Committee, at the request of the MPSC, considered OPO responsibilities surrounding directed donation as well as their opinion regarding informing all families about directed donation. (Item 13, Page 15)
- The Committee discussed the difficulty in accurately collecting data on the Deceased Donor Record (DDR) regarding the DCD donor that deteriorates to brain death. The DDR may need to be modified to accurately collect data on this type of donor. (Item 14, Page 16)
- The Committee formed a joint Work Group with the Organ Availability Committee to review DCD policies and assess the need for revision or additional policies being developed. (Item 14, Page 16)
- The ASTS asked the Committee to review the draft ASTS Guidelines for Procuring Surgeons. The Committee will provide feedback. (Item 18, Page 18)
- The Committee considered a request from the MPSC regarding the potential for labels to be generated directly from DonorNet<sup>®</sup>. (Item 19, Page 19)
- The DEQ requested an opinion from the Committee as to whether a six piece insulation liner for shipping boxes can be considered a container as mandated by policy. (Item 20, Page 20)
- The Living Donor Committee requested Committee input regarding OPOs facilitating packaging, labeling and transporting live donor organs. (Item 21, Page 20)

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**Jeff Orłowski, MS, CPTC, Chair**  
**Lori Brigham, MBA, Vice Chair**

*This report reflects the work of the OPO Committee during its June 26, 2008, and December 5, 2008, meetings in Chicago, IL as well as all committee conference calls. Additionally, the Metrics, Policy Review and Research Codes Subcommittees have met by conference calls.*

**1. Proposed Modifications to Policy 2.0 (Minimum Procurement Standards for an Organ Procurement Organization (OPO)).**

The Committee requests that the Board approve proposed changes to Policy 2.0 (Minimum Procurement Standards for an Organ Procurement Organization (OPO)). These changes would update terminology, clarify confusing policy language that may place OPOs at risk for noncompliance, and eliminate or change policy language that is inconsistent with current OPO practice.

One of the Committee's goals is to review policy language that might place OPOs at risk for noncompliance and policy violations. Initially, the Policy Review Subcommittee requested information from the Department of Evaluation and Quality regarding the most frequent types of OPO violations that occur. The Subcommittee reviewed some of the challenges that OPOs face when implementing policies, and agreed that some policies need clarification. Members reviewed Policy 2.0 and made proposed modifications based on their expertise and current practice. The Committee reviewed the modifications at the June 26, 2008, meeting and voted unanimously to distribute the proposed changes for public comment.

Most of the changes were made to clarify items such as:

- Changing "social-behavioral" history to "medical-behavioral" history to reflect current practice.
- Remove the term "written" to "documentation" to update terminology to allow for electronic information that is stored or transferred.
- The Committee agreed that blood and urine cultures should be required regardless of the time spent in the hospital.
- ABO and sub-typing is required for all donors.
- Urinalysis terminology was clarified as within 24 hours of cross clamp.
- The list of laboratory tests that are required for all donors now includes ABGs in keeping with current practice.
- GGT was removed from the required liver testing required. The Committee agreed that this test is frequently not available at donor hospitals and most often not considered. If available, it can be requested.
- Any test listed with "as requested" (e.g. Amylase) was removed, and one statement was inserted that provides the option of requesting the test if available.
- The OPO with its respective lab will define and document the minimum tissue typing material required to generate a match run (removed "minimum written requirements for tissue typing – need to work with labs to define and document what is needed.)
- The requirement that states, "Tissue typing is initiated only after consent" was removed. There

are many things that are not done until after consent so it was not appropriate to single out only consent actions.

- It is important to document the reasons for non-recovery of all organs, not just liver and pancreas.
- The Committee determined that the requirement to follow an established DCD protocol should include each of the Model Elements as listed in Appendix B of the OPTN ByLaws.

There was considerable discussion about the use of the terms “consent” vs. “authorization” with respect to donor consent practices. Although the term authorization is a more accurate depiction of actual practice, the Committee agreed that any change toward the term authorization will require serious consideration by a community wide forum. The Committee may consider this change in the future; however, at this time, the Committee did not believe it to be the industry standard.

During a Conference Call on January 6, 2009, the Committee reviewed the responses to the proposed modifications from other committees, regions and the general public. The Committee considered each of the public comments and made appropriate changes as outlined in the Briefing Paper (**Exhibit A**). The Resource Assessment and Impact Summary is also provided for implementation and maintenance cost estimates (**Exhibit B**).

The resolution to forward the proposed policy changes for Board consideration was approved by a vote of 14-0-0.

**\*\*RESOLVED, that the modifications to Policy 2.0 (Minimum Procurement Standards for an Organ Procurement Organization [OPO]), as set forth in the Briefing Paper, having been distributed for public comment, shall be approved and implemented pending distribution of appropriate notice.**

The Liver and Intestinal Organ Transplantation Committee supported the change in Policy 2.0 that would eliminate the GTT test from the list of required tests for the liver donor and recommended that the Committee consider removing the GTT from similar language in Policy 3.6.9.1. Following review, the Committee agreed that Policy 3.6.9.1 should be changed to reflect the change in Policy 2 regarding the elimination of the GGT as a required test for potential liver donors. The Resource Assessment and Impact Summary is also provided for implementation and maintenance cost estimates (**Exhibit C**).

The resolution to forward the proposed change to Policy 3.6.9 (Minimum Information for Liver Offers) to the Board for consideration was approved by a vote of 14-0-0.

**\*\*RESOLVED, that the modification to Policy 3.6.9 (Minimum Information for Liver Offers) as set forth below, are hereby approved and implemented pending distribution of appropriate notice:**

### 3.6 ALLOCATION OF LIVERS [No Changes Proposed]

#### 3.6.1 – 3.6.8 [No Changes Proposed]

#### 3.6.9 Minimum Information for Liver Offers.

3.6.9.1 Essential Information Category. When the Host OPO or donor center provides the following donor information, with the exception of pending serologies, to a recipient center, the recipient center must respond to the offer within one hour pursuant to Policy 3.4.1 (Time Limit for Acceptance); however, this requirement does not preclude the Host OPO from notifying a recipient center prior to this information being available:

- (i) Donor name and Donor I.D. number, age, sex, race, height and weight;
- (ii) ABO type;
- (iii) Cause of brain death/diagnosis;
- (iv) History of treatment in hospital including current medications, vasopressors and hydration;
- (v) Current history of hypotensive episodes, urine output and oliguria;
- (vi) Indications of sepsis;
- (vii) Social and drug activity histories; Vital signs including blood pressure, heart rate and temperature;
- (ix) Other laboratory tests within the past 12 hours including:
  - (1) Total Bilirubin
  - (2) ALT
  - (3) INR (PT if INR not available)
  - (4) Alkaline phosphatase
  - ~~(5) GGT~~
  - ~~(6) WBC~~
  - ~~(7) HH~~
  - ~~(8) Creatinine;~~
- (x) Arterial blood gas results;

Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred).

3.6.9.2 – 3.6.13 [No Changes proposed]

## 2. Request for Changes in DonorNet™ (Technical Codes and ABO Verification)

*ABO Verification.* Stacey Burson, IT Business Analyst and Committee IT Support Liaison, reported on an ABO verification programming issue in DonorNet®. Currently, information regarding who enters the donor's ABO and who verifies it is required and entered into DonorNet™. However, these data cannot be displayed and read. The Committee discussed the need to make appropriate changes so that the parties concerned can access the information.

The goal is to modify DonorNet® to:

- Display the name of the user who added the donor to DonorNet® as well as the date and time that the donor was added.
- Display the name of the user who enters the donor's ABO when adding it to DonorNet® along with the date and time that the ABO is entered
- Display the name of the user who verifies the donor's ABO as well as the date and time it was verified.

Currently, UNOS collects these data, so there is no need to add any additional data fields. These data need to be displayed so individuals can identify the person responsible for adding and for verifying the donor's ABO. Additionally, the reader will only be able to read the data and is not able to edit it. This programming change is expected to require approximately 650 man hours and cost approximately \$35,640. The estimated annual maintenance cost is approximately 160 man hours and approximately \$8,773.00. **(Exhibit D)**

The following resolution is recommended to the Board for Consideration:

**\*\*RESOLVED, that changes to DonorNet® to display the following data that is currently collected, as set forth below, shall be approved and implemented pending programming and distribution of**

**appropriate notice.**

- 1. Display the name of the user who added the donor to DonorNet as well as the date and time that the donor was added.**
- 2. Display the name of the user who enters the donor's ABO when adding it to DonorNet along with the date and time that the ABO is entered**
- 3. Display the name of the user who verifies the donor's ABO as well as the date and time it was verified**

The resolution was approved by a vote of 13-0-0.

*Technical Codes.* The Research Codes Subcommittee met by conference call to discuss the accuracy of the current research and organ disposition codes that OPOs report and their appropriateness and value. It was determined that the codes that are labeled as “recovered for research” do not clearly explain what ultimately happens to the organ and, therefore, does not accurately describe the disposition of the organ. There is no guidance as to how to interpret the codes and when it is appropriate to use each. Additionally, there was some discussion as to whether the researcher needed to document, through some form of receipt, that they received the organ. Members agreed that the OPO can attempt to place the organ for research; however, the acceptance of that organ is not in the OPO's control.

If changes are recommended, it was deemed important to determine the impact that these changes would have on DonorNet<sup>®</sup>. Although “research organs” have never been considered as an outcome, this differentiation does provide a way to identify research organs from those organs that are discarded, and gives a more accurate view of the disposition of the organ. It was suggested that UNOS staff inform HRSA that the Committee is considering this research code modification, and seek clarification as to whether or not the OPTN should undertake this project.

Motion: That appropriate UNOS staff contact the HRSA Project Officers to determine if the Committee should pursue these changes in research codes. If deemed appropriate, the Committee will then consider the recommended changes to the disposition codes and move forward at that time. The motion was passed by a vote of 15-0-0.

Following discussion, HRSA determined that the disposition codes for technical reasons should be considered. At the December 5, 2008, meeting, Ms. Burson reported that the disposition codes for “technical reasons” currently apply only to the pancreas. As such, the OPO does not have an accurate way to account for organs other than the pancreas that are recovered for “technical reasons.” The Committee agreed that Code 516 – “Recovered Pancreas for Technical Reasons” should be replaced with 528 – “Recovered for Technical Reasons” and 520 – “Recovered for transplant: Pancreas sent for technical reasons” should be replaced with 529 – “Recovered for Transplant: Sent for Technical Reasons.”

In order to make these changes, corresponding fields on the Deceased Donor Record (DDR) will need to be modified. Ms. Burson reported that the level of effort to implement this project would be approximately 760 man hours for a total of \$41,671.00 (**Exhibit E**). There are no maintenance costs associated with this project. These codes currently are identified as “DMS use only.” DMS is no longer a department and the Committee agreed that DMS be changed to UNOS. The Committee also discussed the potential for error in data when it is converted and recommended that these data (old codes) not be converted. It was also suggested that whenever there is a query regarding a particular type of organ, that the query should show the date when the codes were changed.

The following resolution is recommended to the Board for consideration:

**\*\*RESOLVED, that the “technical reasons” disposition codes 516 and 520 be deactivated and codes 528 and 529, as set forth below, be activated; that “DMS use only” be changed to “UNOS use only;” and that the old data not be converted; shall be approved and implemented pending programming and distribution of appropriate notice.**

**516— Recovered Pancreas for Technical Reasons (DMS use only) should be replaced with 528 – Recovered for Technical Reasons (UNOS use only)**

**520— Recovered for transplant: Pancreas sent for technical reasons (DMS use only) should be replaced with:**

**529 - Recovered for Transplant: Sent for Technical Reasons (UNOS use only)**

The resolution was approved by a vote of 13-0-0.

### **3. Data Management Subcommittee**

Meg Rogers, Region 7 Representative, reported that the Data Management Subcommittee has met to review outside data requests to ensure the legitimate release of data. Most requests are accepted; however, there are occasions when researchers are required to enhance or strengthen their security measures in their research plans.

### **4. Imminent & Eligible Death Data Collection Project**

At the June 26, 2008, meeting, UNOS reported on the status of the Imminent and Eligible (I & E) Death Data Collection Project. The current contract requires that the OPTN collect patient level data for all imminent and eligible deaths. The I & E death definitions, guiding the data collection, were previously approved by the Board of Directors. It is anticipated that patient level reporting of eligible deaths will allow for better performance modeling; however, members are interpreting the definitions differently, which results in inconsistent data reporting. The release of the data was delayed due to these inconsistencies.

The AOPO Quality Council, under the direction of Charlie Alexander MS, MBA, former Chair of the OPO Committee, will create a “Guidance Document” to help OPOs report these data accurately. There was a discussion regarding the problems associated with the definitions of sepsis and multi-system organ failure as exclusionary criteria. Mr. Alexander, will create a preamble and continue to work with the AOPO Quality Council to develop the guidance document.

The Committee suggested specific content that should be included in the Guidance Document. As some OPOs have quality/data staff applying the definitions, members recommended that there be clinicians working with the quality/data staff to ensure accurate reporting. It was also suggested that every OPO report every death. OPOs should continue to have a mechanism to seek clarification, direction and uniformity from UNOS. Members also discussed the inconsistency in data collection when some state laws require two brain death exams prior to declaration of death while others do not. The same donor could be viewed differently in those states because one brain death exam may be completed, and a required second exam not completed thus resulting in the patient not being declared brain dead. In this situation, this patient would be reported as an imminent donor in some states and eligible donor in others. It was suggested that several case scenarios be provided to OPOs to assist them in applying the definition more accurately. The Committee also requested that the document clarify and define sepsis and multisystem organ failure. Once collected, these data will help to approximate expected donation rates. The committee agreed that clarifying definitions would improve data reporting significantly.

Following its development, the Guidance Document was distributed to all OPO Executive Directors and Directors of Procurement. **(Exhibit F)** This document restated the intent of the I & E project, showed OPOs how to apply the I & E definitions, and included various scenarios that occur.

The Subcommittee met by conference calls to discuss perceived discrepancies surrounding the data collected and to address the numerous questions that have been posed during the first six months of data collection about how to apply the definitions. At the December 5, 2008 meeting, Mr. Rosendale reported that the variation in the way the definitions are being applied affect data accuracy. By analyzing the questions posed, the Committee determined that the imminent death definition created more confusion than the eligible death definition; however, there are eligible definition questions as well. Data reported for various subgroups of donors, (donor age, ethnicity, gender, cause of death, etc.) were discussed.

The Committee sponsored two I & E training session in order to provide additional clarifying information to the community. These Live Meeting<sup>®</sup> sessions, conducted on December 9, 2008, and December 16, 2008, addressed questions and clarified the application of the definitions for data collection purposes. Approximately 125 people/groups joined the sessions.

Prior to the December 4, 2008, meeting, the Committee leadership met to discuss the effect of the I & E death data accuracy when multi-system organ failure (MSOF) is present. CMS regulations define MSOF as the failure of 3 or more systems. Although MSOF is exclusionary, OPOs are pursuing single (and sometimes more) organs from these donors. It was determined that the Committee may need to create specific MSOF guidelines for the purpose of the I & E data collection. It was suggested that instead of using the number of failed systems, it might be best to use the concept of “the absence of any transplantable organ” or “the presence of transplantable organ(s).” As such, a donor with any workable organ appropriate for transplant, will be potentially identified as either an imminent or eligible donor.

The Committee will:

- Research and seek community input on the general concept.
- Provide feedback regarding the CMS Interpretive Guidelines and ask CMS to consider a change in the MSOF definition. CMS currently defines MSOF as the failure of 3 systems.
- Seek input from each of the organ specific committees, AOPO procurement directors, and others to review MSOF definitions.

Robert Walsh, Health Policy Analyst, Division of Transplantation, stressed the importance of this initiative, reported that this issue appears on several HRSA meeting agendas, and said that he will pursue it further. Finally, the Committee established a subcommittee to clarify the MSOF definition in order to bring some clarity and consistency to the data reported.

## **5. Pediatric Practice Guidelines**

At the June 26, 2008, meeting, Mr. Alexander reported that the Pediatric Work Group met to discuss pediatric donor management concerns and requested that the Committee discuss the impact of specific donor management medications used in a pediatric donor management situation (anticoagulants). The Work Group asked that the Committee consider developing guidelines; however, the Committee agreed that they do not have the medical expertise and are not the appropriate group to make those decisions.

The Committee previously asked the Pediatric Organ Transplantation Committee and the organ specific committees for guidance in prioritizing multi-organ transplants, such as a heart and lung combination. It was suggested that a priority needs to be developed by the appropriate committees, as allocation is not an OPO function. The OPTN should establish clear guidance in prioritizing the allocation of multiple organ transplants.

The Committee members remarked that it is important for OPOs to know which list to follow for allocation of the organs when a patient appears on the liver list, intestine list and combined list. Currently there are inconsistencies in how organs are allocated and which list should be followed. The OPO Committee would willingly participate in deliberations; however, members agreed that they are not responsible for setting priorities for allocation and that the group should be spearheaded by organ specific committees. Current policy states that multi-organ transplants should be encouraged but there is no allocation algorithm to follow. It would be important for OPO staff to have an understanding of priorities across all organ types and combinations of those organs.

*Recommendation:* That the organ specific Committees prioritize multiorgan versus individual organ allocation and establish very specific guidance for OPOs in setting a priority for the allocation of organs in a multi organ transplant situation. This would be done to ensure consistency of practice and with the understanding that allocation should be done using evidence based principles and not arbitrary decision making. The motion was approved by a vote of 14-0-0.

Mr. Alexander discussed the Pediatric Organ Transplantation Committee's request to consider a requirement for OPOs to provide donor management protocols, guidelines or policies, in the interest of early full disclosure of pre-recovery drugs and protocols that may affect organ function. The Pediatric Committee suggested that all of this information be available in advance of the decision to accept an organ. Additionally, the Committee was asked to consider developing written guidance to settle problems or clinical practice differences that may occur in the OR at the time of organ recovery.

The Committee referred this issue back to the Pediatric Committee Work Group. Members voiced concerns about the administration of medicine during donor management, and possibly after organs are accepted, that may be counter beneficial to specific organs. The Committee considered the question regarding who makes the decision to administer specific medications. It was also determined that OPO Medical Directors mediate any problems that arise in the O.R. Some members felt that it would be impossible to comply with this request regarding written guidelines to settle problems or clinical practice differences and that open communication between recovery teams and procurement personnel is essential.

*Recommendation:* That the Committee draft a letter to the Pediatric Organ Transplantation Committee to explain the Committee's opinion regarding setting multiorgan priority (heart and lung) and their concerns about the development of donor management guidelines. The Committee recommends that recovery teams consult with OPO personnel on donor management issues. This letter should include a statement that processes exist (such as speaking to the administrator on call or request a discussion with the medical director or others on the recovery team) that provide guidance as to how to proceed when issues arise in the OR in order to form some consensus. The motion was approved by a vote of 13-0-0.

A memo was subsequently sent to the Pediatric Organ Transplantation Committee reiterating the Committee's concerns and recommendations.

## **6. NAT Survey**

At the June 26, 2008 meeting, Mr. Alexander reported that the Disease Transmission Advisory Group (DTAG) would like to explore issues with those OPOs that have difficulty in accessing Nucleic Acid Testing (NAT). Screening tests are broader and identify a wider range of diseases. Discordant test results can occur between screening and diagnostic testing and could result in the loss of organ acceptance. It was suggested that if OPOs are using screening assays, they should be encouraged to discuss these with their serologic labs.

The Committee requested that a notification be sent to OPO Executive Directors to make them aware of this testing issue and to encourage them to communicate with their lab(s) to identify the tests they are using and to provide information as to what tests might become available. It was suggested that a notice be placed in the consolidated policy notice that is sent by UNOS regarding Board actions and that it also be placed on the AOPO portal to ensure that all OPOs are informed.

The OPO Committee formed a joint Work Group comprising representatives of the OPO Committee, the Disease Transmission Advisory Group of the Operations Committee, the Centers for Disease Control, and the Histocompatibility Committee. The Work Group's goal was to conduct a survey of OPOs regarding their NAT practices. The survey was conducted via the AOPO portal for Executive Directors, and all 58 OPOs completed it. The Committee discussed the preliminary results at the June, 2008 meeting. When asked if the OPO did NAT, the survey showed that 77.6% said "yes" and 22.4% said "no." Of the 45 "yes" responders, 27 OPOs do NAT on all donors prospectively while 10 OPOs do NAT on high risk donors only prospectively. Of 45 responders, 18 OPOs said they were able to get NAT panel results within 12 hours. The OPO Committee leadership will contact those OPOs that said they could not comply if NAT was made mandatory.

At the December 5, 2008 meeting, The Committee reviewed the final NAT Survey results. **(Exhibit G)** Committee leadership contacted the 12 responders who reported that they could not comply with performing NAT if required in order to identify possible barriers. Mr. Orłowski reported that the 12 OPOs contacted indicated that the problem was logistics. If these OPOs performed NAT using a lab at a distance of several hours, the donor management times would be significantly extended and unacceptable. Additionally, the OPOs reported that if they could resolve the time issue, the cost would be prohibitive. Several OPOs reported that they were working with their labs and centers to try to overcome the issues but have been unsuccessful. There is a large amount of variability in the OPO community as to how NAT is being applied. Survey results will be made available to OPO Executive Directors. Mr. Wilson volunteered to place the information on the AOPO Executive Directors Portal as well. After discussion, the Committee made the following motion:

Motion: That the Committee accepts the NAT Survey Report and distributes the survey report with a one page summary to OPO Executive Directors. The motion was approved by a vote of 13-0-0.

## **7. CDC High Risk vs. Individual OPO High Risk Criteria**

OPTN policy addresses high risk criteria based on the Centers for Disease Control (CDC) criteria; however; there are OPOs that use their individual high risk criteria. It was noted that the CDC criteria, as written, are specific to HIV and do not capture other diseases such as HCV, HBV, West Nile, etc. The Committee agreed that it would be helpful for the CDC to update its criteria and broaden the criteria's application to other diseases. Variation in interpretation creates confusion regarding the identification of a high risk donor.

Based on OPTN/UNOS policies, the surgeon must notify potential recipients when a donor is identified as a high risk donor. There was also a discussion regarding how this notification is documented. The Committee agreed that Policies should clarify that high risk donors are based on CDC high risk criteria and that OPOs should follow CDC Guidelines and not create individual guidelines.

Motion: That the Policy Review Subcommittee modify Policy 3.1 and recommend that the policy incorporate a statement that clearly indicates, from a policy standpoint, when a reference is made to high risk in OPTN policy, it is referring to the most current published CDC High Risk Criteria. The motion was approved by a vote of 15-0-0.

Upon further review, it was noted that Policy 4.1.1 clearly states that CDC definitions of “high risk” should be used. Members discussed the use of local high risk criteria throughout the United States. The Committee agreed that UNOS should review OPO criteria and made the following motion:

Motion: That the Committee request feedback from the Department of Evaluation and Quality’s site visits regarding the consistency of practice in using individual vs. CDC criteria. The motion was approved by a vote of 13-0-0.

Bruce Wilson, Executive Director of the Association of Organ Procurement Organizations, reported that the CDC has contracted with the University of Pennsylvania to draft new CDC guidelines. They have structured expert and external review panels. This group will share information with OPO Executive Directors. The CDC is currently reviewing its guidelines and a draft set of guidelines is anticipated in 6 to 9 months.

## **8. Acceptance Listing and Acceptance Practice Report**

At the June 26, 2008, meeting, Mr. Orłowski discussed the Tiered Acceptance Project that was initiated by the DSA Task Force and chaired by Robert Metzger, MD. The Tiered Acceptance concept is based on the premise that a transplant center will define three different sets of criteria of organ suitability for any particular patient who is being listed. These would include the criteria for an ideal organ, a marginal organ and an organ that they would be considered for a critical situation. This type of listing would be a multivariable acceptance list in order to be more efficient during the allocation process. The Operations Committee accepted the Tiered Acceptance Project but its progress was stalled due to the initiation of the DonorNet<sup>®</sup> system and the need to remedy current issues. The Operations Committee is creating a Work Group with the OPO Committee that will further refine the concept of Tiered Acceptance.

DonorNet<sup>®</sup> efficiency has been of real concern. While DonorNet<sup>®</sup> has somewhat met its original intent of providing multiple offers, the Committee did not agree that it is meeting the expectations of the Community. As such, the transplant community needs to identify ways to improve the system.

Additionally, the Committee discussed specific concerns regarding inconsistent OPOs’ use of DonorNet<sup>®</sup> including:

- Risk factors and anatomical abnormalities only being recorded in the comments section;
- Some OPOs are using DonorNet<sup>®</sup> as a patient database while others only provide the most fundamental information;
- Some OPOs are attaching large documents, such as the donor chart, that are not easily read on a handheld device; and
- Some OPOs have sophisticated systems that upload data into the system and others do not, so there is a great deal of variation as to how individual OPOs can use the system.

The Committee agreed that it is possible that there are organs being wasted because of insufficient information being transferred.

At the December 5, 2008, meeting, Mr. Orłowski reported that the Operations Committee will be assembling a Work Group to address the issue of Tiered Acceptance. Mr. Orłowski also commented on DonorNet<sup>®</sup> efficiency and that UNOS continues to receive comments regarding its efficiency and limitations in screening donors.

## **9. OPO Role in Verification of Death**

The MPSC asked the Committee to consider the OPO's role in the verification of death process and whether policy should apply to "death," as opposed to "brain death." The Committee identified the only OPO's responsibility in the verification of death as being the documentation confirming that the death was declared based on local law. Policy 2.2.1 requires OPOs to verify that death has been pronounced according to applicable laws. The Committee reached consensus that it is not necessary to distinguish between neurologic or cardio-pulmonary criteria used in the determination of death, as death is death regardless of which criteria are used.

Additionally, The MPSC suggested a revision to policy language to place the responsibility on the OPO to ensure that no procedures are involved that might potentially harm the public trust. The Committee agreed that to do so is the obligation of the entire transplant community, not just the OPO community. A new policy would need to include all individuals involved in the care of the donor, not just the OPO personnel.

The Committee agreed that the response to the MPSC should state that this change in Policy 2.2.1 from "brain death" to "death" has occurred and that all members of the transplant community are obligated to ensure that no procedures are involved that would potentially harm the public trust. Members agreed that OPOs do due diligence to ensure that procedures for declaration of death are appropriate. There should be a process in place to determine how an OPO would verify that death has occurred according to applicable laws.

## **10. Organ Transport Labels**

OPOs began using the new standardized labeling system on October 1, 2008. This color coded system contains carbon copies of donor information that are designed to be inserted into the donor chart. It has been suggested that a label for vessels be created that would contain a listing of all serology results. It was suggested that a vessel label, listing all the required serologies, be available on the UNOS website that can be downloaded and printed on an Avery Label.

The Committee reviewed a letter from a clinical coordinator regarding a situation that occurred due to the mislabeling of a research organ. Due to the nature of the problem, the coordinator suggested that all organs for research be labeled as a research organ. The Committee discussed the possibility of labeling organs for research and determined that most organs sent for research were originally intended for transplant and could not be labeled for research. To obligate the OPO to label an organ for research when it is not intended for research is problematic. OPTN and AOPO standards clearly obligate the OPO to label organs in an appropriate and accurate way. In response, the Committee will draft a letter thanking the center for their concern and reiterating OPTN policy. It was agreed that no further action needs to be taken at this time.

At the December 5, 2008, meeting, the Committee considered the following issues regarding the new labeling system.

*Right vs. Left Organ Labeling.* There have been comments made that there should be separate labels for right and left organs. Currently there is one label per organ, and the person responsible for completing the label must check the appropriate box(s) to demonstrate whether it is a right or left organ. Two labels would pose the question as to where the second label would be placed. The large, orange, external label currently reads "check one" for a list of contents of the shipping container and frequently there is more than one organ (vessels, blood, etc.), included. It was agreed that it should be changed to "Contents of box." Additionally, nodes, vessels, and blood should be added to the list of contents. Concerns were voiced regarding the number of labels that are required under the new system. The small labels are designed to maintain documentation as to how the shipping container was labeled as they have carbon

copies that become part of the donor chart.

Motion: That the outer orange label be consistent with the smaller label that reads “Contents of box” and that nodes, vessels, blood and chart will be added to the check box. The motion was passed by a vote of 13-0-0.

*Vessel Label.* There is currently no vessel label in the labeling system. The external label does have a check box to identify when vessels are included. The Committee agreed that there needs to be a vessel label for the container.

Motion: That a poly label for vessels be developed that meets OPTN policy requirements. The motion was approved by a vote of 12-0-0.

*Descriptive information implies that an internal label is required.* Current policy does not require the use of the internal label. However, the flyer used to describe the labels implies that it is mandatory. The Committee agreed that UNOS staff will correct the language to indicate that the internal poly label is not required.

*Unavailable information at the time of packaging.* There is information included on the label, such as flight information, that may not be available at the time of packaging. It was suggested that the label be changed so that the flight and destination information might be completed “if available.”

Motion: That the label should include, “Flight information can be completed if available.” The motion was passed by a vote of 12-0-0.

The Committee will continue to monitor the system to evaluate its efficiency and determine if there are any other issues that impact the labeling process.

## **11. OPO Performance Metrics Work Group Report**

The OPO Performance Metrics Work Group has met by conference call and identified elements from the DDR that might specifically demonstrate and predict organs transplanted per donor (OTPD) or donor yield. The SRTR was asked to create a model that predicts the expected yield given donor characteristics and calculate an actual and expected OTPD by Donation Service Area (DSA).

A preliminary model was developed, and most of the data elements that were studied were significant predictors of the model. The goals for this analysis are to:

- determine if this model works in evaluating organs transplanted per donor per DSA
- review retrospective data that will provide information about the donor when admitted to the hospital
- determine the impact of donor hospital maintenance from admission to consent
- determine the impact of donor maintenance from consent to OR.

OPOs are challenged with self reporting for OPO performance and understand the impact of variances in populations. This study may be an opportunity to look at OPO performance in an objective way allowing for corrections based on true donor case mix adjustment for potential donors.

At the December 5, 2008, meeting, Mr. Alexander and Charlotte Arrington reported on the SRTR analysis from the data request regarding OPO performance in regards to OTPD. The study sample was selected before DonorNet<sup>®</sup> was implemented. The goal of the project is to identify the impact of donor

characteristics on OTPD and to calculate the actual and expected OTPD by Donor Service Area. Results showed that there were a number of data elements that are able to predict the number of OTPD.

The Work Group requested further information from the SRTR regarding additional elements and their impact on OTPD. The project will be ongoing in order to refine the data. The SRTR will create a model based on the mix of types of donors in any given DSA. Adjustments were made based on the number of DCD donors that was part of the OPO's donor mix. The study reviewed those donors that had at least one organ per donor. The next set of questions will include those donors that are pursued with no organs recovered. The Committee agreed that these data could be used to look at variations in practices that make some DSAs more successful. The summary of this project will be reported at the January AOPO Executive Director's Workshop.

Motion: That Committee members will share the concept of this data collection (as these data are preliminary), but not the actual raw data until the model is more refined and more data are studied. The joint MPSA-OPO Committee Work Group must review the data as well. The motion was approved by a vote of 13-0-0.

## **12. Policy Review Subcommittee**

Lori Brigham, MBA, Vice-chair, reported on the work of the Policy Review Subcommittee. The Subcommittee has distributed proposed changes to Policy 2.0 for Public Comment and has worked with UNOS staff to revise Policy 5.0. The Committee met January 6 by Live Meeting to address each of the public comment responses to Policy 2. Final adjustments were made and the final proposed changes are submitted for Board approval at the March 2009 meeting. The Subcommittee will continue to review policies. Craig Van de Walker, Lori Markham, and Posey Durning volunteered to serve on the Policy Review Subcommittee.

The subcommittee participated in a rewrite of Policy 5.0 (Packaging, Labeling and Transportation of organs vessels and tissue typing material). The workgroup, comprising OPO, Operations and POC Committee members; UNOS staff from DEQ and the Organ Center, met several times by Live Meeting to discuss revision of the policy. The Committee approved the subcommittee's proposed changes that included:

- the addition of "corrugated plastic" box to be more inclusive of the types of containers that are being used;
- in the past, red plastic biohazard bags were required. This was changed to include "colored opaque" bags;
- the use of coolers continues to be acceptable and it was determined that hospitals mandate the proper care and cleaning of the coolers. Frequently OPOs do not participate in the packaging of organs, particularly when visiting surgeons remove organs and carry the organs with them;
- the use of an alternate label that contains all required information when using a mechanical preservation machine;
- internal packaging specifications include that intestines are not required to be placed in a rigid container for transportation;
- vessels must be protected by a triple sterile barrier. Language was included that requires the vessels' label to identify the vessels as procured from a CDC high risk patient;
- under the external labeling requirement, it was clarified that the UNOS ID is required as opposed to local ID number;
- the responsibility to label an organ is assigned to the OPO and documentation including the source documents must be included;

- that the transplant center has to have a procedure in place to verify the accuracy of the organs or the vessels;
- identified the internal labeling requirements for tissue typing materials.
- living and deceased organs that are recovered and transplanted in the same suite. The Committee discussed the term “suite” and seeks public comment on the term’s accuracy and universal applicability.

Motion: That the proposed changes to Policy 5.0 (Standardized Packaging, Labeling, and Transporting of Organs, Vessels, and Tissue Typing Materials) be accepted as revised and distributed for Public Comment. The motion was approved by a vote of 11-0-0.

The Committee questioned the thickness requirement for containers and the insulation R-value. UNOS staff will investigate and report to the Committee at the next meeting.

The Joint Commission (JC) requires that all specimens be labeled with two unique identifiers, while UNOS policy requires only one. Several OPOs have asked that the Committee consider this difference to see if UNOS policy should require two unique identifiers in order to be in line with the Joint Commission. As the UNOS Policy does not prohibit OPOs and transplant centers to use more than one identifier and, as such, is not in conflict with JC.

All labeling policies refer to shipping of organs transported in a box with no instruction for the labeling of organs that are transported on a pump. Policy states that every organ that is shipped requires a cardboard box; however, if an organ is shipped on a pump, it is not placed in a box. The Committee discussed whether or not policy needs to be modified to address the organ being transported on a pump. They concluded that ultimately this policy may place OPOs at risk for non-compliance. Members discussed their current practice in applying labels to the pump. It was agreed that the Policy Review Subcommittee will review the policy and draft language to clarify appropriate labeling of organs on a pump.

There was a discussion regarding continued reports that transplant teams are leaving the operating room without appropriately labeling the organ. The group agreed that if the transplant team does not appropriately label the organ, it is the OPO’s responsibility. If the OPO is not provided with the opportunity to label the organ, the OPO should report the incident to the DEQ for investigation.

### **13. Directed Donation.**

At its June 26, 2008, meeting, the Committee considered a request from the Membership and Professional Standards Committee (MPSC) to consider OPO responsibilities in approaching and informing all families about directed donation and to consider developing standards or guidelines regarding how families are approached and informed about directed donation during the consent process. The Committee considered whether a standard that encourages OPOs to include directed donation as an option for a family should be developed. Discussion focused on the appropriateness and helpfulness of some form of guidelines that would demonstrate how directed donation should be introduced to the family.

Current OPO practice is varied. Several members stated that recently they had received requests from UNOS for written documentation regarding directed donation. Some members explained that directed donation was included on their consent forms. The Committee also discussed directed donation in regards to policy and agreed it is clear that policy states organs must be allocated to a specific person and must be unsolicited. Currently, there are no policies dealing with consent. As directed donation is only a small part of an entire process, the Committee suggests that it not be a requirement to include directed donation in their consent process. Members agreed that directed donation is only a small portion of the

consent process and questioned whether or not all issues would then need to be addressed.

Some concerns were voiced that OPOs may be disenfranchising certain groups by not informing families about directed donation. The Committee agreed that the OPTN/UNOS should not be making rules for directed donation as it is governed by the UAGA of which there are various interpretations throughout the US. Policy 2.0 states that OPOs are required to document consent. Therefore, all directed donations should be documented under this policy.

Motion: That the Committee respond to the MPSC regarding directed donation as follows:

- OPOs would not be required to bring up direct donation in the future.
- Consent issues are governed in individual states by the UAGA. It would be difficult to specify a national standard when there are different interpretations of the UAGA throughout the country.
- That the MPSC recommend that OPOs have written documentation in the donor record that authorizes or directs the donation. If the MPSC feels that this should be placed in policy, the OPO Committee will entertain that request.

The Committee approved the motion by a vote of 11-1-0.

#### **14. DCD and Brain Death Capture of Data**

During the December 5, 2008 meeting, Mr. Rosendale provided a summary of the OPTN forms revision process and the need to have all changes approved by the Office of Business Management (OMB). All OPTN forms are due to expire in November, 2010. It is important for the Committee to review the DDR to determine if there are items that are not being captured or if there are variables that are no longer needed. Once the Committee reviews the form, the Ad Hoc Data Management Group and POC will review the proposed changes, and subsequently it will be sent for Public Comment (August 2009). The POC will conduct a final review of Public Comment in the spring, 2010; Board approval will be sought in March, 2010; and the proposed changes will be sent to HRSA in the Summer, 2010.

The goal of this review is to improve patient outcomes, develop transplant donation and allocation policies, determine if members are compliant, determine member specific performance, insure patient safety when no alternative data source exists, and fulfill the requirement of the OPTN Final Rule. The OPTN will only collect data that is contracted by HRSA.

Members were provided with a copy of the DDR and asked to consider the data regarding brain death and DCD reporting. There is no way to identify or capture the data for a brain dead patient that is recovered under a DCD protocol. The DDR does not have a question regarding whether or not the patient was declared brain dead. The only question that is asked is if the patient is a DCD donor. The system sees DCD as exclusionary to brain death. However, DCD is a recovery method, not a declaration of death. It is unclear as to how OPOs are reporting this particular type of patient at this time.

A donor will automatically be recorded as a brain dead donor in DonorNet<sup>®</sup> if not recorded as a DCD donor on the DDR. This may influence center specific data as the DCD donor and may have a lower expected survival rate. This could also influence the expected yield for these donors and as such, influence OPO performance results. There is no way to capture these data on the DDR. If these cases are being recorded as a DCD donor, there is no way to know if the donor was declared brain dead. The declaration of death provides certain challenges. Data must be filled in regarding the declaration of brain death. In the controlled DCD, questions are asked regarding the time of death, removal of support, the agonal phase, etc. Withdrawal of support cannot be listed after death is declared, so if the donor is declared brain dead but recovered under a DCD protocol, then the time is actually going to be after the

declaration of death.

The OPO does not have a way to record these data accurately. In order to validate these donors, OPOs have to report these donors as an uncontrolled DCD or brain dead donor but cannot enter accurate data due to system controls. Several proposed changes were considered. The Procurement and Consent section of the DDR might be changed to ask if the patient was legally declared brain dead. This would allow the OPO to enter the patient as a brain dead donor. Other potential changes were proposed such as changing the wording “Is this a DCD donor?” to “Was this donor recovered under a DCD protocol?”

With the proposed changes, accurate data could be collected. One member suggested that the DDR should contain the ability to enter NAT results. The Committee discussed the proposed changes and suggested that they discuss the proposed changes with their data entry staff. The Committee will convene a conference call in early spring to propose formal changes to the DDR within the OMB form approval process.

## **15. DCD Practice and Policy**

The Committee’s goals include a review of current DCD policy as well as information on uncontrolled DCD. There is currently a policy requiring that OPOs have DCD protocols established with each of their area hospitals and that those policies must include each of the Model Elements found in the ByLaws.

UNOS surveyed all OPOs regarding individual practices in controlled and uncontrolled DCD. AOPO distributed the survey through their Executive Director portal and 100% of OPOs responded. The data were reviewed and showed that there is one OPO that has not performed a DCD donor; however the remaining OPOs have performed 1 to 20 DCD donors in a year. It was reported that 3 OPOs are using ECMO; 1 OPO is using extracorporeal circulation; 8 OPOs reported using a precannulation model; 12 use rapid femoral cannulation after declaration of death followed by core cooling; and 1 used some form of medication in the pre-treatment of the donor. Thirty eight OPOs reported that they used none of the above procedures. There is variability in the length of time between asystole and the declaration of death reported. This time is independent of any waiting time after death has been declared.

Motion: That the Committee accepts the results of the survey as presented. The motion was approved by a vote of 13-0-0.

The ASTS has asked for input on their *DCD Guidelines*. The Committee will meet by Live Meeting to discuss this document in order to respond to the ASTS.

The Committee formed a joint Work Group with the Organ Availability Committee to review DCD policies and to identify areas where policy may be needed.

## **16. Pancreas Issues**

Ms. Rogers reported that the Pancreas Transplantation Committee requests that the HbA1c laboratory test results be included in organ offers as the community is using this information more in determining if the pancreas is transplantable. After discussion, the Committee recommended that the test be included “as available” as some hospitals may not have the capability to provide this test. Policy states that the transplant center can request information and the OPO will provide if available.

Motion: The Committee supports the inclusion of the “HbA1c (if available)” be added to the Pancreas section of required tests in policy 20. The motion was approved by a vote of 12-1-0.

The Committee has requested that the organ specific Committees establish priorities for multi organ allocation. The Pancreas Transplantation Committee is supportive of this request and currently reviewing data to determine how to proceed.

## **17. Negative Crossmatch**

Many labs, OPOs and transplant centers are unaware that they should upload preliminary crossmatches prior to a match run to ensure that candidates appear in the proper classification if they have a high PRA. The requirement no longer exists for kidney allocation and many labs no longer perform preliminary crossmatches prior to the match run for kidney pancreas transplants. Several possible paths forward are suggested:

1. The lab would have R.O.P.E. trays for all highly sensitized pancreas and kidney-pancreas candidates, the lab would perform preliminary cross matches, the OPO would upload those results and the OPO would run the matches. The Committee agreed that this option is the least cumbersome for the OPO. The OPO would not run a KP or P match run until the lab uploads the data from the cross matches that are performed by the lab. Therefore the OPO is allocating knowledgeable of who is negative, and places most responsibility on the transplant center and the lab.
2. The OPO would run a pancreas or KP match and identifies all local sensitized patients, the lab runs cross matches between the donor and the local highly sensitized candidates, upload the cross match results and then rerun the list. The Committee agreed that this approach was redundant.
3. Local transplant centers agree to list the unacceptable antigens of their sensitized candidates and use the CPRA in place of the measured PRA. The OPO would run the match after entering the donor antigens and the match system would perform a virtual cross match. All sensitized candidates who appear could be considered to have a negative preliminary result. The OPO would upload the cross match results in UNet<sup>SM</sup>, and all local, sensitized candidates would appear in the high PRA section. The OPO would rerun the kidney pancreas match.

The Committee considered the options presented and agreed that the options do not address various situations that occur, such as, when an OPO does not have the ability to perform preliminary cross matches prior to going to the OR. In this case, the allocation would not be possible. Also, some OPOs are moving away from performing rope trays altogether and moving toward virtual cross match system; therefore, Option 1 suggests that the OPOs go back to using rope trays. Finally, some OPOs have one central lab that performs the typing of donor. As such, this would require each independent transplant center to have a rope tray which may be creating additional work.

The system is moving toward the CPRA and the virtual cross match model while these options appear to be moving in a different direction. It was suggested that OPOs and pancreas centers work independently in a local environment. The transplant center has a vested interest in having this information in the system so that the patients who benefit from those points are at the top of the list and have the best chance of receiving an organ. The Committee agreed that the transplant center needs to assume a more active role and assume some of the responsibility. OPOs will not always have the time to perform all of the steps listed. The Committee wondered why the list would not be run when the HLA is available and did not understand why, no matter what type of preliminary cross matching is used, it would be an issue.

The Committee agreed that Option 3 is the most acceptable as it reflects the Committee's thoughts regarding the movement toward CPRA and the virtual cross match but suggests that there would be no local match run until the tissue HLA is available.

## **18. ASTS Draft for Standards for Procuring Surgeons**

The Committee was asked to provide feedback to the ASTS regarding the draft Standards for Procuring Surgeons. The Committee considered the requirements a surgeon must have in order to procure organs, including:

- A U.S. medical license or institutional license;
- Proof of liability insurance and CV on file with home OPO;
- Demonstrate the following experience levels;
  - Cardio thoracic – 5 recoveries under supervision
  - Kidneys – 5 recoveries under supervision
  - Extra renal – 10 recoveries
  - DCD – familiar with recommendations from the ASTS and guidelines
- Letter from program director to verify qualifications;
- OPOs must track quality assessment and performance issues to respective transplant centers and report them to UNOS if appropriate action is not taken;
- Diligent search of the abdominal and thoracic cavity for neoplasm and infectious process;
- Diligent search of donor documentation.

The Committee made the following recommended changes and posed the following questions:

- The Committee suggested adding the term “abdominal” to “Extra Renal” as cardio thoracic is also extra renal. (Extra renal abdominal)
- What does an OPO do if the surgeon is not from a transplant program or not affiliated with center?
- DCD is a type of recovery, not an organ specific type of recovery. As such, the Committee suggested that it should be listed separately and encourages the insertion of a minimum number of required DCD recoveries for the surgeon as well as a specified level of experience or status of the surgeon. The Committee agreed that it is essential for the DCD surgeon to be experienced because of the need to move quickly to recover the organs compared to the brain dead donor recovery. Additionally, an experienced surgeon is required to evaluate the organs to determine suitability for transplant. The Committee understood that lung recoveries are rare and it may be difficult to find an experienced surgeon with that experience; however, abdominal recoveries should have an experienced surgeon. The Committee did not wish to determine physician qualifications as the transplant center should determine qualifications. Beyond the experience level that is specified in the document, the Committee wishes to strongly encourage the consideration of the status of the surgeon and what the level of requirements should be in performing a recovery. It was suggested that the procuring surgeon be at an attending physician level and if the surgeon does not hold that title, that minimal experience as expressed in the number of DCD recoveries done, is essential. It is important that the surgeon not only have experience, but a higher level of accountability and responsibility on a daily basis.
- The Committee also requests that the ASTS consider the community surgeon that is trained in recovery but not affiliated with a transplant center.
- Regarding the non-physician procuring organs, it was suggested that special exceptions be available for those OPOs that do not have access to procuring surgeons and utilize trained OPO staff in recovering organs. It was noted that these individuals have years of experience in procurement and that the OPO may not have other options.

The Committee appreciates the opportunity to provide comment on this document and looks forward to reviewing the next draft of the document.

## **19. MPSC request for labeling**

The MPSC asked the OPO Committee to review and evaluate whether or not the DonorNet<sup>®</sup> system

should be modified to generate computerized labels for organs, vessels and blood samples. Although the Committee agreed that it would be helpful, members recognized the cost of such changes. As such, the Committee agreed that when resources are available, that the Committee will consider further investigation into UNOS creating labels through the DonorNet<sup>®</sup> system.

## **20. Inner Shipping Container Specifications**

The DEQ has requested that the Committee consider whether the six piece insulation inner liner of a shipping box, can be considered a container. The term “container” is found in policy and the DEQ is seeking guidance as to how to perceive the six panel container. Historically, the inner container was required to be at least 1 ½ inch thick or have the “R” value equivalent. UNOS staff will investigate the “R” value. The six panel container requires less storage space and is desirable by many OPOs. Members who use the 6 panel container agreed that these paneled containers do not leak.

The Committee agreed that the six panel insulation panels can be considered a container as long as the “R” value is appropriate.

## **21. Role of OPO in Packaging of Live Donor Organs**

The Living Donor Committee requested that the Committee consider the possible issues surrounding OPOs being requested to facilitate the packaging, labeling and transportation of organs recovered from live donors between centers and to distant locations. The practice is becoming more common as living donors (LD) have new options to participate in paired kidney exchanges.

The Committee is concerned about organs being packaged and shipped without specific guidelines in place. OPOs have transported LD organs with some trepidation. In the interim, the Committee suggests that the Living Donor Committee conduct some sort of legal, ethical review of risk for the OPO. The Committee will also seek guidance from OPOs (NEOB and Washington DC) that do package and ship live donor organs. Current Policy 5.0 modifications under consideration suggest that the transplant center is responsible for the packing and transporting LD organs.

The Committee suggests that further information is needed and requests that the LD Committee investigate the national level legal implications and ethical concerns regarding OPOs participating in the packaging of the LD organs. Mr. Orlowski will draft a letter and contact the chair of the LD Committee to discuss this issue. The Committee agrees that it is an area of potential OPO involvement, however, there needs to be further research before the Committee can adequately address the question.

## **22. Credentialing Requirements for Labs Performing Donor Testing**

A laboratory director asked the Committee whether or not there are OPTN standards regarding laboratories that do infectious disease testing on donors. The Committee will investigate if there are policies that address this issue and respond appropriately.

## **23. Public Comment**

1. Criteria for Islet listing. The Committee agreed that there were no issues for OPOs and did not comment on this proposal.
2. Increase the Safety for those Candidates Who Do Not Appear on the Match Run.

The Committee discussed the impact of directed donation on the waiting List. If an organ is

designated, and the recipient does not appear on the list, the OPO is allowed to allocate an organ or organs to a specific candidate named by the person authorizing the organ donation. All recipients of a directed donation must be added to the Wait List prior to transplantation. When a candidate does not appear on at least one of the donor's match runs for at least one of the organs, the transplant center must document why the candidate does not appear on the match run and ensure that the organ is safe and appropriate. The transplant center must maintain all related documentation.

The Committee chose not to comment.

3. Pancreas for technical reasons.

This policy change would allow for the listing of a patient for transplant when the pancreas will be used for technical reasons.

The Committee supports this change and approves it unanimously by a vote of 11-0-0.

<b><i>OPO Committee Attendance</i></b>				
<b>Name</b>	<b>FORMAT (select)</b>	August 21 Teleconference	December 5 In Person	January 6 Teleconference
Jeffrey Orlowski MS, CPTC	Chair	X	X	X
Lori Brigham MBA	Vice Chair	X	X	X
Posy Durning PA, CPTC	Regional Rep.	X	X	X
Michael Holman MD	Regional Rep.		X	
Christopher Hughes MD	Regional Rep.	X		
Samuel Holtzman	Regional Rep.	X		X
Sean Van Slyck BA,CPTC	Regional Rep.	X	X	X
Craig Van De Walker LRCP, CPTC	Regional Rep.	X	X	X
Meg Rogers	Regional Rep.	X	X	X
Suzanne Lane Conrad RN, MS	Regional Rep.	X	Phone	X
Rob Kochik RN, BSN	Regional Rep.	X	Phone	X
Ladora Dils RN, CPTC	Regional Rep.	X	X	X
Satheesh Nair MD	Regional Rep.	X	X	
Charles Alexander RN, MSN, MBA, CPTC	At Large	X		X
Jim Carter	At Large			
Danielle Cornell RN,BSN,CPTC	At Large	X	X	
G. Kent Holloway MSF	At Large	X	X	
Lori Markham RN, MSN, CCRN, CPTC	At Large	X	X	X
Deon Stewart-Miles RN, BSN	At Large		X	X
M. Kevin Stump BS, BSN, CPTC	At Large	X		
Ginny McBride RN,MPH,CPTC	Ex Officio			

Charlotte Arrington	SRTR Liaison	X	X	
Friedrich Port MD	SRTR Liaison			
Erik Roys MS	SRTR Liaison			
Robert Wolfe Ph.D.	SRTR Liaison		X	
Franki Chabalewski RN, MS	Committee Liaison	X	X	X
John Rosendale	Support Staff	X	X	X
Stacey Burson	IT Support Staff	X	X	X
Bob Walsh	HRSA	X	X	X
Rita Maldonado	HRSA		X	X