

OPTN/UNOS Organ Procurement Organization (OPO) Committee
Report to the Board of Directors
November 8-9, 2010
St Louis, MO

Summary

I. Action Items for Board Consideration

- The Board of Directors is asked to approve modifications to Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials). The proposed policy changes would require OPOs and transplant centers to use the standardized, internal labels that are distributed by the OPTN contractor for organ and vessel transport and for vessel storage. Changes also require transplant centers to notify the recovering OPO when they repack an organ. (Item 1, Page 3)

II. Other Significant Items

- New Organ Transport Labels. The Committee has developed a new organ transport labeling system that is color coded and organ specific. This new system was developed to prevent labeling errors and is currently available. Four 1-hour training sessions were conducted by Live Meeting to educate the community. (Item 3, Page 3)
- OPO Performance Metrics. The Committee has worked with the MPSC and the SRTR to develop a performance metrics model that, based on donor characteristics, can predict expected organs transplanted per donor (OTPD) and compare it to the observed OTPD. A conference was held in May to educate the OPO community about the new metrics model and its goal of performance improvement. Currently the Work Group is considering potential flagging methodologies. (Item 4, Page 4)
- Imminent and Eligible Death Definitions. This Committee is identifying ways to standardize the reporting of imminent and eligible death data in order to promote more consistent data reporting. (Item 5, Page 6)
- Standardizing Abbreviations in DonorNet®. The Transplant Administrators Committee (TAC) and OPO Committee are considering standardizing abbreviations in DonorNet®. The Work Group is interested in developing a glossary of accepted terms and abbreviations and in evaluating opportunities to develop additional educational tools. (Item 6, Page 8)
- DCD Joint Work Group. The joint OAC/OPO Committee Work Group has divided into two subcommittees that are addressing: 1) definitions for DCD in the Help Documentation in DonorNet® and 2) DCD policy development and/or modification. The Committee is preparing changes to the DCD Model Elements that will be distributed for public comment in early 2011. (Item 7, Page 9)
- Packaging and Labeling of Living Donor Organs. The Living Donor Committee has requested that the OPO Committee consider a requirement to package and label all living donor organs that leave a donor hospital. (Item 8, Page 10)

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Lori Brigham MBA, Chair
Richard Pietroski MS, CPTC, Vice Chair

This report details the OPO Committee's deliberations during its meeting on September 22, 2010, and Committee conference calls/Live Meetings on May 10, 2010 and August 18, 2010. Additionally, the joint OPO Performance Metrics Work Group, joint OPO/OAC DCD Work Group, Labeling Subcommittee, and Imminent and Eligible Definition Subcommittee have met by conference calls/Live Meeting.

1. Proposed Internal Label Requirement. At the request of the Membership and Professional Standards Committee (MPSC), the Committee reviewed packaging and labeling errors that have occurred within the last several years. Currently only the external label distributed by the OPTN contractor is required by OPTN policy. As such, OPOs develop individual internal labels that are not standardized. The Committee agreed that a standardized internal label would help to decrease the number of labeling errors that occur. The Committee has developed a new labeling system that is a color coded, organ specific label with matching external and internal labels.

Following an extensive review and revision of Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials), the Committee is seeking Board approval to require that the internal label and vessel label be standardized as provided by the OPTN contractor. The Committee also agreed that when a transplant center or OPO repackages an organ, it should notify the recovering OPO of the repackaging and of any other actions that occurred such as touching the organ, anastomosis of the organ, implanting, etc. It was suggested that since this does not occur frequently, it should be highlighted in policy. The proposed changes were distributed for public comment, and the responses were overwhelmingly in support of the changes.

The Committee reviewed the responses from public comment and made slight modifications to the proposed changes. The following resolution is recommended for consideration by the Board:

**** RESOLVED, That the modifications to Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials), as set forth in Exhibit A, are hereby approved, effective pending notice to the membership.**

The Committee approved the resolution by a vote of 15-0-0.

The Resource Assessment and Impact Statement for this proposal can be found in **Exhibit B**.

2. Data Review. UNOS staff provided a summary of donation data for the past year. (**Exhibit C**) There has been a decrease in the number of standard criteria donors; however, the number of organs transplanted has increased, and the average number of organs transplanted per donor has increased. There has been an increase in DCD donors, an increase in the number of DCD organs transplanted and an increase in the number of DCD organs transplanted per donor. There has been a decrease in the number of brain dead donors though June of 2010.
3. New Organ Transport Labels. A new label system has been developed, pilot tested and made available to the OPTN members on September 1, 2010. Members have been given a 3-month period of time to phase out the old label system; however, on January 1, 2011, members must transition to and use the new color-coded, organ specific labels. The Committee developed the system in order to decrease the number of labeling and packaging errors.

Sean Van Slyck, Chair of the Labeling Subcommittee, provided a summary of the project. The Committee sponsored four training sessions by conference call/Live Meeting to educate OPTN members about the correct use of the label system and to review appropriate packaging procedures. **(Exhibit D)** Approximately 397 phone lines were open for this training, and it was confirmed that many of the lines accommodated groups of transplant professionals and not individuals. One session was taped and available for viewing. Some of the questions that were addressed during the sessions included the labeling requirements of research organs and vessels and how to label multi-visceral organs. The Subcommittee will consider developing a label specifically for organs to be sent for research. Additional questions can be posted to a dedicated mailbox at UNOS (orgtrans@unos.org)

The Committee also developed a “Verification Form for Documentation of Packaging and Labeling,” that is available as a resource for transplant professionals. It contains the information required by policy and provides the transplant professional with a concise document to help comply with the required elements when documenting appropriate packaging and labeling of deceased donor organs.

During the 3-month transition from the old labels to the new ones, some OPOs will continue to use the old system while others will start to use the new one. In the event of a label error during this timeframe, the Committee will request that the Department of Evaluation and Quality (DEQ) identify which label system a particular OPO used in order to associate any errors with the appropriate system. The Committee will review packaging and labeling errors after each six month period following implementation of the new label system on January 1, 2011, and determine its effectiveness in decreasing the number of labeling errors. The Committee agreed that there should be an additional training session, and will offer one or two “refresher” training sessions prior to the January 1, 2010, implementation deadline.

The Living Donor Committee has requested that the OPO Committee collaborate to resolve differences in deceased and living donor policies for labeling and packaging of organs. Additionally, the subcommittee will investigate the potential use of bar-coding to track organs that are shipped.

4. OPO Performance Metrics. The OPO Performance Metrics Joint Work Group, comprising members of the MPSC, OPO Committee and Scientific Registry for Transplant Recipients (SRTR), has developed a model that would help assess and predict observed vs. expected organs transplanted per donor (OTPD) by DSA. The Work Group reviewed the donor data that are required fields in DonorNet[®] and identified the medical and social criteria necessary to evaluate. Donor demographics and characteristics collected by the OPTN were utilized in the analysis.

The Work Group reviewed organ specific data and their effect on yield and determined that the model is also able to identify variations in yield by organ. There were instances when an OPO did not meet a specific standard in the aggregate data; however, it was determined that it had a low organ specific yield, not overall yield. Members considered that this may be a reflection of certain factors such as acceptance practices and the presence of local programs. The Work Group agreed that those programs that had local transplant programs might have a greater OTPD.

Differences in each DSA’s donor case mix and the DSA’s expected average yield can also be identified by the model, and is expected to vary among DSAs. Some DSAs would be expected to recover fewer organs, and the reasons why this occurs need to be identified. Committee members questioned whether there are factors such as distance or import export status that can be evaluated. As this model is evolving, some of these factors may be able to be included in the future.

Subsequent to the aggregate model, organ specific models were created. These organ specific models complement the aggregate model and provide an opportunity to identify performance improvement needs in specific areas.

Table 1. Description of Each Column in the Data Table for the OPO Metrics Model.

<i>Column</i>	<i>What the data mean</i>
A	Total number of donors from whom at least one organ was recovered for transplant.
B	Actual number of organs transplanted from those donors
C	The number of organs expected to be transplanted from those donors.
D	Observed yield (O) per 100 donors
E	Expected yield (E) per 100 donors
F	Ratio = observed yield divided by expected yield**
G	The <i>p</i> value that indicates whether the observed yield to expected yield is statistically significantly different than 1. (This value helps to identify if OPOs are performing higher or lower than expected; however it is partially dependent on sample size.)

**In Column F:

- O to E ratio = 1, the OPO has as many OTPD as expected or, other words, it was performing as expected. For every 100 organs, there were 100 organs transplanted.
- O to E ratio is <1, the OPO has fewer OTPD than expected. (For every 100 organs expected, fewer were transplanted.)
- O to E ratio is >1, the OPO has more OPTD than expected. (For every 100 organs expected, more were transplanted.)

Each organ has an equal value (i.e. Kidney and liver are counted the same). A review of the model resulted in the following conclusions:

- The yield models are highly predictive
- The model can be used to adjust for differences in the case mix of donors in DSAs
- The observed rate should be compared to expected rate rather than to the national average
- Signaling tools to consider include:
 - whether the O to E ratio is less than a meaningful threshold, and
 - that clinical significance and statistical significance ensures that the difference from 1 is not due to random chance

Information about the model has been widely distributed to OPOs, and an educational conference was held on May 27, 2010, in Chicago. The SRTR presented the model, and there was discussion regarding the purpose of the metrics.

Jeffrey Orłowski, MS, provided a summary of the activities of the Work Group and provided a description of the model that has been created. The model is a true performance evaluation that will identify performance improvement needs. The Joint Work Group is currently considering flagging methodologies for use by the MPSC. The flagging methodology will identify the DSAs that reach a specific level triggering MPSC involvement. It was stressed that the flagging of a program is not an indictment against the DSA, but is designed to begin a discussion. The metrics model is an ordinal logistic regression model that adjusts for donor factors that impact yield. There is an ordinal logistics model for kidney and logistic model for other organs. The model outputs provide the number of donors, observed number of organs transplanted and expected number transplanted,

Recently the flagging Work Group considered the following criteria and is seeking the Committee's comments.

- Time period for data analysis – the Work Group recommended 2 years as the time frame as this would provide more data to assess the OPO performance.
- Statistical significance
 - Two sided *p*-value allows the review of both ends of the spectrum to identify those programs below expected and those above expected;

- Two sided p -value <0.05 has a 2.5% false positive rate as opposed to a 5% false positive rate for a one sided p -value .05;
- Clinical Significance – How do we measure clinical significance and what raises the output to the clinical significance for the MPSC? There are 3 potential measures that we get from the output.
 - Absolute ratio of O to E;
 - Absolute difference in the numbers transplanted; and
 - O per 100 donors – E per 100 donors <-10 .

Emily Messersmith PhD, Arbor Research Statistician, provided a summary of what it means to have a risk adjusted model and yield component of the model. The Committee also considered that during the 2-year data period, if an OPO was flagged for being lower than expected, it could demonstrate improvement during the second year of the data compared to the first. The Committee was assured that data could be run for one year to demonstrate this type of difference.

To test the flagging criteria, data were analyzed with the model from 2008 and 2009. The model flagged four DSAs for statistical significance and clinical significance, of which only two were mainland DSAs. DSAs that are not mainland have specific geographic and logistical differences that can result in differences in performance. The organ specific runs flagged as follows: one DSA for kidney, one DSA for liver, two DSAs for heart, one DSA for lung, and four DSAs for pancreas. The number of DSAs that would have been flagged for an initial discussion with the MPSC includes four DSAs by the overall model and three DSAs from the organ specific models, to total seven DSAs (only five of which are mainland DSAs).

The Work Group recommended the following flagging criteria:

- Two year time period;
- Two sided p -value; and
- Clinical Significance
 - O to expected $< .90$;
 - O per 100 donors – E per 100 donors <-10 .

Motion: That the flagging methodologies recommended by the Work Group be approved.

The motion was passed by a vote of 15-0-1.

The path forward includes consideration of the input from the OPO Committee by the Joint Work Group and discussion and drafting bylaws by the MPSC.

The Committee agreed that this is an excellent model because it provides a tool for process improvement and improves compliance measurement. It helps to identify improvement opportunities. For non-mainland OPOs, the model can be used to look at the data to determine where there may be opportunity for improvement ignoring those unique circumstances or mitigating factors (i.e. geography) that cannot be adjusted in the model. This model might also provide information about best practices through the identification of those DSAs that are above expected.

5. Imminent and Eligible (I &E) Death Data Collection. The I & E Death Data Subcommittee discussed a path forward for improving the imminent and eligible death data collection and making the data more consistent. It has been determined that the data are inconsistent due to several factors: 1) the definitions are being interpreted differently throughout the country (i.e. multi system organ failure) and 2) some state laws or hospital protocols require two (sometimes more) brain death exams while others only require one. This is particularly important to the data collection because when two exams are required, and only one is completed, the patient is not reported as an imminent or an eligible death. This results in incomplete and inconsistent data.

UNOS Staff presented a summary of the current I & E death data. **(Exhibit E)** Based on data that has been collected from January 2008 to June 2010, donor ethnicity, those reported as multiracial (83), had the highest conversion rate of 81.9%, followed by those reported as white at 76.9%. When data regarding timely referral was analyzed and compared to conversion rates, the conversion rate was 70.5% compared to when the OPO reported that they did not have a timely referral, the conversion rate was 57.5%. If the OPO reported that it was an effective request, the conversion rate was 75.7%, and if not an effective request, it was 46.8%.

Members agreed that these data should be provided to OPOs to assist in improvement measures. It was suggested that these slides be included in regional information and, posted on the AOPO portals (each with appropriate background). The HRSA Quality Improvement Task Force is in the process of developing a one-page “newsletter” that could help to distribute the data more broadly. These data validate what the Committee considers as best practice (timely referral or effective request). It was suggested that OPOs can provide these data to their hospitals and demonstrate the need for their participation in these best practices to improve the donation process in their hospital. These data can help validate these practices. The Committee voiced concerns about the data reporting being inconsistent and that this information should be provided to the community when the data are released. It was suggested that these data be distributed via the AOPO portals with the appropriate explanations and caveats.

Jeff Orlowski MS, Chair of the I & E Subcommittee, reported on the subcommittee’s activities. In order to make the data reporting more consistent, the subcommittee recommended the following fundamental conceptual changes to the eligible definition. It was stressed that the definitions are “reporting” definitions and are not to be considered a guideline for practice. The fundamental conceptual changes suggested by the subcommittee are:

- The Multi System Organ Failure exclusion should be removed entirely from the definition as it is inconsistently applied. In its place, there should be a “rule out” criteria for each individual organ system. This would result in a person’s being reported as imminent or eligible if they have one organ that is transplantable, as long as the person does not have any of the other exclusionary factors. This concept is more simplistic and more easily applied. This would create an inclusionary type of system because if one organ passes through the list of rule out criteria, it can be transplanted.
- In the definitions, the current listed age range is 0 – 70 years of age. Members commented that OPOs frequently have donors over the age of 70, so the possibility of raising the age limit was discussed. It was decided that the upper range should remain the same. It was also discussed that the lower age range for children should not be considered and that the minimum weight range should replace the age. The members agreed that size is a more appropriate consideration when evaluating the pediatric population and will seek guidance from the Pediatric Committee. Data will also be analyzed regarding the donors over 70 to determine the effectiveness of the organs procured from that age group.
- The Committee also considered the potential donor from whom no organs can be placed and determined that this potential donor should not be considered an eligible donor. There are situations when a potential donor meets the requirements for the eligible definition, gets consented, is managed as a donor, but cannot proceed to the OR. This situation could be caused by no one willing to accept the organs, if the donor is taken to the OR but organs are declined, or if organs are recovered but not able to be transplanted. It was determined that a donor who has no organs placed once in the OR or once recovered, will not be considered an eligible death with the caveat that the organ is not used due to human logistics (i.e. airline loses organ, no vessels included, labeling problems). These are not medical variables and are within individual’s control.
- The Subcommittee did not reach a conclusion regarding the calculation of conversion rates, but suggested a tiered approach to performance evaluation:
 - the number of eligible deaths converted to donors;
 - a component of the number of imminent deaths; and

- a total conversion rate to help to understand the OPO's potential. The Subcommittee will continue to evaluate and will advise the Committee.
- Because of the varying methods for declaration of death, it is important to understand the effect of these variations on the data reporting as individuals with the same clinical picture may be declared dead in one state and not in another. The subcommittee will revisit the imminent definition and consider those patients that have met most criteria except for the actual declaration of brain death (i.e. when a patient's clinical picture demonstrates brain death but the patient is not yet declared).
- The Subcommittee also suggested that when considering defining I & E deaths, it might be better for accurate data collection to only focus on individual organs, heart, lung, liver and kidney. Many opined that donors generally do not have only a transplantable pancreas when other organs are not acceptable for transplant. The Subcommittee will consider data available and determine if there is a trend.

Motion: That the Committee accepts these fundamental concepts and that the subcommittee pursue the changes to the definition based on them.

The motion was passed with a vote of 16-0-0.

Two small work groups (organs above diaphragm and organs below the diaphragm) were established to draft the list of exclusionary criteria for each organ system. The Committee's goal is to have solid definitions and to consider them by the end of December, 2010.

Teresa Beigay, HRSA, will speak with AOPO to begin discussions with AOPO, CMS and HRSA. It was determined that when these definitions change, the comparison of data within the entities will be different. HRSA is currently pursuing a donor potential study and the definition of eligible and imminent is critical to the success of the study.

6. Standardizing Abbreviations in DonorNet®. The Transplant Administrators Committee (TAC) requested that the Committee provide feedback regarding their work with standardizing abbreviations in DonorNet®. A subcommittee was formed to develop a glossary of accepted terms and abbreviations and to evaluate opportunities to develop additional educational tools.

The subcommittee evaluated each of the 500+ abbreviations provided by the TAC to determine if the individual abbreviation was a standard abbreviation or not. A grading system was developed that eliminated those abbreviations that were not considered standard and highlighted the most commonly used abbreviations.

The Committee approved the list of abbreviations by a vote of 15-0-0.

Lynn Williams, Chair of the Abbreviations Subcommittee, provided an update on the development of a list of abbreviations. The following recommendations were made and approved:

1. That there be joint accountability on the part of the OPO and transplant center to review and verify all DonorNet® data and information (including abbreviations) and ensure that they are conveyed appropriately and understood. If information is not understood, the center should contact the OPO for clarification.
2. The Joint Commission's "Do Not Use" list should be accepted.
3. Medication abbreviations are not acceptable except for T3, T4 and DDAVP.
4. Abbreviations already listed in DonorNet® and Tiedi® are acceptable.
5. Abbreviations were categorized into acceptable categories (i.e. hospital location such as ER and OR, laboratory tests, measures such as mg, ml, etc., periodic table of elements, etc.)
6. Additional abbreviations were listed for approximately 50 items.

In order to disseminate the information and to educate the community, the Committee recommends the following actions:

1. Conduct an electronic conference call/Live meeting or Webinar (it was suggested that these can be done through HRSA) and have it recorded so individuals can access after the actual session;
 2. Provide the information through a newsletter;
 3. Provide a laminated card or pocket reference for coordinators;
 4. Create a 1-page “drop down” of information the in Help Documentation;
 5. Place on the UNOS Website as a resource;
 6. Present at AOPO Procurement Directors Council meetings or sent through the AOPO portal;
 7. Present the information at UNOS regional meetings.
7. DCD Model Elements. The proposed changes to the DCD Model Elements were approved by the Committee to be distributed for public comment. The Committee will solicit the input of other OPTN Committees and interested constituents and distribute the proposal for comment in the Spring, 2011. The Committee discussed the change in nomenclature from DCD (Donation after Cardiac Death) to DCDD (Donation after Circulatory Determination of Death). One concern voiced was the numerous changes in nomenclature that DCD has experienced in the last several years (i.e. non-heartbeating, asystolic). Members agreed that the DCDD term was confusing and that some will not change nomenclature in hospitals because hospitals are just getting comfortable with DCD nomenclature and processes. Members suggested that it remain as DCD and change the term “cardiac” to “circulatory.” One member felt that the term “determination” made the death sound questionable as opposed to confirmed.

Some additional language was added based on the CMS regulations regarding agreements between the institutions involved. Also, additional changes to the Model Elements have been proposed by the UNOS bylaws writer. These included that the Model Elements include the CMS language; and that the term “Model Elements” be changed to “Guidelines.” Additionally, members agreed that consent should follow authorization in the Model Elements.

Motion: That the Donation after Circulatory Determination of Death (DCDD) proposed nomenclature change in the Model Elements be changed to Donation after Circulatory Death (DCD);

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

A joint Work Group with the Organ Availability Committee (OAC) has also been revising the DCD definitions in the help documentation for DonorNet[®] and is seeking Committee approval for the changes. After review, the Committee made the following motion:

Motion: That the proposed changes to the DCD definitions in the Help Documentation be approved.

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

The Committee discussed the proposed definition of “Uncontrolled DCD” for the Help Documentation and suggested that the terms “femoral” and “expires” be stricken from it.

Motion: That the terms “femoral” and “expires” be removed from the proposed definition.

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

The definition included terminology that the DCD must occur in a controlled environment in the ICU. The Committee agreed that “and happens in the ICU” should be removed.

Motion: To strike the language “and happens in the ICU” from the definition.

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

The current definition of uncontrolled DCD contains “femoral vessels” for cannulation. However, it is believed that somewhere in the future other vessels may be used. It was suggested that “femoral” be removed. The term “expires” should be changed to “declared dead.”

Motion: The proposed language changes were approved by a vote of 16-0-0.

The estimated “Warm Ischemic Time” should be considered different for the pediatric patient than for the adult patient. Language pertaining to pediatric parameters was considered for the agonal definition. The blood pressure parameters listed in C, allows 6-10 years old to have a pressure greater than an adults (90 mmHg). It was suggested that it read “not to exceed 80 mmHg.” Additionally, the time should be entered from the initiation of the agonal phase instead of “cardiac arrest.”

The language should be amended as follows:

“...if this was a DCD donor, enter the estimated number of minutes that elapsed from;

1. The time of ~~cardiac arrest~~ Agonal Phase onset when the systolic pressure meets the following conditions for greater than five (5) minutes: a. Newborn up to 28 days, with a systolic blood pressure less than 60 mm Hg,
 - b. 29 days up to 12 months, with a systolic blood pressure less than 70 mm Hg,
 - c. 1 year up to 10 years, with a systolic blood pressure less than 70 mm Hg, plus 2 times the age of the patient in years, not to exceed 79 mm Hg,
 - d. 11 years or older, with a systolic blood pressure less than 80 mm Hg, **OR** when the oxygen saturation is less than 80% at any age, **AND**
2. when core cooling is initiated”

Motion: That the proposed language for pediatric patient be included in the definition for Warm ischemic Time.

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

8. Packaging and Labeling of Living Donor Organs. The Living Donor (LD) Committee has requested Committee input regarding the responsibility for packaging and labeling of living donor organs. The LD Committee is considering policy that would require that all LD organs be packaged and labeled by the OPO. After a survey of OPOs, it was noted that a sizable number of OPOs do not participate in living donation.

Considering the anticipated increase in the number of kidneys that will be placed outside of the recovering institution, there is a concern that all transplant centers are not well versed regarding correct packaging and labeling procedures. The LD Committee is concerned that if the transplant center personnel are responsible, that there may be organs lost due to incorrect packaging and labeling as they are not considered the experts in this area,. The Committee agreed that this mandate would create a burden for OPOs as well as a cost incurred by the transplant center. Members agreed that OPOs need to be reimbursed and currently have a reimbursement process in place for the recovery of deceased donor organs.

The Committee considered an alternative option to making it mandatory that OPOs package and label the LD organs. It was suggested that OPOs train the transplant centers in the correct packaging and labeling procedures. It was noted that, most often, a heart transplant team packages its own organs and at times, allows the OPO to do it. Members agreed that a surgeon or clinical coordinator could be trained to label and package and that there needs to be a system for properly training the appropriate personnel. Some members opined that this issue goes beyond packaging and labeling and includes the scheduling and transportation needs of the organ.

Members agreed that it should not be a mandate but a choice with the options of the OPO's contracting with the transplant center to perform the labeling and packaging or that the OPO train transplant center personnel. Although it appears that charging the transplant center for services is not a problem, some members described situations when they have packaged living donor organs and have not been reimbursed for services.

Members agreed that packaging and labeling living donor organs should be an optional system, not mandatory, and one that is determined by the individual OPO and transplant center. Some members stated that they would be willing to participate in the packaging and labeling of living donor organs but they cannot get reimbursement or a SAC fee. The Committee also agreed that the OPS Committee should consider this issue from an operations standpoint.

The geography of OPOs and the distance from the recovering center are significant issues. Although living donor organ recoveries are scheduled, some centers are hours away from the OPO. This would require OPO dedicated staff to be available for a prolonged period of time. One member described a situation where a center is hours away from the OPO. The member estimated that it would require that a coordinator travel to the center the evening prior to the recovery, stay in a hotel, and then return home after the recovery. The expense would have to be covered by the center. Also, additional staff would be required to fulfill the responsibilities of the mandate.

Currently, some OPOs are packaging and labeling LD organs for no cost. However, as the number of living donors increases, this practice without reimbursement will be cost prohibitive. One member discussed the need for the receiving institution to pay for the service.

Current policy requires a transplant center to notify the OPO when it repackages an organ. Clearly, transplant centers are packaging organs and have the skill and ability to do so. Some centers are splitting livers and packaging, labeling and shipping the segment. To say that transplant centers are unable to package and label is not accurate. It is, however, imperative that transplant centers be trained in the correct procedures for packaging and labeling.

The Committee does not believe OPOs should be responsible for all packaging and labeling of living organ donors. The Committee agreed that it would be in favor of a system that would have individual centers and OPOs establish a process for safely labeling and packaging LD organs. This would include having the OPO train transplant center staff as well as having an established fee for service when the OPO performs the service. Members agreed that there should be more than one option.

Members agreed that although the LD Committee may feel that this requirement sounds relatively easy to fulfill, the logistics of OPOs and centers would mandate more than one option. OPOs that have huge geographic areas, would incur extreme cost for the coordinator to travel to put an organ in a box, label it and ship it.

Members also were concerned about the liability and responsibility of packaging organs that the OPO has had no control over during the screening and testing procedures. They would suddenly be responsible for any number of issues that might be tied back to the packaging of which they had no part.

Motion: The chair called for a vote as to who would be in favor of an OPTN policy that would require OPOs to package and label all living donor organs.

The Committee unanimously disagreed with this proposed change in policy by a vote of 0-16-0.

The Committee did agree that the packaging and labeling of living donor organs should be a contractual agreement between the OPO and transplant center and that it would be optional, with a fee for service basis.

9. Effective Screening Work Group. UNOS research staff presented an update of the work of the Effective Screening Work Group activities. The goal of this group is to improve the use of offer screening tools, to reduce unwanted offers, improve the efficiency of organ placement, and to reduce organ wastage and deterioration due to increased cold ischemic time. The focus is to increase the efficiency of placing organs. There is currently a limited ability to modify the system, so the Work Group is focusing not on a tiered acceptance component, but on:
- better use of the current system;
 - making modest refinement to the donor risk and donor profile index; and
 - refining the local import split that is allowed today when transplant centers set screening criteria.
- Data analysis has revealed significant opportunities for better or more extensive use of the existing tools to make an impact. The existing capabilities in UNetSM although limited, do have some opportunities to improve screening.

There are many different types of screening capabilities within the system. Information will be disseminated through meetings and educational opportunities, and an article recently appeared in the UNOS *UpDate*. An electronic training session was conducted on Friday, September 24, 2010. A targeted letter and survey will be sent to programs based on the data to ask them to re visit their screening criteria. Committee members suggested that the letter developed for centers also be sent to OPOs as it would be good information for them to have to help their transplant centers.

10. Vessel Recovery Storage and Transplant Work Group. The Operations and Safety Committee (OPS) spearheaded a multi-committee Work Group to review policy related to vessel recovery, storage and transplantation to determine if there are any modifications needed. This Work Group was formed due to a disease transmission that occurred following the storage and transplantation of vessels. The OPS Committee will make proposed policy changes to prohibit the storage of HepC+ extra vessels and verification of serology results. It was noted that previously, transplant centers were to notify the recovering OPOs of the outcome of the vessels when stored and at that time, OPOs were being held accountable. That policy was changed so that the transplant centers are now responsible and must report the disposition of the vessels to the OPTN within a specified time frame.

The Committee will review the changes when distributed for public comment.

11. Policies 2.0 (Minimum Procurement Standards for an Organ Procurement Organization (OPO)) and 4.0 (Identification of Transmissible Diseases in Organ Recipients). The Disease Transmission Advisory Committee (DTAC) has rewritten Policies 2.0 and 4.0 and has asked the OPO committee to comment prior to public comment. Last year, the Committee made changes to 2.0 and removed toxoplasmosis as a required test for heart donors from the policy. The DTAC has included Toxoplasmosis as a requirement for heart donors. Toxoplasmosis testing results would not be available prior to recovery, but if requested, the test could be done and results provided when available. The question was posed as to whether or not the test should be done for donors less than 50 years of age. There are financial implications as OPOs would be conducting these tests on people that will never become heart donors.

The Committee will contact the DTAC reminding them that the results will not always be available when the donor goes to the OR and they may be available at a time significantly after going to the OR, and possibly after transplant. It was also suggested that a tube of blood be provided to the center so they can perform their own testing. Members also discussed that there are other infectious conditions that are not on the list of required testing.

The Committee questioned whether or not a toxoplasmosis positive donor would be ruled out for transplant and determined that the organ could be transplanted, but the recipient would require treatment post transplant. There will be another conference call on October 27, 2010, and the Chair and Vice-chair will address the Committee's concerns on that call.

Although the intent of the change is to have toxoplasmosis testing results for all heart donors; the policy does not want to require those for running the match. The DTAC understands that they will not have the information prior to running the match.

Motion: That the Committee respond to the DTAC and recommend that for toxoplasmosis testing, the OPO provide a tube of blood for the heart programs to run their testing.

The Committee approved the motion by a vote of 16-0-0.

12. Future Meetings. The Committee discussed the timeline for the next meetings.

- Public Comment – A conference call will be established for the end of October/early November. Members need to read the Public Comment proposals and be ready to discuss. Comments will be made on line in SharePoint. Put blank document in with headings for each proposal. Comments could then be made via the SharePoint site also.
- It was determined that the dates for the 2011 meetings will be March 9, 2011, and September 14, 2011, with subcommittee meetings on March 8, 2011, and September 13, 2011.

OPO COMMITTEE

	MONTH	JULY	SEPTEMBER
	DAY	22	22
	FORMAT (select)	Live Meeting/ Teleconference	In Person
NAME	COMMITTEE POSITION		
Lori Brigham MBA	Chair	X	X
Richard Pietroski MS, CPTC	Vice Chair	X	X
George Lipkowitz MD	Regional Rep.		X
Susan Stuart RN, MPM	Regional Rep.	X	X
Lynn Williams	Regional Rep.	X	X
Patrick Giordano FACHE	Regional Rep.	X	X
Lisa Stocks FNP, RN	Regional Rep.	X	X
Katherine Kickertz BSN, CPTC	Regional Rep.	X	X
Meg Rogers	Regional Rep.	X	
Rob Linderer RN, BSN	Regional Rep.		X
Julie Mirkin MA, RN	Regional Rep.		X
Gordon Bowen MS	Regional Rep.	X	X
Michael Marvin MD	Regional Rep.	X	X
Esther Carmichael	At Large	X	X
Meredith Harrison	At Large	X	X
Jeffrey Orłowski MS, CPTC	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	X
Teresa Beigay DrPH	HRSA		X
Robert Walsh	HRSA	X	
Monica Lin	HRSA		X
Emily Messersmith	SRTR Liaison	X	X
Robert Wolfe Ph.D.	SRTR Liaison		X
Ajay Israni	SRTR Liaison		X
Jon Snyder	SRTR liaison		X
John Rosendale	Support Staff	X	X
Franki Chabalewski RN, MS	Committee Liaison	X	X
Margaret Kearns	DEQ	X	By Phone
Tiffany Lord	DEQ	X	By phone
Sarah Herbert	DEQ		By Phone
Darren Stewart	UNOS Research		X
Douglas Heiney	UNOS Admin/Manage		X