OPTN/UNOS Organ Procurement Organization Committee
Report to the Board of Directors
November 16-17, 2009
Orlando, FL

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.) These proposed changes would update terminology and clarify policy language, and eliminate or alter policy language that is inconsistent with current OPO practice. (Item 1, Page 3)

II. Other Significant Items

- The OPTN Contractor began collecting Imminent and Eligible Death patient level data on January 1, 2008. The application of the definition for eligible donor continues to be inconsistent, resulting in inconsistent data reporting. (Item 2, Page 4)

- Multi-system Organ Failure is an exclusionary criterion for the eligible death definition. A subcommittee is considering a change in the definition as OPOs aggressively pursue even one organ from these patients. (Item 4, Page 8)

- The new organ transport labels produced by UNOS became mandatory October 1, 2008. Considerable follow up has been necessary and a new system is currently being considered. (Item 7, Page 10)

- The OPO Performance Metrics Joint Work Group has developed a model to evaluate OPO performance based on donor characteristics and the resulting actual vs. expected organs transplanted per donor. (Item 15, Page 16)

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Jeff Orlowski, MS, CPTC, Chair
Lori Brigham, MBA, Vice Chair

This report reflects the work of the OPO Committee during its April 21, 2009 meeting in Chicago, IL as well as Committee conference calls on May 1, 2009, July 8, 2009, and September 21, 2009. Additionally, the OPO Performance Metrics Work Group, Policy Review, Labeling, and Multi System Organ Failure Subcommittees, as well as the joint OPO/OAC Work Group, has met by conference calls. The Committee will also meet November 5, 2009, and any significant issues will be brought to the Board's attention.

Action Item

1. Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials).

The Policy Review Subcommittee reviewed Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials). In keeping with the Committee goal, this Policy was completely rewritten in order to clarify language, to ensure that the policy was in keeping with current practice, and to identify if there were any gaps in the content. The subcommittee made specific recommendations to the Committee.

The proposed changes to Policy 5.0 were distributed for Public Comment (PC) in February 2009. Subsequently, the Committee reviewed the PC comments that were received and addressed each one. (See Briefing Paper at Exhibit A). The proposed Policy 5 reorganization and summary of changes is detailed in the chart below. (See Exhibit B) This information can be used to find the location of the new proposed policy language that corresponds to the existing policy language.

Currently, the host OPO is responsible for the packaging and labeling of organs. Several commenters, as well as Committee members, expressed concerns about recovering teams that procure organs and transport them back to their transplant centers without providing the OPO the opportunity to properly package and label the organ(s). There was a discussion regarding continued reports that transplant teams are leaving the operating room without appropriately labeling the organ. The Committee agreed that in these situations, the recovering team should be responsible for packaging and labeling the organ(s).

As a result of PC, the Committee proposed new language that makes the recovery team responsible for the labeling and packaging of the organ in collaboration with the OPO. Because this was a substantial change, the Committee wished to have further feedback and therefore distributed the proposed change for public comment in June 2009. The Committee agreed that currently if the transplant team does not appropriately label the organ or refuses to allow the OPO to label the organ; it remains the OPO's responsibility. As such, the OPO is not in compliance with policy. If the OPO is not provided with the opportunity to label the organ, the OPO should report the incident to the DEQ for investigation.

Substantive changes to the policy include:

- The cassette in a perfusion machine must now be labeled.
- When transporting a heart, a rigid container would no longer be required.
- Vessels would require a rigid container if sent separately from an organ.
- "UNOS Donor ID Number" was changed to "UNOS Donor ID" as it is an alpha-numeric identifier, not just a number.
- "Time out" is defined.
- Reporting vessel disposition to the OPO would no longer be required; it must be reported to the OPTN Contractor.
- The Transplant Center personnel may not leave the operating room without allowing the OPO to package and label the organ in accordance with OPTN policy. The OPO must submit a report through the Patient Safety System when a Transplant Center fails to comply with this policy. The OPO will make all reasonable efforts to package and label the organ in a timely fashion.
- Two unique identifiers are required for tissue typing materials.

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 policy needs to be modified to address the organ being transported on a pump and concluded that ultimately this policy may place OPOs at risk for non-compliance. Additionally, the Committee 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.

During the September 21, 2009 conference call, Lori Brigham provided a summary of the public comments made regarding the two items that were sent out for public comment:

- The transfer of responsibility to the transplant center to package and label an organ when the transplant center recovers and transports the organ back to their center.
    - The Committee agreed that there was not consensus reached and much opposition voiced to this part of the proposal
    - Unanimously agreed that it be removed and additional language regarding the requirement that the transplant center allow the OPO to package and label the organ was added.
- The requirement of two unique identifiers for tissue typing materials.
    - Public, regional and Committee comments accepted this proposal. The Committee unanimously approved the content.

The Committee submits the following resolution to the Board of Director for its consideration:

**** RESOLVED, that Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials) shall be amended as set forth in the Exhibit A, effective pending notice to the membership.**

The Committee approved the resolution with a vote of 14-0-0.

2. Imminent & Eligible Death Data Collection Project.

The OPTN Contractor began collecting patient level data for all imminent and eligible (I & E) deaths on January 1, 2008. The I & E death definitions that guide the data collection were previously approved by the Board of Directors. It was anticipated that patient level reporting of

eligible deaths will allow for better performance modeling; however, members are interpreting the definitions differently, resulting in inconsistent data reporting.

There have been several educational sessions conducted by the OPO Committee to provide the OPO Community with information to promote accuracy in data reporting. The Committee sponsored two I & E training sessions in order to provide additional clarifying information to the community. Additionally, the AOPO Quality Council, under the direction of Charlie Alexander MS, MBA, former Chair of the OPO Committee, created a "Guidance Document" to help OPOs report these data accurately. In order to provide OPOs with a mechanism to seek clarification, direction and uniformity from UNOS, a direct mailbox was implemented (IEdeathquestions@unos.org).

In spite of these efforts, inconsistencies in data reporting continue. The committee agreed that clarifying definitions would improve data reporting significantly.

At the April 22, 2009 meeting, the Committee discussed the effect of the I & E death data accuracy when multi-system organ failure (MSOF) is reported. MSOF is defined as the failure of 3 or more systems. Although MSOF is exclusionary to becoming an "eligible" donor, OPOs are pursuing single (and sometimes more) organs from these donors. The Committee determined that specific MSOF definitions or guidelines for the purpose of the I & E data collection are needed. It was suggested that instead of using the number of failed systems to exclude a donor, 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 functioning organ that may be appropriate for transplant will be potentially identified as either an imminent or eligible donor regardless of MSOF.

The Committee agreed that it 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.

During the July 8, 2009, conference call, the Committee reviewed a summary of the subcommittee activities regarding MSOF. The Committee accepted the "rule in" concept as opposed to the "rule out" model and agreed that OPOs must consider factors that rule patients in to donate organs.

The Committee sought input from the organ specific committees regarding their individual definitions of MSOF. During a joint conference call, the Thoracic Organ Transplantation Committee agreed that it is a measure of "function" not of disease, and that it is clearly defined in the critical care community. The Thoracic Organ Transplantation Committee will provide input regarding the critical care community's definition of MSOF and will provide guidance following their committee meeting. The subcommittee has not received any substantive information from the other committees regarding a definition of organ failure.

The Committee sought guidance from the OPTN leadership, Mary D Ellison PhD, Assistant Executive Director, regarding the possibility of redefining MSOF and its implications. Dr. Ellison concluded that it is essential to make data reporting more accurate and encouraged the Committee to pursue their activity in redefining eligible death.

3. OPTN Data and Conversion Rates.

At the April 22, 2009 meeting, UNOS Staff, provided a report summarizing the donor data and the first year of data from the I & E data collection. There has been a decline in the number of donors for the first time since the Breakthrough Collaborative started in 2003 and the organ yield remains flat at 3.0 organs per donor.

It was reported that for the first full year, I & E data can be viewed by subgroup. Conversion rate is defined as the conversion of eligible deaths to eligible donors. By age, it was reported that the conversion rates are highest among the 18-29 year old group with the lowest rates being from the 60-70 year old. The cause of death data show that head trauma patients have the highest conversion rate at 74%, and mechanism of death data show that gunshot wound patients have conversion rates at 78%, followed by blunt injury at 72%.

A report on New Conversion Rate Models was also provided using patient level eligible death data in order to compute an expected conversion rate for each DSA. Since there are now eligible death data, these rates can be calculated based on the characteristics of the individual eligible death and the hospitals in the DSA. Additional variables included age, gender, race, cause of death and whether or not the hospital is a trauma center. The new conversion rate model has a high measure of how well the model predicts which eligible deaths become actual donors. This model is based on the premise that the total number of deaths correlates to the total number of eligible deaths. Age is highly predictive, and the white race has the highest conversion rate for all ethnicities.

The eligible death count strongly correlates to the notifiable death count; however, the ratio is not predictive of the subsequent conversion rate. The medical examiner (ME) consent data show an extremely strong predictor of whether or not someone is a donor. Although ME data statistically was a very strong predictor as to who becomes a donor, the committee did not believe that this element should be used in the analysis as members do not think it is a good predictor, but is a result of a process measure. Hospital characteristics (number of beds, neurosurgery program, metropolitan statistical area size, etc.) and notification rate (eligible deaths/notifiable deaths) showed no difference when these variables are included in the model on an aggregate level. The Committee suggested that the variation would be different by DSA as referral patterns are different by DSA, centralized trauma system vs. not, and other variables by DSA would impact result and predictive power. The notification rate demonstrated no gain in predictive power so it was left out of the model.

The Committee agreed that the trauma level should be included in the model. In the analysis, the predictive model for trauma level, and CMS POS file in aggregate Notification Rate, showed no gain in the predictive model.

The range of observed and expected donation rates among DSAs is 48-84%, showing a large variation. Based on the characteristics of the eligible deaths, the expected rates are 55% to 74%. The conclusions from this data analysis are: (using a p=.05)

- 8 DSAs have observed conversion rates that are significantly lower than expected (observed to expected ratio is .72 - .92.)
- 11 DSA have observed conversion rates that are significantly higher than expected (observed to expected ratio is 1.09 – 1.23.)
- Having individual data has markedly improved the conversion rate model.

- Some hospital level variables previously included are no longer predictive and are no longer included

These observed and expected donation rates will be placed on the private SRTR web site in June, 2009, so each OPO can review their own data and provide feedback. This model allows for the statistical analysis of expected vs. actual conversion rates based on the data as it is reported. However, there is no element of this model that will show actual vs. expected number of eligible deaths.

The Committee suggested the following additional variables that might be considered in future modeling:

- Geography
- Urban vs. rural areas
- Registry or first person consent
- Population density,

The patient level eligible death data collection has markedly improved the conversion rate models. Several hospital level variables previously included in the model are no longer predictive.

As the trauma center level within the DSA had no impact on the projected conversion rate, it was suggested that it be removed from the analysis. It may be possible to identify hospitals that have high or low conversion rates for use as a quality improvement tool; however it is not relevant to this analysis. Many cases reported from trauma centers are deaths from natural causes. Being a trauma center makes very little difference in conversion rates due to the types of deaths that occur at trauma centers. Although the conversion rates may be higher at trauma centers, this phenomenon is explained by variables such as age, cause of death, etc.

Motion: That the SRTR remove the trauma level variable from the analysis.

The Committee approved the motion by a vote of 14-0-0.

The role and impact of the Medical Examiner (ME) variable, while of interest and informative, is actually too predictive of expected consent rate. If adjusted for this variable, the only result would be unknown. Additionally, this variable would not be predictive of conversion rates because the cases that go to the ME already have consent. If the ME does not release the body for donation, then it is a process problem. In a given state, it is important to evaluate the impact of the ME on the OPO and it is probably highly predictive of an impediment to donation. There is some confusion as to the coding on the data collection form. For the field labeled ME/Coroner, the possible response is “yes/no.” It is unknown if that means that the ME consented or was contacted. The Committee questioned whether or not the DDR should be changed to more accurately depict the action of the ME.

Motion: That the SRTR remove the ME variable from the analysis and refine the ME information at a future date on the DDR.

The Committee approved the motion by a vote of 14-0-0.

The Committee discussed potential ways to categorize OPOs other than by conversion and expected conversion rates. Possible scenarios might include the use of statistical significance and a combination of statistical significance (clinical significance) reflected in the ratio of observed vs. expected. The Committee agreed that these data should be tested over a greater amount of

time, such as a 3 year period. In addition to strictly using the *p* value, the Committee asked if the SRTR could study the standard deviation to identify the small number of outliers. They also recommended that a narrower pool be used.

Since this analysis is focused on the DSA level, it would be important to have the number of transplant programs within a given DSA as a variable. Members agreed that this variable would most likely have an impact on results and conversion.

The SRTR reported that this analysis is largely informational but there are steps that are planned. The determination on the use of the model and how they will be displayed lies with HRSA. Statistics will be placed on the SRTR private website in June requesting feedback; direction will be needed as to when the information will be made available to the public.

The Committee should consider the length of time is needed to effectively have the appropriate data. The recommendations made by this Committee will be provided to HRSA and the SRTR will continue to provide feedback to the Committee.

4. Multi-System Organ Failure (MSOF).

Inconsistencies are being identified as the I & E death data are being analyzed. Individuals reporting the data are interpreting the I & E definitions differently. Currently, Multi-System-Organ-Failure (MSOF) is defined as the failure of 3 or more organ systems and is an exclusionary element to being defined as an eligible death. However, OPOs are aggressively pursuing even one organ from these donors resulting in organ(s) being recovered from a patient that does not meet the definition of "eligible death." This "rule out" approach does not allow for correct data reporting on these donors. The Committee discussed their discontent with the "rule out" approach and discussed the possibility of utilizing a more positive "rule in" approach.

At the April 21, 2009, meeting, the MSOF Subcommittee posed the following issues and questions:

- Is it easier to define and consistently apply a "3 failed system" definition or is it easier to approach this from the concept that, "this patient had at least 1 organ that could be transplanted?"
- If an organ is not transplantable but functioning sufficiently to sustain the donor, (e.g. COPD or CABG), is it considered a failed organ just because it is not an acceptable organ for transplant?
- Some OPOs have questions regarding ruling out based on preexisting failure vs. acute failure.

The Committee agreed that it is easier to "rule in" than to "rule out" an organ and would facilitate the development of a consistent application of the definition. The challenge is that some organ system failures are more clearly defined than others. Currently, if a patient has 3 system failure, the only organ that might be placed is the liver; however, this patient cannot be classified as either an imminent or eligible donor. This work would attempt to achieve some consistency in data reporting and make a more uniformly and universally applied definition. As long as this definition is applied subjectively, then it will not be consistent across all DSAs. The Committee agreed that there should be specific criteria to meet when a patient is in organ failure, or criteria that allows for a transplantable organ.

The MSOF Subcommittee also sought guidance as to whether they should pursue "ruling in" or "ruling out." The Committee considered the questions and agreed that objective criteria should be developed. Additionally, the inconsistency in the data reporting affects conversion rates so it

is important to make the data as consistent and valuable as possible. The Committee also agreed that if the OPO pursues a donor with even one organ and has exhausted the list, resulting in no transplantable organ(s), than this donor would not be listed as an eligible or imminent death. Additionally, potential donors with brain tumors frequently have no one accept the offers, so therefore they would not be considered imminent or eligible. However, this still leaves some room for interpretation. The Committee will continue to provide guidance to OPOs as to how to report I & E data. This is guidance, not a policy change, and is not a finished product.

Motion: That the "rule in" methodology is a better model to pursue than the current MSOF "rule out" (3-system failure) model. OPOs must consider factors that rule a patient in as a donor.

The motion was approved by a vote of 12-0-2.

At the July 8, 2009, Subcommittee meeting, Lori Markham provided an update on the discussion that was held with the Thoracic Organ Transplantation Committee (Thoracic Committee) on July 7, 2009 regarding the Committee's request for clarification of a definition of organ failure for the heart and lungs. OPOs are interpreting the exclusionary criteria of 3 failed organ systems differently throughout the country (for the imminent and eligible death data collection) and the Committee is seeking guidance on how to better collect data in a more consistent manner. The Thoracic Committee agreed that failure is a measure of "function" and not of "disease."

Thoracic Committee members opined that organ failure is clearly defined in the critical care community and will provide that information to the OPO Committee. The Thoracic Committee will continue the discussion at their upcoming meeting and provide guidance to the Committee.

The Committee discussed the need to review the definition of eligible death to determine if it would need revising. Providing the community with the Society of Critical Care Medicine's definition of organ failure might be considered. Additionally, moving to a model that focuses on "possible transplantable organs" as opposed to exclusionary criteria might also promote more accurate data collection. The MSOF Subcommittee will address these issues during the next conference call.

5. Acceptance Listing and Acceptance Practice Report.

At The April 22, 2009, meeting, the Committee reviewed the status of the Tiered Acceptance Project, DonorNet® Efficiency and issues surrounding Expedited Placement.

- Tiered Acceptance. The Operations Committee will meet to review the work completed regarding the concept of Tiered Acceptance. This concept allows transplant centers to define more stratified levels of organ parameters for acceptance of organs. The Operations Committee will also develop a plan to move forward. The Committee considered DonorNet® and its ability to make organ offers faster; but agreed that it may not be getting the organ to the appropriate recipient because there are numerous organs being refused from centers that would not accept that particular type of organ. Mr. Orlowski will continue to keep the committee updated on the progress of the Tiered Acceptance project.
- DonorNet® efficiency. Concerns regarding the efficiency of DonorNet® and issues that have surfaced since it was initiated (e.g. concept exhausting the list) are being considered. There is currently no formal process to determine how DonorNet® is being used. Discussions have been held and guidelines may need to be created.
- Expedited Placement. Centers have voiced concerns that they are accepting organs offered as an expedited placement (EP) and worried that they will be in violation of policy as they are accepting organs that are EP. These concerns demonstrate the

inconsistency in how and when decisions are made about EP as well as how they perform EP. The Committee agreed that guidelines for developing EP processes may be needed. Although NOTA requires a "patient driven" list, if an organ is not getting used, and you have a limited amount of time to transplant it, you may have to contact a center that is out of order, to prevent discarding the organ. The Committee agrees that actions should benefit the most people possible and it is important to try to get the organ used by someone who may or may not be a candidate for an ECD.

6 Laboratory Testing Issues.

- HTLV Advisory Group. OPO Committee members sit on an HTLV Advisory Group, formed with members of the Disease Transmission Advisory and Operations Committees. This Advisory Group is preparing a recommendation regarding how to deal with the lack of HTLV testing once Abbott removes their test kits from the marketplace. They are investigating two possible tracks, and a recommendation may be presented to the Board when HTLV testing is not available:
    - Not do the test because of the High false positive rate. Of those confirmed positive, vast majority are non-infectious HTLV2 (no know sequelae of having the virus) vs. HTLV1 (1% confirmed positive infections). Very small number that are confirmed positive. The Advisory Group may recommend that it not be mandatory.
    - Identify and use tests that are in the "Research and Development" stage that may not be FDA approved. These tests could be used as a screening tool, and results are positive, send the sample for more definitive testing. This may not be possible as the test kits may not be able to be sold here as they are all foreign tests and are not FDA approved. This issue is time sensitive.
- NAT Conference**.** Mr. Orlowski reported that he is on one of the workgroups for the upcoming NAT conference and will report back to the Committee when complete. This work group is focused on the availability of NAT technology; current practices in the industry; what data are available on false positives; and the true clinical value of conducting the testing. The results may be a movement toward wider availability of testing, but no mandate for NAT on all donors as this may result in a loss of donors.

7. 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. Due to numerous labeling errors reported to the MPSC, the Label Review Subcommittee reviewed the current labeling system and made recommendations to the Committee including:

- Eliminating the small color-coded label as it has posed specific problems in the community
- Making the UNOS number larger and easier to read
- Enhancing the size of the "contents of the box" section to make it more easily utilized
- Decreasing the size of the flight information as frequently it is unknown
- Ensuring that the ABO verification is more readable
- Eliminating extraneous information

OPOs will be required to have a documentation process in place for their donor record. The Committee will seek guidance from the Department of Evaluation and Quality regarding possible auditing issues. It was also suggested, that a future plan to print the labels directly from DonorNet® would eliminate possible errors from occurring during the transcription of

information. However, due to costs of programming and the current workload of the IT department, the Committee will revisit the issue within the next several years. Members agreed that when a new label is created, training will be needed.

The MPSC has reviewed a large number of labeling errors that occurred recently. Most errors occurred in the transposition of letters or numbers in the UNOS ID. Additionally, most comments about the labeling system from the OPO Community were negative (e.g. cumbersome, too many labels). Members were under the misconception that policy regarding labeling might have been changed and were confused as to how to complete the labels. This labeling system took a great deal of time to create and it may be that the original purpose driving the change no longer is an issue. Some items were added to the label to add to their value; however many of the changes were not policy driven.

There appears to be a heightened awareness for reporting these errors although OPOs understand how errors occur in the middle of the night during a hectic organ recovery. In the past, there was open communication between OPOs and verifying information that might have been written incorrectly.

During the September 21, 2009, Committee meeting, Lori Markham, Labeling Subcommittee chair, reported that they wish to change the entire system to a simplified label, color coded for each organ, with the organ clearly labeled at the top. A draft version was presented. All extraneous information would be removed; only information required by policy would be included. OPO auditors from the Department of Evaluation and Quality have reviewed the label and determined that it contained all elements required by policy.

Motion: That the concept of the new label be accepted and provided to the Operations Committee for comment. The motion passed by a vote of 14-0-0.

It was noted that if this new system would be adopted, OPOs would need to have a system in place to verify ABO. Additionally, the Committee agreed that the new labels should be pilot tested. The Subcommittee reported that 5 OPOs of varying sizes have agreed to participate as pilot sites. It is anticipated that the pilot study could occur in January 2010.

8. DCD.

An OAC & OPO Work Group has been formed to review aspects of DCD and make recommendations regarding the need for policy. The Committees' goals have been merged and this Work Group will continue to work on the goals. Members of the previously formed subcommittee will serve on this workgroup.

9. Second User Verification of ABO A & AB Subtypes.

UNOS staff asked the Committee to provide input on an issue regarding ABO subtype verification. It was reported that currently, before a match run can be generated, DonorNet® requires a second verification to ensure that a donor's ABO has been entered correctly. The system also allows for A or AB subtypes to be entered into DonorNet® at a later time, prior to the match run; however, it does not require a second verification of the subtype by a second user. Although two individuals must verify the ABO entry, only one person has to enter the subtype.

Currently, if an OPO needs to change the subtype that has been entered, they must create a duplicate donor form and complete all of the information a second time. The Committee agreed that this is time intensive and not a good use of OPO staff. Following some discussion, the Committee posed the question, "Should there be a requirement that a second person verify the

subtype information that is entered?" The Committee agreed that this could potentially be a patient safety issue if only one person enters the subtyping information. To resolve the issue, there were two options identified:

- Request a programming change in DonorNet® to require subtyping verification, OR
- Modify policy language, provide education, and require that it be documented in the patient record. (This option would not require programming, but it would require additional time for DEQ review.)

If the Committee agrees that the subtype should be verified, then the Committee can make a recommendation to have this program change analyzed and get an assessment as to the cost of the programming changes. The initial estimate for programming this change was $9,000 dollars without including the cost of testing and maintenance.

Another option would be to not enter the blood type until the subtype is available, entered, and verified. Currently, OPOs can run a list without the subtype being entered into DonorNet®. If an A is entered as the ABO, the OPO runs the list and then subsequently gets the subtype, the list cannot be re-run. One problem that exists is that some centers can subtype and others cannot (e.g. after hours), so getting results after hours may be problematic for some OPOs.

Motion: That the policy be modified that the ABO A subtype be verified. The motion passed by a vote of 13-0-0.

The Policy Subcommittee will draft the language and report back to the Committee.

Motion: This change in the ABO A subtype should be programmed to reflect that once the subtype is entered, a list cannot be run until the subtype is verified.

The motion passed by a vote of 10-0-0.

10. Public Comment.

The Committee considered each of the Public Comment proposals from the February 2009 Public Comment cycle. There responses were as follows:

1. Proposed listing requirements for simultaneous liver-kidney transplant candidates.

   The Committee chose not to comment.

2. Proposal to create regional distribution of livers for Status 1 liver candidates (Policy affected: 3.6 Allocation of Livers) (Liver and Intestinal Organ Transplantation Committee)

   Many OPOs already practice regional sharing for Status 1 liver candidates. It was agreed that there are currently artificial barriers created by regional borders. Although, supportive of the concept of this policy change, the Committee recommends that UNOS evaluate the definition of region, as well as investigate the distance for shipping organs on a more equitable basis. One Committee member commented that it does not seem right to send an organ 500 miles within the region when it could be sent 50 miles in the other direction, although outside of a regional border. The Committee recommends that the Liver and Intestinal Organ Transplantation Committee should open the discussion regarding regions and allocation and that the definition of region be re-evaluated.

Motion: To support the proposal with the recommendation that the definition of region be evaluated.

The proposal was supported with the recommendation by a vote of 11-1-0.

3. Proposal to create regional distribution of livers for MELD/PELD candidates. (Policy affected 3.6 – Allocation of Livers) (Liver and Intestinal Organ Transplantation Committee)

The Committee agreed that due to some of the large geographic areas within DSAs, the proposed changes will have cost implications for OPOs. These changes will impact staffing, logistics, coordination of travel, etc., and will pose a large financial burden on the OPOs. Although there are obvious costs that will be incurred, such as increased travel requirements, there are also hidden costs, such as increased OR time.

Since the local utilization rate decreases under this policy, more than half of livers recovered will most likely be sent elsewhere, thus increasing cost. If this proposal becomes policy, OPOs may need to investigate the possibility of forming regional recovery teams to overcome some of the significant travel challenges in large regions. It was agreed that the benefit is small and cost is large; this change has very broad implications.

It was noted that Region 10 has regional sharing and exports approximately 60% of livers procured; however, in that region, transplant teams perform their own recoveries. Additionally, many OPOs have tiered systems for costs as livers cost more that are sent out of the local area due to such variables as perfusion costs. The Committee agreed that if the community is moving toward maximizing the gift, this proposed change is not maximizing benefit.

Motion: To support the proposal.

The Committee did not support the proposal by a vote of 0-11-0.

4. Proposal to standardize MELD/PELD exception criteria and scores.

The Committee chose not to comment on this proposed policy.

5. Proposal to add the factors “current bilirubin” and “change in bilirubin” to the lung allocation score (LAS)

The Committee chose not to comment on this proposed policy.

6. Proposal to modify the high risk donor policy to protect the confidential health information of potential living donors. (Policy affected 4.1.1 - Communication of Donor History)

The Committee agreed that there needs to be clarification and separation as to what policies apply to living and deceased donors. Although this is not an OPO issue, it seems that if the living donor does not want their personal or health care information shared, they can opt out of the donation at any time. The Committee also understands and supports the concept that there is a new policy being proposed that will house all policies for living donation.

Motion: To support the proposal.

The Committee supported the proposal by a vote of 11-0-1.

7. Proposal to change the OPTN/UNOS Bylaws, to clarify the process for reporting changes in key personnel.

The Committee chose not to comment on this proposed policy.

In September 2009, the DTAC distributed one item for public comment. The Committee commented on that item via email as follows.

1. DTAC proposal to modify Requirements for mandatory HTLV I – II testing for all potential organ donors. (Policy 2.2.3.1)

The OPO Committee considered the proposal regarding HTLV testing and did not support it. The following comments were made:

- Concerns were raised over the risk management of doing retrospective testing. If when an HTLV+ donor is identified, what is the process, who is notified, what are the legal ramifications, etc?
- There is an extremely low incidence and effective tracking of recipient outcomes seems to be a challenge for transplant centers. The Committee questioned whether clear policy language exists to guide transplant centers on follow-up testing.
- One member discussed their continued HTLV I/II testing prospectively on local organ donors and on imported organs. This member is one of the few OPOs that has its own laboratory for serology testing and that purchased a PRISM instrument for the purposes of running the HTLV test for organ donors. The member agreed that they have a unique set of circumstances with
- Sufficient volume of local organ, tissue and eye donors to support the high throughput instrument
- The cost per donor is negligible with the volume of tests per day.
- Some members agreed that it seems very wasteful to test approximately 15,000 - 16,000 organ donors for the possibility of getting 6-8 true positive results. Of those 6-8 positive results, one or two patients may get a disease for which there is no known treatment. Additionally, living donors are not uniformly tested for this disease and many transplant centers do not test recipients during the work-up phase. As such, how can it be determined if it is actually donor acquired?

The Committee did not support the proposal with a vote of 3-15-0.

11. Organ Offer Referral Codes.

The Committee expressed concerns regarding the frequent use by surgeons of the "830 – Donor Quality" refusal code as it makes it difficult to place organs that have been turned down for donor quality. It is difficult to retrospectively evaluate why organs are being refused because frequently these donors are old or have multiple co-morbidities. Code 830 appears to be used frequently for refusing the organ. There are multiple variables that need to be entered into a form and it is difficult to get accurate depiction as to why the organ was turned down.

It is possible to analyze the frequency of use for code 830. These codes have not been reviewed since the implementation of DonorNet® and this may be an issue as to how people are entering the data. Is it possible to do a study on a national and regional basis and look at organ systems to

see how the codes are used. UNOS staff will review the frequency of use of the codes and report to the Committee. The Committee will consider addressing the issue once the data are reported. If there are people using "donor quality" as opposed to such variables as "positive serology," the Committee will need to consider a remedy.

12. Donor Management Goals

The Committee discussed the possible merit in developing standardized donor management goals (DMGs) to incorporate into policy. A recent regional study did not demonstrate a correlation of DMGs to organs transplanted per donor. Out of 6 OPOs, three correlated while three did not. Some regions are attempting to develop standard DMGs and the Collaborative is also working with the Intensivist community to create standardized DMGs. The Committee agreed that there is sufficient work in this area occurring under the Breakthrough Collaborative and will not pursue this issue.

13. Inaccurate Reporting of Serologies.

At the request of the MPSC, during its April 22, 2009, meeting, the OPO Committee considered the possibility of requiring OPOs to scan serology source documents (as PDFs) into DonorNet® so that source documents might be viewed by the staff of potential recipients' transplant centers and OPOs during the organ offer process. This request was in response to OPOs misreporting results of serologies such as Epstein Barr Virus (EBV), and Hepatitis B Surface Antibody (HBsAb) in DonorNet®.

There were several issues that surfaced during the Committee discussion:

- Logistical problems when providing source documents (timing and capability).
- Is the transcription of serology results a process improvement or policy issue?
- Errors in serology reporting affect the match run results.

The Committee agreed with the concept of providing source documents (when possible and available) and also agreed that doing so would promote patient safety through accurate reporting of serology results. The Committee further agreed that individual OPOs and centers should rely more on source documents as opposed to results that are transcribed. Committee members understand how transcription errors can occur, particularly in the middle of the night during a recovery; however, decisions to transplant are made based on these inaccurate transcriptions and can potentially compromise patient safety.

While there are still hospitals in the U.S. that do not have the capability to scan documents, it was determined that OPOs can fax source documents into DonorNet® and they will automatically "attach" to the donor's chart. Members also agreed that there needs to be OPTN assurance that the Organ Center staff will be responsive to assisting OPOs with this transfer of information when the OPO cannot do it because of logistics issues.

Unfortunately, many serology results, if not most, are not available when organs are offered and placed electronically through DonorNet®. As such, it would be impossible to require them to be in the system for all organ offers. Many, perhaps the majority of, organ offers are accepted pending serology results being provided and the recovery itself may occur without serologies being available. Required results are transported with the organ. It was the Committee's collective opinion that entering the information into DonorNet® does not solve the problem. In the cases cited by the MPSC regarding inaccurate results, the Committee is unsure as to whether or not the documentation was available in these two cases and that these cases may be quality improvement issues as opposed to policy issues.

It was also noted that these errors affect the match run. If specific information is entered into DonorNet® incorrectly, then the resulting list is incorrect. Unfortunately, providing hard copies of serology source documents will not remedy this situation.

Motion: That the Committee draft a memo to the MPSC reflecting the Committee's position. While the Committee shares the MPSC's concern regarding accurate record keeping, members do not believe that faxing the source document at the time of making the organ offer is going to solve the record keeping issue. In terms of the patient safety issue, the source document has to be provided to the team with the organ. If it is provided as required by policy, then patient safety is being protected at the recipient end.

The Committee supported the motion by a vote of 9-0-0.

14. Inclusion of HbA1c as a Mandatory Test for Pancreas Donors. At the April 22, 2009, meeting, the Committee considered a request from the Pancreas Committee to consider the inclusion of HbA1c as a mandatory test for pancreas donors. After discussion, the Committee agreed that HbA1c is not universally available and therefore cannot be required. If desired, this test can be requested and the OPO should have the test performed if possible. Based on current policy, any laboratory test can be requested.

15. OPO Performance Metrics Work Group Report. In 2008, the OPO Performance Metrics Work Group 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 OTPD. 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 on performance metrics. 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® 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.

At the April 22, 2009, meeting, It was reported that the SRTR has developed a model based on actual donor characteristics over a three year period. This model can demonstrate how DSAs are performing regarding expected vs. actual OTPD as an assessment of the aggregate of all donors. These data were then reviewed at the DSA level.

The Committee was provided with a presentation regarding Metrics examined from July 1, 2004, through June 30, 2008. All donors with at least one organ recovered for the purpose of transplantation were included in the cohort. Post-DonorNet® donors are included. The number of transplanted organs recovered in that DSA during the time period was compared to the expected number transplanted and the number of organs transplanted per donor was analyzed. This model will allow the identification of underperforming and over-performing DSAs. The Committee discussed the results and identified possible recommendations for the Joint Work Group.

- The Committee agreed that this is an opportunity to look at DSA performance, not only OPO performance. Utilization can be studied and DSAs can be assisted in improving.
- How do we determine clinical significance as opposed to statistical significance?
- This is an opportunity to look at the high performing OPOs or DSAs and can provide assistance.
- One of the goals has been toward more value-added environment to benchmark self to identify where the opportunities are.
- The Committee agreed that the ability to identify objective, biological criteria that have a large impact on the likelihood of getting a particular organ would be valuable to collect for the donors but also for the eligible deaths.
- This project is designed to improve DSA Performance and is not designed to be punitive. Transplant programs are reviewed for graft outcomes. The OPO Community needs data to review to consider outcomes and these data will help to move the community forward. MPSC may have recommendations for organ specific issues.

This information was presented on July 20, 2009, at the MPSC meeting and a general update was provided at the AOPO Executive Director's meeting in January 2009 and at the AOPO Annual Meeting in June 2009. The Committee will get more feedback when the information is provided to the community at large.

16. Policy Review Subcommittee.

Policy 2.0 was presented to the Board of Directors in March and was approved. Following approval, the Executive Committee made several changes based on the DTAC recommendations regarding the use of HTLV tests.

The Living Donor Committee is proposing a new policy that will be limited to policies that are related to living donor. All current policies that have a living donor component will be moved into Policy 12 in a corresponding section.

The DTAC will be re-writing Policy 4.0 related to HIV, therefore this subcommittee will delay review and provide input to the DTAC review group. Kent Holloway and Jeff Orlowski volunteered to participate in the re-write subcommittee.

Policy 5 has been rewritten, distributed for public comment in February, and several substantive changes were distributed for public comment in June. The Briefing Paper provides detailed information about the changes that were made to Policy 5.

17. **OMB Project.** AT the April, 2009 meeting, UNOS Staff presented the OMB data revision project**.** The current forms are due to expire in November of 2010, and the Committee is responsible for reviewing the DDR forms and make appropriate recommendations for change. The recommended changes will be reviewed by the Data Advisory Committee and the Policy Oversight Committee. Previous changes that have been made focused on data reduction; however, currently the Committee must evaluate the need for new data elements and the determination if the current data elements are appropriate. The Committee considered each of the OMB proposed changes to the DDR from the OMB Subcommittee, the OAC and the DTAC that impact the OPOs work and will provide feedback to those Committees.

The Committee was concerned about the listing of DDAVP, vasopressin, and anticonvulsants as they are always present in brain dead donor management and determined that they should be removed. The information is not meaningful as the dosages and time of administration are not listed.

The Committee also discussed the request for serial, minute-to-minute data that was requested by the OAC in order to better understand the time intervals. Although concerned about the data burden, members agreed that the data elements were necessary for placing DCD organs. Although many OPOs do collect these data, concerns were also voiced about the OPOs that may not collect them. The Committee also questioned whether or not the DDR was the appropriate place to collect these data. With DCD donation increasing, these data could be cumbersome, but remain very important. Members agreed that it may make the difference between placement and no placement of DCD organs. With declining utilization of DCD livers, the more we know about the donor can only enhance acceptance of the organ and the Committee supports this proposed change. Ideally, with unlimited resources, DonorNet® could cascade the information to the DDR. All proposed changes to the DDR will be submitted for Public Comment.

18. **Donor Data Quality Monitoring.** At the July, 2009 conference call, UNOS Staff provided an overview of a monitoring project that found discrepant donor data on the organ specific match runs. These discrepant data require the match to be re-initiated to assure accurate organ allocation.

UNOS Staff reported that 100% of the match runs are audited for accuracy. When they find an inconsistency, organ center staff contacts the OPO to identify the problem and to correct whatever value may be incorrect. From 10/1/07 to 2/28/09, Organ Center staff reviewed 7,009 records. Some of the results included 15% of cases demonstrated incorrect online data, and 70% of the matches were run with incorrect data and results are different when rerun with correct data.

The Committee discussed the data presented and felt that this was excellent quality and performance improvement data for the OPOs to receive. Members did not believe that providing this information to OPOs would negatively impact the relationship between the Organ Center and the OPO staff. All agreed that recipient safety and accurate donor information was critical. This type of data provided routinely to the OPOs could be used for performance and process improvement.

It was suggested that the data might demonstrate trends in data errors and result in individual's correction and improvement of performance. The Committee enthusiastically supported the concept to provide this information to OPOs and would like to identify ways to identify errors that may not be coordinated through the OC. UNOS Staff will provide the information so it can be shared via the AOPO Executive Directors Portal.

18. **Reporting/crediting DCD Transfers**. A recent email string on the Collaborative list serve questioned which hospital would get "credit" for the donation when a potential donor is transferred to a different hospital for recovery. Following a review, the Committee agreed that there is currently no policy that defines this situation. It was agreed that this "credit" impacts recognition from the federal government and frequently local recognition as well. Additionally, the question was posed as to how credit would be given when donors are removed from their hospitals and transferred to a recovery center at the OPO.

The Committee discussed that the hospital where the death occurs is the institution that must report the death for the purposes of vital statistics. It was agreed that the center where the death occurred would be reported as the hospital where the donor occurred. As such, the hospital where the death occurred would be given credit for the donation.

Motion: That the Committee develop a statement to clarify that the hospital where the death occurs is given the credit for the donation.

The motion was approved by a vote of 11-0-0.

The Committee charged the Policy Review Subcommittee with the task of identifying where in policy or otherwise a statement of this nature should be placed.

19. **Data Coordinator Defined.** The subcommittee agreed that a multi-prong approach is needed and that all OPOs should be held to the same standard. Training should be provided annually and there should be a process defined as to how organizations insure that their data are accurate. They concurred that there must be a primary person responsible. In practicality, these efforts are team efforts.

- Some responsibilities should be set as standards for all members institutions regarding their data coordinator. It can be one, several or a team depending on the needs, size, volume, etc of the OPO. The subcommittee agrees that this should not be too prescriptive due to the differences in OPOs throughout the country. The intent would be to require the OPO to designate one individual that has the accountability. There needs to be some flexibility within the structure of each OPO.

- Individuals engaged in data coordination and formally identified as data coordinators must attend a specific number of competency based training sessions per year. This training should be offered via face-to-face, LiveMeeting and Conference call each year. This training must be mandated and provided by UNOS. It was suggested that the content of the training might be developed by UNOS and then provided by the AOPO Quality Council. Additionally, web based or electronic training might be considered. UNOS would need to identify practical training opportunities, taking into consideration budgetary restraints.

There needs to be a process within UNOS for auditing and evaluation regarding data accuracy. UNOS Staff will identify specific job descriptions and develop a list of roles and responsibilities that should be held as standards and report back to the Subcommittee.

20. **Vessel Storage.** The Committee has been asked to consider a policy change that would provide direction for vessel outcome when the temperature for vessel storage falls outside the required parameters. There is currently no policy that mandates vessel destruction if the temperature falls outside of the temperature parameters. The AATB does have language that addresses this issue for tissues; however, the Committee agreed that the community as a whole does not want to treat vessels as tissues.

It was agreed that the vessels should be discarded if the vessel is not stored at the proper temperature. If the vessel is not transplanted into a different person, it is a tissue. The Committee might Committee consider adding language to policy that the vessel be destroyed if the temperature falls outside the stated parameters. Since vessels are stored mainly at transplant centers, the transplant centers should address this issue. The Committee questioned when the parameters were developed and it was suggested that the recommended temperature parameters on the UW container labels are being used.

The Committee agreed that consideration of this issue is in the realm of tissue banking and is not a high priority for the OPO Committee. The Committee will consider a statement in policy that when the temperature falls outside the stated parameters, that the vessel be discarded.

Motion: That this issue be tabled until the November meeting and discussed more fully. At that time the Committee will consider a policy change. The motion was passed by a vote of 14-0-0.

21. **CDC Disclosure Forms.** The Committee has been asked to consider a problem regarding the need for the recovering surgeon to sign that he is aware that the donor is a high risk donor. The question was posed as to whether a policy change is needed that allows for the transport of organs that are being shipped to transplant centers that have not signed the release form. Policy 4.1.1. states that the OPO must communicate this donor history information to all institutions receiving organs from the donor. Some OPOs document the time and date when the transplanting surgeon was notified of the high risk status. This is documented on a form and posted on DonorNet. However, there is no policy that mandates a signature of the procurement team and it can be any communication as determined by the OPO as to how that will be accomplished.

Additionally, the Organ Center does not have a form to document the communication specifically; however, on the first page of DonorNet there is a CDC High Risk designation. The question may have been a result of confusion over internal OPO policy with OPTN policy. The Committee will respond to Charles Alexander regarding the fact that there is no policy requiring that the receiving center sign any disclosure form and therefore an issue of OPO internal policy.

OPO Committee Attendance

Name	Position	April 22, 2009 Meeting Chicago	July 2009 Conf call - Live Meeting	September 2009 Conf Call - Live Meeting	November 5, 2009 Meeting Chicago
Jeffrey Orlowski MS, CPTC	Chair	X	X	X	
Lori Brigham MBA	Vice Chair	X	X	X	
Posy Durning PA, CPTC	Regional Rep.	By Phone	**		
Michael Holman MD	Regional Rep.			X	
Christopher Hughes MD	Regional Rep.	X			
Samuel Holtzman	Regional Rep.	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	X	X	
Rob Kochik RN, BSN	Regional Rep.		X	X	
Ladora Dils RN, CPTC	Regional Rep.	X			
Satheesh Nair MD	Regional Rep.	X			
George Lipkowitz	Regional Rep.		X	X	
Lynn Williams	Regional Rep.		X		
Patrick Giordano	Regional Rep.		X	X	
Gordon Bowen	Regional Rep.		X	X	
Richard Pietroski	Regional Rep.			X	
Michael Marvin	Regional Rep.		X	X	
Charles Alexander RN, MSN, MBA, CPTC	At Large	X	X	X	
Jim Carter	At Large				
Danielle Cornell RN,BSN,CPTC	At Large	X	X		
G. Kent Holloway MSF	At Large	X	X	X	
Lori Markham RN, MSN, CCRN, CPTC	At Large	X	X	X	
Deon Stewart-Miles RN, BSN	At Large	By Phone	X	X	
M. Kevin Stump BS, BSN, CPTC	At Large	X		X	
Mary Nachreiner	Board Member			X	
Charlotte Arrington	SRTR Liaison	X	X	X	
Emily Messersmith	SRTR Liaison				
Robert Wolfe Ph.D.	SRTR Liaison		X		
Franki Chabalewski RN, MS	UNOS Committee Liaison	X	X	X	
John Rosendale	UNOS Research Liaison	X	X	X	
Bruce Wilson	AOPO	X			
Bob Walsh	HRSA	X	X	X	
Rita Maldonado	HRSA		X		
Monica Lin	HRSA	By Phone			
Margaret Kearns	UNOS DEQ	By Phone			