

## **OPTN/UNOS OPO Committee Report**

### **Summary**

#### **I. Action Items for Board Consideration**

The Board is asked to approve modifications to Policy 7.1.7 (Imminent Neurological Death.) to update the definition. OPOs are currently required to record the time of death when a patient is identified as an imminent neurological death based on the definition. Tracking every referral to the point of cardiac or brain death poses an unreasonable burden for OPOs as many referred patients that might meet the imminent criteria survive, are moved to other facilities, or may live an extended period of time before dying. Instead of applying the definition and recording the time of death, the proposed change states that the OPO should apply the definition of imminent neurological death to a patient that meets the definition at the time when the OPO certifies the final disposition of the organ donation referral. This modification will decrease the burden on OPOs and will allow for the fulfillment of the data requirements. (Item 1, Page 3)

#### **II. Other Significant Issues**

- A subcommittee was formed to study current practice and trends in regards to screening and laboratory testing. OPOs will be contacted to assess current practice. (Item 8, Page 6)
- A joint workgroup with the MPSC was formed to identify OPO Performance Metrics. (Item 14, Page 10)
- The Committee will partner with AOPO to review predictors of death for the potential DCD donor. (Item 15, Page 12)
- The Committee has begun a review of policies that may place OPOs at risk of policy violations due to clinical practice out pacing changes in policy. (Item 16, Page 12)

*Note: The Committee will meet on January 30, 2007, and an amended Board Report will appear in the Board Book.*

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**OPTN/UNOS Organ Procurement Organization Committee  
Report to the Board of Directors**

**Charlie Alexander RN, MS, MBA, CPTC, Chair  
Jeffrey Orlowski MS, CPTC, Vice-Chair**

**February 20-21, 2008  
Orlando, FL**

*The following summary reflects the OPO Committee's deliberations at their meeting held in Chicago on October 25, 2007, as well as subcommittee and All Committee Conference Calls.*

1. Imminent and Eligible Death Data Collection Project. At the October 25, 2007 meeting, Jeffrey Orlowski, MS, CPTC, Vice Chair, provided an update on the status of the imminent neurological and eligible death data collection project. The Board of Directors has approved the imminent neurological and eligible death definitions, and the data collection schema is being developed. This project is a contract deliverable that requires the collection of patient level data on all eligible and imminent neurological deaths. The definitions are mutually exclusive in that in imminent death, the individual has not been pronounced legally brain dead but has 3 or more absent brain stem reflexes, while patients who are classified as eligible have been legally pronounced brain dead. The imminent death category reflects those patients who are referred to the OPO and who are expected to move into the eligible category if they should deteriorate to brain death or become a potential DCD candidate. Approximately 100 individuals attended the first training session that was held September 20, 2007, in Kansas City, MO. Three more training sessions will be held by Live Meeting in collaboration with AOPO.

A test environment will be available in November 2007, for OPOs to become acquainted with the data collection site. The manual data collection and upload functionality will be implemented on January 1, 2008. The second phase will be the release of the changes to the Donation Data Referral report on February 1, 2008. Jennifer Mekolichick, UNOS Business Analyst, provided an overview of the data collection system and demonstrated many of the data entry fields.

The Committee was concerned that tracking every referral to the point of cardiac death poses an unreasonable burden for OPOs. Under the current wording of the definition, OPOs will be required to follow a patient who was originally referred to the program for donation, but who the OPO chose not to pursue for any given reason, until cardiac death. Reasons OPOs might choose not to pursue a referral include the patient improved, was not a DCD candidate, or was not an imminent brain dead candidate and resulted in an extended stay in the hospital (e.g. as the patient who is sent to rehab for a long period). The discussion focused on various scenarios such as the patient who is admitted to the hospital with a Glasgow Coma Score of 3 and absent brain stem reflexes, but ultimately improves or recovers. The Committee agreed that the definition of imminent death should be administered when the OPO determines that the patient is not a suitable candidate for donation and chooses not to pursue the patient as a donor for any variety of legitimate reasons. The Committee remarked that it was not a good use of OPO staff time to track patients who the OPO had already deemed inappropriate for donation.

Members recommended that the imminent death definition be clarified and that the language included in the definition that states that the patient "must eventually deteriorate to cardiac death (during the referred hospitalization)," be removed from the definition. Currently, under the wording of the definition, the OPO must track any referred patient to the point of cardiac death if the patient is not an eligible donor. Therefore, the Committee agreed that the definition of

imminent death should be applied or administered at the time of the disposition by the OPO and made the following resolution.

**\*\*RESOLVED, that the modifications to Policy 7.1.7 (Imminent Neurological Death) are hereby approved, effective pending distribution of notice and programming in UNet<sup>SM</sup>:**

7.1 REPORTING DEFINITIONS

7.1.1 – 7.1.6 No Change

7.1.7. Imminent Neurological Death. Imminent Neurological Death is defined as a patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who upon clinical evaluation documented in the OO record or donor hospital chart, has an absence of at least three brain stem reflexes but does not yet meet the OPTN definition of an eligible death. Specifically that the patient has not yet been legally declared brain dead according to hospital policy, ~~and who eventually deteriorates to cardiac death (during the referred hospitalization).~~ Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death. For the purposes of submitting data to the OPTN, the OPO should apply the definition of imminent neurological death to a patient that meets the definition of imminent death at the time when the OPO certifies the final disposition of the organ donation referral.

Brain Stem Reflexes:

- Pupillary reaction
- Response to iced caloric
- Gag Reflex
- Cough Reflex
- Corneal Reflex
- Doll's eyes reflex
- Response to painful stimuli
- Spontaneous breathing

7.1.8 (No Change)

The Committee approved the proposed policy change by a vote of 15-0-0.

*NOTE: The amendment to Policy 7.1.7 shall be implemented pending distribution of appropriate notice and programming in UNet<sup>SM</sup>.*

*The implementation of the imminent and eligible death data collection occurred on January 9, 2009.*

2. Data Review. John Rosendale MS, UNOS Research Biostatistician, provided a data review. It was reported that there were no major increases in the number of donors for the first 6 months of 2007, and the number of organs transplanted per donor decreased. It is currently estimated that the number of DCD donors will increase in 2007 to approximately 800, compared to 687 in 2006. Fifty three DSAs have recovered at least one DCD donor. The first data report that is specifically

designed for transplant centers was provided to centers in October 2007. The DSA monthly reports and the Report of Organs Recovered and Transplanted for transplant centers (program specific data) will be provided during the first full week of each month.

3. Tiered Acceptance Project. The Committee was provided with a brief overview of the tiered acceptance work that was completed by the DSA Task Force in December 2006. At that time, the Task Force developed specific criteria for kidney and liver candidates; however the thoracic group did not agree that specific criteria were needed. The concept behind tiered acceptance focused on the ability of the transplant center to have three sets of criteria that would create a unique profile that would be deemed appropriate for specific candidates. This would provide centers the opportunity to “fine tune” the offers that they receive from outside the region and within their DSA. It does become inefficient if offers are being made to centers that will not be accepted.

The OPTN/UNOS Operations Committee is currently developing a workgroup to implement the work of this Task Force. The proposal was presented to multiple committees, presented to the Liver and Intestinal Organ Transplantation Committee, and they voiced their interest in pursuing it. The Pancreas Committee was in favor of the concept; however the Thoracic Committee was not. DonorNet<sup>®</sup> has not provided the screening that was anticipated, and members report that there is sometimes an excessive number of offers currently being made. It was suggested that one organ specific group might adopt these criteria and test the criteria to determine if it is helpful to more precise offers being made.

4. Public Comment. The Committee did not choose to weigh in on the proposed policy as it related to informal discussions with transplant programs and does not involve OPOs. However, the Committee agreed that this concept should be expanded to other areas of action and encourages informal discussions that might rectify situations prior to formal actions being taken. This proposal currently applies to only transplant centers, and the committee agreed that this proposal should be reflective of the member as opposed to transplant center. The Committee agreed that informal discussions should be available for all members and would suggest that the MPSC consider including this provision for all members for different infractions and should be written in policies that affect OPOs and other members as well.

Motion: The MPSC consider including the same provision of allowing informal dialogue for policies that directly influence OPOs as well.

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

5. Kidney Perfusion Data Analysis Data Analysis. Charlotte Arrington MPH, Epidemiologist, Arbor Research, presented data that were requested at the February 28, 2007 Committee meeting regarding kidney perfusion. The fraction of kidneys perfused (1/4 of each group) is similar for all the age groups. There was no difference between discard rates between those kidneys that were perfused and those that were not. There is a different relationship between perfusion and discard rates between OPOs that perfuse a low percentage of their kidneys. The “two for one” kidney graft and survival rates were not as good as would be anticipated. Additionally, there was no difference observed between resistance and graft failure.

The Committee agreed that there needed to be a national randomized prospective study by donor, controlling variables, to clarify the outcomes and correlation between discards and perfusion. It was suggested that a HRSA grant program will be published soon and might be a source of funding. In a European study, that was reported at the TSOT/ETCO meeting in Prague, the

researchers did not separate types of donors (ECD, DCD or SCD). Although they included more kidneys, it was only the ECD that demonstrated a lower DGF and better patient and graft survival when perfused. Cold times had significant variations. The OAC continues to examine this topic. The question was posed as to whether graft and patient survival should be the only way to determine if these kidneys should be used. It would be important to look at the utilization of these organs and then evaluate the net benefit of utilization. It was suggested that OPOs might align with perfusion organizations to seek funding and to conduct the study.

6. Data Management Subcommittee Report. Meg Rogers, CPTC, reported on the Data Management Subcommittee of the Policy Oversight Committee. The Subcommittee has discussed topics such as the DCD data elements and imminent and eligible death data elements that are going to be required, and reviewed several public requests for patient identified information to determine if it was appropriate to release the requested information.
7. DonorNet<sup>®</sup> Information Task Force. There have been no meetings of the DonorNet<sup>®</sup> Rapid Response Task Force or any significant complications with DonorNet<sup>®</sup> that warranted the intervention of the Task Force.
8. Laboratory Screening and Testing – NAT Testing. A Committee member reported on an incident that occurred in their OPO regarding the inability to report discordant results on DonorNet<sup>®</sup> when a positive screening test occurs with a negative NAT test. There was some confusion as to how to enter that type of discordant result when reporting them. A discussion followed regarding the use of NAT testing, particularly on high risk patients, and the results that differ from routine screening results. It was determined that the way to submit the data on DonorNet<sup>®</sup> might require some modifications and programming. There were also some questions regarding how to run the list when screening serology results are positive and the NAT test results are negative.

Some members stated that they are doing NAT testing on all donors; others solely on high risk donors; and some reported that they are not using NAT testing at all.

When discussing the appropriate way to record the discordant result in DonorNet<sup>®</sup>, the Committee agreed that OPOs need to have the ability to input all serologies including NAT testing. The policy language currently states that the patient should be screened; however, members agreed that the screening tests are becoming more obsolete while the diagnostic tests are becoming more commonplace. OPOs should have the opportunity to enter all of the tests into DonorNet<sup>®</sup> so that the transplant surgeon can make an informed decision as to whether or not the organ is acceptable for any particular patient. They also agreed that if the serology is positive and the NAT negative, that allocation should be done using the HEP C list, as any positive result should be viewed as a potential for transferring disease. However, the Committee stated that the Liver and Intestinal Organ Transplantation Committee should be the expert group to make that determination. It is important for procurement coordinators to have the ability to capture all of the data. The policy currently states that the lab testing must be conducted in a FDA approved screening test.

The ELISA screening test is being discontinued; however there are several other diagnostic kits that are being developed. The Committee agreed that there needs to be confirmation regarding how the serologies are being conducted based on current policy. Currently Hep C, Hep B, HIV, West Nile, and Chagas are some of the tests being conducted by NAT testing. It may be prudent to query OPOs to determine all of the testing currently being conducted. Some OPOs may be testing on a case-by-case method based on capability and/or availability of specific testing such as

NAT. Some members reported that it can take 24 hours to get the NAT results, so frequently it is possible to have the results before the donor is taken to the OR.

The Committee agreed that a working group should be formed to:

1. Investigate current OPOs practice regarding testing and try to quantify that work.
2. Work through UNOS to recommend the ability to capture those data and incorporate it into running lists for the algorithms.
3. In order to ensure patient safety and to abide by OPTN policy, explore and identify the current technology of serology labs and identify what is changing.
4. Determine if policy language is consistent with changing practice in lab testing.

The workgroup comprises L. Dils, P. Durning, PJ Geraghty, and S. Nair.

In subsequent conversations with the Operations Committee, it was agreed that the workgroup will be part of the Operations Committee workgroup that will study testing in order to determine current and possible future practice, as well as any UNet<sup>SM</sup> changes that will be necessary. A survey of OPO practice will be conducted.

9. Organ Transplant Labels. It is incumbent on the OPO to ensure that every organ is labeled properly. There have been several situations in the past that have caused patient safety issues due to mislabeling (i.e. left kidney vs. right kidney, wrong UNOS ID number attached to organ, wrong organ sent such as heart instead of kidney). On the new label that will be produced, there are two carbon copies, one for the inside of the container labeling and one that can be fixed to the donor chart.

Members reported that there have been frequent situations arise when a heart or lung team recovers an organ, fails to get appropriate labeling, and rapidly leaves the OR in order to expedite the transplant process. This situation poses a problem and places the OPO staff in a difficult position as they are unable to label the organ as mandated by policy. If the transplant center does not label an organ properly or does not allow the OPO sufficient time to label the organ, the OPO has the ability to contact the UNOS Department of Evaluation and Quality and register a complaint regarding the violation. When this situation occurs, the OPO should document the occurrence. Members agreed that it is incumbent on the OPO to ensure that the organs are packaged and labeled properly in order to ensure patient safety.

Mary D. Ellison, PhD, MHA, UNOS Assistant Executive Director, suggested that UNOS provide education so transplant centers understand that labels must be affixed to every organ recovered. A communications plan can be developed in order to educate the community regarding the problem. Actions such as writing an article for the *UpDate* can address the issues and help educate the community. It would be important to include information that OPOs' have the responsibility to report these policy violations to the UNOS Department of Evaluation and Quality. Regional Administrators and Councilors may be able to address the issues with the centers prior to violations being reported. An Education Campaign targeting the thoracic recovery teams will be developed. Policy 5.2 (Standard Labeling Specifications) states that, "The Host OPO or the transplant center, as applicable, shall be responsible for ensuring that the outermost surface of the transport box containing organs and/or tissue typing specimen containers must have a completed standardized external organ container label (provided by the OPTN contractor)." The Committee agreed that in current practice, the OPO is responsible for ensuring that each tissue or donor organ container that travels outside the recovery facility is labeled

appropriately, although the policy states it is a shared responsibility. The Committee agreed that this issue is a serious patient safety matter and will require an education plan.

One member recalled that several years ago, the OPO Committee reviewed reported labeling events and requested that they again review any incidences that have been reported regarding labeling events of this nature. Dr. Ellison will assemble a group to determine how to move forward. There may also be some incidences reported to patient safety, so the Operations Committee should have the report on any such occurrences.

The Committee agreed that OPTN members need to report any mislabeling or labeling errors to maximize patient safety and to determine if there is a problem or issue that can be remedied. The education plan should encourage the reporting, not as a punitive action, but as an improvement measure. This reporting can be viewed as an opportunity to improve patient safety. The Committee will request information from the Operations Committee regarding labeling errors, review those data, and determine the incidence of this occurrence. These data can be compared to a time period following the implementation of the education plan to determine its effectiveness. There is currently no requirement to report these incidences, however, for those that are reported, the Committee may be able to glean some of the issues that might create a situation when the mislabeling or non-labeling occurs.

Motion: That the Committee request that the Operations Committee provide information regarding the types of organ container mislabeling issues that get reported, the frequency of reporting, and how these situations get reported.

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

The Committee reviewed the content of the new label that has been developed. The NKF Donor Family Council suggested that the label heading be changed to include the word “donated,” in order to demonstrate the gift of the organ.

Motion: Add “Donated” to the label so the heading reads, “Donated Human Organ/Tissue for Transplant.” Additionally, change “UNOS Number” to “UNOS ID,” and add a colon instead of the number sign to ensure consistency throughout the label.

The motion to edit the label as described was unanimously approved with a vote of 15-0-0.

Once the changes are made, the label will be sent for production and made available to the OPO Community.

10. Pediatric Practice Guidelines. The Pediatric Organ Transplantation Committee is forming a workgroup to review at donor management practices (e.g. Medications) and policies that may be detrimental to pediatric patients. Members who will participate are D. Clark, J. Ferreira, and D. Steinberger.
11. Pancreas Allocation Issues. The Committee discussed issues that were brought to their attention by several OPOs that expressed concern over possible violations of policy as a result of pancreata being procured and allocated without the recipient being listed. The OPOs requested clarification and direction. The issues include:
  - Several OPOs have provided a pancreas, in combination with the liver and small bowel, which has not been treated as a transplanted organ, but as a vascular conduit. In this situation, the transplant center did not list their patient on the Pancreas List as part of a

multiorgan transplant, and was requesting not to pay the SAC fee. Therefore, the OPO was allocating an organ to a patient that was not listed for it and was in violation of policy.

- The OPO sacrificed the pancreas to facilitate a multiorgan transplant when the pancreas might have been used for another patient as an isolated transplanted organ. This raises an OPO performance measure issue in that the OPO is providing an organ when the patient does not appear on a list and is missing an opportunity to provide that pancreas to a listed patient.
- The OPO is not being reimbursed for the SAC for the pancreas.

Members discussed that this situation frequently occurs in the OR when the recovering surgeon says that they need the pancreas, as they consider it part of the entire enbloc transplant. However, in the OR, at that time, it is difficult to deal with the situation. The Committee agreed that if a candidate needs a pancreas, even as part of an en bloc transplant, then they should be listed for a pancreas, no matter how the organ will be utilized. The Final Rule states that you cannot allocate an organ to someone who is not on the Waiting List.

The Committee agreed that the center should be charged the SAC for the pancreas no matter how the pancreas, or portion of the pancreas, is going to be used. When this occurred, the OPO was informed that the pancreas is not considered a transplanted organ, but is used to enhance the vascularization of the intestine, and is ultimately discarded. Members were unclear as to whether the head of the pancreas is discarded following the transplant, leaving the vascularization, or if the entire pancreas is removed and discarded. However, members agreed that the pancreas should be considered transplanted, no matter if a portion remains or if it ultimately discarded. The issue is that it is an organ being allocated to a patient that is not listed.

Additionally the OPO should be able to list the pancreas as an organ transplanted as part of their performance statistics. The Committee agreed that whether an organ is transplanted temporarily or not, it is still transplanted in a patient and should be recorded and billed as such. This information needs to be communicated to programs as this is a direct violation of policy.

Motion: That the OPO Committee communicates with the Pancreas, Liver and Intestinal, and Pediatric Organ Transplantation Committees making them aware of the Committee's opinion regarding the need to have patients listed for a pancreas transplant if only used for vascularization, or any other reason. This statement is supported by OPTN policy. Additionally, when OPOs are allocating for multi organ transplants, they need to verify that the patient is listed appropriately as needing a pancreas. If the candidate is not listed, the transplant team needs to make those arrangements so the list can be rerun and allocated properly according to OPTN policy. Patients requiring a pancreas for any reason need to be listed for a pancreas transplant. Currently there are certain criteria that must be met in order to be listed for a pancreas (i.e. diabetes, pancreatic deficiency). There may be a need for a policy change to include criteria for listing patients with multi-organ transplants in order to cover these instances. It is up to the organ specific committees to decide how or under what criteria the transplant candidate can be listed for the organ.

The motion was unanimously approved by a vote of 15-0-0.

In response to the Pancreas Committee question regarding how the use of the pancreas will be charged, the Committee agreed that it is considered a transplanted organ and will be billed accordingly as with all transplanted organs.

Another issue was discussed regarding a situation that occurred when an OPO had placed the liver and kidney with one center for a multiorgan transplant, and a kidney and pancreas placed locally at another center for a multiorgan transplant. When going to the OR, the HLA results were received, and a zero mismatch was identified. The OPO was told that one of the patients was not going to receive the multiorgan transplant.

The Committee will raise the question with the appropriate Committees regarding how to determine which transplant takes priority. The Committee discussed the need for a hierarchy of multiorgan transplants to determine which kidney will be placed with the zero mismatch candidate, and which multiorgan transplant will not occur. In the above situation, the kidney-pancreas transplant was not done as the kidney was allocated to the zero mismatch patient. The OPO attempted to place the 26 year old isolated pancreas unsuccessfully and the pancreas was discarded. In this case, an organ that the family wanted to donate was wasted, and the OPO's yield for this donor decreased from four to three. There has been a long standing message that multiorgan transplants are encouraged and take some precedence over individual organ transplants. However, there is no policy language that supports that message and practice, and this broadly held concept needs to be clarified. The question may be whether or not the OPO places each individual organ first and then allocates for multiorgan transplants. However, there needs to be a determination as to when the multiorgan transplant takes precedence over the placement of individual organs.

When patients are in the hospital and the organs have been allocated, at what point does the zero mismatch allocation take precedent? Jeff Orłowski, Vice Chair, is sending a letter to each of the involved committees to address the issues. Additionally, one member was advised that they only needed to send one zero mismatch kidney out (if multiple mismatches occurred) and the second kidney could be allocated as a multiorgan. Members agree that the policy needs to be clarified.

Motion: The Committee should draft a memo to the UNOS Department of Evaluation and Quality and request that they look at the policy to determine if there is a problem with the language. The Committee will also seek guidance as to how to address this situation.

The Committee will identify all of the multi organ transplant policies for review and determine a path forward. In November, 2006, there was a memo regarding allocation of kidneys when zero mismatch exists, that clarified this situation.

12. Data Management Subcommittee. The Subcommittee of the Policy Oversight Committee has had two conference calls to consider data requests. The group also considered public requests for data.
13. DonorNet<sup>®</sup> Task Force. There have been no serious issues with DonorNet<sup>®</sup> requiring the convening of this Task Force.
14. Goal – Maximize Organ Availability by Developing Performance Metrics. Developing OPO performance metrics is a goal for the Committee as set forth by the OPTN/UNOS President. Current OPO metrics, such as organs transplanted per donor and conversion rates, have been established by CMS. The Committee recognizes that not all donors are the same and not all DSAs are the same, as demonstrated by varying donor demographics. An example of this difference includes the ECD donor; which was created based on a kidney model and may not be as relevant to a liver donor. The SCD may have wide variation as this donor can be the young, healthy, motor vehicle accident victim with no social or medical history, or could be an older individual with a current, strong social history.

It was recommended that the Committee review and revise these definitions to ensure more similarity between categories of donors. The Committee suggested a retrospective review of data that can then be applied prospectively to determine a donor scoring index. This index might create expected transplantation outcomes based on donor specific demographics, account for the medical and social complexities that differentiate donors, level the playing field, and provide OPOs with metrics to equally measure performance on donor yield and clearly identify where the community is succeeding and where it needs improvement.

The SRTR is developing a Donor Profile Index that currently focuses on liver donors, but may ultimately apply to all organ donors. This index should be formalized and applied to all OPOs. OPOs know how to determine their conversion rate, but struggle to determine the potential organ yield per donor type. An example includes the variation in DCD donors of varying ages (i.e. 22 and 58) that are still treated the same in performance measures. Informally, some OPOs have already created new categories of donors such as SCD-F (Standard Criteria Donors with factors such as positive serologies or CDC high risk). These OPOs are tracking these patients internally for their own research and evaluation.

The Committee can bring people together to gain consensus on what would be an expected outcome per donor. The Committee discussed the possibility of investigating expected outcome per donor in aggregate as opposed to investigating by donor organ, to possibly look at commonalities for positive donor outcomes. If OPOs identified those variables that are associated with donors that yield four or more organs, specific predictors might be identified as to why a given type of donor might have yielded more organs. A review might start with donor demographics in order to form a foundation and extend to factors involved in donor management, as well as mechanism of injury that may preclude organs from being transplanted. There will always be issues that are uncontrollable affecting the donor yield (i.e. serologies) that will need to be taken into account. To account for changing issues during the donation process, there might be an admission, time of consent, and terminal score with a risk adjustment to identify the changing donor clinical picture. Distance may also be a significant factor in the donor outcome. It was suggested that the Committee review SRTR historical data and identify those data that may be helpful for this pursuit.

The Policy Oversight Committee is currently reviewing program goals that will be used by the MPSC to drive the study of those centers that do not meet goals. This project will help the OPO community identify those areas where the OPO is meeting goals and where improvement is needed. From a transplant center perspective, a donor profile index will help to make decisions regarding an organ offer. Each donor system might identify those donor factors that are important to each organ transplant. The Committee will try to identify factors that result in high yield and look at those variables that are changeable.

To move forward, Mr. Alexander will create a preamble as to how to start this process and draft a document that states the Committee's intent and goal. An OPO Performance Metrics Workgroup will review those factors that affect yield and study which factors are most predictive of whether or not a patient becomes a donor. The workgroup will identify common factors among donors that produce a higher yield. The ultimate goal is to maximize the utilization of organs. It was suggested that the workgroup should start with the identification of the donors that provide the maximum number of organs, and identify what factors are common to those high yield donors. The SRTR will look at risk adjustment models, post transplant survival, and the donor factors that are listed. On the USTransplant.org web site, there are risk adjustment measures for graft and

patient outcomes with donor factors listed. There are two very distinct measures to consider: 1) yield and the factors that affect yield, and 2) the factors that affect outcomes.

The workgroup comprises C. Alexander, Chair, J. Orlowski, C. Hughes, D. Clark, J. Rosendale, V. McBride, and G. Levine, as well as members of the MPSC. This workgroup will determine how to move forward, make recommendations for the data that are needed, get baseline data information, and study potential factors that would improve yield and outcomes.

15. DCD – As part of the goals for this year, the Committee will partner with AOPO and review work that has been completed to identify the prediction of time of death for the DCD donor. The Committee discussed the need for a consensus document to be produced. However, this task will be difficult until definitions within the DCD process (e.g. agonal phase) are agreed upon. A subcommittee was formed comprising L. Dils, M. Rogers and C. Hughes.
16. Review of Policies – The Committee discussed the need to review policies and determine if the policies are congruent with current practice, and to identify any policy that may place the OPO at risk of violation. The Committee will ask the UNOS Department of Evaluation and Quality to identify specific issues or violations that might surface frequently in order to help direct the subcommittee to specific policies that might be outdated, confusing, conflict with other policies, or may be non-existent. C. Alexander, L. Brigham and K. Holloway will serve on the subcommittee and report at the next All Committee Conference Call. The Committee reviewed policies approximately 5 years ago and will review this work that has already been completed. John Rosendale will look for the report of the Committee's review of policies.

Following the October 25, 2007, meeting, the OPO Committee asked the Department of Evaluation and Quality to compile a list of the most common OPO violations that the Department identifies. The Committee agreed that reviewing the violations may help to identify those policies that may not be congruent with current OPO practice. The following list of violations was provided and each violation was discussed by conference call by the subcommittee as noted.

*A. Rigid Containers for Packaging Pancreata. There are exceptions for liver and lungs but not pancreata. Some OPOs feel these types of containers are not necessary.*

The Subcommittee discussed the possible reasons for the exceptions for liver and lungs and speculated that the exceptions are due to size of organs. The DEQ stated that surgeons, in response to policy violations, indicated that they do not need rigid containers for pancreata when recovered.

Motion: The subcommittee will ask the Pancreas Committee to respond regarding their preference for containers, as well as the reason as to whether rigid containers should be required for pancreata.

*B. Policy 2.7.1 – The liver and pancreas are expected to be procured from donors if each organ is transplantable. If both the liver and pancreas are not procured, the surgeon(s) should document in writing on the donor form the reasons for failing to procure both organs. Currently, transplant coordinators and not surgeons are documenting these instances.*

The subcommittee agreed that the responsibility to document the reasons for non-procurement of the liver and pancreas currently falls to the OPO staff that is coordinating the procurement. As such, the policy language, which states it is the surgeon's responsibility, may be problematic. The subcommittee will ask the Committee to consider the following proposal.

Motion: That Policy 2.7.1 (Multiple Abdominal Organ Procurement) be amended as below to reflect that the responsibility to document the non-procurement of the liver or pancreas rests with the OPO.

**Policy 2.7.1. Multiple Abdominal Organ Procurement.** It is expected that both liver and pancreas should be procured from a donor if each organ is transplantable and/or recipients are identified for each organ. If both the liver and pancreas are not procured, the ~~surgeon(s)~~OPO should document in writing on the donor form the specific reason(s) for failure to procure both organs.

C. *Chest X-ray is required for all donors. However, the AOPO forms have the Chest X-ray section under thoracic organs. For liver or kidney only donors, chest x-rays are sometimes not documented.*

The Subcommittee agreed that a chest x-ray is an invaluable screening tool that is necessary in the evaluation and possible placement of organs for all organ donors. As such, the subcommittee wants to restate that the chest x-ray is required and reinforce its importance to the community. The subcommittee discussed the location to document the chest x-ray and agreed that with current electronic documentation, the information should be readily available no matter where the information is located in the electronic chart.

Motion: That the Committee generate a document stating that a chest x-ray is required on all organ donors and that this document be sent, in collaboration with AOPO, to all OPOs, and discuss with UNOS the current process for documenting and viewing CXR results in DonorNet®.

D. *OPOs do not perform urinalyses for liver-only donors.*

The subcommittee agreed that a urinalysis is a test that provides a wealth of information and should always be performed on every organ donor, no matter which organs are going to be recovered. The requirement for a urinalysis is currently stated in current policy, but it is listed in a section that may make it less obvious as a minimum requirement for all donor charts, regardless of organs recovered. The subcommittee will ask the Committee to consider the following proposal.

Motion: That policy 2.2.8.1 be amended to reflect the inclusion of a urinalysis in the list of mandatory tests for all potential donors.

**Policy 2.2.8. Performing pertinent tests including:**

**2.2.8.1 For all Potential Donors:**

- CBC;
- Electrolytes;
- Hepatitis screen; including HBsAg, HBcAb, and Anti-HCV;
- VDRL or RPR;
- Anti-HTLV I/II;
- Anti-CMV;
- EBV antibody screening;
- Final urinalysis within 24 hours of cross clamp;

- Blood and urine cultures if the donor is hospitalized 72 hours or longer; and
- Chest x-ray

The subcommittee also agreed that the entire Policy 2.0 [Minimum Procurement Standards for an Organ Procurement Organization (OPO)] needs an in depth review and possible rewriting, and will ask the Committee for consideration and recommendations.

*E. Out of sequence allocations – OPOs initiating out of sequence allocations prematurely in cases where organ viability is not compromised.*

The subcommittee discussed the urgency in placing organs and that frequently it is the OPO's discretion to offer organs to aggressive centers in an expedited manner. The subcommittee asked when and how the Membership and Professional Standards Committee determines how and why organs are compromised and will draft a question to the MPSC to pose that question.

Members of the subcommittee agreed that frequently, the OPO Medical Director or Administrator-on-Call instructs the OPO staff to go to the OR as quickly as possible and to find someone who will accept the organ offer due to donor related instabilities. As such, the subcommittee will ask the Committee to consider a policy that would require every OPO to have an "expedited placement" policy and to make that policy available for OPTN review.

Motion: That the Committee consider developing a policy that would require every OPO to have an "expedited placement" policy and make the policy available for OPTN review at the time of site audits.

*F. OPOs do not provide the minimum amount of HLA typing materials outlined in OPTN Policy 2.5.5*

The subcommittee considered policy 2.5.5 regarding requirements for tissue typing material required to generate match runs for local or regional placement of all organs.

Motion: That the Committee ask the Histocompatibility Committee if these parameters are appropriate and, if not, the Committee may consider a policy change. The Committee should consider issues regarding OPO pre-recovery and identify a "reasonable" amount of tissue required.

*G. Directed Donations – OPOs must ensure that the recipients of the directed donations are waitlisted if they do not appear on the match run and that the proper donor/recipient compatibility verification occurs. UNOS is currently working on policy modifications that will require certain safety checks.*

The Committee should consider reminding the OPO Community that all directed donations need to appear on the match run. If the recipient is not listed, they will not appear on the match. The subcommittee agreed that this is a patient safety issue.

*H. Double Kidney Allocations using the ECD match run. The OPTN/UNOS Kidney Transplantation Committee indicated that current policy needed to be revised so that the ECD match run could be used for double kidney allocations. UNOS is currently in the process of identifying the programming needs and other potential issues associated with this change.*

The subcommittee determined that this issue is being considered by the Kidney Committee and will wait for possible policy revisions.

- I. OPOs allocate the liver using the intestine match run and do not follow the specific requirements outlined in OPTN Policy 3.11.4.*

Policy 3.11.4 (Combined Intestine-Liver Organ Candidates), states that “For candidates awaiting a combined intestine-liver transplant, the liver *may* be allocated by the local OPO to a local, regional or national intestine recipient based upon priority for receipt of the intestine using the intestine Waiting List unless there is a Status IA or 1B liver candidate locally, regionally or nationally.”

The subcommittee agreed that the language “may be allocated,” does not provide clear guidance and may put the OPO at risk as they are determining how the liver is allocated. This policy allows that the liver be offered from the intestine list. This might effectively allow the multivisceral organ allocation to take priority.

Motion: That the Committee ask the Liver and Intestinal Organ Transplantation Committee (LITC) to review Policy 3.11.4 (Combined Intestine –Liver Organ Candidates) and provide direction through firm policy language.

- J. Allocation of the segmental liver*

The subcommittee discussed Policy 3.6.11 (Allocation of Livers for Segmental Transplantation) and agreed that the policy allows an OPO to accept a liver, segment it and determine the allocation.

Motion: The Subcommittee would like input from the LITC to identify better wording of the policy.

- K. Accurate data entry in DonorNet<sup>®</sup>. If information is entered incorrectly, it could affect the match run sequence/outcome.*

The need for accurate data input was discussed and the subcommittee agreed that OPOs should have quality assurance programs in place. It was also suggested that UNOS should be strict about data entered into DonorNet<sup>®</sup> to ensure accuracy and upholding minimal standards. There needs to be a way to quantify and check verification. In the past, good quality has been checked following submission; however, OPOs need to check for accuracy of data up front when entered.

The subcommittee would like to ensure that OPOs and centers have a quality assessment programs in order to ensure quality throughout the industry.

Motion: The subcommittee will discuss this with AOPO and UNOS staff to determine what quality assessment programs might assist the community.

- L. OPOs with high payback debts are not displaying due diligence in satisfying their payback debt.*

The subcommittee discussed the problem with rising payback debts and recognized that there are some disincentives to lowering the payback debt. The subcommittee asked if paybacks are really going to no longer be required once policy changes are made as members have heard that the Kidney Transplantation Committee has sent that message.

Motion: The Committee should request clarification from the Kidney Transplantation Committee and work with AOPO to provide information to the community.

*M. OPOs are currently concerned about policy 2.2.8.1 regarding the use of “screening” versus diagnostic testing for potential organ donor candidates.*

It was discussed that the DTAG is currently evaluating this dilemma, and is expected to set forth a recommendation shortly. This topic is also being discussed in a workgroup that has been established by the Committee.

17. Research reporting codes for Deceased Donor Registration (DDR) forms and discrepancies as to how to report organs for research. Codes that are currently on the DDR form are outdated. A subcommittee will review those research codes, identify codes for those organs sent for research and make appropriate recommendations for change. Consistency is necessary across OPOs. The group will look at organ disposition codes. The subcommittee comprises L. Brigham, J. Rosendale, K Holloway, D. Clark and S. Taranto.

*The subcommittee met by conference call on December 10, 2007.*

K.Holloway reported that he is a member of an AOPO workgroup that is currently reviewing the measurement of organs for research. UNOS currently collects information on organs sent for research with the use of two distinct organ disposition codes:

1. Those organs recovered for the purpose of transplant, but not transplanted and sent for research.
2. Those organs recovered for the specific purpose of being sent for research (not included in the counts of organs recovered for transplant).

There is currently a lack of a solid definition for research as there is a difference between organs for “research” and organs for “education and training,” as the whole body is donated for education. This difference should be explicit in a definition. Therefore, the subcommittee recommends that a definition of research be developed.

The existing codes may be applicable; however they should be evaluated to determine if they would be applicable to a new definition. There was also some discussion regarding the use of tissue for therapy, such as the pancreas for islet cells or heart valves that are not transplanted but sent for research. There may be a need to be specific about the reporting of multivisceral organ recovery as it may be viewed as one organ (en bloc) or many. The split liver concept was also discussed regarding the potential to have one portion be used for transplantation and one part be used for research and the need to be able to capture that in coding. Mr. Holloway will review the CMS codes and report to the Committee at the January 30 conference call.

18. DonorNet® Screening Issues. The Thoracic Organ Transplantation Committee has requested the OPO Committee’s participation in a joint subcommittee that will explore DonorNet®’s unintended consequence of enabling organ offers that are professionally considered medically unsuitable for transplantation; and, recommend to the Operations Committee the Subcommittee’s suggestions for eliminating this unintended consequence. The objectives are to:

1. Discuss the impact on professional practice when organs that are medically unsuitable for transplantation are offered;

2. Discuss the impact on transplantation when organs that are medically unsuitable for transplantation are offered;
3. Discuss alternatives for eliminating offers of organs that are medically unsuitable for transplant; and
4. Develop recommendations for the Operations Committee to consider as it continues to improve DonorNet<sup>®</sup>.

Members of the Committee that will serve on this subcommittee are M. Rogers, J. Ferreir, and D. Savaria.

19. Future Meeting Dates. The next meeting will be held on Wednesday, January 30, 2008, from 3:00 pm to 5:00 pm Eastern Time through Microsoft Live Meeting.

The following Committee meeting will be planned for June 26, 2008 in Chicago.

**OPTN/UNOS OPO Committee  
October 25, 2007 Meeting  
Chicago, IL**

Committee Members Attending

Charles Alexander, RN, MSN	Chair
Jeffrey P. Orlowski, MS, CPTC	Vice Chair and Region 9
Posy Durning, PA, CPTC	Region 1
Lori Brigham	Region 2
Christopher Hughes	Region 3
PJ Geraghty, BS, CPTC	Region 5
Diana L. Clark	Region 6
Beth Plahn, RN, BA, MHA	Region 7
Martin D. Jendrisak, MD	Region 8
Ladora A. Dils, RN, CPTC	Region 10
Satheesh Nair MD	Region 11
Joseph Ferreira	At Large
G. Kent Holloway	At Large
Marlon Levy, MD	At Large
Maureen Popke, RN, CCRN	At Large
Meg Rogers	At Large
Dina Steinberger, PA-C	At Large
Virginia McBride, HRSA	Ex-Officio
Deborah Savaria, RN, CPTC	Ex-Officio

Committee Members Unable to Attend

Danielle Cornell	At Large
Samual Holtzman	Region 4

UNOS Staff Attending

Franki Chabalewski RN, MS	Committee Liaison
John Rosendale, MS	Research Liaison
Stacey Burson	Committee Support Staff, Business Analyst (IT)

SRTR Staff Attending

Greg Levine PhD  
Charlotte Arrington PhD  
Jack Kalbfleisch PhD