OPTN/UNOS Operations and Safety Committee
Report to the Board of Directors
June 21-22, 2010
Richmond, VA

SUMMARY

I. Action Items for Board Consideration:

- None

II. Other Significant Items:

- The Committee considered its renewed focus on patient safety and the systems thinking approach to the transplant process in relation to adverse effects, near misses, and failure to take a proactive approach to addressing issues.

- The Committee reviewed trends in reporting to the Patient Safety System[sm]. (Item 1, Page 3)

- The Committee reviewed the UNOS Organ Center transportation reports identifying instances of near misses and failures. (Item 6, Page 7)

- The Committee reviewed the Vessel Policy Work Group's proposed modifications to Policy 5.0 regarding vessel recovery, storage, and transplant. (Item 7, Page 8)

- The Committee reviewed proposed modifications to current policies regarding ABO subtyping for deceased and living donors. Modifications are intended to ensure accurate subtyping determination, and verification. (Item 9, Page 10)

- The Committee considered applicable Public Comment Proposals dated March 19, 2010.

- The Committee considered the work of the Tiered Acceptance Work Group and the change in the group's focus to donor and candidate screening and education. (Item 11, Page 13)

This page is intentionally left blank.

OPTN/UNOS Operations and Safety Committee
Report to the Board of Directors
June 21-22, 2010
Richmond, VA

Richard D. Hasz, Jr., M.F.S – Chair
Phillip C. Camp, Jr., M.D. – Vice-Chair

This report represents the OPTN/UNOS Operations and Safety Committee (O & S) on discussions and deliberations during its meeting held in Chicago, Illinois on April 15, 2010.

1. Flow of Information – The Committee reviewed its new focus on patient safety and its task of reviewing events reported to the Organ Procurement and Transplantation Network (OPTN) by using a high level systems thinking approach in an effort to apply systems thinking to the transplant progress. By reviewing reported events from this perspective, the Committee can address the issues, and ones similar to it, that may result in error, failure or safety risk in various aspects of transplantation. The Committee reviewed all portals within UNOS in which safety events are reported and how these events are entered into the Patient Safety System[sm].

2. Patient Safety Reports Trends and Patterns – UNOS staff reviewed with the Committee patient safety events reported to the OPTN during the timeframe of August 15, 2008 and August 17, 2009 and were considered by the Membership and Professional Standards Committee (MPSC) in 2009 (**Exhibit A**). This data was provided to give the Committee an idea of the number and types of cases that are currently being reported into the Patient Safety System[sm]. The majority of cases are being reported through the electronic reporting system, Patient Safety System[sm] within UNet[sm], which accounted for 28 cases reported directly by a member in 2009. Other issues of patient safety events were identified through allocation analysis, member complaints, patient complaints, or member self referrals. Data was shared with the Committee that indicated the severity of action taken by the MPSC with the member for the events reported in 2009. Many of the cases reviewed by the MPSC resulted in actions taken with the member such as a notice of uncontested violation or the case was closed with no action taken. Cases closed with no action represented over 80 percent of the 2009 cases reviewed by the MPSC. The data was also reviewed by type of event showing areas in which the Committee could work to make an impact on patient safety. Fifty-five percent of the reported events were packaging and labeling complaints or errors reported, 19 percent were related to inaccurate serological reporting or potential disease transmission, 10 percent were related to data entry errors, and 16 percent were other such as communication errors and surgical errors. Some of the events fell into multiple categories.

   The Committee discussed that the data reviewed does not appear to accurately reflect the number of events that are happening in the community. It was considered by the Committee that members are unwilling to report such cases because all events are reviewed by the MPSC suggesting that there is under reporting of safety events by members. It was noted that all events reported are screened for identification of policy violations and if violations are not found then those events do not go to the MPSC for review. The Chair commented that as work is done by this Committee to heighten awareness of patient safety within the transplantation system and attempt to change the thinking of the punitive nature of reporting, referrals from members and other committees will increase. The Committee discussed that it needs to distribute information on opportunities for improvement to the community as there is no formal portal for addressing process or safety issues

through the Association of Organ Procurement Organizations (AOPO) or other societies. There is a Quality Improvement Council in which the transplant community can post questions and get answers. The Committee discussed that the Patient Safety System^{sm} could become a portal in which feedback is obtained that would help the member address safety and process concerns that are identified within their institution. To encourage reporting, it is important to get information to those that are completing the initial report into the system, not just to the physicians, surgeon and administrators, but to the transplant and data coordinators as well. There appears to be confusion in the community about the outcome of reporting to the OPTN and education on what and how to report needs to take place. Throughout the process, data should be collected, filtered, and analyzed to assess for trends and patterns in reporting and this should be shared with the community.

It was agreed by the Committee that a work group should be developed to address safety and process related issues related to packaging and labeling of organs and vessels which accounted for 55 percent of events reviewed by the MPSC in 2009.

3. Patient Safety Planning Development Group (PSPDG) – The Committee was provided information regarding the current status of the PSPDG's development of the process by which safety events reported to the OPTN will be reviewed by the Committee. Humans are cognitively wired to take short cuts and make mistakes. It doesn't matter how smart, how careful or conscientious, how well rested a person is, as a human handling data, mistakes will be made and the way to solve that issue is to build robust systems that make it hard to do wrong and easy to do right. People are inspired to report potential safety issues that are identified before someone is harmed and there is a celebration that a "good catch" was made. When rules are broken many automatically think the practitioner should be punished but cases in which confirmation bias comes into play, we learn that our brains do not work the way we thought they did. When it is known that something could be deadly then rules must be created. There is more publicity when high harm events occur. These should be handled in the same way as the "good catch" or near miss when investigating. A safety culture is a product of individual and group values that commit to the prevention of harm. People have to feel free to confess errors. To do that there must be a just culture on how the organization handles blame and punishment. There must be a commitment to learning from mistakes and near misses to correct hazards and danger by disseminating the information learned and the culture must be one that adapts to changing demands and successfully manages the unexpected.

   The process being development with the PSPDG and UNOS leadership will allow patient safety staff to adequately collect information regarding reported events in the beginning of the report process, will assist staff by providing tools to conduct a thorough investigation of the event, provide information and tools to members on how to conduct a root cause analysis (RCA), and allow for data collection to track trends and patterns in reporting by using a high level systems thinking approach. The PSPDG has become familiar with the reporting system and portals, gained understanding of how the events are currently investigated, is beginning to assess for efficiencies within the system, and is analyzing data from reported cases as shared with the Committee. Increased reporting will only happen when people see that good things are coming from their efforts in reporting. It has been identified that there needs to be two different ways to approach the reported events whether high harm or not. Education begins with providing members with an understanding of what type of instances to report and disseminating lessons learned with the community.

   The Committee discussed that there is a willingness to report high harm cases but not near misses that happen every day. There are multiple reporting mechanisms within UNOS and the process

becomes more complex as information that may be usable in multiple areas or by different committees may not be appreciated and is lost. The Committee will assess how it really needs to look at the data and begin to educate members on what to report and how to use the system efficiently. Developing a safety culture will take time but in the end will be less expensive to the transplant community and will streamline processes for improvements in patient safety.

4. Ad Hoc Disease Transmission Advisory Committee (DTAC) Update – The Committee was provided a presentation regarding DTAC's current activities and disease transmission case reporting trends. The DTAC completed its semi-annual review of potential disease transmission events reported to the Patient Safety System[sm]. Eighty cases were reviewed and classified based upon the probability of donor-derived disease transmission. DTAC has removed the expected or unexpected category for future case consideration. Cases will now be grouped into additional categories to focus on process improvements and determine which cases should be considered by the Operations and Safety Committee. Examples of these process categories include: Communication, repeat testing, and false positive or negative test results. A new classification of "Unlikely" as created and defined as "inadequate testing to definitively exclude transmission and no documented disease, but clinical circumstances make diagnosis unlikely."

   A brief update was given related to ongoing efforts to analyze trends and patterns noted in bacterial, tuberculosis, fungal and viral cases reported to the Patient Safety System[sm] as a potential disease transmission. There were 16 reports of potential transmission, 16 confirmed transmissions of a recipient or multiple recipients, and three contributable deaths that were identified in cases reviewed in 2009. Some infections, such as pseudomonas, were associated with a high proportion of recipients being infected and had significant mortality. DTAC plans to develop manuscripts and/or guidance documents for each of these areas in an effort to educate the transplant community and help prevent potential transmissions based upon what has been learned from these case reviews. Feedback from the bacterial review will be used to respond to a memo from the MPSC regarding possible development of a policy or guidance document regarding time periods for assessing for previous positive cultures for donors that were admitted to the hospital prior to donor evaluation.

   Hepatitis C was the top viral infection reported in 2009. Many of the reported viral cases included transmissions as in the case in which a Hepatitis C positive vessel was used in a Hepatitis C negative recipient as a result of the center not reviewing serology information of the donor and recipient prior to transplant. There were also several reported transmissions of West Nile Virus (WNV), Parvo virus B19, and H1N1 virus. There were fewer reports of false positive nucleic acid testing (NAT) testing results in 2009. Ten cases of potential transmission of Tuberculosis were reported with seven confirmed transmissions. There was one reported case of Balamuthia transmission which was widely publicized in the media. A higher number of fungal potential transmissions were reported in 2009. These cases are associated with a high mortality rate. Since the time the reporting system has been in affect there have been 338 reports, 141 confirmed transmissions, and 34 attributable recipient deaths.

   DTAC has begun to go beyond counting cases. Working groups have been formed to identify what could be learned from the trends and case reviews. The Bacterial Working Group reports that about one third of potential bacterial transmissions reported result in transmission. This is probably under-estimation due to under-recognition of transmission and under-reporting. Bacterial transmissions are a common event but because many recipients receive prophylactic antibiotics post transplant and clinical disease isn't recognized. Many of the transmissions that do occur have occurred when multi-resistant bacteria are transmitted and there is significant morbidity. Areas identified by DTAC for process improvement are: OPO access to all available

donor data, communication about pathogens, lack of follow up of cultures to assess impact of antibacterial therapy, and less than desirable choices in donors as in those with open soiled abdomens. DTAC will address these issues by educating through a newsletter, proposed policy changes that are currently out for public comment, and to requiring that all OPOs and transplant centers to identify a patient safety contact available 24 hours a day, seven days a week and responsible for sharing information with a clinical decision maker.

The Tuberculosis Working Group reports that there are no approved donor screening methods for Tuberculosis, limited follow up of outstanding donor cultures as they take six to eight weeks to grow the bacteria, poor linkage of specimens with the donor, and poor communication of donor suspicious findings during the procurement process. DTAC has addressed these issues by highlighting these concerns in the newsletter, has proposed policy changes are currently out for public comment, and is preparing a document in the near future that will highlight the data and concerns.

The Fungal Working Group identified that many fungal transmissions are associated with exceptionally high mortality. In many cases reviewed, donor screening could have identified infected donors that could be safely used with appropriate prophylaxis in recipients of these organs. The group identified the following issues for potential process improvement: lack of awareness of donor disease during donor assessment, delayed recognition of donor transmission, delayed or atypical clinical symptoms of fungal infections, and absence of serological response in infected recipients. DTAC plans to address these issues by highlighting the data and in a guidance document. Proposed policy changes are currently out for public comment that will require OPOs to establish a procedure for obtaining post-recovery donor screening or diagnostic test results and share this information with transplant centers and requiring all OPOs and transplant centers to identify a patient safety contact available 24 hours a day, seven days a week and responsible for sharing information with a clinical decision maker.

In 2009, DTAC reports that there were 43 malignancy cases reported to the Patient Safety System^{sm}. The majority of the cases are renal cell carcinomas. There were 15 confirmed transmissions and one confirmed death related to lung cancer transmission. The Malignancy Subcommittee has identified the following issues for potential process improvement: renal cell carcinomas (47 percent of all malignancy reports) are very frequently recognized peri-donation, significant variability in utilization of organs associated with malignancy, variability in management of patients when malignancies are recognized during or post procurement, targeted communication about suspicious findings in the donor at procurement, autopsy results are frequently available very late post-transplant, limited follow-up data on cases reported to the Patient Safety System^{sm}, variability in who is reviewing a frozen section or "first look" biopsies, and frequently a trainee's interpretation may be reversed at a later time by an attending physician. The Subcommittee is addressing these issues by developing a comprehensive risk stratification system, providing guidance on care based on donor risk deferring all clinical decisions to transplant centers, policy changes may be proposed to allow variable follow-up of cases and change in how malignancies are reported on data forms. The DTAC's Malignancy Subcommittee has a draft manuscript meant to provide guidance to the transplant community by categorizing relative tumor-independent transmission risk when considering a donor. The Subcommittee populated risk categories with individual tumors according to the data available. DTAC voted unanimously to present the manuscript to the Board of Directors as an informational item and pursue publication in a transplant journal.

5. Patient Safety Referrals for Review – The Chair discussed two referral memos from other committees related to incidences that resulted in a report to the Patient Safety System^{sm}. One

such referral was related to a heart/lung allocation near miss in which the Center received an offer for a heart and the patient needed a heart/lung block. During the process of confirmation by the transplant center the OPO had placed the lungs with another center not realizing that the heart center's recipient also needed the lungs with the heart offer. It was discussed early in the process of DonorNet® that there could be silos in the allocation in that when multiple organs are offered, attention has to be paid to a comment field that indicates if the candidate for which the organ is offered needs an additional organ. DonorNet® does not communicate across match runs to identify multi-organ candidates, but the referral was to suggest a DonorNet® system fix to identify multi-organ candidates more prominently for allocation of multiple organs. A root cause analysis was performed by the OPO and safety steps were put in place to prevent this from occurring again. The Committee considered what opportunities were available to get this information out to the community to make them aware of similar cases. Members discussed that some OPOs make arrangements with the area transplant centers they serve based on the type of organ candidates needed in that area. For instance, allocating from the heart match run all status 1A candidates first then allocate from the liver match all status 1A candidates, then go back to allocate from the heart list for status 1Bs that also need a liver. There are also issues of heart allocation in nautical miles and liver allocation is different. A policy in this area would not work in all regions due to geographic location. A member suggested that a reminder could be added to an allocation checklist and the multiple scenarios that may occur. It was also suggested that there could be further education on how to review a match run and all information available at the time of allocation and reminders sent to OPOs when centers have multi-organ candidates waiting. The Committee considered how to collect common or best practices regarding how OPOs were handling the problem and disseminate to the community.

The second referral reviewed was from the MPSC requesting the Committee to address whether it is necessary to develop requirements for OPO and transplant center communications when an organ is returned to an OPO. This request was based on a case in which a center accepted an organ, partially implanted the organ by beginning the anastomosis, then removed and repackaged the organ sending it back the Host OPO for re-allocation. The center had only informed the OPO that they were not able to use the organ due to recipient issues and that the organ was being sent to the blood bank for pick up. Once the organ was retrieved it was re-allocated to a backup center. The Operations and Safety Committee discussed that policy is currently being proposed in public comment by the OPO committee to address these types of instances that this issue will be discussed with the public comment proposal.

6. Organ Center Transportation Report – The Committee reviewed the Organ Center (OC) transportation report which revealed transportation failures during the months of August 2009 through January 2010 (**Exhibit B**). This report reviews the transportation issues related to any national or regional organs allocated through the OC. Failure was defined in this report as an organ that does not make it to its intended destination transplant center or arrive at the intended transplant center but had a significant delay which rendered the organ to be unacceptable for transplant. Some of the transportation failures did not result in a discard but were able to be salvaged and transplanted into a different candidate but most organs were discarded. A near miss was defined as a transportation failure that didn't result in a failure but a delay of two or more hours from the original estimated time of arrival. The failures and near misses were further broken down into four groups for the Committee's review: airline misdirected, OPO or transplant center issue, weather or mechanical delay, and courier or driver issue. Kidneys were involved in the majority of incidences followed by pancreas. For the past six months there were 20 failures for a rate of just fewer than two percent. The 20 failed shipments represented 27 organs and of those 21 were discarded. For the past six months there were 14 near misses for a rate is 1.23 percent. Over 50 percent of failure and near misses were related to airline misdirected issues.

In reviewing the last 20 months of data it appears that transportation failures have increased slightly over the past six months from 1.54 percent to 1.77 percent but this increase is not likely a statistically significant one. The near miss rate has decreased from 2.11 percent to 1.23 percent. The OC will continue to enhance this report to capture additional categories of events.

The Committee questioned whether the OC had put any practices in place to prevent failures and/or near misses as the data appears to show that near misses have decreased. It was also discussed that near misses could be down because of decreased national sharing of zero antigen mismatches and because of the elimination of paybacks. A member commented that some OPOs to not allow one courier to transport two organs at the same time. Organs should be flown direct or as close as possible to the transplant center as often as possible to decrease the incidences of near misses and failures. The Committee discussed that the report should be shared with the Organ Procurement Organization (OPO) Committee and the Living Donor Transplantation Committee for review as it will be important to consider how kidneys can most effectively be transported in situations of paired exchange. This could be an issue that the Committee can address by identifying good or best practices and sharing that information with the community.

7. Vessel Recovery, Storage, and Transplant Policy Modification Proposal – The Committee reviewed the Vessel Policy Work Group's proposed modifications to policy 5.0 regarding vessel recovery, storage, and transplant. It was discussed that there had been several disease transmissions reviewed by DTAC and the MPSC as a result of the use of deceased donor vessels that were stored and used in a secondary recipient. The Work Group was created to discuss how long these vessels should be kept once stored, how they should be labeled, and how to appropriately collect data on disposition. The group comprises representatives from the Transplant Administrator Committee (TAC), MPSC, Pediatric Transplantation Committee, DTAC, Operations and Safety Committee, as well as representatives from the Health Resources and Services Administration (HRSA) and Centers for Disease Control and Prevention (CDC).

   The Vessel Policy Work Group discussed that there are currently no policy restrictions on the storage of Hepatitis C antibody positive, Hepatitis B surface antigen positive, and Human Immunodeficiency Virus (HIV) antibody positive for subsequent transplant. The data reviewed by the Work Group indicated that there were few Hepatitis C antibody positive vessels transplanted (approximately 2.6 percent) and less than 1 percent Hepatitis B surface antigen positive transplanted during the years of 2008 and 2009 (**Exhibit C**). The Group proposed that these types of vessels should not be stored if not transplanted into the intended recipient at the time of the original transplant. It was discussed that most liver programs that procure and store vessels usually have one or more stored vessels available that are not Hepatitis C antibody positive or Hepatitis B surface antigen positive, as the data reviewed showed that only 2.6 percent of stored vessels were of this type. Positive serology vessels should not be arbitrarily assigned to another recipient, as allowed by current policy, and the work group considered this not to be an acceptable safety risk as there are usually other conduit options available other than Hepatitis C antibody positive and Hepatitis B surface antigen positive vessels.

   The data reviewed showed that in 2008 and 2009, 52 percent of vessels recovered for transplant did not have disposition reported to the OPTN as of February 5, 2010. The Work Group agreed that disposition reporting by the transplant center is not done in many cases and that there should be more stringent requirements for reporting disposition of transplanted vessels. Based on the discussion among the work group members it was agreed that there is confusion within the transplant community on how and when to report disposition of vessels. The Work Group proposed that disposition of transplanted vessels must be reported via an electronic mechanism,

preferably in UNet^{sm}, within three working days of the vessels transplant into a secondary recipient. Electronic reporting would require programming but should not hold the remaining proposal from being approved while awaiting the programming.

It was discussed that the recipient of a vessel should be informed in the same manner that the recipient of the high risk donor organ would be treated or informed. Therefore, proposed requirements for informed consent in instances in which risk high donor vessels are used for transplant into a secondary recipient were suggested. Participants on the work group discussed current packaging and labeling requirements within policy and agreed that the addition of the phrase "discard within 14 days" could be added to the label as an additional safety measure for those monitoring stored vessels.

The Committee requested that the work group consider an alternative to discarding Hepatitis C positive antibody vessels as some committee members were not in agreement with this proposed requirement. It was feared that surgeons may decline to accept Hepatitis C antibody positive donors if the vessels could not be available for subsequent reconstructions or revascularization after the initial transplant. It was discussed that some transplant centers store Hepatitis C antibody positive vessels for use in the intended recipient if reconstruction or revascularization issues arise and require a vessel use. These are often cases where no other suitable vascular reconstruction would have been possible. It was also requested that the work group consider requirements specific for labeling or containers to identify Hepatitis C positive vessels as high risk or be labeled with the intended recipient's name and the donor ID. A separate storage area for these vessels could also be considered. The Committee agreed that labels must be affixed to the specimen collection container and not just the bag holding the container.

8. Removal of Liver Candidates within 24 Hours of Transplant – The Committee reviewed updated data regarding member compliance with the 24-hour removal policies (**Exhibit D**). The concerns raised previously were that knowledgeable personnel to enter lab values at the time of removal may not be available to enter accurate data on Fridays and weekends. It has been identified that inaccurate data may be entered to comply with the policy requirement and afterward a request is sent to UNOS research staff to correct the data with provided information. The goal of the data analysis was to review compliance with removal of candidates within 24 hours of transplant particularly for liver programs and how often data is corrected at the request of the transplant center. The data shows a higher delayed removal rate on weekends and particularly if Monday is a holiday. Kidney, kidney/pancreas, and pancreas removal rates were noticeably higher than other organs. Liver did not stand out as having a higher delayed removal rate although all organs did have higher noncompliance with removal on weekends. Overall the delayed removal rate for all programs as of 2008 was 16.5 percent. If policy requirements were modified to require removal by the next business day, the number would drop to 6.9 percent overall. In 2003, fifty percent of all organs removed for transplant were delayed. In 2008 this number had decreased to 16.5 percent. Heart, lung, and liver were all under 10 percent whereas kidney, kidney/pancreas, and pancreas were still above 20 percent. As of 2009, the data shows a continued decrease in noncompliance with removal within 24 hours of transplant to the total of 10 percent. The data shows that an offer refused because the patient had already been transplanted was only about one out of every five liver match runs. The data also shows that when a transplant occurs on the weekend, the rate of lab modification request almost doubles than when a transplant occurs on a weekday.

The Committee did not feel that the data revealed a patient safety issue to be addressed at this time. It was agreed that the Committee would refrain from moving forward with a proposed

policy modification and that this data should be forwarded to the Transplant Administrator Committee (TAC) for consideration.

9. Blood Group A Sub-typing –The Committee reviewed data on ABO subtyping that was reviewed in-depth at the September 2009 meeting (**Exhibit E**). The data analysis reviewed with the Committee disclosed the number of transplants where donors were subtyped for allocation by recipient type, and identified how often subtyping of a donor takes place to estimate the incompatibility risk. The main goal of the data analysis is to quantify the number of opportunities for graft rejection if the donor subtype is incorrect and to calculate the risk or probability associated with each opportunity. The Committee reviewed data for all transplants from July 2004 to March 2009 in which the donor was subtyped as A2 or A2B, including deceased and living donors. Nine-five percent of cases within this timeframe were donors in which subtyping was indicated as being A2. The data were also reviewed by deceased versus living donors and recipient blood type. Overall the data show 316 opportunities for subtyping errors during the timeframe of the data review. This is an average of up to 60 transplants per year and this trend has increased each year. The probability of error rate was estimated at approximately 3.5 percent for each subtyping event. If taken into account that there were 100 transplants per year with 3.5 percent error for subtyping there would potentially be three to four events of subtyping errors reported each year. When independent double typing was performed the error rate fell to 0.032 percent resulting in an estimate of one reported event in 30 years. If a policy were proposed to require independent double subtyping it would decrease errors therefore decreasing events of hyperacute rejection and missed opportunities for transplant of blood type O and B candidates with these donors. It is important to realize that there are variable interpretations of independent testing and this would need to be defined by the Committee.

   After the brief data review, the Committee reviewed the internal work group's suggested changes to policies affected by requirements for second verification subtype testing of blood group A deceased and living donors. After its review, the Committee recommended that a multi-committee work group, along with experts in the field of blood typing, be formed to address issues surrounding timing and logistics of ABO subtyping. The Committee stressed that the intent of the proposal was always to require that in the event two separate typing instances cannot be obtained or the subtype cannot be verified or validated, the blood type must be recorded as blood group A as a patient safety precaution. The Committee further recommended that UNet^{sm} and DonorNet® support the function of double verification of ABO typing and subtyping and verification, but this effort could be undertaken at a later time as requiring two subtypings for verification would address the major concerns for patient safety.

10. Review of Policies and Bylaws Issued for Public Comment – The Committee considered current proposed policies, which were included in the Public Comment document dated March 19, 2010. The Operations and Safety Committee's opinion is shown below for the selected proposals the Committee considered within its purview:

    - Liver and Intestinal Organ Transplantation Committee – Proposed Ohio Alternative Local Unit (ALU). Three Donation Service Areas (LifeBanc, Life Connection of Ohio and LifeCenter Organ Donor Network) are requesting a single, combined new Alternative Local Unit in the State of Ohio. There will be a single waiting list within the ALU for liver allocation.

      The Committee chose not to vote on this proposal, but requests that any specific safety issues identified through public comment be discussed with the Committee for their consideration.

- Liver and Intestinal Organ Transplantation Committee – Proposed OneLegacy Split Liver Alternative Allocation System. OneLegacy and the five liver transplant programs in its donation service area (DSA) are proposing a variance, or alternative allocation system (AAS), to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). This AAS would permit the institution to accept a liver for an acceptable candidate at their institution, split that liver and transplant one lobe into that candidate (known as the index patient) and then transplant the other lobe into any other medically suitable patient listed at the same institution.

  The Committee commented that the policy should be clear about consent of the index and secondary recipient prior to splitting a liver. A member commented that this proposal would bypass other recipients within the region if the index patient consents to split and this should be considered. The Committee voted to support the proposal: 14 - For, 1 - Against, 1-Abstention.

- Liver and Intestinal Organ Transplantation Committee – Proposed Region 2 Split Liver Alternative Allocation System. Region 2 is proposing a variance, or Alternative Allocation System (AAS), to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). Under this AAS, if a candidate in Region 2 is suitable for a segmental transplant, the transplant center may accept a liver offer and transplant the right lobe of that liver into that suitable candidate (known as the index patient). Then center would then be allowed to transplant the left segment of that liver into another medically suitable patient listed at the same center or at an affiliated pediatric institution.

  The Committee commented that this policy needs to be clear that consent of the index and secondary recipient must be taken prior to splitting a liver. There should also be clarification of that all Region 2 were in agreement with this proposal. If all Region 2 is in agreement with the proposal the Committee voted to support the proposal: 15 - For, 0 - Against, 0 - Abstentions.

- Pancreas Transplantation Committee – Proposal to Develop an Efficient, Uniform National Pancreas Allocation System. The purpose of this proposal is to improve the national pancreas allocation system. This improvement is consistent with the OPTN long-range strategic goals and priorities: to increase geographic equity in access and waiting time to deceased donor organs for transplantation; to maximize capacity of deceased donor organ transplantation; to achieve operational efficiency and cost-effectiveness of implementing and maintaining the organ allocation system.

  The Committee offered the following discussion:
  - This proposal appears to establish a uniform local pancreas allocation system and not a national pancreas allocation system
  - Please clarify if the kidney/pancreas match can be run before donor HLA becomes available as this can be an issue for OPOs trying to identify a surgeon that will fly out to look at the graft and determine if it's a good for use. A member commented that when consent is obtained on the donor, HLA is sent, and allocation is started, but if the OPO has to wait for HLA to come back to allocate the pancreas, then the OPO will go back to allocation meantime the OPO is ready to go to the operating room for other organs there will be a delay for getting pancreas recovery teams. It would be beneficial to be able to run the match prior to HLA availability to allow the OPO to begin to identify and assist with travel arrangements for surgeons that are interested in procuring the pancreas

- Communication will be vital in cases where the recovering surgeon for a pancreas alone may not like the look of the pancreas at recovery and decline for his patient but another center that has a patient further down the list may accept it for a combined kidney/pancreas recipient to facilitate placement of the pancreas

The Committee voted to support the proposal: 15 For - 0 Against – 0 Abstentions.

- Ad Hoc Disease Transmission Advisory Committee (DTAC) – Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events. The proposed modifications are meant to clarify and/or improve current OPO and transplant center requirements for screening for, communicating and reporting all potential or confirmed donor-related disease and malignancy transmission events. These changes are expected to: Help improve patient safety and recipient outcomes by making policy consistent with current clinical testing practices in the organ recovery transplant communities and creating a Patient Safety Contact; Place all content related to donor evaluation and screening into one policy section; Further define and standardize the elements of informed consent and the communication of clinically significant information regarding potential disease transmission events; and Provide a clear, plain language policy format that will be easier for members and other readers to understand and follow.

  The Committee voted to support the proposal: 15 For - 0 Against - 0 Abstentions.

- Histocompatibility Committee – Proposal to Require that Deceased Donor HLA Typing be Performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-Pancreas, Pancreas, and Pancreas Islet Offers. This proposal would require that OPOs and their associated laboratories perform HLA typing of deceased donors by DNA methods and identify the HLA-A, -B, -Cw, -DR and -DQ antigens before making any kidney, kidney-pancreas, pancreas, or pancreas islet offers.

  The Committee commented that allocation from a kidney/pancreas match run may be slowed down if HLA typing is required before the match could be run. This could lead to decreased utilization of pancreata. The Committee voted to support the proposal: 15 - For, 0 - Against, 0 - Abstentions.

- Living Donor Committee – Proposal for the Placement of Non-Directed Living Donor Kidneys. This proposal would establish procedures for the placement of non-directed living donor kidneys. Under the proposal, transplant centers would select the recipient of non-directed living donor kidneys based on a match run.

  The Committee did not vote on this proposal but voiced concerns about the inability of some centers to provide this service for their patients, thus only centers with large resources can provide this type of service and this may be an ethical issue that will bias organ donation since the organ will not be allocated according to a match run for the donation service area (DSA).

- Living Donor Committee – Proposal to Require Reporting of Non-utilized and Redirected Living Donor Organs. These proposals require that the organ recovery center report all instances of: living donor organs recovered but not utilized for transplant; living donor organs recovered but then redirected and transplanted into a recipient other than the intended recipient. These events would be reported through the UNet^{SM} Patient Safety System. If a

living donor organ is transplanted into a recipient other than the intended recipient, all required donor and recipient information must still be submitted through Teidi®.

The Committee commented that all organs that are recovered and re-directed, whether transplanted or not, should be reported to the Patient Safety System℠ for data purposes. The Committee requested to clarify how re-directed organs are placed based on this proposal. The Committee voted to support the proposal: 15 – For, 0 – Against, 0 - Abstentions.

- Organ Procurement Organization (OPO) Committee – Proposal to Require Use of a Standardized, Internal Label that is Distributed by the OPTN and that Transplant Centers Notify the Recovering OPO when they Repackage and Organ. Current OPTN policy only requires that the external label distributed by the OPTN contractor be used for transporting organs and vessels. This proposed policy change would require OPOs and transplant centers to also use standardized, internal labels that are distributed by the OPTN contractor for organ and vessel transport and for vessel storage. This change will make both internal and external labeling consistent throughout the U.S. The proposal also: requires transplant centers to notify the recovering OPO when they repackage an organ; makes the language consistent by changing the term - provided by the OPTN contractor- to the term -distributed by the OPTN contractor-; moves Policy 2.5.6.1 which lists the required documentation that accompanies an organ or vessel to policy 5.5.1. clarifies labeling requirements for vessel storage The goal of this proposed change is to improve patient safety and reduce the number of wasted organs by reducing the number of labeling errors

  The Committee was not able to devote adequate time to review this proposal during its April 15, 2010 meeting. The Committee convened via conference call on May 17, 2010 and offered the following discussion:
  - Clarity should be provided within policy 5.4.1, 5.4.3, and 5.10.2 to define what an internal label is and where it is attached (outer bag versus rigid container). There are cases in which extra vessels must be relabeled for storage because the label during transport was attached to the outer bag. This adds a risk for error in recording donor and serology information by the transplant center at the time of storage
  - Current labels that are being piloted should provide for areas to document not only the Donor ID but also another unique identifier as CMS already requires this information. This would keep from having to change the labels and re-educate members at a later date
  - Consider also adding an area on the label for documentation of ABO subtype in cases of ABO A donors
  - A time out step could be added with the addition of a check off box to the external label to document that verification of the information on the label had taken place. This could ensure that verification of the label takes place before organs leave the OR, but should not replace that documentation on the verification form

  A quorum for Committee vote was not available on the conference call that took place on May 17, 2010. Those members that were present supported the proposal: 9 - For, 0 - Opposed, 0 - Abstentions.

11. Tiered Acceptance Working Group – The Committee reviewed a summary of the Tiered Acceptance Working Group's focus and how it has changed over the past several months (**Exhibit F**). The work group will now be called the Effective Screening Work Group and will focus on educating members regarding the screening criteria that are currently available within UNet℠. The group plans to create a newsletter for the purpose of education on screening and

allow members to ask questions related to the content, then a survey of select centers will be submitted to obtain information regarding the philosophy and understanding of how screening criteria is used within their institution, and lastly review the data to see if these educational efforts have been effective.

OPTN/UNOS OPERATIONS COMMITTEE MEETING ATTENDANCE

Name	Position	Chicago, Illinois April 15, 2010
Richard Hasz, Jr., MFS	Chair (Region 2)	x
Phillip C. Camp, Jr., MD	Vice Chair (Region 1 Rep)	x
Barbara Turci, RN, BSN, CPTC	Region 2	x
Erin Wray, CTBS	Region 3	
Jaymee S. Mayo, RN, BSN	Region 4	x
Nance D. Conney, BS	Region 5	x
Wayne Dunlap, RN, BSN, CPTC	Region 6	x
Julie K. Heimbach, MD	Region 7	x
Paul Nelson, MD	Region 8	x
Lisa Johnson-Berger, RN, NP, CCTC	Region 9	x
Steven Rudich, MD, PhD	Region 10	By phone
Patrick Northup, MD, MHS	Region 11	
Karen R. Cox, PhD, RN	At Large	x
Stacey L. Doll, MPA	At Large	By phone
Emily L. Goldbloom, BS	At Large	x
Michael Ison, MD	At Large	x
Anton Skaro, MD, PhD	At Large	
Sharon E. Swofford, MA, RN, CNN, CCTC	At Large	x
Janel N. Tedesco, ACNP, CCTC	At Large	x
Donna Woods, EdM, PhD	At Large	x
Michael Hagan, DO, MHSA, CMQ	Visiting BOD Member	x
Robert W. Walsh	Ex Officio/HRSA	x
Andrew Barnes	SRTR	By phone
Jean Davis	Guest/Lifelink Foundation, Inc.	By phone

UNOS staff attending:
Mary D. Ellison, Ph.D., Assistant Executive Director, Federal Affairs
Lin McGaw, RN, MEd, Director Professional Services Department
Brian Shepard, Director of OPTN Board and Committee Operations
Darren Stewart, Biostatistician**,** UNOS Research Department
Kimberly Taylor, RN, Patient Safety Specialist, Committee Liaison
Gloria Taylor, RN, MA, CPTC, Resource Manager, Professional Development, Staff Ethicist