

**OPTN/UNOS Operations and Safety Committee
Report to the Board of Directors
November 16-17, 2009
Orlando, FL**

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items:

- The Committee considered its future direction and renewed focus on patient safety. This new direction will apply a systems thinking approach to the transplant process in relation to adverse events, near misses, and failure to take a proactive approach to addressing patient safety issues. (Item 1, Page 3)
- The Committee reviewed patient safety trends reported to the Patient Safety System. (Item 2A, Page 3)
- The Committee reviewed a request from UNOS Executive leadership to assess the operational and logistical issues that the H1N1 pandemic may cause the transplant system. (Item 2C, Page 5)
- The Committee reviewed the Organ Center transportation reports identifying instances of near misses and failures. (Item 2D, Page 6)
- The Committee considered applicable Public Comment Proposals dated July 10, 2009 and August 17, 2009. (Item 3, Page 6)
- The Committee reviewed a request from a Member to review applicable Policy and assess issues of noncompliance for removal of transplant candidates within 24 hours after transplant. (Item 4A, Page 8)
- The Committee reviewed a request from the Membership and Professional Standards Committee to examine current policies regarding ABO subtyping for deceased and living donors to ensure accurate subtyping determination and verification. (Item 4B, Page 8)

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OPTN/UNOS Operations and Safety Committee
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November 16-17, 2009
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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 matters discussed during its meetings held in Chicago, Illinois on May 7, 2009, and September 10, 2009.

1. Renewed Committee Focus on Safety – UNOS Staff provided insight regarding the Committee’s new focus on patient safety. The Committee is tasked with reviewing events reported to the Organ Procurement and Transplantation Network (OPTN) contractor by using a high level systems thinking approach in an effort to apply this way of thinking to the transplant progress and begin to proactively address potential patient safety events. 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’s previous operational and systems work was more technological in nature. This approach did not invoke systems thinking and operations research, but one of resolving issues of technological operations. The name of the Committee was originally inspired by the term “Operations Research” and was soon diverted to advise the UNOS regarding improvements of data systems like DonorNet®.

The Committee’s name has been changed to the Operations and Safety Committee. The Committee has been asked to address issues from the field of transplantation by a systems thinking approach. Systems thinking is said to be very effective on the most difficult problems to solve, especially those involving complex issues that depend on the actions of others, and those stemming from ineffective or loose coordination among those involved. A process will be developed to determine how issues make their way to the Committee for consideration. It is the goal of the Committee to develop and standardize the processes by which events are reviewed as well. The Committee will work to encourage the reporting of events, as it is believed that patient safety situations are currently under reported.

2. Patient Safety System:

- A. Disease Transmission Cases Trends – The Committee reviewed a presentation of disease transmission case reports during the time period of January 1, 2006 to August 31, 2009. Trends of operational issues that resulted in safety events were identified by the Ad Hoc Disease Transmission Advisory committee (DTAC) and referred to this Committee for review. Staff reported that potential disease transmission cases reported to the Patient Safety System have steadily increased each year since the beginning of the system in spring 2006 and predictions indicate that 2009 will reach approximately 152 case reports.

The Committee reviewed trends within bacterial, mycobacterium tuberculosis (TB), fungal, and renal cell carcinomas (RCC) categories of disease transmission events. Reporting of incidental RCC findings have steadily increased. These lesions are oftentimes identified at the time of transplant, or discovered after the time of transplant by radiographic imaging. There

have also been increased reporting of potential bacterial and fungal transmissions. Within these events, DTAC has identified several types of communication issues leading to untimely or no reporting, to the transplant centers of donor organs, of positive donor cultures. These cultures results are often not brought to the attention of the transplant center at the time of the offer or prior to transplant. DTAC is also concerned that when results are reported that they are often times not reported to an appropriate clinical person that could make decisions about the treatment of the recipient receiving an organ from the donor. This is especially important in cases of multi-drug resistant infections identified in the donor. Through case reviews of potential transmission of TB, DTAC has identified issues in which suspicious donor findings are oftentimes not reported to all transplant center whether at the time of offer, procurement, or at transplant. These cases require timelier reporting of donor test results due to public health safety implications of this disease. In some cases it has been noted that there were significant delays in the reporting of final donor culture and sensitivity results to transplant centers.

The Committee noted that there are no standard guidelines for reporting of culture results by OPO's. Additionally, the transplant community does not have a mechanism to identify donors who formally lived in high risk areas. For instance, *Coccidioides* is predominately found in the southwestern United States (US). During donor evaluation, questions are asked about whether a donor travels outside the US, but not if the donor spent significant time in endemic regions. From a systems perspective, the Committee decided that this should be addressed with caution as not to encourage refusal of donors that have traveled to specific endemic areas. The Committee commented that the risk should be identified and the transplant community made aware that risk exists. Since some transplant centers may not pay attention to the fact that a donor spent time in a specific region that is endemic. It is important to allow centers accepting organ offers to put a safety plan in place while collecting additional information on a donor.

B. Ad Hoc Disease Transmission Advisory Committee (DTAC), H1N1, and HTLV 1/2 Update

The Committee was updated on the current work of the DTAC. DTAC has realized that there are little data available regarding H1N1 transmission in organ donation, yet there is a potential risk to transplantation. Data suggest involvement in the lungs with viral RNA detected for a long period of time in the stool. GI tract involvement indicates that some patients with severe disease have viremia. Dr. Ison clarified that there is a big difference in the risk of viremia depending on the mechanism of death in the donor. Realizing that there could be potential H1N1 impact on the healthcare community, DTAC's goal is to minimize the potential impact of this pandemic on organ transplantation in the US. The issues that have been identified from an organ procurement organization (OPO) and transplant center standpoint are staffing issues, vaccination for appropriate staff, and evaluation of potential donors and recipients. For the transplant center it is realized that hospitals have pandemic plans but oftentimes transplant centers may not be incorporated into the plan or the transplant center impact may not be known to be addressed. A group from Health Resources and Service Administration (HRSA), Centers for Disease Control (CDC), and DTAC met to discuss these issues. In collaboration with DTAC and other OPTN committees, a set of guidelines were developed to give guidance to the transplant community and addressed specific informed consent for transplantation of known H1N1 positive donors, utilization of infectious disease experts within the transplant center and OPO when evaluating donors and recipients, evaluation of pandemic plans for the OPO and transplant center, and to determine how influenza vaccine will be made available to transplant patients and staff. Specific guidance was included to address evaluation and management of potential donors and

patients in recognition of symptoms, appropriate testing, and treatment of the donor prior to procurement as advisable per current CDC guidelines. DTAC identified certain key points of information for the OPO to collect to provide for the transplant centers that will facilitate informed decision making. Information regarding date of onset of influenza like illness, how the diagnosis was made, date and type of testing completed, subsequent testing, antiviral management of donor (include the name, dose, and duration of therapy), and lastly the specific cause of death of the donor. The transplant community should refer to the guidance that has been posted on the UNOS and OPTN websites, the CDC website, and the American Society of Transplantation (AST) website. AST has posted a clinical guidance document from its infectious disease group that will be updated every few weeks. It should be noted that guidance will change as the season progresses and more is learned about H1N1.

DTAC has proposed HTLV retrospective testing in deceased donors due to the elimination of a widely used HTLV 1/2 testing platform. This proposal is currently out for public comment ending on September 30, 2009. After public comment, DTAC will review the feedback and formulate a recommendation for the Board of Directors regarding the proposal. DTAC continues to review Policies 2 and 4 to address areas in need of updates or revisions to clarify infectious disease testing and reporting. DTAC is also discussing how to close disease transmission cases that have been reviewed. DTAC has been very good about collecting information, categorizing, and reviewing the cases, but there is not a process for getting information back to the involved members.

C. Operational and Logistical Issues Regarding Possible H1N1 Pandemic Feedback -

The Committee was asked by the UNOS Executive leadership to assess the potential operational and logistical issues for the transplant system in relation to the H1N1 pandemic. Current policies and bylaws address what to do when members' infrastructure is devastated or obliterated by disaster and outline the alternatives for conducting business. The Committee believes that a pandemic would be a medical catastrophe, and that this situation is not specifically addressed in existing policies and bylaws. Additionally it is believed that there are mechanisms in place to assist members in the event of a regional or local pandemic and that the incapacitating impact is going to be far more of a risk for transplant programs than for the OPOs. The following recommendations, guidance, and suggestions were provided to the UNOS Executive leadership:

- 1) If a transplant program is inactive for fewer than 15 days due to a pandemic, the Committee recommends that the program utilize appropriate existing turndown codes to indicate the reason for inactivity (e.g., program not available, surgeon not available, etc.). The transplant program could select "other" from the turndown code options and type in the pandemic reasoning whether it is staff illness or unavailability, surgeon illness, or hospital administrative protocol, etc. The Committee was very cognizant of the transplant programs' concern of utilizing the turndown codes as they may call attention to their program by the UNOS Department of Evaluation and Quality. The Committee thought that employing the "other" turndown code would help prevent escalation of any actions.
- 2) The Committee recognizes the need to modify the reactivation process for programs that are impacted by a pandemic for greater than 15 days and have to temporarily inactivate. The risk of losing CMS accreditation because of a medical catastrophe seems severe and some special considerations can be made. A long-term solution may be a policy modification to cover medical catastrophes. The Committee thinks if a transplant program knows within 15 days that it is going to be severely impacted, an intermediate process that they can activate would be advantageous.

- 3) The Committee suggests that to decrease transplant programs anxiety and confusion OPTN/UNOS guidance indicating possible strategies mentioned above to help alleviate potential problems should be provide. Additionally, there should be a point person within UNOS who members could communicate with (via email) if they have questions or know they are going to have to inactivate their program. The program could also submit an advisory indicating the expected impact to their program.
- 4) The Committee believes that OPOs will be able to conduct business by reaching out to neighboring OPOs to ask for help, if necessary. The Committee did not think that any policy or bylaw modifications were necessary for OPOs.
- 5) Reviewing how Toronto coped with the SARS outbreak may provide insight as during that medical catastrophe the number of transplants decreased and some hospitals were not able to perform transplants.

D. Organ Center Transportation Report –

The Committee reviewed the Organ Center transportation reports at its May 2009 and September 10, 2009 meetings. The reports indicated that transportation failures have increased as compared to near misses reported in previous years (**Exhibit A**). The Organ Center has begun to collect specific data to capture information of failures that resulted in the organ being discarded. The report reviewed at its September 2009 meeting provided information regarding transportation issues involved in the reported failures or near misses. The Organ Center will continue to enhance this report to capture additional categories of events. A survey of OPOs was conducted by the Organ Center to collect data regarding transportation issues seen during a three month period. One third of OPOs participated in the survey. The number of expected events was higher than anticipated. Based on the information received in this survey, it is believed that the Organ Center is capturing about one sixth of events that are occurring within the community.

This topic is timely given the current climate of kidney exchange programs in which kidneys are being moved to the recipient and not necessarily the living donor moving to the recipient. These exchanges sometimes occur in instances in which the donor and recipient may be in different states or regions so transportation issues can delay organs from arriving at their destination with the appropriate preservation and in a timely fashion. In the past kidneys were transported by commercial airlines with the pilot. Today organs are riding in the baggage section of the plane. Tracking and accounting for organs is sometimes out of an OPO's or, in the case of a kidney exchange, the transplant center's control. This report shows that these issues are under-reported events and will be particularly important for the committee to address from a systems approach. The Committee agreed to have a subcommittee decide what should be reviewed in relation to this issue, define the scope, and form a multi-committee working group to collaborate on the project.

E. Labeling and Packaging Issues with Thoracic Recovery Teams

The Committee reviewed the continuing safety concerns regarding visiting thoracic recovery teams not packaging and labeling thoracic organs according to current Policy. The Committee provided comment to the Thoracic Organ Transplantation Committee regarding this issue and recommended an educational process that could start with the Thoracic Organ Transplantation Committee. The Committee was also aware that the OPO Committee is currently addressing the re-write of Policy 5.0 regarding packaging and labeling and that a pilot is underway to test new donor organ labels for use by the OPO.

3. Review of Policies and Bylaws Issued for Public Comment.

The Committee considered current proposed policies within its purview, which were included in the Public Comment document dated, July 10, 2009 and August 17, 2009.

- Proposal to Improve the ABO Verification Process for Living Donors Affected Policies: Policy 12.3.1 – ABO Identification, Policy 12.8.1 – Reporting Requirements. The Committee supports this proposal to promote safety and consistency while suggesting that ABO subtyping be added to this proposal.
Committee Vote: 18-For, 0-Against, 0- Abstention.

- Proposal to Add Language to the Bylaws Requiring Transplant Center and OPO Members to Follow State Law Regarding Anatomical Gifts. Policy/Bylaws affected: Bylaws, Article I, Section 1.10 (Member Obligations), Appendix B to Bylaws, Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership, Section I (Organ Procurement Organizations) and Section II (Transplant Hospitals), Policy 3.4 (Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation). The Committee agrees with the addition of “surgical or operative” preceding procedure in the proposal. An example where the pronouncing physician may be asked to re-intubate the donor was cited. The Committee asked if this proposal could potentially impact small, rural donor hospitals. Discussion of the Committee seemed to indicate that to this point there has been no feedback to indicate that this would be in issue. The UAGA would cover this and those centers should be in compliance already. The Committee discussed DCD donor situations where anesthesia will not pronounce the donor dead in the operating room. The discussion continued to address who would be pronouncing the donor dead in the operating room. If an attending of record, or their designee, were not available in the operating room and anesthesia would not pronounce, the Committee was concerned that the transplant surgeon might be asked to perform this duty. The Committee agreed that DCD protocols need to be clarified to address these types of situations.
Committee Vote: 18-For, 0- Against, 0-Abstention.

- Proposal to Change Requirements for Labeling and Packaging Organs Procured by Visiting Transplant Center Teams and for OPO Labeling of Tissue Typing Materials. Policy affected: Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials). The Committee does not support the proposal as written. The following points were discussed in relation to this proposal:
 - 1) The Committee did not support the shift of responsibility to the transplant center (recovery team) from the OPO. The majority of the Committee views the responsibility for packaging and labeling deceased donor organs as a mutual duty or obligation of the OPO and transplant center in order to ensure patient safety. Some Committee members believe a shared or mutual duty or responsibility is too vague in terms of how a process gets implemented.
 - 2) Some Committee members were in favor of some formalized crosscheck process with the employment of a checklist with signatures that ensures which organ, what blood type, which preservation solution, what tissue typing materials, etc. are included and properly labeled before any recovery team leaves.
 - 3) The Committee supports reporting of these packaging and labeling violations in the Patient Safety System as a patient safety situation.
 - 4) The Committee realizes that many transplant programs utilize fellows to recover organs and supports promoting following policy as part of the culture and training of these individuals.
 - 5) There is no approved list of secondary unique identifiers that can be employed for a crosscheck on the tissue typing materials.

Committee Vote: 0-For, 18-Against, 0-Abstention.

- Proposal to Modify Requirements for Mandatory HTLV 1/2 Testing for All Potential Deceased Donors. Affected/Proposed Policy: Policy 2.2.3.1 (For All Potential Donors). The Committee voted to support the elimination of prospective HTLV donor testing and not advocate for retrospective testing. The dilemma of what to do with positive retrospective test results was discussed by the Committee and found to be problematic. The Committee suggested that transplant centers may want to discuss this change internally regarding pre-transplant consenting processes.

Committee Vote: 18-For, 0-Against, 0-Abstention.

4. Policy Items:

A. Removal of Liver Candidates within 24 Hours of Transplant –

The Committee reviewed a request from a Member to evaluate compliance rates of all transplant centers with Policy regarding removal of candidates within 24 hours of transplant or death. The initial request outlined the removal process for liver transplant centers that requires clinical information to be entered for removal of the candidate. At its May 2009 meeting, the Committee requested additional data for review to compare weekday and weekend compliance rates. UNOS staff prepared the data request and presented the findings to the Committee at its September 10, 2009 meeting (**Exhibit B**). The data reviewed all Waiting List removals for transplanted candidates for the years of 2003-2008. Results indicate that there are higher delayed removal rates on Friday, Saturday, and Sunday for all organs and for kidney, pancreas, and kidney/pancreas on all days of the week. However, compliance with these existing policies has improved over the 5-year period. In 2003 almost 50 percent of removals across different organ types were delayed greater than 24 hours. In 2008 this percentage is down to 16.5 percent. Liver does not stand out as having a higher rate as thought, but rates had come down to under 10 percent in 2008. In reviewing trends of removal by the day of week, the data show an increase in removal greater than 24 hours on Fridays, Saturdays, and Sundays for all organs. If policy required removal by the next business day, the delayed removal rates decreased to six or seven percent. There would be a potential increase in compliance, and the noncompliance of removal on the weekends would be almost eliminated.

Removal within 24 hours by knowledgeable personnel was questioned. Accurate data may be difficult to comply with for transplants that are performed afterhours, weekends, and holidays. There was speculation that staff performing these duties afterhours may not be trained to obtain the accurate information and could be entering temporary data to meet the 24 hour requirement with the intent to go back at a later time and correct the data. Transplant centers cannot change the data entered, but must submit a help desk request for staff to make corrections.

This proposal was shared with the organ specific committees to get pre-public comment feedback. The Thoracic Organ Transplantation Committee was concerned that changing policy may give centers a more relaxed approach to removing candidates after transplant and could lengthen the allocation process. A change to this policy may create an issue of candidates that have been already been transplanted remaining on the list if a broader sharing allocation is implemented in the future. The Committee discussed centers' option of inactivating candidates when unable to remove them. If the intent of the policy was to

decrease the time it takes the OPO to allocate organs, then the policy could state that the requirement is to remove candidates within 24 hours and if this cannot be done to inactivate the candidates. Inactivating candidates does not remove them from the Waiting List and this approach would also require a change in policy language. The Committee recommended holding this proposal and reviewing data again in six months to one year. The committee voted 13 –For, 0-Opposed, 0-Abstentions in support of this recommendation.

B. Blood Group A Subtyping –

UNOS staff reviewed the Committee’s data request to quantify the risk of incorrect ABO subtyping (**Exhibit C**). Policy requires two independent tests for ABO typing for all recipients and deceased donors but does not specify such a requirement for ABO subtyping. DonorNet[®] requires an independent verifier, the blood type of the donor. If an erroneous blood type or subtyping entry is discovered, DonorNet[®] requires the creation of a new donor record. This can be a timely and duplicative data entry process when attempting to allocate organs.

In review of a recent incompatible living donor kidney event, it was discovered that an incompatible A1 living donor organ, thought to be A2, was transplanted into an O recipient which led to hyperacute rejection. It was determined that the lab had performed one test that was double checked for ABO subtyping as opposed to two independent tests. 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. There were two instances in which heart patients received incompatible ABO transplants and may have been a pediatric recipient which is permissible. 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. A midwest OPO has researched this issue found error rate in subtyping was higher than just for ABO typing alone. 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 required independent double subtyping it would decrease error 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.

At its May 2009 meeting, the Committee realized that this was a patient safety issue that should be addressed by reviewing all ABO typing requirements that are found within policy. The Chair recommended that the Committee propose that all deceased and living donors be ABO typed and subtyped twice to provide an additional safety step. Also UNetsm and DonorNet[®] will need to support the function of double verification of ABO typing, subtyping and verification. If independent labs report different results from the same donor, whether A1 or A2, then the Committee would also recommend that blood type A be considered ideal for

moving forward with transplant in an effort to ensure the safety of the recipient. The Committee voted: 19-For, 0-Opposed, 0-Abstention in support of these proposed ideas.

C. National Pancreas Allocation System –

The UNOS Liaison to the Pancreas Transplantation Committee gave an update on concepts being discussed by the Committee of a new allocation system for pancreas to assess feedback from various committees and regions. The goals are to increase utilization of the pancreas, to increase outcomes for SPK and pancreas candidates, reduce waiting time of pancreas candidates without adversely affecting adult and pediatric renal transplant candidates, reduce geographic inequities in access and waiting time, and to reduce the burden of disease for pancreas candidates. Approximately 66 percent of pancreata are allocated to simultaneous kidney/pancreas (SPK) candidates. However, there is no uniform national system for allocating pancreata in the context of SPK transplantation. Consistent SPK listing criteria would need to be developed.

It was noted that by allowing OPOs to choose to not allocate SPK or pancreas regionally or nationally, after the local list is exhausted, is inherently discarding a transplantable pancreas. The Chair commented that the Pancreas Transplantation Committee may wish to consider re-evaluating pancreas islet requirements as some believe that high BMIs don't necessarily correlate to a fatty pancreas and that the pancreas list should be exhausted before islets are allocated. It was commented by several committee members that combining the list for ease of use, allocation, and increased utilization of the pancreas should be supported.

D. Living Donor Registration Requirement Prior to Surgery –

The Living Donor Committee sought feedback from the Committee regarding the living donor registration requirement prior to surgery. In previous months, the Living Donor Committee has provided to the Transplant Administrators Committee (TAC) and the Transplant Coordinators Committee (TCC) a reference document to assist in the generation of a donor ID for living donors. This was an effort to educate Members on the requirement to register donors prior to the surgery. Members have not consistently registered living donor prior to the day of surgery creating a situation in which the Center cannot remove a candidate that has been transplanted from the waiting list without the generation of a donor ID. A Committee member commented that centers may be concerned for the loss of waiting time in instances where living donor transplants do not function. In this instance, wait time needs to be re-instated. There needs to be community education regarding the purpose of the requirement along with assurance that the waiting time of the candidate is not altered until the candidate is removed, and time can be re-instated should there be a situation in which the living donor organ does not function. The Committee recommended that UNOS provide a communication update to Members related to the purposes of this requirement to increase compliance.

E. Living Donor Organ Wastage -

The Living Donor Committee sought pre-public comment feedback for implementing policy that requires Members to report through the UNetsm system within 72 hours of organ recovery living donor organs that are wasted. It was noted that some OPOs are beginning to look at data related to this issue to determine why organ(s) were not usable and who decided that the organ(s) were not usable. UNOS staff commented that making policy may be necessary but not sufficient. It may be that the Committee needs to communicate to the public ways in which related problems and the parallel pathways that may need to occur are being addressed. This may increase the comfort level of reporting among members by allowing them to understand that issues are being addressed with an eye towards systems review for prevention

of errors as well as review of policy violations that need to be addressed. The Committee will need to create a subcommittee to develop a process that will be followed when issues of this nature come forth needing to be addressed. Root cause analyses are not a standard part of the process, but could become a part of the process that the Committee oversees. A Committee member commented that it is important to present this data at transplant meetings, regional meetings, and publications to increase awareness. This will also increase excitement and sensitivity of members by becoming aware that by reporting events they are impacting awareness and policy. The Committee will need to begin to build a culture within the transplant community that allows Members to feel they can mitigate into the system about near misses or actual events freely and comfortably with the focus being to improve the work of the system and making patients safe. The Committee supports this proposal and recommended that there be education to the transplant community to ensure that centers are reporting through the Patient Safety System and not just reporting on the living donor follow up (LDF).

5. Technology Items:

A. Implementation Subcommittee –

The Implementation Subcommittee reviews any proposal that would go forth from the Committee that requires programming of UNOS computer systems. This is a subgroup that works with the IT department and business analyst to ensure that business requirements are captured along with the recommendations of the committee. This subcommittee currently has two remaining members since the Committee composition changed as of July 1, 2009. There is opportunity for those interested to participate in this group.

B. Tiered Acceptance Working Group –

UNOS Staff provided summary report of the Tiered Acceptance Working Group that met via LiveMeeting[®] on April 28, 2009 and September 8, 2009. The working group acknowledged that this is a concept worth investigating, programming options will be investigated, and members need to be educated regarding screening criteria that currently exists within DonorNet[®] to with waiting list management. The group has requested to review data to identify clusters of centers in which we can identify philosophies of screening criteria and usage of current tools available, what is the benefit from a tiered acceptance concept related to match run lengths, organ types, ischemic times, reduction of organ wastage, and the dynamics of DonorNet[®] data to access how often data is changing.

C. UNOS Research DonorNet[®] Data Reports –

At its May 2009 meeting, the Committee reviewed requested DonorNet[®] data reports provided by UNOS staff. The reports included the Donor Screening Criteria, Donor Refusal, and Organ Utilization: Identifying Combinations of Donor Characteristics in Adult and Pediatric Donors, and Patterns in Donor/Organ Utilization and Waiting List Characteristics. This information was considered valuable by the Committee and will be considered in light of projects moving forward.

OPTN/UNOS OPERATIONS COMMITTEE MEETING ATTENDANCE

Name	Position	Chicago, Illinois May 7, 2009
Richard Hasz, Jr., MFS	Chair (Region 2)	x
Marwan Abouljoud, MD	Vice Chair (Region 10)	
Philip Camp, Jr., MD	Region 1	x
Kevin Carney, RN, CCTC	Region 2	x
Erin Wray, CTBS	Region 3	
James Cutler, CPTC	Region 4	x
Shanna Perales	Region 5	x
Wayne Dunlap, RN, BSN, CPTC	Region 6	x
Barry Friedman, RN, BSN, MBA, CPTC	Region 7	x
Douglas Bremers, BA, CPTC, CTBS	Region 8	x
Lisa Johnson-Berger, RN, NP, CCTC	Region 9	By phone
Steven Rudich, MD, PhD	Region 10	By phone
Patrick Northup, MD, MHS	Region 11	x
William Cotts, MD	At Large	
Karen Cox, PhD, RN	At Large	By phone
Oscar Grandas, MD	At Large	
Julie Heimbach, MD	At Large	
Michael Ison, MD	At Large	x
Gwen McNatt, MS, RN	At Large	x
J. Elizabeth Tuttle-Newhall, MD	At Large	
Emily Goldbloom, BS	At Large	x
Michael Hagan, DO, MHSA, CMQ	BOD Liaison	x
Robert Walsh	Ex Officio	x
Craig Lake, MS	SRTR	By phone

UNOS staff attending:

Gloria Taylor, RN, MA, CPTC, Committee Liaison
 Mary D. Ellison, Ph.D., Assistant Executive Director, Federal Affairs
 Leah Edwards, Ph.D., Assistant Director, Research
 Darren Stewart, Biostatistician, Research

UNOS staff attending via conference call:

Jory Parker, Business Analyst, Federal Affairs

OPTN/UNOS OPERATIONS COMMITTEE MEETING ATTENDANCE

Name	Position	Chicago, Illinois September 10, 2009
Richard Hasz Jr , MFS	Chair	X
Phillip Camp Jr., M.D.	Vice Chair/Regional Rep. 1	X
Barbara Turci	Regional Rep. 2	X
Erin Wray	Regional Rep. 3	
Jaymee Mayo, RN, BSN, BS	Regional Rep. 4	X
Nance Conney, BS	Regional Rep. 5	X
Wayne Dunlap RN, BSN, CPTC	Regional Rep. 6	By Phone
Dawn Brim, RN, CPTC	Regional Rep. 7	X
Paul Nelson, MD	Regional Rep. 8	X
Lisa Johnson-Berger RN, NP, CCTC	Regional Rep. 9	X
Steven Rudich MD, PhD	Regional Rep. 10	X
Patrick Northup M.D., MHS	Regional Rep. 11	X
Karen Cox PhD, RN	At Large	X
Stacey Doll, MPA	At Large	X
Emily Goldbloom, BS	At Large	X
Michael Hagan DO, MHSA, CMQ	At Large/BOD Liaison	X
Julie Heimbach, MD	At Large	
Michael Ison, MD	At Large	X
Anton Skaro, MD, PhD	At Large	X
Sharon Swofford, MA, RN, CNN, CCTC	At Large	X
Janel N Tedesco, ACNP, CCTC	At Large	X
Donna Woods, EdM, PhD	At Large	By Phone
Robert Walsh	HRSA	X

UNOS staff attending:

Gloria Taylor, RN, MA, CPTC, Committee Liaison
 Kimberly Taylor, RN, Committee Liaison
 Darren Stewart, Biostatiscian, Research
 Mary D. Ellison, Ph.D., Assistant Executive Director, Federal Affairs
 Robert Metzger, M.D., Medical Director

UNOS staff attending via conference call:

Jory Parker, Business Analyst, Federal Affairs