

**OPTN/UNOS OPERATIONS COMMITTEE REPORT
SUMMARY**

I. Action Items for Board Consideration

- The Board is asked to approve modifications to Policy 3.1.4 (Waiting List) to clarify the intent of the phrase “two separate occasions” in reference to ABO typing requirements. (Item 1, Page 3)
- The Board is asked to approve modifications to Policy 5.4 (Packaging) to clarify organ packaging requirements. (Item 2, Page 4)

II. Other Significant Items

- The Committee discussed the continuing organ transportation issues and will work to transportation standards. (Item 4, Page 5)
- The Committee reviewed a Member request regarding other countries’ inability to review electronic donor information and how this impacts the non-U.S. organ placement process. (Item 5, Page 5)
- The Committee charged the Disease Transmission Advisory Group (DTAG) with examining the public comment provided for Policy 4.0 and providing appropriate proposed policy modification language for full Committee consideration. (Item 6, Page 6)
- The Committee charged the DTAG with exploring current testing standards for potential organ donor serologies in order to formulate recommendations for proposed policy modifications for full Committee consideration. (Item 10, Page 7)
- The Committee reviewed member requests regarding the term “high risk” donor and referred the issue to the OPTN/UNOS OPO Committee for consideration. (Item 11, Page 7)
- The Committee sponsored policy modifications to Policy 4.1.1 (Donor History) that were approved by the Executive Committee on Decemberr 18, 2007. (Item 24, Page 12)

This page is intentionally left blank.

**REPORT OF THE OPTN/UNOS OPERATIONS COMMITTEE MEETING
TO THE BOARD OF DIRECTORS**

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

**Richard Hasz, MFS, Chairman
Marwan Abouljoud, MD, Vice-Chairman**

The following report represents the Operations Committee's deliberations and recommendations on matters considered by the Committee during its meeting on October 4, 2007, the Executive Committee conference call on December 18, 2007, and an Operations Committee Live Meeting on January 4, 2008.

The Operations Committee met on October 4, 2007, and the meeting was led by Rick Hasz, Chairman.

At the beginning of the meeting, minutes from the April 19, 2007 Committee meeting were reviewed and were approved with one revision that Kristi Ross was in attendance during the April meeting (Vote 14-0-0). The Operations Committee Goals and HHS Program Goals for the OPTN were reviewed by the Committee. Additional information which included the Committee Regional Representatives' Responsibilities, Media Relations, and the OPTN Strategic Plan was presented by Gloria Taylor, Committee Liaison.

1. DEQ Language Clarification Request for Policy 3.1.4 – The Committee reviewed a request from the UNOS Evaluation and Quality department regarding policy language necessary to clarify the intent of the phrase “two separate occasions” in reference to ABO typing requirements. The Committee recommends the following proposal to clarify policy language for the Board of Directors consideration:

****RESOLVED, that the following modifications to Policy 3.1.4 (Waiting List.) as set forth below are hereby approved, effective pending distribution of notice to the Members:**

3.1.4 Waiting List. The Waiting List is the computerized list of candidates who are waiting to be matched with specific donor organs in hopes of receiving transplants. Waiting List candidates are registered on the Waiting List by member transplant centers. The candidate's transplant program shall be responsible for ensuring the accuracy of candidate ABO data on the waiting list. Each transplant program shall implement and operate procedure for providing on-line verification of a candidate's ABO data on the waiting list against the source documents by an individual other than the person initially entering the candidate's ABO data in UNetSM. The transplant program shall maintain records documenting that such separate verification of the source documents against the entered ABO has taken place and make such documentation available for audit. Upon entry of the candidate's waitlist data, the candidate will be added to the waitlist but will not be listed as an active candidate until separate verification of the candidate's ABO data has taken place.

3.1.4.1 All transplant candidate interactions will be required to be completed through UNetSM by transplant programs. The Organ Center will facilitate candidate listings and modifications in the event of computer and/or Internet failure. When the Organ Center facilitates a candidate's listing or modification due to computer and/or Internet failure, the transplant center will be required to submit a statement explaining the event.

3.1.4.2 Each transplant candidate must be ABO typed on two separate occasions prior to listing. Two separate occasions is defined as two samples, taken at different times, sent to the same or different labs.

Committee Vote: 12 For; 0 Against; 1 Abstaining

2. Member Request for Consideration of Modification to Policy 5.4 – The Committee considered proposed policy modifications to Policy 5.4 submitted by a member. The Committee determined that the language is clarifying and does not change the initial policy intent. Therefore, the Committee recommends the following proposal to clarify Policy 5.4 for the Board of Directors consideration:

****RESOLVED, that the following modifications to Policy 5.4 (PACKAGING) as set forth below are hereby approved, effective pending distribution of notice to the Members:**

5.4 PACKAGING. In all circumstances during which donor organ is transported outside the recovery facility, the Host OPO or the Transplant Center, as applicable is responsible for packaging, labeling, and handling the organ in a manner which ensures arrival without compromise to the organ(s). Proper insulation and temperature controlled packaging including adequate ice or refrigeration shall be used to protect the organs during transport. All packaged organs, using disposable transport boxes, must have a red plastic bio-hazard bag that is water tight secured to allow for safe handling by medical and non-medical personnel during transport. This red bag may be placed between the waxed cardboard box and the insulated material holding the wet ice and the organ.

All organs that have been packaged on the donor's back table must be handled using universal precautions. The packaged organs from the donor's surgical back table are to be placed directly into the wet iced shipping container.

Committee Vote: 10 For; 3 Against; 0 Abstaining

3. OPO Requesting a Variance for Donor Screening Laboratory Testing Policy 2.0 – An OPO which procures approximately 50 organ donors per year requested a variance to address the use of a FDA approved *diagnostic* HIV laboratory test as an organ donor screening test. The OPO has historically used the HIV FDA approved screening test kit; however the components of the kit are no longer available. Testing solutions have been considered at state, regional and national laboratories and an interim solution with an out of state lab was implemented. However, the OPO was recently informed that the lab will not be able to continue to provide the service. The OPO has considered organ availability and utilization issues and has determined that the potential for loosing extra renal organs exists due to the logistics of sending specimens long distances, which may potentially add 6-8 hours of test result turn-around time.

Currently, Policy 2.2 states that donors are to be screened using FDA licensed Anti HIV I and II tests and Policy 4.0 states all potential donors are to be tested using a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV).

The OPO requested that the Operations Committee support a variance to use an FDA approved diagnostic test kit, which has not been validated and approved by the FDA for screening purposes in a cadaveric population. The Committee discussed the request for variance. It was determined by the Committee that it does not have the ability to grant a variance, however the Committee opted to recommend that the Executive Committee or OPTN/UNOS Board of Directors grant a variance for this OPO and consider including all such future requests in the decision.

****RESOLVED, that OPOs may, upon request and approval of the Executive Committee, utilize diagnostic laboratory testing for screening potential organ donors until an investigation of current OPO practices and an assessment of sensitivity and specificity for diagnostic vs screening tests for potential organ donors can**

be completed by the Disease Transmission Advisory Group, and proposed policy modifications are approved by the OPTN/UNOS Board of Directors.

****FURTHER RESOLVED** that Carolina Donor Services' request to utilize diagnostic laboratory testing from the ADVIA Centaur system for screening potential organ donors for HIV I and II, is hereby approved, effective December 18, 2007.

Committee Vote: 11 For; 1 Against; 1 Abstaining

This resolution was amended and approved by the Executive Committee on December 18, 2007 by a vote of 8 for, 0 against, and 1 abstention:

***RESOLVED, that OPOs may, upon request and approval of the Executive Committee, utilize an FDA approved diagnostic laboratory testing for screening potential organ donors until an investigation of current OPO practices and an assessment of sensitivity and specificity for diagnostic vs. screening tests for potential organ donors can be completed by the Disease Transmission Advisory Group, and proposed policy modifications are approved by the OPTN/UNOS Board of Directors.*

A related resolution was also discussed by the Executive Committee and revised to include the language, "FDA approved" to refine the description of acceptable diagnostic laboratory testing. Thereafter, the Executive Committee approved the following revised resolution by a vote of 8 for, 0 against, and 1 abstention:

***RESOLVED, that Carolina Donor Services' request to utilize FDA approved diagnostic laboratory testing from the ADVIA Centaur system for screening potential organ donors for HIV I and II, is hereby approved, effective December 18, 2007.*

4. Organ Transportation Request for Proposal (RFP) – During previous Committee meetings, the significant need in the transplant community for standardized and expedited shipping of organs from a recovery location to awaiting recipient centers has been discussed. Information was provided for the Committee regarding an airline industry meeting and the misperceptions regarding the handling of organs. It was noted that organs have appeared on baggage carousels with regular luggage, traveled with cargo, and do not travel in the airplane cockpit. The Committee also discussed that a request to the Federal Aviation Administration (FAA) to develop mandates for standardizing organ shipments among all commercial airlines be pursued. A Committee member will contact Southwest Airlines to ask if other mechanisms exist within the airline industry to vet the Committee's request prior to making a formal request to the FAA. This information will be provided during the next Committee Meeting. The Committee will continue to monitor reported patient safety situations dealing with organ transportation/wastage and work toward creation of organ transportation standards.

5. Request for Consideration of a Formal Agreement with Territories outside the United States to Access Donor Information within DonorNet® – Due to the efficiency of the DonorNet® electronic offer process, OPOs in several Northern states are exhausting the national list more often. These OPOs are turning to Canada to offer these recovered organs for transplant. The main reasons these organs are not transplanted in the U.S. is due to incompatible ABO and size. Annually, 50-60 recovered organs are exported and transplanted outside the U.S., which is slightly higher since implementation of DonorNet®. It was suggested that Mexico be considered part of this international discussion as well. The Committee will make a specific data request regarding this phenomenon.

The Committee considered theoretical agreements between UNOS and Canadian OPOs and transplant centers to allow read-only access of patient charts in DonorNet®. This suggestion will need further investigation as there are policies in place which require UNOS membership in order to access to the OPTN data system. However, there is currently an exception for international organ offers, which must be offered through the Organ Center. It was noted that the records in DonorNet® do not represent a patient medical record and were intended for use in organ offer notification and acceptance.

6. Reconsideration of modifications to Policy 4.0 (Disease Screening and Reporting) - Post public comment – The Committee discussed public comment feedback and the role of the Disease Transmission Advisory Group (DTAG) as the subject matter experts regarding this policy language. Michael Ison, DTAG Chair, outlined the three goals for DTAG in the upcoming year, which included organization of DTAG members, standardizing data management, and collection and analysis of reported transmission data and publication of the DTAG position statement and data for the community.

The Committee considered the legal ramifications and quality improvement opportunities associated with reporting potential disease transmission events into the OPTN Patient Safety System. It was discussed that the peer review privilege should apply to all reported potential and confirmed disease transmission events. UNOS staff agreed to discuss peer review with UNOS Legal Counsel and report the findings to DTAG immediately and to the Committee during the next Committee meeting. The Committee approved a resolution which charges DTAG with exploring possible modifications to Policy 4.0 and reporting the modified policy language to the Committee.

****RESOLVED**, that the Operations Committee charges the Disease Transmission Advisory Group (DTAG) with exploring possible modifications to Policy 4.0 that would encourage disease reporting while protecting the reporter.

Committee Vote: 14 For; 0 Against; 0 Abstaining

The Committee requested that DTAG re-explore Policy 4.0 public comment feedback and provide appropriate policy modification language for full Committee consideration. These newly proposed modifications will likely be recommended to the Board of Directors in 2008.

****RESOLVED**, that the DTAG re-explore the public comments provided for Policy 4.0 and provide appropriate policy modification language to include Policy 2.0 for full Committee consideration.

Committee Vote: 14 For; 0 Against; 0 Abstaining

7. Reconsideration of modifications to Policy 7.0 (Recipient Death Reporting) - Post public comment – The Committee examined public comment feedback and the additional policy modifications proposed by the Policy Oversight Committee to Policy 7.0. The Committee elected to defer modifications to Policy 7.0 to the Policy Oversight Committee and include proposed policy modifications related to recipient death from donor transmitted disease in Policy 4.0 modifications.
8. Directed Donation Organ Allocation in UNetsm Update – The Committee reconsidered the patient safety issues regarding directed donation. There are no OPTN policies which describe directed donation. However, existing OPTN policy requires that every candidate appear on the match. Currently it is possible that an intended candidate may be screened off the match due to allocation algorithms. A working group was created to explore the concerns, advise UNOS IT staff, draft policy language, and present options for full Committee review at its next meeting.
9. Organ Allocation to Multiple Organ Transplant Candidates – The Committee reconsidered the patient safety issues regarding organ allocation to multiple organ transplant candidates. A subgroup was created to explore the concerns, advise UNOS IT staff, examine policy language, and present options for full Committee review at its next meeting.
10. Infectious Disease Testing of Donor Organs – The Committee reviewed multiple member requests addressing various aspects of potential deceased donor screening including a request for variance from one OPO and consideration of Nucleic Acid Testing (NAT) for all infectious disease organ donor screening. Dr. Ison provided background information about NAT testing. Infectious disease testing using NAT for all donor specimens does have limitations, which include logistics and balance of sensitivity, specificity and the potential for increased false positive results. The Committee recognized the need for subject matter experts to examine many of these issues and asked DTAG to get expert input and recommend how NAT could be operationalized. DTAG's findings will be forwarded to the OPTN/UNOS OPO Committee for consideration.

**RESOLVED, that DTAG explore the current testing standards for serologies in order to formulate recommendations for proposed policy modifications for full Committee consideration.

Committee Vote: 13 For; 0 Against; 0 Abstaining

11. CDC Guidelines for High Risk Behavior – The Committee reviewed a member request regarding a blinded deceased donor case that highlighted confusion that exists regarding CDC High Risk Behavior and what qualifies as a “high risk” donor. The Committee acknowledged the perplexities of the “high risk” term as well as the need for education within the transplant community. The Committee’s discussion will be summarized in a letter to the member and the matter will be referred to the OPTN/UNOS OPO Committee for consideration.
12. Disease Transmission, Malignancy, and Patient Safety Report – Joyce Hager, MPH, Patient Safety Manager, provided a summarized report of all reported events since April 19, 2007. The Committee reviewed 43 new disease transmission reports since the previous meeting. 18 reported cases were infectious diseases, 20 cases were malignancy, and 5 cases were false positive laboratory or pathology results. Specifically six renal cell carcinomas were reported. Each case was reviewed by the DTAG via the secure Share Point site dedicated to potential disease transmission discussions and chart review. The Committee then reviewed the 17 patient safety situations reported since April 19, 2007. The Committee discussed and requested further information regarding two reported events involving donor quality. The Committee requested reports at every meeting of cases involving donor quality patient safety reports. All situations involving potential policy violations were referred to the Department of Evaluation and Quality for further review.
13. Transplantation Transmission Sentinel Network (TTSN) Update – Ms. Hager, TTSN Project Coordinator, provided an updated report of the cooperative agreement with the CDC. This agreement will produce a central communication system for the organ, tissue, and eye communities to communicate urgent information regarding likelihood of disease transmission; link a donor and all associated recipients to allow for high-speed tracking; and collect relevant clinical data.
14. DonorNet[®] 2007 Update – Mr. Blaine Hess, UNOS Acting Assistant Executive Director for Information Technology, provided a project status report that included the September 2007 OPTN/UNOS Board recommendations, August 2007 DonorNet[®] Implementation Subcommittee report, and July 2007 DonorNet[®] data. Questions were entertained.
15. Tiered Acceptance Criteria – The Committee reviewed the feedback of the OPTN/UNOS Thoracic Organ Transplantation Committee regarding Tiered Acceptance Criteria. The Committee discussed the screening criteria in DonorNet[®] and how this may be helping to achieve what Tiered Acceptance had intended. However, it was noted that DonorNet[®] deals with individual patient screening levels, while Tiered Acceptance creates candidate profiles that can be used for entire programs. The Committee opted to create a working group to address Tiered Acceptance Criteria. Three Committee members volunteered to serve on the subgroup and former members of the DSA Task Force will be invited to participate as well. This group will advise the Committee of possible paths forward regarding the topic at its next meeting.
16. Update on New OPTN System Development – UNOS staff provided an overview of this initiative, its concepts, and the plans for developing the new OPTN system. Questions were entertained.
17. Organ Transportation/Organ Wastage – Reports from the Organ Center detailing transportation errors/near-misses and results of a three-month OPO organ transportation/organ wastage survey were examined by the Committee. Additionally, the Committee revisited the idea of exploring the option of commercial transportation vendors bidding to transport deceased donor organs and will recommend that a Request for Proposal resolution be presented to the OPTN/UNOS Board of Directors in February 2008.
18. Match List Re-running – Reports prepared by UNOS Research staff regarding organizations which routinely re-run match lists were reviewed and discussed by the Committee.

19. Internal Organ Packaging Labels – Dr. Michael Hagan, Region 10 Committee Representative, reported regarding an informal poll of the AOPO Quality Improvement Council members regarding the use of internal organ packaging labels. The current practices of most OPOs already include using a secondary internal labeling procedure.
20. Review of Draft E-Quality Newsletter – The draft design for the E-Quality newsletter was presented. The Committee deliberated on the newsletter’s content and UNOS staff will explore additional content options and report back to the Committee.
21. Status report on ABO verification policies – A status report from UNOS Research regarding ABO modifications made for candidate and donor listings was provided to the Committee. It was noted that there was little change in the data since the last Committee meeting. The Committee will continue to receive this status reports.
22. Candidate ABO Typing Prior to Listing – A report from UNOS DEQ regarding ABO discrepancies reported to the OPTN/UNOS Membership and Professional Standards Committee between July 2006 and May 2007 was provided to the Committee. No action was taken by the Committee.
23. Proposed Modifications to Modifications to: Policy 3.5.3.5 (Organ Offer Limit), Policy 3.8.1.7.1 (Time Limit), and Policy 7.6.1.2 (Validation of Offers of Organs Placed through the Organ Center) – On January 4, 2008, the Committee met by LiveMeeting to review and discuss proposed policy language modifications to the time limits for organ offers for zero antigen mismatched kidneys, pancreata and kidney/pancreas. These modifications will change kidney and pancreas policy to require that OPOs and the Organ Center must make a specified number of zero antigen mismatched organ offers instead of offering the zero antigen mismatched organs for a specified number of hours. The Committee approved the policy modifications and recommended that the policy be sent for Public Comment in February 2008.

**Resolved, that the Operations Committee will send out for public comment proposed modifications to Policy 3.5.3.5- Organ Offer Limit, Policy 3.8.1.7.1- Time Limit, and Policy 7.6.1.2- Validation of Offers of Organs Placed through the Organ Center. These modifications will require OPOs and the Organ Center to make a specified number of zero antigen mismatched organ offers instead of offering the zero antigen mismatched organs for a specified number of hours.

The modifications to Policy 3.5.3.5 (Organ Offer Limit), Policy 3.8.1.7.1 (Time Limit), and Policy 7.6.1.2 (Validation of Offers of Organs Placed through the Organ Center) appear below. For your convenience in reviewing, the new language is presented as it would look if this proposal is approved. Following the proposed new language is the existing language with new language double underlined and language that is to be removed with ~~double strikethroughs~~. Language with a single underline or a ~~single strikethrough~~ was changed by the Board of Directors at a previous Board meeting but has not been implemented yet.

3.5.3.5 Organ Offer Limit. Kidneys to be shared as zero antigen mismatches, either alone or with pancreata, must be offered to the appropriate recipient transplant centers through UNetsm or through the Organ Center within 8 hours after organ procurement for standard criteria donors and within 4 hours after organ procurement for expanded criteria donors (organ procurement is defined as cross clamping of the donor aorta). For standard criteria donor (SCD) kidneys, offers must be made for at least the first 10 zero antigen mismatched potential recipients.¹ If there are less than 10 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list- For expanded criteria donor (ECD) kidneys, offers must be made for at least the first 5 zero antigen mismatched potential recipients. If there are less than 5 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers

¹ For the purposes of Policy 3.5.3.5, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO may:

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1 (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

If the Host OPO chooses to continue offering the kidney(s) for zero antigen mismatched potential recipients beyond the 10th potential recipient for a SCD or 5th potential recipient for an ECD, no obligation to pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) will be generated, even if the kidney is accepted for a zero antigen mismatched potential recipient. If the Host OPO chooses to share the zero antigen mismatch through UNetsm, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the organ(s) recovery, defined as cross clamping of the donor aorta, to report the sharing. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share; and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNetsm. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

3.8.1.67.1 Organ Offer Limit. All pancreata to be shared as zero antigen mismatches, either alone or in combination with kidneys, must be offered to the appropriate recipient transplant centers through UNetsm or through the Organ Center within eight hours after organ procurement. Offers must be made for the first 10 zero antigen mismatched potential recipients² according to the national lists of candidates waiting for combined kidney/pancreas or isolated pancreas transplantation, as applicable. If there are less than 10 zero antigen mismatched potential recipients on the match list, offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO-may:

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1, as applicable (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

If the Host OPO continues to offer kidney/pancreas combinations for zero antigen mismatched potential recipients beyond the 10th potential recipient, a kidney payback will be generated pursuant to Policy 3.5.5- Payback Requirements. If the Host OPO chooses to share a zero antigen mismatched kidney/pancreas combination through UNetsm, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the recovery of the organ(s), defined as cross clamp of the donor aorta, to report the share. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share; and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNetsm. No obligation to payback the pancreas will be generated. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

7.6.1.2 Validation of Organ Center Offers. Recipient specific refusal reasons recorded by the Organ Center will be considered validated as recorded. The Organ Center staff will use the online procedure available in UNetSM for this purpose.

Current Language with Proposed Language in Double Strikeouts and Double Underlines

² For the purposes of Policy 3.8.1.67.1, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

3.5.3.5 Organ Offer Time Limit. Kidneys to be shared as zero antigen mismatches, either alone or with pancreata, must be offered to the appropriate recipient transplant centers through UNetsm or through the Organ Center ~~within 8 hours after organ procurement for standard donors and within 4 hours after organ procurement for expanded criteria donors (organ procurement is defined as cross clamping of the donor aorta).~~ For standard criteria donor (SCD) kidneys, offers must be made for at least 10 zero antigen mismatched potential recipients³ ~~candidates, or all candidates.~~ ~~If fewer~~ there are less than 10 zero antigen mismatched potential recipients ~~appear~~ on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. For ~~extended~~ expanded criteria donor (ECD) kidneys, offers must be made for at least the first 5 zero antigen mismatched potential recipients ~~candidates, or all candidates.~~ ~~If fewer~~ there are less than 5 zero antigen mismatched potential recipients ~~appear~~ on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), ~~The Organ Center will attempt to place standard donor organ(s) for zero antigen mismatched candidates according to the national lists of candidates waiting for combined kidney/pancreas or isolated kidney transplantation, as applicable, for a period of four hours (starting from the time the Organ Center makes the first offer) after which time the Organ Center will notify the Host OPO that it may;~~

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1 (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

If the Host OPO chooses to continue offering the kidney (s) for zero antigen mismatched potential recipients beyond the 10th potential recipient for a SCD or 5th potential recipient for an ECD, no obligation to pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) will be generated, even if the kidney is accepted for a zero antigen mismatched potential recipient. ~~The period of time allowed for acceptance of zero antigen mismatched standard kidney offers made within the four hours permitted for placing these organs, but with less than an hour before the four hours will expire, shall equal the time remaining within the four hour period for placement of standard zero mismatched donor kidneys. In the event the Host OPO declines the opportunity to allocate standard donor organ(s) locally, then the Organ Center shall continue to attempt to place the organ(s) for zero antigen mismatched candidates according to the national lists of waiting candidates. Acceptance of organs declined by the Host OPO will not generate an obligation to pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) even if accepted for a zero antigen mismatched candidate. The Organ Center will attempt to place expanded criteria donor organ(s) for zero antigen mismatched candidates according to the national lists of candidates waiting for expanded criteria donor kidney transplantation for a period of two hours (starting from the time the Organ Center makes the first offer) after which time the Organ Center will notify the Host OPO that it may allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 (first locally, then regionally, and then nationally) for candidates designated as eligible to receive expanded criteria donor kidneys. The period of time allowed for acceptance of zero antigen mismatched expanded criteria donor kidney offers made within the two hours permitted for placing these organs, but with less than an hour before the two hours will expire, shall equal the time remaining within the two hour period for placement of expanded criteria zero mismatched donor kidneys. Time available for organ acceptance, if shorter than one hour, shall be communicated with the organ offer. The Organ Center will document each offer and each response. If the Host OPO chooses to share the zero antigen mismatch through UNetsm, the Host OPO must submit a completed Kidney Payback Accounting Sheet ~~it must contact the Organ Center~~ within 5 business days ~~24 hours~~ of the organ(s) recovery, defined as cross clamping of the donor aorta, to report the sharing. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share; ~~the Host OPO contacts the Organ Center~~ and 2) the zero antigen~~

³ For the purposes of Policy 3.5.3.5, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNetsm. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

NOTE: The amendments to Policy 3.5.3.5 (Time Limit) shall be effective pending distribution of appropriate notice and programming in UNetsm. (Approved at the September 2007 Board of Directors Meeting)

3.8.1.67.1 Time Organ Offer Limit. All pancreata to be shared as zero antigen mismatches, either alone or in combination with kidneys, must be offered to the appropriate recipient transplant centers through UNetsm or through the Organ Center within eight hours after organ procurement. ~~The Organ Center will attempt to place the organ(s) for~~ Offers must be made for the first 10 zero antigen mismatched ~~candidates~~ potential recipients⁴ according to the national lists of candidates waiting for combined kidney/pancreas or isolated pancreas transplantation, as applicable. If there are less than 10 zero antigen mismatched potential recipients on the match list, offers must be made for all zero antigen mismatched potential recipients on the match list. for a period of four hours (starting from the time the Organ Center makes the first offer) after which time the Organ Center will notify ~~If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO that it may:~~

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1, as applicable (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

~~The period of time allowed for acceptance of zero antigen mismatched pancreas offers made within the four hours permitted for placing these organs, but with less than an hour before the four hours will expire, shall equal the time remaining within the four-hour period for placement of zero mismatched donor pancreata. Time available for organ acceptance, if shorter than one hour, shall be communicated with the organ offer. In the event the Host OPO declines the opportunity to allocate the organ(s) locally, then the Organ Center shall continue to attempt to place the organ(s) for zero antigen mismatched candidates according to the national lists of waiting candidates. If the Host OPO continues to offer kidney/pancreas combinations for zero antigen mismatched potential recipients beyond the 10th potential recipient, a kidney payback will be generated pursuant to Policy 3.5.5 (Payback Requirements). Acceptance of organs offered to declined by the Host OPO will not generate an obligation to pay back the kidney pursuant to Policy 3.5.4 (Payback Requirements) will be generated, even if accepted for a zero antigen mismatched candidate. The Organ Center will document each offer and each response. If the Host OPO chooses to share a zero antigen mismatched kidney/pancreas combination through UNetsm, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the recovery of the organ(s), defined as cross clamp of the donor aorta, to report the share. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share; and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNetsm. No obligation to payback the pancreas will be generated. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.~~

NOTE 1: The amendments to Policy 3.8.1 (Pancreas Organ Allocation) shall be implemented pending appropriate notice and programming in UNetSM. (December 14, 2006 BOD Meeting)

7.6.1.2 Validation of Organ Center Offers of Organs Placed Through the Organ Center. Recipient specific refusal reasons for offers made recorded by the Organ Center ~~(including offers of all mandatory kidney shares for zero mismatched recipients)~~ will be recorded by the Organ

⁴ For the purposes of Policy 3.8.1.67.1, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

~~Center staff to assure accuracy, and~~ will be considered validated as recorded. The Organ Center staff will use the online procedure available in UNetSM for this purpose.

Committee Vote: 14 For; 0 Against; 1 Abstaining.

24. Proposed Modifications to Policy 4.1.1 (Donor History) – In an effort to strengthen requirements for the informed consent for recipients regarding CDC high risk donors, the Operations Committee sponsored proposed modifications to Policy 4.1.1 that were considered by the Executive Committee on December 18, 2007. The Executive Committee had several concerns including: does the policy now require a second, donor-specific consent form at the time of organ offer acceptance? It was suggested that this additional documentation requirement will not accomplish the goal it was intended to achieve. If high risk donors are identified under the CDC guidelines, the potential recipient has the right to know this information prior to accepting the donor organ. The objection was raised to the requirement for the execution of a separate consent form in the middle of the night by a potential recipient – this documentation of potential for a high risk donor offer should be made well in advance and then the specific qualities of the donor organ should be discussed at the time of the organ offer without the need for a separate documentation at the time of the organ offer acceptance.

This resolution was approved by the Executive Committee on December 18, 2007 by a vote of 9 for, 0 against, and 1 abstention:

***RESOLVED, that the following modifications to OPTN/UNOS Policy 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Recipient Diseases Or Medical Conditions, Including Malignancies, of Donor Origin) as set forth below are hereby approved, effective pending distribution of notice to the Members.*

***FURTHER RESOLVED, that these modifications shall be submitted for public comment and reconsidered by the OPTN/UNOS Board of Directors, as appropriate.*

4.0 ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), HUMAN PITUITARY DERIVED GROWTH HORMONE (HPDGH), AND REPORTING OF POTENTIAL RECIPIENT DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES, OF DONOR ORIGIN

4.1 SCREENING POTENTIAL ORGAN DONORS FOR HIV. All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV). If the potential donor's pre-transfusion test for HIV is negative and blood for subsequent transfusions has been tested and found to be negative for HIV, retesting the potential donor for HIV is not necessary. If no pre-transfusion sample of the potential donor's blood is available, the Host OPO (as defined in Policy 2.1) must provide, to the recipient transplant center the screening test results and a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organ. Organs from donors with a positive screening test are not suitable for transplantation unless subsequent confirmation testing indicates that the original tests' results were falsely positive for HIV. If additional tests related to HIV are performed, the results of all tests must be communicated immediately to the Organ Center and all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.1.3 below.

4.1.1 Communication of Donor History. The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control and Prevention (CDC). If the donor meets the criteria below,⁵ the Host OPO must

⁵ Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports.

communicate this information regarding donor history to all institutions receiving organs from the donor.

Behavior/History Criteria

- i) Men who have had sex with another man in the preceding 5 years.*
- ii) Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years.*
- iii) Persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates.*
- iv) Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years.*
- v) Persons who have had sex in the preceding 12 months with any person described in terms i-iv above or with a person known or suspected to have HIV infection.*
- vi) Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane.*
- vii) Inmates of correctional systems (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population).*

Pediatric Donor Criteria

- viii) Children meeting any of the criteria listed above for adults.*
- ix) Children born to mothers with HIV infection or mothers who meet the behavioral or laboratory criteria for adult donors (regardless of their HIV status) unless they are greater than 18 months of age, have not been breast fed within the last 12 months and the child's antibody tests, physical examination, and review of medical records do not indicate evidence of HIV infection.*
- x) Children less than or equal to 18 months of age who are born to mothers with or at risk for HIV infection or who have been breast fed within the past 12 months.*

Laboratory and Other Medical Criteria

- xi) Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g., hemodilution that could result in false-negative tests), or another other reasons.*
- xii) Persons with a repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays.*
- xiii) Persons whose history, physical examination, or medical records reveal other evidence of HIV infection or high-risk behavior, such as a diagnosis of AIDS, unexplained weight loss, night sweats, blue or purple spots on the skin or mucous membranes typical of Kaposi's sarcoma, unexplained lymphadenopathy lasting greater than 1 month, unexplained temperature greater than 100.5 F (38.6 C) for greater than 10 days, unexplained persistent cough and shortness of breath, opportunistic infections, unexplained persistent diarrhea, male to male sexual contact, sexually transmitted diseases, or needle tracks or other signs of parenteral drug abuse.*

If the transplant center receives information from the Host OPO that the donor meets any of the above criteria, the transplant center must inform the potential recipient prior to implantation. The transplant center shall maintain documentation of the potential recipient's informed consent to receive an organ from the donor who meets any of the above criteria. In the event that the potential recipient is not able to provide informed consent, the legal next of kin, designated healthcare representative, or appropriate surrogate may provide consent on this matter.

[No further changes to Policy 4.0]

Next Meeting

The next Operations Committee meeting is scheduled for Thursday, April 17, 2008, at the O'Hare Hilton Hotel in Chicago.

The October 4, 2007 Operations Committee meeting was adjourned at 4:00 p.m.

OPTN/UNOS OPERATIONS COMMITTEE MEETING ATTENDANCE

Name	Position	Chicago, Illinois October 4, 2007	Live Meeting January 4, 2008
Richard Hasz, Jr., MFS	Chair (Region 2)	x	x
Marwan Abouljoud, MD	Vice Chair (Region 10)	x	x
Laine Krisiunas, BS, MBA	Region 1	x	x
Kevin Carney, RN	Region 2	x	x
Lee Langley, RN	Region 3	x	x
James Cutler, CPTC	Region 4	x	
Shanna Perales	Region 5	x	x
Kristi Ross, BSN, RN	Region 6	x	
Barry Friedman, MBA, RN	Region 7	x	x
Douglas Bremers, BA	Region 8	x	x
David Bekofsky, MS	Region 9	x	x
Michael Hagen, DO	Region 10	x	x
Nancy Knudsen, MD	Region 11	x	
William Cotts, MD	At Large	x	x
Karen Cox, PhD, RN	At Large		
Oscar Grandas, MD	At Large	x	x
Michael Ison, MD	At Large	By Phone	x
Gwen McNatt, MS, RN	At Large	x	x
J. Elizabeth Tuttle- Newhall, MD	At Large		
Marlon Levy, MD	Ex Officio	x	x
Richard Durbin, MBA	Ex. Officio	By phone	x

UNOS staff attending:

Gloria Taylor, RN, MA, CPTC	Committee Liaison
Joyce Hager, MPH	Committee Liaison, Patient Safety Specialist
Blaine Hess	Acting Asst. Executive Director, Information Technology
Leah Edwards, PhD	Assistant Director, Research
Stacey Burson	IT Business Analyst
Catherine Monstello	IT/Policy Analyst