

OPTN/UNOS KIDNEY & PANCREAS TRANSPLANTATION COMMITTEE REPORT

SUMMARY

I. Organ Availability

None

II. Patient Access Issues

Action Items for Board Consideration

- Proposed Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Recipients of Living Donor Kidneys (Item 1, Page 1).

Other Significant Issues

- Review of OPTN/UNOS Board Action on Committee-Sponsored Study to Permit Kidney Waiting Time Accrual to Commence from the Initiation of Chronic Maintenance Dialysis (Item 2, Page 4).

III. Other Issues

Action Items for Board Consideration

- Proposed Modifications to OPTN/UNOS Policies 3.5.5 (Payback Requirements) and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals) (Item 3, Page 6).
- Proposed Modifications to OPTN/UNOS Policies 3.8.1.5 (Islet Allocation Protocol) (Item 4, Page 9).
- Proposed Modifications to OPTN/UNOS Policy 3.8.1.6 (Mandatory Sharing of Zero Antigen Mismatched Pancreata) (Item 5, Page 12).
- Proposed Modifications to OPTN/UNOS Policies 3.5.5.1 (Kidney/Non-Renal Organ Sharing) and 3.5.5.2 (Deferment of Voluntary Arrangements) (Item 6, Page 14).
- Proposed Modifications to OPTN/UNOS Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) (“Exemption of Kidneys Recovered from Donation after Cardiac Death (DCD) Donors from Sharing Requirements for Zero Antigen Mismatched Kidneys or Payback) (Item 7, Page 17).
- Proposed Modifications to OPTN/UNOS Policy 3.5.5 (Payback Requirements) (“ECD Kidney Exemption from Payback Sharing Requirements”) (Item 8, Page 19).
- Request from Midwest Transplant Network Regarding Allocation of A₂ and A₂B Kidneys (Item 9, Page 21).
- Request from LifeLink Foundation Regarding Pancreas and Kidney/Pancreas Allocation (Item 10, Page 21).
- Request from LifeGift Organ Donation Center Regarding the Lubbock Alternative Local Unit (Item 11, Page 22).
- Review of OPTN/UNOS Board Actions and Resolutions (Item 12, Page 23).

Other Significant Issues

- Requests for Patient Waiting Time Adjustment (Item 13, Page 24).
- Review of the OPTN/UNOS Histocompatibility Committee Proposed Modifications to OPTN/UNOS Bylaws Appendix B Attachment 1 (Standards for Histocompatibility Testing) Standard H3.100 and Proposed New Policies for Kidney Transplantation – 3.5.17 (Prospective Crossmatching), and for Pancreas Transplantation – 3.8.8 (Prospective Crossmatching), and Proposed Appendix D to Policy 3 (Item 14, Page 30).
- Review of the OPTN/UNOS Ad Hoc International Relations Committee Proposed Modifications to OPTN/UNOS Policy 6.4 (Exportation and Importation of Organs – Developmental Status) (Item 15, Page 30).
- Review of the OPTN/UNOS Ad Hoc Living Donor Committee Proposed Guidelines for Living Kidney Donor Evaluation (Item 16, Page 31).
- Review of the OPTN/UNOS Ad Hoc Operations Committee Proposed Modifications to OPTN/UNOS Policy 3.1.4 (Patient Waiting List) (Item 17, Page 31).
- Review of the OPTN/UNOS Ad Hoc Operations Committee Proposed Modifications to OPTN/UNOS Policy 3.2.3 (Match System Access) (Item 18, Page 32).
- Review of the OPTN/UNOS Transplant Administrators Committee Proposed Modification to the Criteria for Institutional Membership, OPTN/UNOS Bylaws, Appendix B, Section III (C) (Transplant Programs): Proposed Modifications to Item 15 (Social Support) (Item 19, Page 32).
- Review of the OPTN/UNOS Transplant Administrators Committee Proposed Modifications to the Criteria for Institutional Membership, OPTN/UNOS Bylaws Appendix B, Section III (C) (Transplant Programs): Proposed New Item 20 (Clinical Transplant Pharmacist) (Item 20, Page 32).
- Request from Texas Organ Sharing Alliance (TOSA) Regarding Kidney Allocation (Item 21, Page 33).
- Alternative System Requests from Gift of Hope Organ and Tissue Donor Network (Item 22, Page 34).
- Request from Transplant Resource Center of Maryland for Review of Their Long Term Kidney Debt Status (Item 23, Page 37).
- Presentation on OPTN Final Rule and Draft Response to Board Resolution (Item 24, Page 38).
- Presentation on KPSAM (Item 25, Page 40).
- Report of the OPTN/UNOS Kidney and Pancreas Transplantation Subcommittee on Kidney Allocation and KPSAM (Item 26, Page 42).
- Presentation on Living Donor Paired Kidney Exchanges (Item 27, Page 43).
- OPTN/SRTR Data Working Group Proposed Transplant Endpoints (Item 28, Page 44).
- Report of the OPTN/UNOS Joint Kidney and Pancreas/Pediatrics/Minority Affairs Subcommittee (Item 29, Page 48).
- Proposed Modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) (Item 30, Page 52)

- Report of the OPTN/UNOS Joint Kidney and Pancreas/OPO/Transplant Administrators Subcommittee (Item 31, Page 56).
- Report of the OPTN/UNOS Joint OPO Subcommittee (Item 32, Page 57).
- Report of the OPTN/UNOS Joint Kidney and Pancreas and Organ Availability Subcommittee (Item 33, Page 59).
- ECD Mortality (Item 34, Page 61)
- Report of the OPTN/UNOS Joint Ad Hoc Living Donor and Kidney and Pancreas Transplantation Subcommittee (Item 35, Page 62).
- Proposal for Priority for Candidates with Intermediate Sensitization Levels (Item 36, Page 63).
- OPTN/UNOS OPO Committee Review of the Reuse of Disposable Transport Containers and Standardization of Organ Packaging Transport (Item 37, Page 64).
- Request from the OPTN/UNOS OPO Committee Regarding Coordinating OPOs (Item 38, Page 65).
- Request from the OPTN/UNOS Operations Committee for Review of Required Listing Criteria to Assure More Accurate Patient Listing and Donor Acceptance Criteria (Item 39, Page 66).
- Aggressive Organ Placement Issues (Item 40, Page 66).
- Requested Clarification of Pancreas Donor Match Issue – Matching Includes Pancreas Donor to the Candidate and Previous Kidney Donor to the Candidate (Item 41, Page 66).
- Requested Review of P24 Antigen Screening for HIV Test (Item 42, Page 67).
- Proposed Pancreatic Islet Conference (Item 43, Page 67).
- Food and Drug Administration (FDA) Advisory Meeting on Islets (Item 44, Page 67).
- West Nile Virus Alert (Item 45, Page 67).
- Organ Infection Request for Proposal (Item 46, Page 68).
- Double Kidney Allocation (Item 47, Page 68).
- Review of Updated UNOS Travel Policy (Item 48, Page 68).
- May Committee Meeting Schedule Change (Item 49, Page 68).
- OPTN/UNOS Membership and Professional Standards Committee Metric Data and Analysis (Item 50, Page 68).

**REPORT OF THE
OPTN/UNOS KIDNEY & PANCREAS TRANSPLANTATION COMMITTEE
TO THE
BOARD OF DIRECTORS**

**Minneapolis, Minnesota
June 24-25, 2004**

**Alan B. Leichtman, M.D., Chairman
Mark D. Stegall, M.D., Vice Chairman**

This report includes items addressed by the OPTN/UNOS Kidney and Pancreas Transplantation Committee at its meetings held on January 20-21, 2004, and May 19-20, 2004.

I. Organ Availability Issues

None

II. Patient Access Issues

1. Proposed Modification to Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys. Public comments on the proposed amended local voluntary alternative system for assigning priority in kidney allocation to original intended candidates for living donor kidneys and the Committee's responses are set forth in **Exhibit A**. The proposed modification would rank intended candidates (IC), in situations where more than one IC appeared on a match run, in order of date of donation from the living donor. The term "time waiting" would be eliminated from this portion of the alternative system so as not to be confused with the standard meaning of candidate waiting time. The intent of the alternative system approved by the Board was to facilitate kidney donation by living persons and increase the availability of organs for transplantation overall. The present proposal is intended to assign priority among ICs when more than one in a manner that better reflects the alternative system's overall objectives.

At its May 19, 2004, meeting, the Committee discussed the proposal in light of the public comments. Of the 44 individuals who commented on the proposal, 98% supported and 2% opposed the proposal. Of the 11 Regions, each Region supported the proposal, including 6 Regions unanimously.

Some of the public commentary received expressed concerns that the proposal might disadvantage ABO blood type O candidates otherwise listed for kidney transplantation since it would be expected that a substantial number of the intended candidates receiving higher priority under the proposal would be ABO blood type O. The Committee reaffirmed its previously stated position with respect to blood group O candidates. While it is acknowledged that blood type O patients might be disadvantaged by the proposal, these candidates face relatively long waiting times apart from this proposal. The intent of the proposal is to increase organs available for transplantation generally so that individuals may be transplanted and removed from the Waiting List freeing up deceased donor organs for other candidates on the list. Candidates are benefited overall, although individual candidates may not realize an advantage. It is hoped that implementation of the protocol as a generic alternative allocation system will permit collection of data sufficient to determine if the policy does disadvantage blood type O candidates. The protocol's analysis plan specifically requires that impacts of the system upon candidates by blood group be studied. Appropriate modifications could then be made to the generic alternative system.

Responses to the public comment also expressed that a candidate from the transplant center of the original intended candidate should receive the living donor kidney that was incompatible with the original intended candidate. Some Members of the Committee also questioned whether the alternative allocation system should specify the allocation algorithm to be used for the intended living donor organs in order to ensure equitable distribution of the kidneys. The alternative system presently permits OPOs to elect how best to allocate the incompatible living donor kidney. While the proposed system does not specify the allocation algorithm, the Committee offered guidance in Appendix 2 for the allocation of incompatible living donor kidneys. Though the guidance does not constitute a requirement, the Committee's recommendation is for OPOs to follow the local standard allocation system, but acknowledged the practical issues that might indicate living donor nephrectomy

and transplantation should occur in the same transplant center so as to minimize cold ischemic time, costs, and accidental loss of or damage to the kidney.

Some Members expressed that discretion over allocation of the living donor kidneys should remain with the OPO, but OPOs, as part of the application process, should be required to submit documentation specifying how the living donor kidneys will be allocated under this original intended candidate system. The intent is to ensure these kidneys are allocated equitably and appropriately based on a defined protocol, rather than by random selection. After further consideration, the Committee agreed to amend the proposal to require documentation of the living donor kidney allocation protocol as part of the application to participate in the system by a vote of 24 For; 0 Against; 0 Abstentions. OPOs still would be permitted discretion in terms of the protocol developed, but they would be required to define the protocol as part of the application process..

After further discussion, the Committee unanimously agreed to offer the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modification to the local voluntary alternative system for assigning priority in kidney allocation to original intended candidates having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee with an amendment, shall be approved and implemented pending programming on the UNOS System:**

Goal

The primary goal of this prospective alternative system for kidney allocation is to facilitate kidney donation by living persons and increase the availability of organs for transplantation overall. Using live donor/paired candidate registries in situations where the original intended candidate for a living donor kidney is incompatible with his/her living donor has been problematic historically due to factors such as size of that subgroup of the living-donor pool and inability to match donors to transplant candidates. Assignment of priority for deceased donor kidney allocation to the original intended candidate (IC) when the patient's intended donor donates to a candidate on the list of patients waiting for a deceased donor kidney provides a mechanism to expand this pool of potential donors for the living donor's original intended candidate. The alternative system acknowledges the ABO or HLA antigen factor resulting in incompatibility between donor and candidate that prevented the intended live donor organ transplant to occur. It also acknowledges the difference in expected graft survival between a living donor kidney transplant and a deceased donor kidney transplant (*i.e.*, > 80% vs. > 70% 3-year graft survival¹). A primary principle of the system is, therefore, to get the original intended candidate transplanted expeditiously.

System Background and Rationale [No Proposed Changes to This Section]

System Design

The following allocation sequence will not supercede the allocation algorithm (OPTN/UNOS algorithm or local alternative system) used by the participating OPO, but will be superimposed on to their allocation algorithm. It will apply only at the local level of organ allocation. Transplant programs participating in the alternative system are required to provide appropriate guidance to living donors and patients who elect to take part in this system to enable understanding by these individuals of how the system works.

Allocation Sequence

- Zero antigen mismatched combined kidney/pancreas patients who are highly sensitized (*i.e.*, panel reactive antibody (PRA) level \geq 80%). See note 1 below.
- Zero antigen mismatched isolated kidney patients. See note 2 below.
- Prior living donors subsequently listed for kidney transplantation.
- UNOS Paybacks (Debits/Credits)

¹ Terasaki PI, Cecka JM, Gjertson DW, Takemoto S. High Survival Rates of Kidney Transplants from Spousal and Living Unrelated Donors. N Engl J Med 1995; 333: 333.

- Local Waiting List, Highest Scoring High PRA Candidates
- Local Waiting List, Surpassed Pediatric Goals
- Original intended candidates for living donor organs who meet the criteria for this priority as described below, **by time waiting in order of donation date of their respective original intended living donor** if more than one. See note 3 below.
- Other mismatched patients according to the standard algorithm.

Note 1: An exception to this priority exists for patients receiving kidneys with non-renal organs other than the pancreas.

Note 2: An exception to this priority exists for patients receiving kidneys with non-renal organs.

Note 3: An exception to this priority exists for patients receiving kidneys with non-renal organs. An exception to this priority may exist based upon preference assigned locally for patients considered medically urgent following a cooperative medical decision of local kidney transplant centers under OPTN/UNOS Policy 3.5.11.4 (The Point System for Kidney Allocation – Medical Urgency).

The intent is to assign original intended candidates for living donor organs who meet the protocol’s criteria sufficient priority in kidney allocation to get them transplanted expeditiously (i) without modifying priorities assigned for other candidates based upon unique utility and/or medical benefit of the kidney transplant, and (ii) acknowledging the standard order of kidney paybacks (debts/credits) in the national system.

Definition of Original Intended Candidate for Living Donor Kidney [No Proposed Changes to This Section]

Guidelines for Listing Patients as Original Intended Candidates for Living Donor Kidneys [No Proposed Changes to This Section]

Living Donor Considerations [No Proposed Changes to This Section]

Allocation of Living Donor Kidneys

The proposed protocol does not direct how kidneys procured from living donors who elect to take part in the system shall be allocated. The committee does offer guidance with respect to allocation of these organs as set forth in Appendix 2 of this document [Appendix 2 is included in **Exhibit A, pages 12-16**, to this report for reference]. **Additionally, applications to participate in the system must include a description of the protocol that will be used to allocate living donor kidneys from donors who are incompatible with their original intended candidate.**

Sign –up Process [No Proposed Changes to This Section]

Time Line [No Proposed Changes to This Section]

Analysis Plans [No Proposed Changes to This Section]

[Please see **Exhibit A, page 17** for proposed modifications to Appendix 3, Application to Participate in the Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys, consistent with changes noted above.]

2. Review of OPTN/UNOS Board Action on Committee-Sponsored Study to Permit Kidney Waiting Time Accrual to Commence from the Initiation of Chronic Maintenance Dialysis. The proposal, as modified and approved by the OPTN/UNOS Board of Directors during its November 20-21, 2003, meeting, would permit a study allowing kidney waiting time accrual to commence for primary transplant candidates, from the time of initiation of chronic maintenance dialysis once listed as an active transplant candidate even if this time pre-dates the date of listing, and for repeat transplant candidates, from the date the candidate returns to chronic maintenance dialysis after graft failure once re-listed even if this time pre-dates the date of re-listing. The study would not change current policy allowing a patient's waiting time to accrue upon attaining a creatinine clearance level or calculated GFR of 20 ml/min or less, with no time accrued based upon these criteria prior to the date of the patient's listing. The intent of the study is to help address disparities patients may face in gaining access to the waiting list for kidney transplantation.

During its January 20-21, 2004, meeting, the Committee was informed of the Board decision to modify the proposal from a Committee-sponsored alternative system to a study. Though the change still permits testing the Committee proposal, the Board modification emphasized the importance of assessing the impact of the system and reporting back to the Board with a policy recommendation based on the assessment. One of the concerns expressed by the Board was that the Committee-sponsored alternative system might be allowed to continue indefinitely without rigorous analysis of its impact.

Alan Leichtman, M.D., discussed the proposal presentation made to the Board in November 2003 (**Exhibit B**). The Committee's hypotheses for this alternative system expressed to the Board included increased access for minorities, increased access for patients with end stage renal disease (ESRD) whose only insurance is Medicare or Medicaid, no delay in time to kidney transplant referral for patients with ESRD, and no adverse impact upon case mix resulting in poorer post-transplant outcomes. Assessing whether the system increases minority access will be determined by examining the number of minority kidney transplants, the ratio of minority kidney transplant recipients to the minority candidate pool, the ratio of minority kidney transplant recipients to the minority ESRD populations, and the ratio of the minority candidate pool to the minority ESRD populations. Similar measures would be reviewed to determine whether the system increases access for patients with Medicare and Medicaid. Organ offers versus actual transplants also may be assessed to study impacts on patient access.

The Committee agreed to have a subgroup of the Committee meet the morning of January 21, 2004, prior to the Committee meeting, to discuss the implementation and creation of the infrastructure for this Board-approved study.

The subgroup agreed that OPOs should be the smallest local unit able to apply for participation in the wait time study. Any Region could adopt the study if all OPOs within the Region agree to do so. In order to participate, the OPO or Region would submit a completed application with the required signatures documenting approval of the participating transplant centers and OPOs. All OPOs, including those currently operating under other alternative allocation systems, are eligible to participate in the study. However, those OPOs with other alternative systems may need to aggregate their data when assessing the performance of the study.

Transplant candidates listed with a center whose OPO adopts the wait time study will have two waiting times. For purposes of local kidney allocation, a candidate waiting for their primary kidney transplant would begin accumulating waiting time at the initiation of chronic maintenance dialysis (or upon meeting the policy's other renal function measures, if earlier in time). The same candidate would begin accumulating waiting time, for purposes of regional (unless the study is adopted region-wide) and national kidney allocation, from the date the candidate is listed on the waiting list and meets waiting time criteria of either measured (actual urinary collection) creatinine clearance level or calculated GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min or initiation of dialysis.

The Committee subgroup also discussed methodologies for evaluating the outcome measures proposed for the wait time study. Comparisons could be made, for instance, of donor service area outcomes before and after adoption of the wait time study and between donor service areas that participate and do not participate in the study. Alternatively, a control group could be established within each participating donor service area by alternating donor kidneys allocated by the study and standard system protocol. Outcomes measured should be

stratified by ABO blood group and ethnicity of candidates listed and transplanted under the study. The Committee should examine the ratio of minority kidney transplant recipients under the study to the minority population. Finally, the Committee should monitor the number of offers made to candidates with the number of transplants. A question is whether minority transplant candidates, in general, experience a disparity in the number of kidney offers when compared to white transplant candidates.

The Committee subgroup agreed that notice of the wait time study should be distributed to all OPO Executive Directors, OPO Medical Directors, Kidney and Pancreas Transplant Physicians and Surgeons, Directors of Organ Procurement, Kidney and Pancreas Clinical Coordinators, and Transplant Administrators for Kidney and Pancreas Transplant Programs.

Due to time constraints, the Committee subgroup was unable to formulate a finalized proposal for the full Committee to review at the January 21, 2004, meeting. However, the Committee subgroup agreed to meet prior to the next Committee meeting to continue their discussion. That meeting was held on March 23, 2004, via conference call.

The Committee subgroup was informed that several donor service areas have expressed interest in participating in the wait time study. Some Members commented that obtaining participation of entire Regions will be difficult, but multiple OPOs are likely to participate. The expected patient population within these donor service areas should suffice for study purposes.

The Committee subgroup agreed on the importance of examining post-transplant outcomes within the study. Some of the donor service areas that expressed concerns with first iterations of the proposal suggested that the protocol will impact patient case mix resulting in poorer post-transplant outcomes. The study should answer these concerns, particularly if the goal is to adopt the study as national policy in the future. The data and experience of Region 1 was suggested as a possible resource, but some Members felt that Region 1's alternative allocation system differs enough that a true assessment of the Committee wait time study could not be obtained. For instance, Region 1 does not allow an adult candidate's waiting time to start to accrue until he or she is on dialysis, but does not back date a candidate's waiting time to the date of first dialysis if listed after that date.

Adjustments will be made in the assessment of the study for age, gender, cause of ESRD, year of incidence for starting dialysis and waitlisting, race/ethnicity, comorbidities, dialysis unit type (private vs. hospital), donor service area, and insurance. The two categories of comparison will be outcomes in participating donor service areas before and after the study is implemented and outcomes between participating and non-participating donor service areas.

One alternative methodology proposed for consideration by the subgroup was to randomize patients to have their waiting time counted either from the date of first dialysis or the date of wait listing. Organs would then be divided between the two algorithms. However, some Members stated such a proposal would be difficult to administer and ensure balanced opportunities between the two study populations. One suggestion was to use alternate algorithms for allocating each of the two kidneys from a donor. This may make assessment of any changes to patient access to transplantation more difficult, however.

One potential benefit of the study discussed is that the study would better tie the patient therapy received to the progression of the patient's disease. This appears consistent with the Final Rule's emphasis on assigning priority by medical urgency. The study could also potentially help address disparities in access to transplantation. For instance, under the study, a candidate who suffers the inequity of not being referred for transplantation upon initiation of dialysis would have the option of administrative redress by backdating their waiting time to the date of dialysis once listed for a transplant.

After further discussion, the subgroup agreed to preserve all of the information included in the initial proposal submitted to the Board, but draft a new document detailing the study and analysis plan for review by the subgroup at its next meeting.

The Committee subgroup met again during the evening of May 19, 2004, to review the initial draft developed from the March 23 discussion. The draft consisted of statistical methodology, including hypotheses, study

design, statistical methods, endpoints on improving access, along with questions for the subgroup to consider (**Exhibit C**). The subgroup agreed that the goal of the study is to evaluate the effectiveness of an alternative method of assignment of waiting time based on the earlier of the dates of first dialysis regardless of the listing date or creatinine clearance/GFR \leq 20 ml/min but no earlier than the listing date. The study is designed to minimize disparities in time from dialysis to transplantation among ethnic groups, regardless of when patients are placed on the waiting list.

Under the approved wait time study, all donor service areas wishing to participate in the wait time study would need to enroll within the first year or some time period to be determined so that the comparison groups will be more similar. Some Members stated the enrollment period should be extended to the full length of the study term to permit maximum participation. It is anticipated that the study period will commence from the time the study allocation protocol is first programmed on the UNOS Computer for any participating donor service area rather than from the time of Board approval. Therefore, any delay in implementing the study should not shorten the study period itself.

The study design is proposed so that each outcome will be compared between donor service areas (DSAs) that elect to participate and those DSAs that choose not to participate. Outcomes within participating DSAs will also be compared before and after the policy is implemented. The initial study period will be three years. The measures for the study group will include time to transplant with only locally recovered deceased donor kidneys. Members of the subgroup agreed that candidates under the study should receive their waiting time when listed as inactive even prior to the implementation date of the policy allowing waiting time accrual for inactive status. Additionally, waiting time for candidates included in the study, who already are listed for kidney transplantation at the start time of the study, would be re-calculated according to the study protocol's terms.

An important issue considered by the Committee subgroup was whether to allow the study to apply to those donor service areas that elect to participate but currently operate with alternative allocation systems. Alternative allocation systems will not only pose a more substantial complexity in terms of implementation, but could also complicate the final analyses of the study. The subgroup decided that the study requires a relatively large population in order to yield any meaningful data. Since some of the donor service areas that have indicated an interest in participating in the study operate under alternative allocation systems, the subgroup agreed to allow such donor service areas to participate.

The Committee subgroup also discussed whether the wait time study should be stratified by adults and pediatrics, or whether pediatric candidates should be excluded from the study altogether. One suggestion is to revise the priority for pediatric candidates within the study to address any potential impacts as a result of adult transplant candidates obtaining a relatively higher increment of waiting time adjustment. If such revision to the study allocation algorithm is required, the study may need to be submitted back to the Board for approval. Some Members stated, however, that the pediatric priority issue should be considered separately from the wait time study.

The subgroup decided that the OPTN/UNOS and the SRTR should collaboratively develop a power analysis to attempt to identify the number of patients who would need to be enrolled under the study.

The Committee subgroup ultimately decided to develop a steering subgroup, to be chaired by Gabriel Danovitch, M.D., to complete the study design. The intent is to finalize the study design in time for review by the full Committee during its July 2004 meeting.

James Wynn summarized the Committee subgroup discussion during the May 20, 2004, Committee meeting. Volunteers for the steering subgroup include Drs. James Wynn, Peter Stock, Ken Andreoni, and Alan Leichtman.

III. Other Issues

3. Proposed Modifications to OPTN/UNOS Policies 3.5.5 (Payback Requirements) and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals). Public comments on proposed

amendments to OPTN/UNOS Policies 3.5.5 and 3.5.11.5.1 and the Committee's responses are set forth in **Exhibit D**. The proposed modifications, originally developed by the OPTN/UNOS Joint Kidney and Pancreas, Pediatric Transplantation, Minority Affairs and Histocompatibility Subcommittee, would elevate the priority at the local level of organ distribution assigned to high scoring high panel reactive antibody (PRA) candidates and pediatric candidates who surpassed their transplant goals ahead of payback debts and credits. The intent is to provide better opportunities for transplant for pediatric candidates who surpass their transplant goals as well as high PRA candidates who would rank ahead of these children but for the pediatric preference. The proposal was supported for public comment distribution by both the OPTN/UNOS Kidney and Pancreas Transplantation and Pediatric Transplantation Committees.

At its May 19, 2004, meeting, the Committee discussed the proposal in light of the public comments. Of the 44 individuals who commented on the proposal, 100% supported the proposal. All 11 Regions supported the proposal, including 4 Regions unanimously.

After further discussion, the Committee agreed to approve the proposal as submitted for public comment by a unanimous vote of 24 For; 0 Against; 0 Abstentions. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modifications to Policies 3.5.5 (Payback Requirements) and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals) having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System (additions and deletions recommended in this specific proposal are noted by bolded text):**

3.5.5 Payback Requirements. Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), ~~and~~ 3.5.5.2 (Exception for Prior Living Organ Donors), **and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals)**, when a kidney is shared pursuant to: (i) the mandatory zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor⁴, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

3.5.5.1 Kidney/Non-Renal Organ Sharing. [No Change]

3.5.5.2 Exception for Prior Living Organ Donors. Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.

3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon

implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered long-term debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (*i.e.*, incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3 (Mandatory Sharing).

[No Additional Proposed Changes until Policy 3.5.11]

3.5.11 The Point System for Kidney Allocation. When information about a standard donor is entered into the UNOS Match System, all patients who have an ABO blood type that is compatible with that of the donor and who are listed as active on the UNOS Patient Waiting List will be assigned points and priority as follows:

3.5.11.1 Time of Waiting. [No Changes]

3.5.11.1.1 Time of Waiting Points. [No Changes]

3.5.11.2 Quality of Antigen Mismatch. [No Changes]

3.5.11.3 Panel Reactive Antibody. [No Changes]

3.5.11.4 Medical Urgency. [No Changes]

3.5.11.5 Pediatric Kidney Transplant Candidates. Kidney transplant candidates who are less than 11 years old shall be assigned four additional points for kidney allocation. Candidates who are 11 years old or older but less than 18 years old will be assigned three additional points for kidney allocation. These points shall be assigned when the candidate is registered on the UNOS Patient Waiting List and retained until the candidate reaches 18 years of age.

3.5.11.5.1 Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals. Kidneys that are not shared mandatorily for 0 HLA mismatching, for renal/non-renal organ allocation, or locally for prior living organ donors pursuant to Policy 3.5.11.6 (Donation Status) shall be offered first for transplant candidates who are less than 18 years of age at listing and who have not received a kidney transplant within the time periods set forth in Policy 3.5.11.5.2 irrespective of the number of points assigned to the candidate relative to candidates 18 years old and older, with the exception of candidates assigned 4 points for PRA levels of 80% or greater under Policy 3.5.11.3 (Panel Reactive Antibody) who otherwise rank higher than all other listed patients based upon total points assigned under UNOS policy. When multiple pediatric transplant candidates are eligible for organ offers under this policy, organs shall be allocated for these patients in descending point sequence with the patient having the highest number of points receiving the highest priority. The priority assigned for pediatric patients under this policy does not supercede obligations to share kidneys as a result of a zero antigen mismatch pursuant to Policies 3.5.3

(Mandatory Sharing of Zero Antigen Mismatched Kidneys) and 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates) ~~or in satisfaction of payback debts pursuant to Policy 3.5.5 (Payback Requirements).~~

3.5.11.5.2 Pediatric Goals for Transplanting Kidney Transplant Candidates.

The goals for transplanting pediatric kidney transplant candidates are as follows:

- (a) Candidates 0-5 years old at time of listing- within 6 months of listing.
- (b) Candidates 6-10 years old at time of listing- within 12 months of listing.
- (c) Candidates 11-17 years old at time of listing- within 18 months of listing.

3.5.11.6 Donation Status. [No Changes]

[No Further Changes]

4. Proposed Modifications to and Implementation Protocol for OPTN/UNOS Policy 3.8.1.5 (Islet Allocation Protocol). Public comments on proposed amended OPTN/UNOS Policy 3.8.1.5 and the Committee's responses are set forth in **Exhibit E**. The proposal would determine how modifications to OPTN/UNOS Policy 3.8.1.5 recently approved by the OPTN/UNOS Board of Directors are to be implemented on the UNOS Computer. The intent of the policy is to better address the need for applying medical judgment in pancreatic islet transplantation decisions and avoid islet wastage.

At its May 19, 2004, meeting, the Committee discussed the proposal in light of the public comments. Of the 32 individuals who commented on the proposal, 94% supported and 6% opposed the proposal. Of the 11 Regions, 10 Regions supported and 1 Region opposed the proposal. The 1 Region that opposed the proposal indicated that it would be inclined to support an amended version of the proposal requiring a detailed rationale when the intended candidate was bypassed in favor of another candidate. Some of the public comment suggested that the OPTN/UNOS should not have any policy on islet allocation since it is a developing field. The Committee reemphasized that the OPTN/UNOS should be involved in pancreatic islet transplantation precisely because it is a developing field within transplantation that requires some oversight to ensure patient safety. The present proposal is an attempt to balance need for flexibility in the process, allowing appropriate exercise of medical judgment and increased experience with islet transplantation, with equitable opportunities for organ offers for patients in need of both whole pancreas and pancreatic islet transplant therapy. The Committee determined that requiring submission of written justifications for selecting candidates to receive pancreatic islets under the proposal would be overly burdensome to transplant programs. Instead, the Committee anticipates review of program practices by UNOS Policy Compliance staff and investigation of any activity that appears inappropriate. Reports of such activity to the Committee could lead to further refinement of the policy if deemed necessary.

After further discussion, the Committee agreed to approve the proposed amended policy as submitted for public comment by a vote of 24 For; 0 Against; 0 Abstentions. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modifications to Policy 3.8.1.5 (Islet Allocation) and implementation plan described in Exhibit E having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System:**

3.8 PANCREAS ALLOCATION. The following policies shall apply to the allocation of pancreata.

3.8.1 Pancreas Organ Allocation. For local pancreas allocation, recipients may be selected from candidates awaiting an isolated pancreas, kidney-pancreas combination, or a combined solid organ-islet transplant from the same donor, unless there is a patient on the UNOS Patient Waiting List who meets the requirements of Policy 3.5.4 or Policy 3.8.1.6 and for whom there is a zero antigen mismatch with the donor. Within each Patient Waiting List, length of time waiting shall be considered for the selection of organ recipients. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive. For combined kidney-pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.1, unless there is a zero antigen mismatch between the candidate and donor and the candidate is highly sensitized as defined in Policy 3.5. 4. If the pancreas is not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch patient or pursuant to Policy 3.5.4, the pancreas, if procured from a donor less than or equal to 50 years old and with body mass index (BMI) less than or equal to 30 kg/m², shall be allocated regionally and then nationally, or for patients listed for facilitated pancreas placement as described in Policy 3.8.1.3, in the following sequence. Pancreata procured from donors greater than 50 years old or with body mass index (BMI) greater than 30 kg/m² that are not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch patient or pursuant to Policy 3.5.4, shall be allocated according to Policy 3.8.1.4 below.

3.8.1.1 Regional Whole Pancreas Allocation. Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

- Isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2, and the kidney must be paid back as specified in Policy 3.5.5.

3.8.1.2 National Whole Pancreas Allocation. Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

- Isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2, and the kidney must be paid back as specified in Policy 3.5.5.

3.8.1.3 Facilitated Whole Pancreas Allocation. In the event that the UNOS Organ Center has attempted, but has been unable, to place the pancreas for a period of at least five (5) hours, or upon notice to the Organ Center that organ retrieval is anticipated within one (1) hour, then irrespective of whether the entire regional and/or national Waiting List of patients has by that time been exhausted, the pancreas shall be offered through the UNOS Organ Center for patients listed with those transplant centers that have recorded in writing their desire, to participate in the UNOS system of facilitated pancreas allocation. A pancreas offered by this facilitated method shall be offered to patients who have not previously received an offer for that pancreas. The pancreas shall be offered, in the following sequence, based on the transplant candidate's length of waiting time within each of the enumerated categories below. Candidates shall continue

to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

- Isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is voluntarily being offered. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2, and the kidney must be paid back as specified in Policy 3.5.5.

Any transplant center desiring to participate in this system shall be allowed to do so provided that it (a) agrees to accept offers for pancreata that have been procured by institutions located outside of its OPO (b) agrees to accept offers for pancreata on a conditional basis pending tissue typing information and redistribution of the organs pursuant to UNOS Policy 3.8.1.6 in the event there is a patient on the Waiting List for whom there is a zero antigen mismatch with the donor, and (c) documents this agreement and its desire to participate in the system to UNOS in writing.

3.8.1.4 Islet Transplantation. If the donor is less than or equal to 50 years old and has body mass index (BMI) less than or equal to 30 kg/m² and a suitable recipient is not identified by the allocation criteria specified in Policies 3.8.1, 3.8.1.1, 3.8.1.2, or 3.8.1.3, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.

If the donor is greater than 50 years old or has BMI greater than 30 kg/m², and a suitable recipient is not identified at the local level of organ allocation by the criteria specified in Policy 3.8.1, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation., and then regionally followed by nationally for whole organ transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.

3.8.1.5 Islet Allocation Protocol. Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. If after islet processing is completed, the islet preparation is medically unsuitable for the candidate, the islets from that pancreas will be reallocated to the next most suitable candidate within the OPO that the Investigational New Drug (IND) application allows. The purpose of this policy is to allow for the application of medical judgment and to avoid islet wastage. The outcomes of this allocation policy will be reported to the OPTN/UNOS Board of Directors by the OPTN/UNOS Kidney & Pancreas Transplantation Committee within three years. Two active status codes will be used, Status 1 (Urgent) and Status 2 (Non-Urgent). At the regional and national level islet allocation shall be as follows:

- Matching — 0 HLA Mismatch — 3 points
1 HLA Mismatch — 2 points
2 HLA Mismatch — 1 point
3-6 HLA Mismatch — 0 points

~~Status 1 A patient that receives a clinical islet transplant becomes a Status 1 for a three-week period. (Recipients need islets from four or more donors within three weeks). Status 1 islet candidates shall have~~

~~priority over Status 2 candidates at each level of allocation, (i.e., local, regional, then national).~~

~~Status 2 All patients on the clinical islet transplant list who do not meet the Status 1 criteria.~~

- ~~• **Waiting Time** ———~~ ~~Waiting time shall begin when a patient is placed on the UNOS Patient Waiting List. Waiting time will accrue for a patient until he/she has received a maximum of three islet infusions or the transplant center removes the patient from the waiting list, whichever is the first to occur. If the patient is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew. Waiting time as a Status 1 begins when the patient becomes a Status 1 and continues until they are no longer a Status 1. If a patient returns to a Status 2, their entire waiting time continues. One point will be assigned to the patient waiting for the longest period with fractions of points assigned proportionately to all other patients, according to their relative waiting time. For example, if there are 75 patients waiting for islets, the patient waiting the longest would receive 1 point ($75/75 \times 1 = 1$). A person with the 60th longest time of waiting would be assigned 0.2 points ($(75-60)/75 \times 1 = 0.2$). The calculation of points is conducted separately for each geographic (local, regional and national) level of islet allocation. The local points calculation includes only patients on the local Patient Waiting List. The regional points calculation includes only patients on the regional list, without the local patients. The national points calculation includes all patients on the national list excluding all patients listed on the Host OPO's local or regional waiting list. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.~~

[No further changes to Policy 3.8]

- 5. Proposed Modifications to OPTN/UNOS Policy 3.8.1.6 (Mandatory Sharing of Zero Antigen Mismatch Pancreata).** Public comments on proposed amended OPTN/UNOS Policy 3.8.1.6 and the Committee's responses are set forth in **Exhibit F**. The proposed modifications would eliminate requirements for sharing isolated pancreata for zero antigen mismatched patients except for highly sensitized candidates, defined as candidates with panel reactive antibody (PRA) levels of 80% or higher. The intent is to allow for increased simultaneous pancreas-kidney transplantation by not requiring sharing of zero antigen mismatched pancreata, except for highly sensitized candidates whose opportunities for an isolated pancreas offer are limited.

At its May 19, 2004, meeting, the Committee discussed the proposal in light of the public comments. Of the 40 individuals who commented on the proposal, 95% supported and 5% opposed the proposal. Of the 11 Regions, 7 Regions supported, 1 Region supported with an amendment and 3 Regions opposed the proposal. Of the Regions in opposition to the proposal, the commentary stated that the proposal would further limit isolated pancreas transplantation and that the data did not justify the elimination of mandatory sharing for isolated zero antigen mismatched pancreata. Region 2 approved an amended proposal to eliminate priority for all zero antigen mismatch isolated pancreas candidates due to the difficulty of completing HLA typing on high PRA candidates prior to allocating the pancreas or kidney organ.

The Committee reiterates that the data do not demonstrate a statistically significant survival benefit with receipt of a zero antigen mismatched isolated pancreas transplant. Moreover, relatively few pancreata are accepted for transplantation from outside the local organ procurement organization (OPO) area. The proposal maintains the requirement to share the optimally HLA matched pancreata broadly only for highly sensitized candidates for whom the transplant can yield substantial benefit even absent expectations for improved outcomes. The proposal should facilitate pancreas placement and serve as a compromise among the positions articulated by the Regions.

After further discussion, the Committee agreed to approve the proposal as submitted for public comment by a vote of 24 For; 0 Against; 0 Abstentions. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modifications to Policy 3.8.1.6 (Mandatory Sharing of Zero Antigen Mismatch Pancreata) having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System:**

3.8 PANCREAS ALLOCATION. The following policies shall apply to the allocation of pancreata.

3.8.2 Pancreas Organ Allocation. [No Changes]

3.8.1.1 Regional Whole Pancreas Allocation. [No Changes]

3.8.1.2 National Whole Pancreas Allocation. [No Changes]

3.8.1.3 Facilitated Pancreas Allocation. [No Changes]

3.8.1.4 Islet Transplantation. [No Changes]

3.8.1.5 Islet Allocation Protocol. [No Changes]

3.8.1.6 Mandatory Sharing of Zero Antigen Mismatch Pancreata. In the event there is a patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the pancreas from that donor shall be offered, first, to the appropriate UNOS member for any highly sensitized patient waiting for a combined kidney/pancreas transplant with a zero antigen mismatch, pursuant to Policy 3.5.34 (first locally, then regionally, and then nationally, based upon length of time waiting). The pancreas shall then, be offered to the appropriate UNOS member for any highly sensitized (i.e., panel reactive antibody (PRA) level \geq 80%) patient waiting for an isolated pancreas transplant with a zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting, unless there is a patient listed on the Host OPO's local patient waiting list for combined kidney/pancreas or isolated pancreas transplantation who is mismatched with the donor and also has ~~panel reactive antibody (PRA)~~ level of 80% or greater based on historical or current serum samples, as used for crossmatch to determine suitability for transplant, and there is a negative preliminary crossmatch between the donor and that patient. In this event, for local allocation, the pancreas shall be offered for the mismatched patient(s) with PRA greater than or equal to 80% and a negative preliminary crossmatch (based upon length of time waiting if more than one patient meets these criteria) before being offered for highly sensitized zero antigen mismatched isolated pancreas transplant candidates regionally or nationally.

3.8.1.6.1 Time 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 the UNOS Organ Center. The UNOS Organ Center will attempt to place the organ(s) for zero antigen mismatched patients according to the national lists of patients waiting for combined kidney/pancreas or isolated pancreas 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 3.5.5 and pancreas allocation under Policy 3.8.1, as applicable (first locally, then regionally, and then nationally). 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 UNOS Organ Center shall continue to attempt to place the organ(s) for zero antigen mismatched patients according to the national lists of waiting patients. Acceptance of organs declined by the Host OPO will not generate an obligation to pay back the kidney pursuant to Policy 3.5.4 (Payback Requirements) even if accepted for a zero antigen mismatched patient. The UNOS Organ Center will document each offer and each response.

[No Further Changes]

6. Proposed Modifications to OPTN/UNOS Policies 3.5.5.1 (Kidney/Non-Renal Organ Sharing) and 3.5.5.2 (Deferment of Voluntary Arrangements). Public comments on proposed amended OPTN/UNOS Policies 3.5.5.1 and 3.5.5.2 and the Committee's responses are set forth in **Exhibit G**. The proposed modifications would increase the ABO blood group payback debt threshold from four to six in terms of an OPO's ability to retain local kidneys or receive shared kidneys to be used in a simultaneous kidney-pancreas transplant. The intent of the proposal is to provide additional flexibility in the payback system and enhance opportunities to use both kidneys and the pancreas from donors.

At its May 19, 2004, meeting, the Committee discussed the proposal in light of the public comments. Of the 38 individuals who commented on the proposal, 84% supported and 16% opposed the proposal. Of the 11 Regions, 9 Regions supported and 2 Regions opposed the proposal.

Public commentary varied between suggesting that (1) the proposal's increased flexibility for OPOs to manage kidney payback debt was too liberal and would allow inappropriate debt accumulation, to (2) the proposal does not go far enough to provide opportunities to use donor pancreata with a kidney. Region 2, for instance, supported the proposal, although the Region's kidney/pancreas transplant programs opined that the ABO blood group payback debt threshold should remain four. Region 5, which narrowly supported the proposal, stated the proposed modification would allow more leeway for OPOs that fail to monitor their payback debts. Region 9 opposed the proposal and stated the current policy should remain. Finally, Region 8 opposed the proposal because it would not solve the perceived problem, but merely increase by two the number of debts an OPO could accumulate with regard to kidney/pancreas transplants. Other public comments stated that OPOs should learn to manage their payback debts under the current system.

The OPO that submitted the original request to reconsider the policy that limits the ability of an OPO owing four or more payback kidneys within any blood group to retain a kidney of that blood group to use locally with a pancreas (except for zero antigen mismatched candidates) in lieu of offering the kidney in satisfaction of payback obligations, from which the Committee proposal was developed, presented their perspective to the Committee during its May 19, 2004, meeting.

In general, the OPO believed the Committee proposal is not flexible enough to ensure that opportunities for using pancreata shared with kidneys for simultaneous kidney and pancreas transplantation are realized. In addition, the continued restrictions imposed by the kidney payback system will result in decreased pancreas procurement, jeopardizing efforts to maximize organ procurement, due to challenges in placing pancreata without a donor kidney. Finally, the OPO was concerned that the policy requirement of offering both donor kidneys for payback once the OPO has reached a debt threshold requiring that both kidneys be offered, rather than one kidney offered for payback and the other shared locally for a combined kidney/extra renal transplant, becomes a de facto withholding of the extra renal organ (*e.g.*, pancreas) if the organ cannot be placed for an isolated transplant. Due to the limited number of pancreata transplanted within this OPO's Region as an isolated pancreas transplant, it is often difficult for this OPO to place isolated pancreata for transplant.

The OPO offered an alternative proposal to alleviate some of their concerns with the current policy and the proposed modifications to the policy. The OPO suggested an increase in the total payback debt limit (all blood groups combined) from 9 to 12 debts. In addition to the increased total debt limit, the OPO proposed a time delay of, for instance 12 months, before the restriction on retaining a kidney or importing a kidney for a simultaneous kidney-pancreas transplant would be enforced. Under this portion of the proposal, an OPO would be exempted from the payback requirements as it pertains to simultaneous kidney-pancreas transplants until that OPO exceeded the debt threshold longer than the specified time delay.

Some Members suggested that the core issue is an OPO's inability to manage its payback debt levels. The Committee is not aware that this is a significant concern for other OPOs. There is no limit on use of kidney-pancreas combinations for OPOs that maintain debt levels within policy standards. Members also emphasized that the current policies and proposed modifications do not preclude an OPO from procuring any organs. Resolution of the OPO's concern might better be accomplished by examining operational issues between the OPO and some of its recovery surgeons who may be reluctant to procure pancreata for isolated transplants. Additionally, OPOs and their transplant centers are not obligated to accept zero antigen mismatched kidney offers, placing them in jeopardy of reaching the payback thresholds. Instead, these offers may be declined removing the possibility of payback debt as a barrier to opportunities for use of kidney/pancreas combinations locally. Moreover, the OPO's proposal would merely establish a new baseline for payback debts and would not cause any OPO to review and improve its payback debt management. Finally, the kidney payback system attempts to maintain system balance by ensuring that optimally HLA matched kidneys are not shared to the disproportionate disadvantage of any patient populations. Candidates waiting for a simultaneous kidney-pancreas transplant, in general, will wait a shorter time for transplant than candidates waiting for an isolated kidney transplant. If a candidate misses an opportunity due to the OPO's excessive debt threshold, the chances of a relatively quick subsequent transplant opportunity are very likely. Thus, it is expected that simultaneous kidney-pancreas candidates will not be disadvantaged by this policy.

Some Members moved that simultaneous kidney-pancreas transplants be exempted from the kidney payback system. However, other Members reiterated the views noted above and expressed additional concern that candidates on the isolated kidney transplant list, especially those listed with OPOs that operate separate kidney and kidney/pancreas waiting lists, would be disadvantaged and experience increased waiting times from such a proposal. As discussed above, in general, combined kidney/pancreas candidates wait for much shorter time periods for a transplant relative to isolated kidney transplant candidates. After further discussion, the motion was withdrawn for lack of support.

The alternative proposal offered by the OPO failed as no Committee Member was willing to offer the motion. After further discussion, the Committee agreed to approve the proposal as submitted for public comment by a vote of 23 For; 1 Against; 0 Abstentions.

The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modifications to Policies 3.5.5.1 (Kidney/Non-Renal Organ Sharing) and 3.5.5.2 (Deferment of Voluntary Arrangements) having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System (additions and deletions recommended in this specific proposal are noted by bolded text):**

3.5.5 Payback Requirements. Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), and 3.5.5.2 (Exception for Prior Living Organ Donors), when a kidney is shared pursuant to: (i) the mandatory zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor⁴, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

3.5.5.1 Kidney/Non-Renal Organ Sharing.

3.5.5.1.1 Deferment of the Kidney/Non-Renal Exception. OPOs that have accumulated ~~four~~**six** or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for kidneys allocated for a kidney-pancreas transplant pursuant to UNOS Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The kidney/non-renal exception shall be deferred until the OPO has reduced its payback obligation to less than ~~four~~**six**.

3.5.5.1.2 Deferment of Voluntary Arrangements. OPOs that have accumulated ~~four~~**six** or more payback obligations within the same blood type shall not be offered, and, if offered, shall not accept kidneys shared with a non-renal organ from a donor of the same blood type as the accumulated payback obligations, except for kidneys allocated for a kidney-pancreas transplant pursuant to UNOS Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The offer/acceptance of kidneys voluntarily shared with non-renal organs shall be deferred until the OPO has reduced its payback obligation to less than ~~four~~**six**.

3.5.5.2 Exception for Prior Living Organ Donors. Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.

3.5.5.4 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered long-term debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii)

shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (*i.e.*, incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3 (Mandatory Sharing).

[No Further Changes]

7. Proposed Modifications to OPTN/UNOS Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) ("Exemption of Kidneys Recovered from Donation after Cardiac Death (DCD) Donors from Sharing Requirements for Zero Antigen Mismatched Kidneys or Payback"). Public comments on proposed amended OPTN/UNOS Policies 3.5.3.3 and 3.5.5 and the Committee's responses are set forth in **Exhibit H**. The proposed modifications would exempt Donation after Cardiac Death (DCD) donor kidneys from the requirements of the zero antigen mismatch kidney sharing policy, except at the local level of organ distribution, as well as, kidney payback policy. OPOs would retain the option to offer DCD donor kidneys for payback, but would not be required to do so under the policy. The intent of the proposal is to place DCD donor kidneys as rapidly as possible to avoid adverse impacts from increased cold ischemia time, as well as, increase organ donation by providing an incentive for transplant centers to develop and enhance their DCD donor programs.

At its May 19, 2004, meeting, the Committee discussed the proposal in light of the public comments. Of the 45 individuals who commented on the proposal, 91% supported and 9% opposed the proposal. All 11 Regions supported the proposal, including 5 unanimously.

Some of the public commentary suggested possible disadvantage to sensitized candidates, especially in the event DCD kidney usage increases measurably. There was particular concern for African American and other minority candidates due to relative likelihood of sensitization being an important issue for these populations. The Committee affirmed their previously stated position and noted that during the two-year period studied (2001 - 2002), a total of only 13 DCD kidneys were transplanted into sensitized candidates with PRA > 20% who had a zero mismatch with the donor. Of the total 441 DCD kidney offers to zero antigen mismatched candidates, only 50 were accepted. There simply is not broad use of these organs outside the local procurement area, at least at this time. A future where DCD donation and utilization rates increased substantially would be welcome as a means to increase overall organ procurement and transplantation. A national policy exempting DCD donor kidneys from zero antigen mismatch sharing beyond the local level and payback requirements could help increase those rates as centers would be permitted to use more of these kidneys for their local candidates with less cold ischemia time. The exemption from sharing requirements for zero antigen mismatched patients also is supported by the outcomes data reviewed by the Committee. That is, among shared zero mismatch transplants, recipients of DCD kidneys had a significantly higher rate of post-transplant graft failure compared to recipients of deceased heartbeating donor (HBD) kidneys (RR= 1.84; p-value= 0.048). The Committee will, however, continue to review the effects of the proposal to determine the future impact on various groups, including sensitized candidates and minorities.

After further discussion, the Committee approved the proposal as submitted for public comment by a unanimous vote of 24 For; 0 Against; 0 Abstentions. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modifications to Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System (additions and deletions recommended in this specific proposal are noted by bolded text):**

3.5.3.3 Mandatory Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, **and deceased kidneys procured from Donation after Cardiac Death donors**² if there is any patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate ~~OPTN~~UNOS member for the patient with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, **and deceased kidneys procured from Donation after Cardiac Death donors**², if there is any patient on the UNOS Patient Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate ~~OPTN~~UNOS member for the patient with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a patient with a zero antigen mismatch does not have the implicit right to choose between the two kidneys. The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a patient with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all patients for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. **For kidneys procured from Donation after Cardiac Death donors, if there is any candidate on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to remaining zero antigen mismatched candidates according to the sequence set forth below.** When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

3.5.3.3.1 [No Changes]

3.5.3.3.2 [No Changes]

3.5.3.4 Kidney/Non-Renal Exception. [No Changes]

3.5.3.5 Time Limit. [No Changes]

3.5.4 Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates. [No Changes]

3.5.4.1 Mandatory Sharing. [No Changes]

² **For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a patient who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a patient who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.**

3.5.5 Payback Requirements. Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), and 3.5.5.2 (Exception for Prior Living Organ Donors), when a kidney is shared pursuant to: (i) the mandatory zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable standard donor **that does not meet the criteria for a Donation after Cardiac Death donor**², six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

[No Further Changes]

8. Proposed Modifications to OPTN/UNOS Policy 3.5.5 (Payback Requirements) (“ECD Kidney Exemption from Payback Sharing Requirements”). Public comments on proposed amended OPTN/UNOS Policy 3.5.5 and the Committee’s responses are set forth in **Exhibit I**. The proposed modifications would exempt expanded criteria donor (ECD) kidneys from the requirements of the kidney payback policy. OPOs would retain the option to offer expanded criteria donor kidneys for payback, but would not be required to do so under the policy. The Committee based its proposal on data previously reviewed and discussed by the Committee, including data showing that approximately only 10% of ECD payback offers have been accepted since the implementation of the ECD kidney policy in November 2002. The intent of the policy is to minimize cold ischemia time and maximize use of the ECD kidneys.

At its May 19, 2004, meeting, the Committee discussed the proposal in light of the public comments. Of the 43 individuals who commented on the proposal, 95% supported and 5% opposed the proposal. All 11 Regions supported the proposal, including 5 unanimously.

After further consideration, the Committee approved the proposal as submitted for public comment by a vote of 24 For; 0 Against; 0 Abstentions. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

* **RESOLVED, that the following modifications to Policy 3.5.5 (Payback Requirements) having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System (additions and deletions recommended in this specific proposal are noted by bolded text):**

3.5.3.3 Mandatory Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors² if there is any patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate ~~OPTN/UNOS~~ member for the patient with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death

donors², if there is any patient on the UNOS Patient Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate OPTN/UNOS member for the patient with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a patient with a zero antigen mismatch does not have the implicit right to choose between the two kidneys. The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a patient with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all patients for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after Cardiac Death donors, if there is any candidate on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to remaining zero antigen mismatched candidates according to the sequence set forth below. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

3.5.3.3.1 [No Changes]

3.5.3.3.2 [No Changes]

3.5.3.4 Kidney/Non-Renal Exception. [No Changes]

3.5.3.5 Time Limit. [No Changes]

3.5.4 Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates. [No Changes]

3.5.4.1 Mandatory Sharing. [No Changes]

3.5.5 Payback Requirements. Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), and 3.5.5.2 (Exception for Prior Living Organ Donors), when a kidney is shared pursuant to: (i) the mandatory zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor², six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood

type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

[No Further Changes]

9. Request from Midwest Transplant Network Regarding Allocation of A₂ and A₂B Kidneys. The Committee reviewed a request for an alternative allocation system submitted by Midwest Transplant Network during its January 20-21, 2004, meeting (**Exhibit J**). The request sought to expand the OPO's alternative system, which allocates A₂ and A₂B kidneys from standard criteria donors to ABO B and O recipients, to allow allocation of A₂ and A₂B kidneys from expanded criteria donors (ECDs) to ABO B and O recipients on their waiting list. Midwest Transplant Network previously had such an alternative allocation system that applied to all local donors, including ECDs, until the OPTN/UNOS ECD allocation policy was implemented and superceded all local alternative allocation systems. The intent is to facilitate more equitable kidney allocation to ABO B and O candidates while minimizing the detrimental effects on ABO A candidates. After further discussion, the Committee voted to approve the request. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

* **RESOLVED, that the Midwest Transplant Network's request to modify its alternative system for kidney allocation, attached as Exhibit J, shall be approved for implementation pending programming on the UNOS System.**

Committee Vote: Unanimous

10. Request from State of Florida Regarding Pancreas and Kidney/Pancreas Allocation. During its May 19-20, 2004, meeting, the Committee discussed a request from LifeLink Foundation (LifeLink), submitted on behalf of the OPOs and pancreas and kidney/pancreas transplant centers in Florida, regarding an alternative distribution system for pancreas and simultaneous kidney/pancreas organs in the state of Florida (**Exhibit K**). Thomas Gonwa, M.D., Region 3 Representative, presented the request to the Committee. The request sought to dissolve the current alternative local unit (ALU) in Florida whereby pancreata and kidney/pancreas combinations are allocated as follows: standard algorithm for zero antigen mismatched candidates with allowed exceptions for highly sensitized candidates (defined as PRA greater than or equal to 80%), and using the state as the local unit of organ distribution, then other candidates based on a single statewide pancreas waiting list, then regionally, and then nationally. In place of the ALU, the Florida OPOs and pancreas and kidney/pancreas transplant centers requested an alternative distribution system that mirrors its current kidney alternative distribution system. Under the proposed system, pancreata and kidney/pancreas combinations would be allocated using OPO as the local unit for organ distribution, then statewide, then regionally, and then nationally. The intent of the proposed system is to increase use of pancreata by reducing cold ischemic time, increase procurement of marginal pancreata that may have otherwise been discarded, and improve patient outcomes.

The request received unanimous support from all of the OPOs and pancreas transplant programs located in Florida. It was noted that approval of the proposal by Life Alliance Organ Recovery Agency signifies that the OPO agrees also to terminate its presently approved alternative system for pancreatic islet allocation since the proposal adopts the standard system for allocating pancreata (both for whole organ and islet transplantation). The proposal received nearly unanimous support from the Region 3 Members; however, two transplant centers opposed the proposal at the Regional level. The reason(s) for the dissenting votes were unknown at the time of the meeting. The same individual serves as UNOS Representative for these institutions and voted against the proposal.

Data supplied with the alternative system request indicate, in 2003, Region 3 was a net exporter of 27 pancreata and Florida a net exporter of 2 pancreata. Therefore, the national impact of this alternative system request should be minimal, if any.

The Committee was informed that the OPTN/UNOS is currently working with HRSA to ensure that policy language in response to a Committee recommendation that would limit alternative system requests to a three-year duration is consistent with the Final Rule. Current policies place a three-year time limit on ALUs and the Florida ALU for kidneys is due for review.

Some Members were concerned with the possible reasons the two transplant centers in Region 3 opposed the request. The transplant centers should be given the opportunity to voice their dissent. However, other Members disagreed and stated the Florida request merely seeks to reallocate local pancreata and kidney/pancreas combinations within the state of Florida. The request will not affect the number of grafts available to leave the state for regional allocation to any greater degree than their currently approved system and will not impact the two transplant centers opposing the request relative to the existing approved allocation system in Florida. Further, there is no requirement of unanimous Regional approval for such requests under OPTN/UNOS policies.

Other Members felt Florida needs to provide data on whether their current allocation system is better or at least similar in terms of outcomes and equity as the national standard allocation system before any additional alternative allocation system is approved by the Committee. For instance, it is unknown how many pancreata would have been allocated outside Florida for Regional transplantation if Florida followed the national allocation system. On the other hand, some Members stated there is little data to support one geographic allocation system versus another without, perhaps, simulation modeling. Therefore, reviewing data on this subject probably will not resolve the issue.

After further discussion, the Committee approved the Florida request with the condition that it will be re-assessed in one year. The Committee also agreed that the Florida kidney ALU will be reviewed in one year together with the pancreas and kidney/pancreas alternative distribution system. The vote of the Committee was 14 For; 3 Against; 4 Abstentions. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the Florida request for an alternative system for pancreas and kidney/pancreas distribution, attached as Exhibit K, shall be approved for implementation with the condition that it will be re-assessed in one year and pending programming on the UNOS System. RESOLVED FURTHER, that the current Florida Alternative Local Unit (ALU) for kidney distribution will be re-evaluated in conjunction with re-assessment of the state's pancreas and kidney/pancreas alternative distribution system. At the expiration of one year, the Florida OPOs and pancreas, kidney/pancreas, and kidney transplant centers shall determine whether they wish to continue their alternative system for pancreas and kidney/pancreas distribution and their ALU for kidney distribution, and, if so, shall produce for Committee review data and justifications for the continuation of such systems.**

11. Request from LifeGift Organ Donation Center Regarding the Lubbock Alternative Local Unit. During its May 19-20, 2004, meeting, the Committee reviewed a request from LifeGift Organ Donation Center (LifeGift) regarding application to the Lubbock Alternative Local Unit (ALU) of their current alternative allocation system for assigning no priority for HLA matching (other than at the zero antigen mismatch level) utilized by the Houston and Fort Worth ALUs (**Exhibit L**). The alternative allocation system currently used by the Houston and Fort Worth ALUs assigns 0 points for HLA matching for renal allocation. Currently, the Lubbock ALU uses the OPTN/UNOS allocation system for points assignment based on degree of match (2 points for a 0 DR mismatch and 1 point for a 1 DR mismatch). The intent is to eliminate any disadvantage for minorities within the OPO resulting from HLA matching. The OPO's alternative system for allocating kidneys also assigns an additional 0.5 point for children 10-16 years old in the Houston area, and patients in the OPO overall are assigned 0.5 point for each full year of waiting time.

LifeGift has operated their alternative allocation system with respect to HLA matching in Houston and Fort Worth since 1993. After reviewing the OPTN/UNOS national allocation system, LifeGift believes that awarding allocation points for degree of match is not justified by the small improvement in graft survival compared to the injustice of longer waiting times for African Americans and Hispanics. Though outcome data justify sharing kidneys to 0 ABDR mismatched candidates, LifeGift contends there is little evidence to support awarding priority for lesser degrees of match. Therefore, time waiting is the primary determinant of a candidate's position on the waiting list under the LifeGift system. Waiting times for African Americans, Hispanics and Caucasians are virtually equal in the Houston and Fort Worth ALUs.

Some Members were concerned with the possible precedent for accepting new requests to eliminate points for HLA matching. During the development of the current HLA priority system that awards 2 points for 0 DR mismatch and 1 point for 1 DR mismatch, the Committee decided that those OPOs operating with alternative allocation systems that awarded fewer or no points for HLA matching would be invited to apply to continue their current systems in lieu of the national system. However, out of concern of the further fragmentation of the national allocation system, the Committee determined that new applications, as a general rule, would be declined until the national system was in place for a sufficient amount of time to determine its effectiveness and confirm the value of DR matching. Approval of the LifeGift request could be construed as approval of a new request even though 2/3 of the OPO did not award points for HLA matching prior to the current national system and was approved to continue this protocol after implementation of the modified national system. However, other Members stated that this request differs because it is an OPO merely asking to apply their existing, previously approved alternative allocation system to their entire area of service. It does not constitute a new request. In addition, the application contains a hypothesis and a decade's worth of supporting data, clearly articulating the OPO's objective and rationale.

The application lacked concise data on transplant and waiting time rates for candidates in the Lubbock ALU to demonstrate that the request might improve a current problem in that particular portion of the OPO. However, some Members expressed that the data supplied was sufficient to extrapolate experience from the Houston and Fort Worth ALUs to expectations for the Lubbock area and make a determination on the merits of the proposal.

After further discussion, the Committee agreed to approve the LifeGift request by a vote of 19 For; 3 Against; 1 Abstention. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the LifeGift Organ Donation Center request for modification to the OPO's alternative allocation system, attached as Exhibit L, shall be approved for implementation pending programming on the UNOS System.**

12. **Review of OPTN/UNOS Board Actions and Resolutions.** During its January 20-21, 2004, meeting, the Committee reviewed several action items and resolutions from the OPTN/UNOS Board of Directors meeting, November 20-21, 2003. First, the Committee was informed, and commended, the Board decision rejecting proposed modifications to Policies 3.2.2 (Multiple Listing Permitted) and 3.2.2.1 (Waiting Time Transferal) that would have restricted multiple listing. The Committee was also informed of the Board directive requiring every transplant program to inform every patient about the options of multiple listing, transferring primary waiting time, and transferring care to another transplant center without loss of accrued waiting time (**Exhibit M**). This directive further requires transplant programs to document this activity and provide patients with written materials regarding their options. Members of the Committee expressed interest in the OPTN/UNOS or the UNOS Communications Department developing the patient education materials relevant to this directive. There were concerns that the new directive could result in unexpected financial burden for transplant centers unless OPTN/UNOS provided this assistance at no cost to the centers. In addition, the patient education materials should provide patients with an overview of the listing process, including listing criteria, patient inactive status, and directions on correcting listing errors, as well as, information to educate and obtain agreement from patients regarding expanded criteria donor (ECD) kidney acceptance. The Committee recommended this Board directive be delayed until the patient education materials are developed and reviewed by the Committee. After further discussion, the Committee agreed to forward the recommendation to the OPTN/UNOS. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the UNOS Communications Department shall be charged with the task of developing patient education materials relevant to the resolution summarized below, approved by the OPTN/UNOS Board of Directors on November 20-21, 2003, and that these materials shall provide patients with an overview of the wait listing process, including listing criteria, patient inactive status, and directions on correcting listing errors, as well as, information to educate and obtain agreement from patients regarding expanded criteria donor (ECD) kidney acceptance. FURTHER, RESOLVED, that the effective date of the November 20-21, 2003, resolution be deferred pending availability of the new educational materials at no cost to Transplant Centers.**

Board Resolution Summary: The Board directed that every transplant program must inform every patient about the options of multiple listing, transferring primary waiting time, and the option to transfer his or her care to another transplant center without loss of accrued waiting time, during the evaluation process and maintain documentation that this was done and provide the patient written material on these options.

Committee Vote: Unanimous

Members of the Committee also expressed their concern and frustration with the fact that this Board-approved proposal was never submitted for public comment and was not provided to the organ specific and other OPTN/UNOS Committees for their input prior to presentation to the Board. Although it is recognized that the Board has the authority to propose and approve directives beyond those submitted through these processes, the traditional approach for policy development is through the Committee structure and public comment process. This ensures that all OPTN/UNOS constituencies, as well as the public, are provided opportunity for input on proposed policy developments that potentially affect them. The Committee agreed to express its concerns informally to the OPTN/UNOS Board President.

The Committee also discussed the Board resolution directing the Committee to further study and develop an allocation system to offer blood group A₂ (non-A₁) kidneys to blood group B candidates. The Committee agreed that such an alternative system, proposed by the OPTN/UNOS Minority Affairs Committee, was already approved and implemented. In addition, the Committee intends to review this issue and decide whether to develop a policy proposal during future meetings. Therefore, the Committee feels that additional action is not warranted at this time.

13. Requests for Patient Waiting Time Adjustment. OPTN/UNOS Policy 3.2.1.8 provides a mechanism to request an adjustment to a patient's kidney or pancreas waiting time on the UNOS Computer. The policy allows time to be reinstated in the following cases without review by the appropriate OPTN/UNOS committee or Board of Directors:

- Incorrect removal of the patient due to an error or miscommunication. In this case, the reinstated time includes time accrued under the previous registration and the time interval between the previous and current registrations.
- Removal of the patient for medical reasons (other than receipt of a transplant) followed by a re-listing for the same organ with the same diagnosis. In this case, the reinstated time includes only time accrued under the previous registration.

In all other cases (not otherwise addressed in policy), the request must be:

- Approved by unanimous agreement among the kidney or pancreas (as applicable) transplant hospitals within the local area in which the patient is listed and submitted to UNOS for consideration with appropriate supporting documentation (including, without limitation, documentation that the patient met applicable waiting time criteria as of the listing date requested), or, if such agreement cannot be obtained despite efforts to do so, submitted to UNOS for consideration along with reasons provided by the dissenting party(ies) for any disagreement and other appropriate supporting documentation; and
- Reviewed and approved by the Kidney and Pancreas Transplantation Committee.

Policies 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients) and 3.8.7 (Waiting Time Reinstatement for Pancreas Recipients) provide separate mechanisms for requesting adjustment to a patient's kidney or pancreas waiting time in the event the patient has received a transplant and experienced immediate and permanent non-function of the graft.

At its meeting held on January 20, 2004, the full Committee reviewed 9 requests for waiting time adjustment under Policy 3.2.1.8. The Committee considered each case individually.

The case shown in **Exhibit N** requests an adjustment of patient kidney waiting time to August 22, 2003, from a current listing date of November 21, 2003. The application includes signatures indicating approval from the appropriate kidney transplant programs and supporting documentation indicating intent to activate the patient on the date requested. The Committee determined that the request should be approved. The Committee, therefore, reports the following action to the Board of Directors:

- * RESOLVED, that the request for waiting time modification attached as Exhibit N shall be approved for implementation pending programming on the UNOS Computer.

Full Committee Vote: Unanimous

The case shown in **Exhibit O** requests an adjustment of patient kidney waiting time to March 20, 2003, from a current listing date of October 6, 2003. The application includes documentation indicating approval from all of the appropriate kidney transplant programs. However, the application is not clear regarding actual or requested listing dates for your patient. For example, the front page of the application indicates a requested listing date of March 20, 2003, while the second page then discusses a requested listing date of September 3, 2003, as well as requesting time accrued between March 20, 2002 – August 6, 2002. UNOS Wait List histories show that the patient was only first listed on December 3, 2003. This is not consistent with the current listing date of October 6, 2003, written on the front page of the application, or assertions that the patient was listed during the 2002 time period. The Committee also noted that there is no documentation, supporting any requested listing dates, such as, for example, patient selection minutes. Finally, the application does not include documentation indicating whether and upon what date the patient met waiting time criteria (i.e., either on dialysis or creatinine clearance level or GFR less than or equal to 20 ml/min). The Committee, therefore, agreed that additional information is required before it can make a determination regarding the request. The Committee, therefore, reports the following action to the Board of Directors:

- * RESOLVED, that the request for waiting time modification attached as Exhibit O shall be approved for implementation pending: (1) receipt of documentation indicating whether the patient met waiting time criteria as of March 20, 2003, (2) receipt of documentation clarifying the actual listing date requested, and (3) programming on the UNOS Computer.

Full Committee Vote: Unanimous

The case shown in **Exhibit P** requests an adjustment of patient kidney waiting time to July 31, 2002, from a current listing date of November 7, 2003. The application includes documentation indicating approval from all of the appropriate kidney transplant programs. However, the application does not include documentation demonstrating whether the patient met waiting time criteria (i.e., either on dialysis or creatinine clearance level or GFR less than or equal to 20 ml/min) as of the listing date requested (July 31, 2002). In addition, the application does not provide any corrective actions taken by the transplant center to prevent future occurrences. The Committee, therefore, agreed that additional information is required to make a determination regarding the application. The Committee, therefore, reports the following action to the Board of Directors:

- * RESOLVED, that the request for waiting time modification attached as Exhibit P shall be approved for implementation pending: (1) receipt of documentation indicating whether the patient met waiting time criteria as of July 31, 2002, (2) receipt of documentation specifying the corrective actions taken by the transplant center to prevent future occurrences, and (3) programming on the UNOS System.

Full Committee Vote: Unanimous

The case shown in **Exhibit Q** requests an adjustment of patient kidney waiting time to November 12, 2002, from a current listing date of June 20, 2003. The application includes documentation indicating approval from all of the appropriate kidney transplant programs. However, the application does not include documentation demonstrating whether the patient met waiting time criteria (i.e., either on dialysis or creatinine clearance level or GFR less than or equal to 20 ml/min) as of the listing date requested (November 12, 2002), or documentation supporting the narrative provided with the application, such as, for example, the kidney activation form that is referenced. In addition, the application does not provide any corrective actions taken by the transplant center to

prevent future occurrences. The Committee, therefore, agreed that additional information is required to make a determination regarding the application. The Committee, therefore, reports the following action to the Board of Directors:

- * **RESOLVED**, that the request for waiting time modification attached as Exhibit Q shall be approved for implementation pending: (1) receipt of documentation indicating whether the patient met waiting time criteria as of November 12, 2002, (2) receipt of documentation specifying the corrective actions taken by the transplant center to prevent future occurrences, and (3) programming on the UNOS System.

Full Committee Vote: Unanimous

The case shown in **Exhibit R** requests an adjustment of patient kidney waiting time to January 9, 2003, from a current listing date of May 3, 2002. The application includes documentation indicating approval from all of the appropriate kidney transplant programs. While the application includes documentation demonstrating that the patient met waiting time criteria (i.e., either on dialysis or creatinine clearance level or GFR less than or equal to 20 ml/min) as of the listing date requested (January 9, 2003), this date is after the current listing date of May 3, 2002, listed on the application. The Committee requests written confirmation that the requested listing date is January 9, 2003, and acknowledgment that, if waiting time is adjusted for this patient as requested, she will lose waiting time. Finally, the application does not provide any corrective actions taken by the transplant center to prevent future occurrences. The Committee determined that submission of the additional information described in this letter is necessary before it can make a determination with respect to this application. The Committee, therefore, reports the following action to the Board of Directors:

- * **RESOLVED**, that the request for waiting time modification attached as Exhibit R shall be approved for implementation pending (1) receipt of documentation indicating whether the patient met waiting time criteria as of January 9, 2003, (2) receipt of documentation specifying the corrective actions taken by the transplant center to prevent future occurrences, (3) confirmation of the requested listing date, and (4) programming on the UNOS System.

Full Committee Vote: Unanimous

The case shown in **Exhibit S** requests an adjustment of patient kidney waiting time to August 30, 2001, from a current listing date of June 22, 2001. The Committee previously reviewed and approved a request for adjustment of patient kidney waiting time to the current listing date of June 22, 2001. The application includes documentation indicating approval from all of the appropriate kidney transplant programs. The application also includes documentation indicating the patient met waiting time criteria (i.e., either on dialysis or creatinine clearance level or GFR less than or equal to 20 ml/min). However, the Committee would like confirmation that the requested listing date is August 30, 2001, and acknowledgment that, if waiting time is adjusted for this patient as requested, the patient will lose waiting time. The Committee agreed to request additional information with respect to this application. The Committee, therefore, reports the following action to the Board of Directors:

- * **RESOLVED**, that the request for waiting time modification attached as Exhibit S shall be approved for implementation pending (1) confirmation of the requested listing date, and (2) programming on the UNOS System.

Full Committee Vote: Unanimous

The case shown in **Exhibit T** is a resubmission and requests an adjustment of patient kidney waiting time to June 1, 2001, from a current listing date of October 14, 2003. The application includes signatures indicating approval from the appropriate kidney transplant programs. However, the application does not include documentation supporting the listing date requested, such as, for example, patient selection minutes. The application also does not indicate the corrective actions taken to prevent future occurrences. Finally, the application requests two different listing dates. The waiting time modification form requests a listing date of June 1, 2001, but documentation within the application requests a listing date of June 16, 2001. The Committee, therefore, agreed to approve the request for waiting time adjustment pending receipt of the

following information and determination that it is adequate to support the application: (1) documentation supporting the listing date requested, (2) corrective action plan, and (3) clarification of listing date requested. The Committee, therefore, reports the following action to the Board of Directors:

- * RESOLVED, that the request for waiting time modification attached as Exhibit T shall be approved for implementation pending: (1) receipt of documentation indicating whether the patient met waiting time criteria as of June 1, 2001, (2) receipt of documentation specifying the corrective actions taken by the transplant center to prevent future occurrences, (3) clarification of the listing date requested, and (4) programming on the UNOS System.

Full Committee Vote: Unanimous

The case shown in **Exhibit U** requests an adjustment of patient kidney waiting time to July 18, 2003, from a current listing date of November 3, 2003. The application includes documentation indicating approval from all of the appropriate kidney transplant programs. However, the Committee determined that the application fails to demonstrate any intent to list the patient for a deceased donor kidney transplant before November 3, 2003, the actual date of listing. Instead, it appears that until November 2003, living donor organ transplantation was the sole course pursued and contemplated. In addition, the application does not meet the requirements for Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients) because the patient must first have accumulated waiting time that can be reinstated. The patient did not begin to accrue waiting time until his listing date of November 3, 2003. The Committee, therefore, agreed to deny the request for waiting time adjustment. The Committee, therefore, reports the following action to the Board of Directors:

- * RESOLVED, that the request for waiting time modification attached as Exhibit U shall be denied.

Full Committee Vote: Unanimous

The case shown in **Exhibit V** is a resubmission of an application previously approved pending documentation that the patient met waiting time criteria and documentation of intent to list as of the listing date requested. The resubmitted application requests an adjustment of patient kidney waiting time to June 26, 2000, from a current listing date of June 17, 2002. The resubmitted application includes documentation that the patient met waiting time criteria as of the listing date requested. However, the application does not include documentation demonstrating intent to list the patient as of June 26, 2000. While it appears from the information provided with the application that the cardiac catheterization required as part of the patient's transplant evaluation was performed, it also appears that other required tests or procedures had not been completed as of June 26, 2000. For instance, evidence of stress test results and documentation that the patient was reviewed by a patient selection committee are not included in the application. The Committee, therefore, agreed to deny the request for waiting time adjustment. The Committee, therefore, reports the following action to the Board of Directors:

- * RESOLVED, that the request for waiting time modification attached as Exhibit V shall be denied.

Full Committee Vote: Unanimous

At its meeting held on May 19, 2004, the full Committee reviewed 8 requests for waiting time adjustment under Policy 3.2.1.8. The Committee considered each case individually.

The case shown in **Exhibit W** requests an adjustment of patient kidney waiting time to February 8, 2000, from a current listing date of March 4, 2004. The application includes signatures indicating approval from the appropriate kidney transplant programs and supporting documentation indicating intent to activate the patient on the date requested. The Committee determined that the request should be approved. The Committee, therefore, reports the following action to the Board of Directors:

- * RESOLVED, that the request for waiting time modification attached as Exhibit W shall be approved for implementation pending programming on the UNOS Computer.

Full Committee Vote: Unanimous

The case shown in **Exhibit X** requests an adjustment of patient kidney waiting time to September 4, 2003, from a current listing date of October 2, 2003. The application includes signatures indicating approval from the appropriate kidney transplant programs and supporting documentation indicating intent to activate the patient on the date requested. The Committee determined that the request should be approved. The Committee, therefore, reports the following action to the Board of Directors:

- * RESOLVED, that the request for waiting time modification attached as Exhibit X shall be approved for implementation pending programming on the UNOS Computer.

Full Committee Vote: Unanimous

The case shown in **Exhibit Y** requests an adjustment of patient kidney waiting time from a current listing date of March 16, 2004. However, the application does not include documentation indicating approval from all of the appropriate kidney transplant programs. The application also does not include documentation demonstrating whether the patient met waiting time criteria (i.e., either on dialysis or creatinine clearance level or GFR less than or equal to 20 ml/min) as of the listing date requested. Further, the application is not clear regarding the specific time adjustment being requested. The Committee, therefore, agreed that additional information is required to make a determination regarding the application. The Committee, therefore, reports the following action to the Board of Directors:

- * RESOLVED, that the Committee cannot make a determination regarding the request for waiting time modification attached as Exhibit Y due to incomplete information. The Committee requests the following to enable further consideration of the application: (1) documentation indicating approval from all of the appropriate kidney transplant programs, (2) documentation demonstrating whether the patient met waiting time criteria as of the listing date requested, and (3) clarification of the patient's listing history and the specific time adjustment being requested.

Full Committee Vote: Unanimous

The case shown in **Exhibit Z** requests an adjustment of patient kidney waiting time to July 9, 2003, from a current listing date of June 27, 2000. The candidate was inadvertently placed on Status 7 in July 2003 and did not accrue waiting time during this period. The application includes signatures indicating approval from the appropriate kidney transplant programs. The application also includes corrective actions taken to prevent future occurrences. However, while the application indicates the candidate met waiting time criteria by being on dialysis, the application is not substantiated with supporting documentation as required. The Committee, therefore, agreed to approve the request for waiting time adjustment pending receipt of the following information and determination that it is adequate to support the application: (1) documentation supporting the listing date requested. The Committee, therefore, reports the following action to the Board of Directors:

- * RESOLVED, that the request for waiting time modification attached as Exhibit Z shall be approved for implementation pending: (1) receipt of documentation indicating whether the patient met waiting time criteria as of July 9, 2003, and (2) programming on the UNOS System.

Full Committee Vote: Unanimous

The case shown in **Exhibit AA** requests an adjustment of patient kidney waiting time to June 1, 2003, from a current listing date of March 18, 2004. The application indicates that a miscommunication with the insurance company and patient resulted in the patient being listed late. The application includes signatures indicating approval from the appropriate kidney transplant programs. The application also includes corrective actions taken to prevent future occurrences. However, the application does not include documentation indicating whether the patient met waiting time criteria as of June 1, 2003. In addition, the application does not include documentation indicating final authorization from the insurance company. The Committee, therefore, agreed to approve the request for waiting time adjustment pending receipt of the following information and determination that it is adequate to support the application: (1) documentation supporting the listing date requested, and (2)

documentation indicating final authorization from the insurance company. The Committee, therefore, reports the following action to the Board of Directors:

- * **RESOLVED**, that the request for waiting time modification attached as Exhibit AA shall be approved for implementation pending: (1) receipt of documentation indicating whether the patient met waiting time criteria as of June 1, 2003, (2) receipt of documentation indicating final authorization from the insurance company, and (3) programming on the UNOS System.

Full Committee Vote: 22 For; 1 Against; 0 Abstentions

The case shown in **Exhibit BB** requests an adjustment of patient kidney waiting time to October 17, 2002, from a current listing date of January 29, 2004. The application includes signatures indicating approval from the appropriate kidney transplant programs. The application also includes corrective actions taken to prevent future occurrences. However, while the application indicates the candidate met waiting time criteria by being on dialysis as of the listing date requested, the application is not substantiated with supporting documentation as required. The Committee, therefore, agreed to approve the request for waiting time adjustment pending receipt of the following information and determination that it is adequate to support the application: (1) documentation supporting the listing date requested. The Committee, therefore, reports the following action to the Board of Directors:

- * **RESOLVED**, that the request for waiting time modification attached as Exhibit BB shall be approved for implementation pending: (1) receipt of documentation indicating whether the patient met waiting time criteria as of October 17, 2002, and (2) programming on the UNOS System.

Full Committee Vote: Unanimous

The case shown in **Exhibit CC** requests an adjustment of patient kidney waiting time to November 22, 1999, from a current listing date of August 25, 2003. The application includes documentation indicating approval from all of the appropriate kidney transplant programs. However, the application does not include documentation indicating whether the patient met waiting time criteria (i.e., either on dialysis or creatinine clearance level or GFR less than or equal to 20 ml/min) as of the listing date requested. The Committee believes that this can be confirmed through researching the patient's listing history through UNOS. The Committee, therefore, reports the following action to the Board of Directors:

- * **RESOLVED**, that the request for waiting time modification attached as Exhibit CC shall be approved for implementation pending (1) confirmation that the patient met waiting time criteria as of the listing date requested as well as the patient's listing history reported in the application, and (2) programming on the UNOS System.

Full Committee Vote: Unanimous

The case shown in **Exhibit DD** requests an adjustment of patient kidney waiting time from a current listing date of April 2, 2001. The application indicates that the patient was placed in inactive status from April 1, 2003, to November 13, 2003, when the patient's initial transplant program became inactive. The application includes signatures indicating approval from the appropriate kidney transplant programs. The Committee determined that the request should be approved pending confirmation of the patient's listing history as reported in the application. The Committee, therefore, reports the following action to the Board of Directors:

- * **RESOLVED**, that the request for waiting time modification attached as Exhibit DD shall be approved for implementation pending (1) confirmation of the patient's listing history as reported in the application, and (2) programming on the UNOS Computer.

Full Committee Vote: Unanimous

Due to concerns regarding the volume and type of waiting time modification applications the Committee is reviewing, the Committee requested a report on the number of such cases, by institution and number of patients

listed with the institution. Additionally, the Committee requests that the current listing date included in the application be confirmed prior to review by the Committee. The Committee was pleased to learn that the Membership and Professional Standards Committee also is looking at transplant center waiting time modifications as a possible indicator of need for further review.

14. Review of the OPTN/UNOS Histocompatibility Committee Proposed Modifications to OPTN/UNOS Bylaws Appendix B Attachment 1 (Standards for Histocompatibility Testing) Standard H3.100 and Proposed New Policies for Kidney Transplantation – 3.5.1.7 (Prospective Crossmatching), and for Pancreas Transplantation – 3.8.8 (Prospective Crossmatching), and Proposed Appendix D to Policy 3. During its May 19-20, 2004, meeting, the Committee considered this proposal submitted for public comment. The proposal seeks to apply H3.100 to laboratory practice, establish the clinical practice policies for prospective crossmatching relative to kidney and pancreas organs, and put forth guidelines for the development of joint written agreements between histocompatibility laboratories and transplant programs regarding risk assignment and the timing of crossmatch testing.

Members of the Committee noted that most of the proposed modifications were previously discussed and/or suggested by the Committee. The proposed modifications are an attempt to bring the policies up to date with clinical practice.

After further discussion, the Committee agreed to approve the proposed modifications to H3.100, the proposed Policy 3.5.17, and the proposed Policy 3.8.8 each by a vote of 22 For; 0 Against; 0 Abstentions.

During the review of Appendix D to Policy 3, some Members noted that there should be a line in Table 2 of Appendix D that addresses the isotype (IgG Vs IgM) of the antibody. The Committee was informed that the OPTN/UNOS Histocompatibility Committee previously received a similar comment and intends to modify the proposal prior to review by the Board during the June 2004 meeting.

The Committee also was informed the OPTN/UNOS Histocompatibility Committee will recommend the policy be implemented in January 2005 to allow adequate time for histocompatibility laboratories and transplant centers to develop joint written policies.

After further discussion, the Committee agreed to approve the proposed Appendix D to Policy 3 by a vote of 21 For; 0 Against; 0 Abstentions.

The Committee acknowledged Drs. Susan Saidman, Karen Nelson, Deborah Crowe, Daniel Hayes, Michael Cecka and the Histocompatibility Committee for their efforts in developing these necessary standards.

Some Members stated their concern with the apparent variability in techniques and results for histocompatibility laboratories determining PRA levels. For instance, some transplant centers have a waiting list with a relatively high percentage of candidates with PRAs greater than 80%, while other transplant centers have a nominal number of high PRA candidates. The question was raised as to whether this variability is real or the result of differences in methods. Members of the Committee agreed that variability in PRA testing results exist due to programs using different techniques, including testing for peak PRA and current PRA levels. Due to time constraints, the Committee was unable to discuss this issue further, but agreed to place it on the agenda for the next Committee meeting.

15. Review of the OPTN/UNOS Ad Hoc International Relations Committee Proposed Modifications to OPTN/UNOS Policy 6.4 (Exportation and Importation of Organs – Developmental Status). During its May 19-20, 2004, meeting, the Committee considered this proposal submitted for public comment during its May 19-20, 2004, meeting. The proposal seeks to require higher standards of verification from foreign exporters of organs into the United States.

Members of the Committee inquired as to the number of kidneys imported into the United States and were informed that during the last two years only 5 kidneys were imported. The Committee agreed that the proposal should be amended to specifically include Donation after Cardiac Death donor kidneys. The proposal, at Policy 6.4.2, presently limits donation by stipulating certification of death by brain death protocols. In addition, the

Committee agreed that the proposal should clarify how the imported organs will be allocated. The proposal, at Policy 6.4.2.1, presently allows allocation to the OPO *or* transplant center that arranges the organ importation and does not specify the allocation protocol to be followed.

After further discussion, the Committee agreed to send the Committee suggestions to the OPTN/UNOS Ad Hoc International Relations Committee by a vote of 21 For; 0 Against; 0 Abstentions.

16. Review of the OPTN/UNOS Ad Hoc Living Donor Committee Proposed Guidelines for Living Kidney Donor Evaluation. During its May 19-20, 2004, meeting, the Committee considered this proposal submitted for public comment. The proposal seeks to establish guidelines for potential living kidney transplant recipient and donor evaluation.

During its May 10, 2004, meeting, the OPTN/UNOS Ad Hoc Living Donor Committee modified the proposal submitted for public comment. Some of the modifications included revising the definition of “independent donor team” in response to concerns that the concept was not clearly articulated.

Some Members of the Committee were wary of the fact that multiple groups are discussing and developing guidelines related to living kidney donor issues without necessarily communicating with one another. The OPTN/UNOS should define its purpose with regard to living donors. While it is recognized that living donation has inherent risks, living kidney donation has been performed for many years and risks should be distinguished from those applicable to living liver or other organ donation. The current proposal will result in unnecessary regulations and potential increased costs to the transplant system in terms of staffing and monitoring. Other Members stated that the OPTN/UNOS should be responsible for establishing standards for living donor workups. It is the most appropriate organization to ensure the public that living donation is being performed safely. Though extensive regulations are not necessary, certain guidelines could help establish a national standard to protect patients. Endorsing the concept of a donor advocate is beneficial.

Other Members were concerned about some of the specific provisions in the proposed guidelines, including the recommendation of a psycho-social evaluation of the donor and the statement that donor kidney function should be tested to determine serum creatinine, calculated creatinine clearance, and urine protein excretion. Committee Members suggested that a general guideline to ensure living donor and transplant candidate quality care is appropriate, but that the level of detail included in the present proposal is neither warranted nor constructive.

After further discussion, the Committee considered the motion to table further consideration of the living kidney donor guidelines included in the proposal pending future discussions and guideline development between the OPTN/UNOS Ad Hoc Living Donor and Kidney and Pancreas Transplantation Committees in the context of other recent conferences that have considered this topic. The Committee voted to approve the motion by a vote of 22 For; 0 Against; 0 Abstentions.

17. Review of the OPTN/UNOS Ad Hoc Operations Committee Proposed Modifications to OPTN/UNOS Policy 3.1.4 (Patient Waiting List). During its May 19-20, 2004, meeting, the Committee considered this proposal submitted for public comment. The proposal seeks to ensure the accuracy of a transplant candidate’s ABO blood type on the waiting list.

The proposed modifications to Policy 3.1.4.1 and 3.1.4.3 were accepted by the Committee by votes of 22 For; 0 Against; 0 Abstentions. However, some Members of the Committee expressed concern with the proposed 3.1.4.2, which provides that each transplant candidate must be ABO typed on two separate occasions prior to listing. Transplantation ABO typing requirements should not go further than the standards required of the blood transfusion industry as the risks of possible adverse outcomes for errors in ABO blood typing are similar. Other Members expressed skepticism with whether two blood draws and blood typing would improve the transplant system. Two blood draws may only double the opportunity for errors to occur. However, some Committee Members believed the policy provision is a necessary requirement that will help prevent future blood typing mistakes that can have devastating consequences. It was suggested that ABO blood typing near misses occur more often than the Committee realizes. Certain of those errors or near misses can probably be attributed to transcription errors. Through the proposed requirement of two blood draws, any transcription error could be discovered by a second blood draw and typing. The proposed provision does not represent a large burden,

financially or otherwise, and yet could result in an important benefit to patient safety. After further discussion, the Committee agreed to support the proposed provision 3.1.4.2 by a vote of 14 For; 7 Against; 0 Abstentions and forward the comments of the opposition minority.

18. Review of the OPTN/UNOS Ad Hoc Operations Committee Proposed Modifications to OPTN/UNOS Policy 3.2.3 (Match System Access). During its May 19-20, 2004, meeting, the Committee considered this proposal submitted for public comment. The proposal seeks to require two separate determinations of the donor ABO blood type prior to initiating the organ recovery incision and add policy language for the process of distributing organs using the match.

Based on the proposed policy language, Members of the Committee were uncertain whether the proposal requires two separate blood draws and blood typing or two instances of blood typing from the same blood draw. Even if the intent of the proposal is to require two separate blood draws and typing, some Members questioned how the situation should be handled when a trauma patient receives a transfusion and subsequently expires and becomes a donor. In addition, some Members were skeptical as to whether errors in donor blood typing are a significant problem. Blood transfusions are performed in substantially greater numbers each year compared to transplants and there is not a known typing problem experienced by transfusion recipients. The proposal does not specify any actual data supporting the contention that errors in donor blood typing are a problem. Other Members stated they understand the proposal to require two separate blood draws and typing of each. The typing procedure is relatively quick and will help improve patient safety. While data may not exist, there are compelling stories to indicate a potential problem requiring this proposal.

After further discussion, the Committee accepted the proposed modifications to Policy 3.2.3 by a vote of 16 For; 6 Against; 0 Abstentions.

Some Members stated that safeguards for ABO blood typing should be specified for living donors as well. However, the safeguards should be developed in a manner that allows living donor exchanges between incompatible pairs. Other Members stated and moved that living donation ABO blood typing policies should be tabled until such time, if any, when the OPTN/UNOS develops allocation policies for living donor organs. After further discussion, this motion was approved by the Committee by a vote of 14 For; 5 Against; 1 Abstention.

19. Review of the OPTN/UNOS Transplant Administrators Committee Proposed Modification to the Criteria for Institutional Membership, OPTN/UNOS Bylaws, Appendix B, Section III (C) (Transplant Programs): Proposed Modifications to Item 15 (Social Support). During its May 19-20, 2004, meeting, the Committee considered this proposal submitted for public comment. The proposal seeks to delineate a transplant program's specific responsibilities in providing psychiatric and social support services (psychosocial services) for transplant candidates, recipients, living donors, and family members.

The Committee acknowledged that the proposal, as written, is a recommendation rather than a mandate. Some Members suggested the provision should allow for mental health services versus psychiatric evaluations as some transplant programs have difficulty communicating need for the later with their patients.

After further discussion, the Committee agreed to accept the proposal with the modification that psychiatric references become mental health by a vote of 21 For; 3 Against; 0 Abstentions.

20. Review of the OPTN/UNOS Transplant Administrators Committee Proposed Modifications to the Criteria for Institutional Membership, OPTN/UNOS Bylaws Appendix B, Section III (C) (Transplant Programs): Proposed New Item 20 (Clinical Transplant Pharmacist). During its May 19-20, 2004, meeting, the Committee considered this proposal submitted for public comment. The proposal seeks to delineate the specific responsibilities of a clinical transplant pharmacist in an active transplant program.

Members of the Committee questioned whether many of the small and mid-size transplant programs would be able to meet such specific criteria for a transplant pharmacist, or even have a transplant pharmacist on staff due to financial restraints. Some transplant programs with transplant pharmacists delegate duties specified in the proposal among various individuals beyond the pharmacist. For instance, physicians and transplant

coordinators can perform some of the duties detailed under the proposal. Though transplant pharmacists can be beneficial members of a transplant program, specifications outlining the position duties and expectations should not be included in OPTN/UNOS membership criteria. The proposal appropriately highlights the real value of a transplant pharmacist, but is too detailed in terms of membership criteria.

However, other Members of the Committee pointed out the proposal is a recommendation rather than a mandate, which allows those centers lacking in sufficient resources to elect to not have a transplant pharmacist on staff. A transplant pharmacist can be an important aspect of transplant programs in terms of patient safety and education. Transplant coordinators possibly do not stay current on drug formularies, drug substitutions and interactions as well as pharmacists. In addition, a transplant pharmacist may be more important for small and mid-size transplant programs that do not have resources to otherwise address these responsibilities. The presence of an OPTN/UNOS provision could give smaller programs the support needed to obtain approval for such positions from their administrative staff.

Some Members responded that despite the fact that the proposal is a recommendation, interested third parties could attempt to hold transplant programs accountable if they fail to meet the recommendation. Therefore, centers might feel compelled to abide by the recommendation despite the financial strains on their already limited budgets.

After further discussion, the Committee considered a motion to approve the proposal with the caveat that it is too specific and should be reconstructed in general terms. The Committee voted down the motion by a vote of 7 For; 16 Against; 0 Abstentions. The Committee then approved a motion stating that the presence of a transplant pharmacist is important and encouraged for transplant programs, but should not be mandated nor the duties so specified by a vote of 22 For; 2 Against; 0 Abstentions.

21. Request from Texas Organ Sharing Alliance (TOSA) Regarding Kidney Allocation. During its January 20-21, 2004, meeting, the Committee reviewed a request for an alternative allocation system submitted by Texas Organ Sharing Alliance (TOSA) in response to a Texas state law requiring state-wide sharing for kidneys to unsensitized candidates with the longest waiting time (**Exhibit EE**). Specifically, the request sought to create a pool of the top 20% of kidney candidates by waiting time within each ABO blood group and with panel reactive antibody (PRA) less than 10%. The pool would receive every fifth kidney from Texas donors and would be allocated to the next candidate in the pool based on waiting time. Matching points would not be used under the requested system, though the Committee was unclear whether matching would still be used for those candidates outside of the 20% pool. The standard protocol for sharing kidneys for candidates who are a zero antigen mismatch with the donor would continue to apply. The intent is to expedite kidney transplantation for those candidates waiting the longest time in Texas for a transplant.

Southwest Transplant Alliance (STA) and LifeGift Organ Donation Center (LifeGift), the other two OPOs serving Texas transplant candidates, submitted letters referencing the TOSA proposal (**Exhibit FF**). The STA letter, dated December 19, 2003, stated that Southwest Transplant Alliance and its member transplant centers stand ready to work with TOSA and UNOS in the consideration of [TOSA's] proposal for the benefit of patients, and to consider other proposals that may be brought forward through the UNOS process to benefit waiting patients in Texas.

After reviewing the documentation provided, the Committee could not determine whether the proposal submitted was a final proposal or whether additional work was in progress or contemplated. It also was not clear whether the proposal was submitted for application in allocating kidneys throughout Texas, only within an individual OPO, or within multiple but not all Texas OPOs. The Committee further noted that data demonstrating the existence of waiting time disparities in Texas and how the proposal would address these disparities were not included with the request.

The proposed elimination of priority for HLA matching (other than zero antigen mismatches between donor and candidate) concerned some Members of the Committee. The Committee was unclear whether the TOSA proposal sought to eliminate HLA matching from the allocation algorithm only for those candidates in the top 20% pool or for all TOSA kidney candidates. The TOSA proposal, some stated, would transplant those candidates who possess the greatest opportunity for transplant within the newly created candidate pool based on

sensitization levels, at the expense of candidates with higher sensitization levels. This could have an adverse impact particularly for minority patients who often possess higher sensitization levels relative to whites. In addition, the proposed elimination of HLA matching could predispose transplant candidates to increased sensitization levels following transplantation, and thus, reduce those candidates' opportunity of receiving a subsequent transplant with a negative crossmatch. Finally, pediatric candidates, who often have less waiting time relative to adults but benefit medically from quicker transplants, could also be disadvantaged by the TOSA proposal.

The Committee agreed that the OPTN/UNOS is committed to work with all three Texas OPOs and their transplant centers in the consideration of the proposed kidney sharing arrangement(s); however, the Texas OPOs need to specify their intent and what is being requested. If the intention of TOSA, Southwest Transplant Alliance and LifeGift Organ Donation Center is to submit one alternative allocation system and sharing agreement applicable to all three OPOs, it is the responsibility of the relevant OPOs to agree on the terms of the proposal, document such agreement with signatures from all OPOs and the respective transplant centers, and submit a single application detailing the proposed system, its rationale, and supporting data. If the intention of the submissions, at the present time, is only to inform the Committee of the OPOs' progress in developing a final proposal for later presentation to the Committee, this should be made explicit. If the intention of TOSA is to submit a separate proposal applicable only to TOSA, then this should be clarified. The Committee would be able to consider the OPO's proposal accordingly upon receipt of documentation of transplant center agreement and a final application.

After further discussion, the Committee agreed to table the request pending additional information, including clarification of which Texas OPOs and transplant centers agree to the request, clarification of whether HLA matching will be used under the system to any extent, and submission of a formal alternative allocation system proposal detailing the specific intent, hypotheses and supporting data, analysis plan and other information required by such application. The Committee vote was 23 For; 0 Against; 0 Abstentions. The Committee's decision will be communicated to TOSA, Southwest Transplant Alliance, LifeGift Organ Donation Center, and Senator Karen Nelson, Chair of the Texas Senate Committee on Health and Human Services.

Some Members raised the issue of potential conflicts between state laws and the OPTN. The Committee was informed that the Final Rule, in a preliminary iteration, included language specifying federal law preemption of conflicting state laws pertaining to organ transplantation. However, such language was removed prior to the implementation of the Final Rule as the Department of Health and Human Services felt federal preemption was implicit. Some states have passed organ allocation laws, but to date at least they contain language allowing for reciprocal sharing and consistency with federal regulation. The Texas state law that initiated the TOSA proposal acknowledges the national OPTN organ sharing system and directs the Texas OPOs to develop a protocol consistent with the OPTN.

During its May 19-20, 2004, meeting, the Committee reviewed communications from TOSA, Southwest Transplant Alliance and LifeGift Organ Donation Center, requesting the Committee table any further consideration of the alternative allocation systems (**Exhibit GG**). During the Region 4 meeting, the three OPOs agreed to form a committee including representation from each of the three OPOs to reconcile the multiple proposals into one formal proposal.

22. Alternative System Requests from Gift of Hope Organ and Tissue Donor Network. The Committee reviewed a request for an alternative allocation system for pancreas allocation from Gift of Hope Organ and Tissue Donor Network (Gift of Hope) (**Exhibit HH**). Gift of Hope previously submitted a proposed alternative system for pancreas allocation during development of the modifications to the national standard pancreas allocation policy. The Committee had declined to approve the proposed alternative system in light of the effort underway to revise national policy. Gift of Hope requested that the Committee re-consider this decision and evaluate the OPO's application on its merits before completion of the national policy changes. The Committee responded to this request at its January 20-21, 2004, meeting. Dr. Martin Mozes, a representative of Gift of Hope, participated in the meeting by telephone to address questions from the Committee.

Gift of Hope proposed to allocate pancreata according to the following sequence:

- Zero antigen mismatched, highly sensitized (PRA \geq 80%) candidates waiting for combined kidney/pancreas transplantation, locally, then regionally, then nationally.
- Highly sensitized (PRA \geq 80%) candidates waiting for combined kidney/pancreas or isolated pancreas transplantation, locally.
- Other zero antigen mismatched candidates waiting for combined kidney/pancreas or isolated pancreas transplantation, locally, then regionally, then nationally.
- Blood type identical candidates waiting for SPK/PAK transplantation (candidates initially intended for simultaneous pancreas-kidney transplantation who are still waiting for a combined transplant, received a kidney only transplant and are waiting for a pancreas transplant, or received the combined organ transplant with immediate loss of the pancreas graft), locally. The proposal notes that based on the OPO's kidney payback debt, one donor kidney may first need to be offered to satisfy a payback debt.
- Blood type compatible candidates waiting for PTA/PAKP transplantation (all candidates in need of pancreas transplantation not included in the SPK/PAK category).
- Candidates waiting for pancreatic islet alone or simultaneous islet-solid organ transplantation (blood type identical for kidney-islet; blood type compatible for others), locally.

Within each of the above-listed categories, candidates would be prioritized by waiting time; within each of the above-listed categories except the last, pediatric candidates (age \leq 18 years) would receive preference ahead of adult candidates at the local level of organ allocation.

After discussion, the Committee noted the following concerns. First, for allocation to SPK/PAK transplant candidates, the proposal indicated that the OPO's kidney payback debt volume could require allocation of one donor kidney in satisfaction of this debt. Based upon the OPO's debt volume, OPTN/UNOS policy could require that both donor kidneys be offered in satisfaction of payback debt. The Committee requested clarification that the OPO intends to adhere to standard policy in this regard.

Second, the Committee understood that Gift of Hope proposes to assign priority to SPK/PAK candidates ahead of PTA/PAKP candidates to avoid discouraging patients in need of the multiple organ transplant from accepting a suitable kidney while they continue to wait for the pancreas. Committee Members were concerned, however, that the result of the protocol is to assign patients in need of pancreas following kidney transplantation different allocation priorities despite the common condition they appear to share.

Third, the Committee continues to believe that allowing the OPO to retain all pancreata for islet transplantation locally, rather than share pancreata designated by the modified standard policy for whole organ transplantation outside the OPO (if not used locally for whole organ transplantation), is not consistent with the objectives of the policy. Organ procurement and placement efficiency is enhanced by a systematic approach to identifying pancreata intended for whole organ versus islet use prior to organ recovery. The proposal addresses this by using donor characteristics to indicate whole organ or islet use. OPOs should be able to anticipate, based upon donor age and BMI and prior to procurement, whether the pancreas will be used for whole pancreas or islet transplantation. These expectations would be diminished if OPOs are allowed to dismiss the policy's distinctions. Additionally, there is concern that continued reliance by OPOs upon alternative systems to retain all pancreata for islet transplantation would perpetuate the need for any OPO whose transplant centers wish to offer islet transplantation to request the same or a similar system. This is contrary to the notion of a single unified system for pancreas allocation, and jeopardizes appropriate balance in pancreas availability for candidates in need of whole organ versus islet transplantation.

Based upon these concerns, the Committee voted against approving the Gift of Hope application. The vote of the Committee was 23 in favor of not approving the application; 1 Against; and 0 Abstentions.

The Committee reviewed an additional request for an alternative system for kidney allocation from Gift of Hope (**Exhibit II**), which sought to allocate kidneys at the local level of organ distribution as follows:

- First, for 0 antigen mismatched candidates according to the standard national algorithm, with the exception of assigning first priority for pediatric patients < 13 years old, second priority for pediatric patients ≥ 13 and < 18 years old, and third priority for all others.
- Next, for pediatric ABO identical candidates, with first priority for pediatric patients < 13 years old and second priority for pediatric patients ≥ 13 and < 18 years old.
- Next, for other ABO identical candidates, followed by ABO compatible (blood group A) candidates, with first priority for prior living donors.
- Next, for double kidney allocation.

Points for waiting time and PRA ≥ 80% would be assigned consistent with standard national policy. In the event candidates within any of the priority categories listed above have equal points, priority would be determined based upon: longest time on the waiting list, then fewest mismatches at the DR locus, and then alphabetical order.

The Committee had questions regarding several components of the proposal. First, Committee Members expressed concern regarding the suggested priority assignment for prior living donors. Prior living donors receive priority ahead of kidney payback offers and children who have reached their time goals to transplantation without receiving a transplant in the standard national system of kidney allocation. This is consistent with Gift of Hope's stated intent to "emphasize priority for patients who have previously donated an organ for transplantation." Dr. Mozes offered that he believes the OPO would be willing to adjust the proposal to assign the same priority for prior living donors and kidney payback offers as assigned in standard policy.

Second, Committee Members questioned the OPO's intent in assigning last priority for double kidney allocation. OPTN/UNOS Policy 3.5.7 (Double Kidney Allocation) requires that adult donor kidneys be offered singly unless the donor meets certain enumerated criteria. In the event the criteria are met and the OPO wishes to offer both donor kidneys together, then the kidneys are to be allocated, first, locally according to the algorithm for either standard criteria donor kidneys or expanded criteria donor kidneys, as applicable. It is not clear whether Gift of Hope intended to conform to Policy 3.5.7's criteria for offering both kidneys from a donor together. It also is not clear whether Gift of Hope intended to change the allocation sequence for such kidneys from the standard national allocation sequence. The Committee would like clarification of these issues.

Third, Committee Members were concerned with using alphabetical order of candidate names in determining allocation priority. The Committee understands that Gift of Hope is trying to ensure an orderly mechanism in the event of point ties among patients. There was concern, however, that there is no basis in medical criteria for using alphabetical order. Furthermore, there was concern regarding how candidates would view this factor. Would this appear arbitrary, for example, since there is no medical/scientific basis? Additionally, because UNetsm can calculate candidate waiting time to multiple increments it is unlikely that ties would occur.

Fourth, Committee Members were concerned with the proposal's complete elimination of priority for HLA matching (with the exception of 0 antigen mismatches) from the OPO's system. The Committee has determined that for the nation overall there continues to be a significant graft survival benefit from receipt of a 0 or 1 DR mismatched kidney transplant. Some priority has, therefore, been retained in the allocation algorithm for this factor. Committee Members noted, in particular, that the analysis of the effect of HLA matching on graft survival rates included with the proposal does not report results for patients receiving 2 DR mismatched kidney transplants. The modified national policy attempts to increase the number of HLA DR matched transplants, thereby increasing system utility, while reducing disparities in access to transplantation that resulted from prior emphasis in the policy upon matching HLA antigens that are uncommon among various ethnic groups. Committee Members expressed concern that Gift of Hope's proposal would miss this opportunity to improve system utility unless the OPO assigns some priority for matching at the DR locus.

Finally, Committee Members noted that the proposal's assignment of absolute priority to ABO identical HLA mismatched children ahead of HLA mismatched adults is not consistent with the objectives the Committee is pursuing for children in standard national policy. The Committee has determined that in an effort to get children transplanted expeditiously to avoid debilitating effects of dialysis and renal failure upon growth and development, these candidates are not remaining on the waiting list long enough to receive well-matched

transplants. The likely result is poorer outcomes and increased sensitization for children. Alternatively, if children were assigned additional priority for highly DR matched kidneys when available, it is hoped that the goals of rapid transplantation, together with improved outcomes and reduced sensitization following transplant, would be achieved for pediatric patients. The Committee has developed a proposal to modify the national standard criteria donor kidney allocation system to assign 6 points to pediatric candidates who are a 0 DR mismatch with the donor.

After additional deliberation, the Committee voted unanimously to table the OPO's proposal pending reconsideration of the application by Gift of Hope in light of the Committee's comments and concerns.

23. Request from Transplant Resource Center of Maryland for Review of Their Long Term Kidney Debt Status.

The Committee initially reviewed a request from Transplant Resource Center of Maryland regarding its struggle with repaying long-term ABO AB blood type donor debts during its October 1-2, 2003, meeting. Transplant Resource Center of Maryland requested elimination of the AB debts from their long-term debt obligations in the payback system.

The policy defining long-term and short-term debts was developed to address concerns that the kidney payback system was not functioning as intended. All kidney debts owed prior to March 1, 2001, were defined as long-term debts. The OPOs were instructed to reduce their long-term debts annually according to schedules negotiated with the Kidney/Pancreas Committee. Failure to meet these annual thresholds would result in adverse consequences.

In its review of currently outstanding long-term debts for all OPOs, the Committee discovered there were only 17 outstanding. Sixteen of the 17 outstanding long-term debts are for ABO AB kidneys. Acknowledging the difficulties inherent in satisfying the ABO AB debts, changes in the system already permit payback of the long-term ABO AB kidney debts if only one such debt is owed. Despite the challenges in reducing these debts, the Committee recognized that Transplant Resource Center of Maryland was able to reduce their AB long-term debt to 3 by the time of Committee review of their request. The implication in the OPO's request is that all long-term ABO AB debts should be forgiven.

The Committee agreed to retain the debts for all OPOs with long-term AB debts but allow the OPOs additional time to meet the reduction mandate. A term of two years was thought to be adequate. The Board approved the Committee recommendation during its November 20-21, 2003, meeting, and notification to all of the OPOs with long-term ABO AB debts is being provided.

The Committee reconsidered the issue during its January 20-21, 2004, meeting (**Exhibit JJ**). Transplant Resource Center of Maryland contends that some OPOs are beginning to selectively incur ABO AB blood type short-term debts due to concerns about their inability to pay back such debts. Despite their best efforts to reduce this debt, they felt it is unlikely they will be able to eliminate the long-term ABO AB debts.

Members of the Committee reviewed an updated report of the remaining short-term and long-term kidney debts by ABO blood type as of January 9, 2004 (**Exhibit KK**). According to the report, only 13 of the 144 short-term debts were for ABO AB blood type. Of those OPOs with short-term ABO AB debts, 2 OPOs had 2 debts, 9 OPOs had 1 debt and the majority of OPOs had 0 short-term AB debts. Based on these numbers, there does not appear to be substantial risk to OPOs of exceeding short-term debt limits based upon AB debt levels.

Some Members, however, noted the slow rate of reduction of long-term ABO AB debts among the OPOs. This may indicate a problem in the payback system. The Committee once again raised the issue of removing all ABO blood type long-term debts. Other Members suggested that cancellation of the remaining long-term kidney debts, an action without Committee precedent, would be unfair to the majority of OPOs that have worked hard to eliminate their long-term debt. The Committee does not know the reason some OPOs may experience particular difficulty in paying back long-term ABO AB debts. This could be due to relatively low procurement volumes generally or the quality of organs procured. After further discussion, the Committee denied the proposal by a vote of 1 For; 19 Against; 1 Abstention.

Committee Members agreed to examine the explanations for the difficulty some OPOs experience in paying back ABO AB long-term debts. During its next meeting, the Committee will review data on refusal codes for ABO AB blood type kidney offers for those OPOs with long-term AB debts. In addition, the Committee will review AB kidney recovery rates for those OPOs with long-term AB debts.

24. Presentation on OPTN Final Rule and Draft Response to Board Resolution. During its January 20-21, 2004, meeting, the Committee discussed requirements for organ allocation policy under the OPTN Final Rule and a resolution approved by the Board of Directors in November 2003 with respect to OPTN policy development, the Final Rule, and OPTN long range planning. The Board resolution requires OPTN/UNOS Committees to specifically address the performance goals, including performance indicators to measure the achievement of performance goals and transplant center performance, set forth in the OPTN Final Rule when making policy recommendations to the Board (**Exhibit LL**). The Committee will be working with UNOS Staff to draft introductory language to the kidney and pancreas allocation policies that address the Final Rule requirements and direction from the Board.

As background to the Board resolution, the Committee reviewed a presentation on the OPTN Final Rule, its interaction with and requirements for OPTN allocation policies (**Exhibit MM**). The Final Rule, which became effective in 2000 as a Federal regulation, is incorporated into the OPTN contract with the Department of Health and Human Services, Health Resources and Services Administrations (HRSA). Under the Final Rule, the OPTN Board is responsible for developing allocation policies addressing the following issues: equitable allocation of deceased donor organs, donor testing to prevent the spread of infectious diseases, reduction of socio-economic inequities, physician and surgeon requirements for designated programs, and any issue the Secretary of Health and Human Services directs. The OPTN/UNOS Board is required to seek public comment on proposed changes to allocation policies. Policies become enforceable under Section 1138 of the Social Security Act (potentially impacting hospital Medicare participation) only after the Secretary of Health and Human Services approves them as enforceable. Programs that fail to adhere to such a policy can have their Medicare eligibility removed by the Secretary. To date, none of the OPTN/UNOS policies are enforceable under Section 1138 of the Social Security Act. All OPTN/UNOS policies are monitored for compliance, however. Non-compliant behaviour is addressed through action intended to bring the Member back into compliance, including, for example, possible letters of warning or reprimand, probation, or declaration of Member Not in Good Standing. The Secretary is also authorized to refer policies to the Advisory Committee on Transplantation (ACOT), direct the OPTN to modify policies deemed inconsistent with the National Organ Transplant Act (NOTA), and review appeals made by interested parties with respect to allocation policies.

Allocation policies must be based on a number of criteria including sound medical judgment, best use of organs, right of refusal for programs, organ-specific characteristics, avoidance of organ wastage, promotion of patient access, and promotion of efficient organ placement. Candidate geographic location can be considered only in light of the other policy criteria.

The Final Rule establishes certain performance goals. First, the OPTN is to standardize objective listing and removal criteria. Candidates are to be prioritized by objective measurable medical criteria and shall be ranked according to urgency. The Final Rule also requires distribution of organs over as large an area as feasible in order of decreasing urgency. In addition, inter-program variances should be reduced as reasonable in order to maintain a more national allocation system. Finally, the OPTN allocation policies must specify performance indicators to measure the achievement of defined performance goals and transplant center performance. Such performance indicators should include baseline data evaluating how the current policy meets the goals, amount of improvement to be achieved by any new policy in meeting the performance goals, and any indicators proposed by the Board and approved by HHS or required by HHS.

Finally, the Final Rule requires the OPTN to assess the allocation policies and inter-program variances. For each organ specific policy, a number of issues shall be examined including, organ procurement and allocation, access to transplantation, effects on transplant programs by volume and OPO, and OPTN contractor performance. Required assessment data should be analyzed, as appropriate, by organ and patient status, program and OPO, program size, by OPO, Regionally and Nationally, or by other geographic areas required by HHS. Data assessed on inter-program variances shall include risk-adjusted total life years, both pre- and post-transplant, risk-adjusted patient and graft survival, and risk-adjusted waiting time and transplant rates.

The Committee discussed whether the urgency criteria of the Final Rule apply to all organs, including kidneys, for which the concept of urgency as used for certain of the other organs has not been incorporated for allocation, at least historically. Some Committee Members stated that the Final Rule was written with other organs, namely liver, in mind. Development of an allocation system similar to liver and based on urgency for kidneys is not the best approach. The nature of kidney dialysis and transplantation distinguishes kidneys from other organs where urgency is a more appropriate factor. The Committee was informed that the drafters of the Final Rule provided flexibility in the requirements to allow for organ-specific distinctions. In fact, the preamble to the Final Rule specifically addresses the differences among organs and references kidneys in particular. Each organ allocation policy should be specific to that particular organ. Even given the noted flexibility of the Final Rule, Members commented that urgency already is accounted for in kidney allocation. One example of urgency in kidney allocation includes priorities for pediatric candidates who experience unique problems associated with dialysis and disruption to expected growth and development processes due to renal failure.

The Committee continued this discussion and reviewed a draft response to the Board resolution during its May 19-20, 2004, meeting (**Exhibit NN**). With respect to the draft response to the Board resolution, the Chair indicated that the text was good and asked for Members to send any comments individually to staff for incorporation. The version of the document attached to this report includes these modifications. Committee discussion focused on the section on policy performance measures. The draft response proposed a list of measures, though not exclusive, to be assessed by the Committee through modeling and non-modeling tools with respect to kidney and pancreas allocation as follows:

- Pre- and post-transplant graft and patient survival;
- Listing, transplant, death and removal rates for various patient groups (*e.g.*, diagnostic groups, allocation point ranges, demographic (*e.g.*, blood type, ethnicity, age), and geographic groups);
- Indicators of morbidity and quality of life, as measured by available data and current methodologies;
- Profile of recipient characteristics that are factors in kidney allocation (*e.g.*, HLA mismatch level, PRA level, age);
- Risk of progression of disease;
- Organ discard rates;
- Impact upon organ availability.

These measures could be evaluated by the Committee as it reviews the kidney and pancreas allocation policies. However, a critical issue for the Committee is to specify the overall goals it seeks to accomplish through such allocation policies.

Henry Krakauer, M.D., Ph.D., discussed the Division of Transplantation (DOT) perspective on how the Committee might assess performance issues. A good departure point for assessing performance is consideration of how much good comes to a patient by the strategies deployed in the management of the patient. Within that consideration, one should understand the patient's expectations and how physicians can respond to those expectations and needs. All other issues are essentially technical details. The establishment of clear, fundamental objectives can allow the Committee to focus policies on obtaining those objectives.

The development of goals for the kidney and pancreas allocation systems is a complicated, intense and worthwhile endeavor. Some Members stated that an additional forum or Committee meeting might be necessary to fully contemplate and develop these goals.

A variety of perspectives on possible allocation goals were discussed during the meeting. Some Members expressed that the Committee should focus on transplanting the maximum number of organs while maximizing utility, but avoid issues of access to the waiting list and transplantation for end stage renal disease patients. The Committee could provide input to CMS as it develops Medicare regulations governing access to transplantation but this is outside the experience of the Committee to have an impact. However, other Members articulated that any issue related to transplantation should be within the purview of the Committee due to its expertise and focus on transplantation. The goal should be to provide a transplant to every person who needs one. The Final Rule provides focus on listing criteria as well as organ allocation, which broadens the Committee emphasis. Due to

the differing perspectives on the role of the Committee, some Members stated that perhaps direction is needed from the OPTN/UNOS and HRSA as to how broadly the Committee should define its role. However, other Members suggested that the Committee itself should define its role.

One topic that illustrates the differing perspectives on the Committee's role is living donation. Some Members expressed that the Committee should take a proactive, primary role in developing procedural regulations and patient safeguards for living donation. On the other hand, some Members of the Committee stated that living donation is outside of the purview of the Committee.

An additional option considered by the Committee was delaying any further specification of overall allocation goals until KPSAM is available to provide some insight, and then use the model to help the Committee review the entire allocation system, and determine which goals are feasible with the current organ supply. The current allocation system has been developed and revised over time, with particular focus upon several categories of patients who face unique medical circumstances. The system may work well for these particular patient groups, but not patients overall. Articulating objectives of the allocation system will involve consideration of patient, transplant center and system objectives and needs, and realization that these objectives and needs may conflict at times.

Some Committee Members stated the goals of the allocation system should be a fair system that is as simplified and open as possible. Transplant candidates often lack a true understanding of how the allocation system works, which could be attributable to lack of education from their transplant programs, but also because the system itself is rather complex. The Committee should strive to make the transplant system transparent to candidates and the transplant community.

Finally, some Members suggested the Committee goal as maximizing or optimizing benefits, recognizing that multiple benefits exist, with the most important benefit being patient survival. At the same time, the Committee should minimize disease burdens and disparities, both medical and non-medical, in terms of access.

Some Members commented that the Committee drafted a white paper after the Final Rule was developed to articulate and describe the current allocation system and how it met the requirements of the Final Rule. This white paper could be a useful reference to integrate into future deliberations of the issues. However, the Committee acknowledged that their charge is changing along with the operating environment, support tools and personnel, and perhaps the Committee should contemplate the system from a fresh perspective.

Laura St. Martin, M.D., MPH, offered some insight from HRSA's perspective on the Committee role. One of the issues the Committee should discuss is developing criteria for appropriate transplant candidates (*e.g.*, listing and de-listing criteria). The Committee decision and policy development processes should at least consider some of the pre-transplant factors patients encounter. HRSA could help relay Committee concerns or recommendations to the appropriate agencies if the Committee considers a transplantation issue beyond their policy-making capabilities.

The Committee agreed to consider this matter further after the meeting and forward suggestions, perspectives and topics to the next Chair, Mark Stegall, M.D. The Committee will continue this discussion at its next meeting.

25. **Presentation on KPSAM.** The Committee continues to examine the role of various objective medical factors in the kidney and pancreas allocation systems. During the January 20-21, 2004, meeting, Keith McCullough presented an update on the Kidney- Pancreas Simulated Allocation Model (KPSAM) (**Exhibit OO**). The SRTR will continue to work on the model and deliver the final draft to HRSA on March 31, 2004. Subsequent to HRSA review and approval, KPSAM will be available for public use through the Committee. KPSAM will have features the other organ specific SAMs do not possess, including the ability to account for paybacks, HLA mismatch score, the allocation point system with time thresholds, models of graft failure, and the possibility of relisting a candidate after graft failure.

KPSAM is not intended to perfectly replicate the allocation and distribution system, or the outcome data of a given year, but rather to predict the consequences of directions and changes to allocation policies.

Deterministic and random factors will be incorporated into the allocation model component of KPSAM. The model will allow the user to provide inputs into the system, which will then produce outputs based on candidate and organ input data from the OPTN and SRTR database from 2001. KPSAM will use an event-sequenced Monte Carlo Simulation in which all steps of the simulations are determined by data and allocation rules. The events after the match run, including organ placement, time from transplant to death and relisting events and history, are probabilistic. The model will predict the numbers of transplants, graft failures and deaths resulting from Committee proposed national allocation policies, and can change the order of and rank within any categories that are available from the OPTN wait list database. In addition, the user can combine existing categories or create new categories if data are available.

Validation efforts for KPSAM are focused on attempted replication of the actual transplantation system from 2001. The year 2001 was chosen because it is the most recent year with completed transplant recipient follow-up data. The database contains waitlist status changes and mortality for those recipients who were transplanted in real life. In order to model possible changes to allocation policy, the model appends a completed history for patients who were not transplanted in 2001 by matching such candidates with actual 2001 recipients who have similar characteristics. Patients are only considered for status history matching if they meet a number of qualifications including, listing for the same organ, similar length of waiting time, same active status, age category and diabetic status, and the closest risk of mortality based on the waitlist survival models.

KPSAM also contains a placement model component, which models the factors leading from an organ offer to transplantation. The placement model includes organs recovered for transplant, but not organs completely rejected. In addition, positive crossmatches are included in a probabilistic fashion as candidates with high PRA levels are deemed more likely to have a positive crossmatch.

The Committee applauded the efforts of the SRTR in developing KPSAM, but expressed some reservations. For instance, KPSAM does not incorporate center-specific patient graft and survival report factors into the modeling efforts. The center-specific report is used for public reporting of results and is useful for determining patient graft/survival post-transplant. In addition, the center-specific report could aid in validation efforts for KPSAM. Some Members noted that the databases and general statistical approaches used by KPSAM and the center-specific report are similar, but exclude different factors depending on how the databases are constructed and the goals of the analyses. It should be expected that some elements will differ between the analyses. Some Members emphasized that relevant factors demonstrated by KPSAM should be incorporated into future center-specific reports and vice versa. These comments will be relayed to the SRTR for further consideration.

KPSAM will not incorporate alternative allocation systems as the intent is to examine the implications of changes to the national allocation system assuming application to the entire nation. Some Members stated that differences in the model validation data could be attributed to the use of data from OPOs operating with alternative allocation systems during 2001.

Members expressed concerns over the use of pre-transplant factors with no actual post-transplant data to predict post-transplant outcomes. Post-transplant factors, such as immunosuppressive regimens, rejection episodes, hypertension, diabetic and lipid control all potentially impact graft survival and patient mortality. KPSAM does not incorporate such information because it is available in the database only for recipients who actually received a transplant in 2001. Therefore, when a user inputs a change in the allocation policy into the model, post-transplant data histories would be lacking for those candidates not transplanted in 2001. Some Members stated that the model could apply actual post-transplant histories to candidates not transplanted but who exhibit factors similar to the recipient. These concerns will also be communicated to the SRTR.

After the final version of KPSAM is approved and operational, the SRTR plans to model different allocation systems proposed by the Committee using the 2001 data to determine how the allocation system would have differed under various systems.

In future discussions, the Committee intends to consider the definition of “benefit” of a transplant as it continues to balance justice and utility in the allocation system. Some of the possible definitions include quality

of life, life years gained from a transplant compared to life years if the candidate remains on the waiting list, or some combination thereof.

26. Report of the OPTN/UNOS Kidney and Pancreas Transplantation Subcommittee on Kidney Allocation and KPSAM. A meeting of a subgroup of the OPTN/UNOS Kidney and Pancreas Transplantation Committee and the respective Chairs of the OPTN/UNOS Pediatric Transplantation, Minority Affairs and Histocompatibility Committees was held at the offices of URREA in Ann Arbor, Michigan on February 11, 2004 (**Exhibit PP**). The intent of the meeting was to review and discuss the structure and functions of the Kidney and Pancreas Simulated Allocation Model (KPSAM) being developed by the SRTR, as well as future directions for allocation policy. With this meeting focus, the subcommittee discussed a variety of topics, including a general overview of KPSAM and modeling, waitlist mortality and possible approaches for study, KPSAM validation efforts, the OPTN Final Rule with respect to policy development, defining and reducing disparity in access to kidney and pancreas transplantation, and special pediatric considerations for future policy development. Due to time constraints, a number of topics were deferred for discussion at a full Kidney/Pancreas Committee meeting at a later time.

During its May 19-20, 2004, meeting, the Committee briefly reviewed a few of the topics discussed during the Ann Arbor meeting, which were very consistent with the scope of the Committee's discussion of the OPTN Final Rule and response to Board resolution in item 24 (above) of this report. First, validation results from KPSAM where the model results were compared to the actual data from the first six months of 2001 were presented to the Committee. In general, KPSAM results agree well with the actual experience from the first half of 2001. Discrepancies with actual data are expected due to many factors including physician and OPO permissible discretion, local alternative allocation systems, and en bloc transplants and medical urgency. KPSAM will model outcomes assuming the allocation rules are followed without variation on a national basis. The Committee was informed that KPSAM has been modified since the February subcommittee meeting and the validation results are even better in its current iteration.

Dale Distant, M.D., one of the subcommittee Members, presented some of the slides on possible remedies for geographic, racial/ethnic, and insurance disparities from the subcommittee meeting. For instance, possible remedies considered for geographic disparities in terms of access to the waiting list include candidate transportation benefits, outreach to underserved areas, professional education on survival and morbidity with living donors, preemptive and early transplantation, medical school curricula, standardized referral form with linkage of data, enforceable CMS standards on referral that are tied to dialysis reimbursement rates, and federal regulation of Medicaid transplant-related benefits. Some of these remedies were acknowledged as presently unfunded mandates, but given their possible impact on transplantation, not outside the scope of the Committee. The Committee also briefly reviewed the possible remedies for geographic disparities in terms of transplantation, racial/ethnic disparities in terms of access to the waiting list and transplantation, and insurance disparities in terms of access to the waiting list and transplantation (see Exhibit).

Some Members commented that the single greatest factor determining candidates' time to transplant is their respective donor service area of listing. A number of factors affect a donor service area's ability to transplant its candidates in a timely fashion. For instance, some donor service areas have high transplantation rates, but low recovery and listing rates. The difficulty in assessing this example is determining whether this donor service area is performing well or poorly. However, the Committee should focus on the donor service area, which includes the OPOs, transplant centers and dialysis centers within the area, in assessing the system. It was suggested the Committee also needs to account for the potentially inherent differences between the donor service areas.

Some Members stated that the real challenge is the organ shortage in the United States. For example, there are approximately 58,000 candidates waiting for a kidney transplant, but only approximately 15,000 kidney transplants performed annually. Perhaps the Committee should focus its efforts on mechanisms to increase organ donation. Other Members of the Committee stated, however, that attention to current disparities in patient access to the waiting list and transplantation must be considered as well. The Committee can and should work on increasing the number of available kidneys and pancreata suitable for transplantation, but cannot avoid the current challenges that exist within the allocation/distribution system. Some remedies being pursued by the Committee may, in fact, help to address organ availability as well as allocation factors.

27. Presentation on Living Donor Paired Kidney Exchanges. Mitchell Henry, M.D., presented the efforts of the Ohio Solid Organ Transplantation Consortium over the last two years to address the issues of paired kidney exchanges and develop a match run system for such exchanges during the Committee meeting of May 19-20, 2004. The first match run was performed within the last two weeks and is evolving into an important clinical activity.

The purpose of a paired exchange is to increase the number of live kidney transplants for recipients with willing but incompatible live donors. As waiting times for deceased donor kidney transplantation increase, living donation becomes increasingly prevalent. Living donation also has the benefit of increasing the projected half-life of the graft relative to deceased donor kidneys. In fact, during the last few years, the number of living kidney donors outnumbered the number of deceased kidney donors; therefore, living donation has become a substantial portion of the kidney transplant world.

A direct kidney exchange, also known as a live donor/live donor exchange, is one in which the donor from pair 1 cannot donate to the candidate from pair 1 because they are blood type incompatible or have a positive crossmatch. The same situation exists for the donor and candidate from pair 2. If the donor from pair 1 is compatible with the recipient from pair 2 and vice versa, an exchange can take place such that each candidate can have a kidney transplant.

The Ohio Solid Organ Transplantation Consortium formed a committee on living kidney donation composed of voluntary members from all providers of kidney transplant services within Ohio to define medical eligibility and matching criteria for the paired exchanges. Though each potential incompatible donor and candidate are evaluated by the local transplant program, the committee intends to review and approve each match list and paired exchange to ensure the specified goals have been achieved. The committee also will define fiscal policies, approve all scientific and grant proposals prior to submission, determine quality assurance data points, and maintain the paired exchanges database.

The clinical protocol requires for participation that a potential candidate not have a compatible living donor. The candidate also must have a medically suitable donor who is ABO or crossmatch incompatible. In order to participate in the paired exchange, donors and candidates must meet a number of criteria, including but not limited to, serology tests, creatinine, cardiac stress test if indicated, PRA testing, psychosocial screening, and dental evaluation. Once the pairs have been identified, the details of the program are carefully explained and a written brochure is provided to the potential donors and candidates.

Both the donors and candidates are given standardized consent forms, which are witnessed and renewed on an annual basis at minimum. The donor agrees to supply re-consent periodically if there is a change in the exchange scenario. The donor also agrees to meet with the transplant team to confirm the donor's commitment to donation. Once the donor pair is approved by the local transplant program, the pair is placed on the list for a monthly computer match run. The candidate sera is sent to the donor program for crossmatching compatibility with other pairs. For high PRA candidates (defined under this protocol as PRA > 75%), crossmatching is limited only for well-matched donors. All preliminary crossmatching is performed at the local transplant center and the final crossmatch is conducted at the center in which the transplant is performed. Positive crossmatch results will conclude the potential exchange.

Upon referral to the transplant center, the donor/candidate pair is counseled again. The minimum information shared includes age, height, weight, blood pressure, GFR/creatinine clearance levels, and serologies. Consent is then obtained at the candidate transplant center to which the adult donor is assigned and where the transplant occurs. Pediatric candidates and their donors, particularly if the donor is a parent of the pediatric candidate, may remain at the same hospital. The organ would then be transported to the candidate center. The donor is counseled one last time by the assigned transplant center, the renal anatomy is imaged and a final crossmatch is performed.

The paired exchange occurs on the same date and both donor procedures are begun simultaneously to prevent a situation where one donor might back out of the exchange after a procedure was begun on the other donor. The

laparoscopic donor nephrectomy is the preferred method of kidney procurement. Subsequent to transplant, donor follow-up will be arranged by the performing center usually via the recipient transplant center.

Assuming an incidence of end stage renal disease (ESRD) of 300 patients per 1,000,000 population per year as a national average, and given the Ohio population of approximately 11,000,000 people, Ohio expects to have an ESRD population of approximately 3,300 residents per year. The Ohio Solid Organ Consortium estimates that approximately 50%, or 1,650, of the 3,300 Ohio residents newly diagnosed with ESRD each year will be suitable for transplantation. Approximately 50% of the 1,650 transplantable ESRD patients will have a willing living donor. One third of this population, or 275 patients, are estimated to have willing but incompatible living donors. Then one third, or 92, of the 275 patients are expected to participate in the living donor paired exchange program. This is the figure the Ohio Solid Organ Consortium hopes to reach each year to demonstrate whether the program is successful.

One of the unique aspects of the paired exchange program in Ohio is the existence of a computer-based sharing program where the computer, rather than a human staff member, matches the pairs. The computer sharing program will calculate the point system devised by the Ohio Solid Organ Consortium as follows:

Category	Points
Wait Time	3+
Distance	3
Recipient vs. Donor Age Disparity	3
Donor vs. Donor Age Disparity	2
HLA Match	6/3
Pediatric Bonus	6
PRA Bonus	2
CMV/EBV Bonus	2/2
Blood Group A/B Bonus	6

A central database will be maintained for the paired exchange program, but each center will be responsible for entering their own data and uploading the information once per month. The Medical Review Committee will evaluate the top ten matches each month for transplant suitability. Subsequent to the Committee decision, the potential pairs are informed of their potential match and given the opportunity to accept or decline the offer. If the candidate declines three sequential offers, the candidate is required to proceed through the living donation counseling procedures again.

Members of the Committee expressed enthusiasm about the efforts on paired exchanges by the Ohio Solid Organ Consortium and interest in the possibility of adopting the system nationally through the OPTN/UNOS. Transportation and follow-up costs and logistics are primary concerns if the paired exchange program were developed nationally. The concept should move forward, but perhaps a trial period in Ohio could provide some insight for application to the nation.

Some Members of the Committee were skeptical of the paired exchange program's ability to provide additional transplant opportunities for highly sensitized candidates. However, other Members stated that a large enough number of potential pairs in the donor pool will result in a number of highly sensitized candidates being transplanted with a negative crossmatch. Application of the paired exchange program on a national basis could dramatically increase transplant access for highly sensitized candidates.

The Committee agreed to formulate a subcommittee to develop a proposal to develop and apply the paired exchange program to the nation. Dr. Ken Andreoni will lead the effort and will be joined by Drs. Mitchell Henry, Dolly Tyan, George Blessios, Albin Gritsch and Peter Stock.

28. **OPTN/SRTR Data Working Group Proposed Transplant Endpoints.** During the May 19-20, 2004, meeting, Lawrence Hunsicker, M.D., Chair of the OPTN/SRTR Data Working Group (DWG) presented to the Committee a proposed study to evaluate multiple transplant outcomes (**Exhibit QQ**).

One of the tasks undertaken by the DWG was to determine whether all of the information needed to understand the impact of transplantation was being collected. Essentially from the beginning, analysis of transplant outcomes has focused on time to death and time to graft loss. While these are clearly important transplant outcomes, with improving patient and graft survival rates they are no longer the only relevant outcomes to consider. In fact, the Advisory Committee on Transplantation (ACOT) has recommended the OPTN begin to collect and analyze information on the impact of transplantation on “quality of life.”

Limitations exist with the current focus on death and graft failure. For instance, in deceased donor kidney allocation, priority is assigned to pediatric candidates based on the intellectual, physical, and social maturation and needs of children; however, there is no OPTN data dealing with the impact of early transplantation on these outcomes. In addition, since life expectancy in children following transplant is typically long, it is difficult to obtain sufficient data on the impact of transplantation on survival. Further, certain conditions experienced by candidates waiting for other organ transplants, for instance, liver candidates with cholestatic disease and lung candidates with COPD, may receive lower priority within their respective current or proposed allocation systems than some would argue is warranted by the degree to which these patients actually suffer from illness for a very long time. The data to make this determination are not currently collected, however.

A number of perceived statistical advantages to broadening the examined endpoints exist. First, there is a strong likelihood that alternative outcomes such as morbidity and functional status will be highly correlated with mortality risk. Second, graft failure data or mortality can only be observed once per graft or patient and then it is too late to collect additional data. In addition, cumulative morbidity and functional status can be measured on many occasions and may offer greater statistical power in analyses. Finally, time-series analyses on non-terminal outcomes may permit early intervention on high risk patients who are hospitalized more frequently.

The DWG examined and developed five proposed domains of transplant outcomes, including mortality, cumulative mortality (adverse medical events), functional status (ability to perform functions required/desired in daily life), psychological distress, and resource use (needed to care for the patient). Under these outcomes, it is important to collect both pre- and post-transplant data for both transplanted recipients and those selected for transplant but still waiting.

Current and proposed data sources were discussed by the DWG for the five proposed domains of transplant outcomes. Mortality is currently captured by the OPTN/UNOS system and supplemented by death data from the Social Security Master File or the National Death Index. These measures are probably sufficient and do not require supplemental data sources.

With respect to morbidity, limited hospitalization data are currently collected on transplant recipients. The new transplant follow up forms will ask post-transplant recipients about all hospitalizations, not just transplant-related hospitalizations, since the last reports. However, the OPTN/UNOS does not collect data on wait list candidate hospitalizations. CMS collects complete data on kidney candidates and recipients with Medicare primary insurance coverage and has agreed to provide the data for analysis. Finally, the states of Pennsylvania and Virginia have consented to provide comprehensive hospitalization data on transplant candidates and recipients from those particular states.

The OPTN/UNOS currently collects functional status information on transplant recipients at transplant and on follow-up forms. The information collected is assessed on four levels of functional status, including no limitations on activity, requires some assistance with daily activity, requires total assistance and hospitalized. However, information on transplant candidates is only collected at the time of listing. While these data correlate with outcomes, the grading is not sufficiently granular to capture less than the gross loss of function. In order to achieve a greater degree of granularity, the DWG proposes to capture additional functional status through a pilot study using the SF36 physical scale. The DWG also proposes replacing the current UNOS functional scale with the Karnofsky Index, which has 10 levels of function from minor impairments to a moribund state. The Karnofsky Index is considered by some the standard, best validates objective scale for functional status and can be quickly completed during a patient clinic visit.

No data are currently collected by the OPTN/UNOS on psychological distress. The DWG proposes collecting the information directly from patients using the SF36 mental scale.

Finally, the OPTN/UNOS does not currently collect data on resource use, although the National Organ Transplant Act (NOTA) mandated assessment of the costs. The DWG proposes to estimate the effort needed to care for a patient from hospitalization data initially, using uniform coding based on the admission DRGs, weight and length of stay. The DRG scale adjusted for length of stay is a widely accepted measure of the severity of various issues.

The DWG is not a policy development body with the OPTN/UNOS and does not intend for the proposed analyses to force any particular approach to the formulation of deceased donor organ allocation or other OPTN/UNOS policy. The proposed analysis will merely inform the Committees more broadly on the outcomes of transplantation and the Committees are free to use the data as they find appropriate.

Three approaches to analyze the alternative endpoints were reviewed by the DWG. First, the DWG could analyze each endpoint separately using traditional methods. However, this approach would not facilitate the study of mutual correlations and trade-offs among the transplant outcomes. Second, the DWG could integrate the impact of the endpoints using a quality adjusted life years approach. The drawback of this method is the arbitrariness and variability of the weighting assigned to the various outcomes among individuals. The DWG does not intend to make value judgments on the data, but rather seeks to inform the Committees and allow the Committees to determine the valuations that should be given. Finally, the DWG decided the best method is a multiple outcomes approach that can be studied in a model with a multivariate outcome. In other words, outcomes in all the various domains can be considered as a single number, per individual. This approach allows the direct observation of mutual correlations among the outcomes, is objective, and leaves the weighting of components to the policy makers, physicians and patients. The observation of negative correlations can elucidate trade-offs in therapeutic decisions.

An analysis of a multivariate outcome (multiple outcomes in a single model) is a statistically innovative and challenging approach, particularly when the outcomes are scaled differently. The DWG assumes that different groups, including the SRTR, the OPTN, and HHS, may want to develop different methods depending on the anticipated goals (*e.g.*, optimize the use of limited resources or optimize the outcomes for a particular patient).

Dr. Hunsicker also presented some information provided by Robert Wolfe, Ph.D., on analyzing multiple outcomes for transplant candidates and recipients. Evaluation of the benefit of transplant involves many outcomes, including rate measures, (*i.e.*, mortality, hospitalization), and scaled measures (*i.e.*, days in hospital, resource use, functional status, and psychological distress). The analytic methods could include the combined method previously discussed, as well as, tabulation and descriptive analyses, stratified analyses to show the average outcome for each subgroup of patients, regression analyses to predict each outcome based on multiple patient characteristics, longitudinal models to predict outcome based on past history, and correlation models. One of the new methods being considered for use to model combined outcomes is the frailty model, which introduces a patient specific covariate to account for correlation. Frailty is an unmeasured covariate and predicts the outcomes of interest.

Dr. Hunsicker also presented findings from an article entitled “Beyond Survival: Predicting and Using the Burden of Disease to Support Decision-Making in Organ Transplantation,” by Henry Krakauer, M.D., Ph.D., R.C. Bailey, and Monica Lin. The burden of disease approach discussed in the article is based on four critical decisions:

1. Every component is to be represented by a cumulative measure, that is, a quantity accumulated over the period of observation.
2. The probability that a range of the values of a measured component or a set of ranges of values of any combination of components will be observed in an individual will be computed as the consistent metric in the analyses and the predictions.
3. The mathematical representation of the components of the burden of disease must conform as closely as possible to the patterns actually observed. This is most easily achieved by the use of fully parametric representations tailored to the observed distributions.

4. The interdependence of the components (correlations) must be modeled explicitly.

The burden of disease approach could answer various questions related to benefit, differences in outcomes from policy changes, differences among subgroups of patients, variation between individuals and correlation.

Based on this information, the DWG has made two recommendations to the OPTN/UNOS Data Advisory Committee (DAC), each of which was approved in principle by the DAC and will be submitted to the Board of Directors at the June 2004 meeting. First, the DWG recommended the replacement of the present functional status scale on the UNOS data collection forms with the Karnofsky Index. This change would not require any action by the OMB and could be implemented soon after approval. Second, the DWG recommended endorsement of the proposed pilot study of collection of SF36 data. The SF36 data study would target 500 returns per group from a distribution of 600 forms for adult patients selected using random sampling. The adult patients solicited would include patients of each organ transplant type, patients on the waiting list, and transplant recipients. Transplant centers will be contacted to obtain the patient addresses and alert the centers of the study, but will not be further involved in the study. The forms will be mailed by and returned to the OPTN/UNOS to simplify IRB review and approval. Patients not returning forms will be contacted by mail and by phone to maximize returns. The DWG would also design a separate trial for children in cooperation with the OPTN/UNOS Pediatric Transplantation Committee. The intent is for the study to be conducted as part of the OPTN/UNOS contract for the next budget cycle.

After feedback from the OPTN/UNOS Committees, the DWG plans to formulate a detailed analytic plan based on these recommendations and input from the Committees.

Some Members of the Committee questioned whether the quality of data collected is sufficient for the pilot study. The DWG discovered that not only are transplant centers submitting most of the data required, but the quality of the data is actually quite good. The addition of the Karnofsky Index to patient clinic flow sheets would be easily managed, though education of clinic staff would be required. Part of the education process would need to focus on justifying the usefulness of the study as local acceptance of the study importance will be crucial to success. Some Members also expressed concern that the quality of data collected under the proposal may be compromised if, for example, some clinicians completed the Karnofsky Index after the patient evaluation but without the patient present to observe. However, if the Karnofsky Index is recorded, there is no reason to believe that inaccuracies will occur with any more prevalence than from the recording of biological scores such as albumin and creatinine. In addition, the patient self-assess will be correlated with the Karnofsky Index and could be used to determine whether any data collection issues exist.

The addition of the death indices data to the abundance of already collected data will be beneficial. Currently, not much information is collected on candidates who lose graft function or expire and these additional indices will help fill in those gaps. Some Members questioned whether the study should focus extensively on transplant candidates and recipients from a few centers or use a registry-type approach. The problem with a registry approach is that it lacks the randomization, whereas randomized approaches lack the ability to look beyond common conditions and events. Each approach helps answer different questions.

Since it is difficult to predict outcomes from situations with multiple variables, some Members expressed concern that any data gathered from this study might skew future allocation policies in an inappropriate or erroneous direction. This concern is central to any collection of past data, particularly when examining long term outcomes. The intelligence of those reviewing the data will be required to interpret the results and accommodate for any perceived insufficiencies. In addition, there are mechanisms by which complex systems can be reduced to more simple terms in order to yield data results accurately.

The pilot study is designed for a three year duration after which the decision will be made by the DAC and the Board to continue or terminate the data collection efforts. Some Members expressed that three years is insufficient to accomplish the goals of the study. Five and ten year follow-ups of these patients is needed to truly ascertain an accurate picture of transplant outcomes.

Perhaps the Committee should discuss and determine the future direction of kidney and pancreas organ allocation to help frame the questions asked and data collected under the pilot study. It is also important to

know how the public will view the future policy proposals that may be developed from the data collected because the public perception of the transplantation system can differ from the intended purpose. The DWG intends to only collect the data and allow the Committees and the Board to decide whether policies should be developed based on the data.

29. Report of the OPTN/UNOS Joint Kidney and Pancreas/Pediatrics/Minority Affairs/Histocompatibility Subcommittee. The OPTN/UNOS Joint Kidney and Pancreas/Pediatrics/Minority Affairs and Joint Kidney and Pancreas/Minority Affairs/Histocompatibility Subcommittees agreed to consolidate their issues into a new Joint Subcommittee, which held its first meeting on January 13, 2004.

The Joint Subcommittee discussed and developed proposals related to pediatric allocation priorities, which were later approved by the Committee and distributed for public comment (See items 3 above and 30 below).

Review of Data Analyses Previously Requested by the Joint Subcommittee

The Joint Subcommittee deferred several data requests until KPSAM is operational, including the effect on pediatric patients of an allocation algorithm that allocated zero DR mismatched kidneys to pediatric candidates following zero antigen mismatched candidates, the number of allocation points that would be needed to effect the percent of pediatric patients who receive a transplant, and the effect on minority children of a policy that awards extra points for A and B matching to zero DR mismatched pediatric patients.

Pediatric Priority for Adolescent Donor Kidneys

The Joint Subcommittee reviewed an updated analysis of the impact of preferentially awarding 11-17 year old (adolescent) donor kidneys to pediatric transplant candidates (0-17 years) (**Exhibit RR**). The study population included 39,682 patients who received their primary deceased donor kidney-only transplant between January 1, 1996, and December 31, 2001. The relative rate of graft failure was calculated as the time from transplant to death or graft failure, censoring at the earliest of last known follow-up date, maximum date of expected follow-up, or December 31, 2002. The analysis used Cox models to ascertain the relative rate of graft failure and adjusted for recipient sex, recipient ethnicity, recipient BMI, year transplanted, PRA, ABO blood type, diagnosis group, time on dialysis, donor sex, donor ethnicity, cold ischemic time, donor cause of death, number of HLA mismatches, number of pre-transplant transfusions, double kidney transplant, and donor history of diabetes or hypertension.

Table 4.1 depicted the number and percent of recipients, by age of recipient and donor. During the study period, 4,352 (94.1%) adolescent donor (age 11-17) kidneys were transplanted in adults and 271 (5.9%) were transplanted in pediatric recipients. The relative rate of kidney graft failure for pediatric recipients was shown in Table 4.2. During the study period, 1,470 pediatric candidates received kidney transplants. Pediatric recipients experienced the lowest relative risk of graft failure when transplanted with an adolescent donor kidney (RR=0.82; p=0.17), though the numbers lacked statistical significance. In comparison, pediatric recipients experienced relative risks of graft failure of 0.86 (p=0.39) when transplanted with a young donor (age < 11) kidney and 1.00 (p=Ref.) when transplanted with an adult donor kidney.

When compared to adult recipients, pediatric recipients of adolescent donor kidneys experience a significantly higher rate of graft failure. For instance, the relative risk of graft failure for pediatric recipients was 1.48 (p=0.0043) and 1.00 (p=Ref.) for adult recipients aged 35-49 years. The analysis suggests that the disparity in graft survival rates between pediatric and adult recipients does not support preferential allocation of adolescent donor kidneys to pediatric recipients.

While acknowledging the poorer graft survival rate of pediatric recipients who receive adolescent donor kidneys relative to adult recipients, some Members disagreed with the conclusion suggested by the analysis. Pediatric recipients, subsequent to suffering loss of their graft, may become sensitized and will have relatively more opportunity for additional kidney transplants. This is especially the case for pediatrics who receive less well-matched kidneys. An alternative perspective is to determine the best donor available for pediatric recipients to ensure long-term graft survival. In general, the best donor for this result is an adolescent donor.

Additionally, data from a previous analysis separating younger pediatric patients from adolescent patients show a trend toward improved graft survival for younger pediatric patients when transplanted with adolescent donor kidneys, although differences do not reach significance (**Exhibit SS**). Members agreed that the allocation policies should preserve a balance between pediatric priority for adolescent donor kidneys and opportunity to receive a well-matched kidney. One suggested option is to provide priority for adolescent donor kidneys to pediatric candidates who surpass their time to transplant goals. Current policy awards priority to such pediatric candidates for all donor kidneys (adult and pediatric) after zero antigen mismatched candidates, highly sensitized candidates and paybacks. Some Members noted that many pediatric recipients are transplanted with less well-matched kidneys under the current policy, which could be attributed to their elevated priority in the allocation system. An alternative suggestion is to reduce the allocation points awarded for a 2+ DR mismatch for pediatric candidates who exceed their time to transplant goals. The intent is to protect children from less well-matched kidney offers while leaving them with high priority on the list.

After further discussion, the Joint Subcommittee agreed to defer the issue of pediatric priority for adolescent donor kidneys until KPSAM is available and modeling of the impact is analyzed.

Cross-reactive HLA Antigen Groups (CREG)

Following Board approval of the recommendation from the OPTN/UNOS Histocompatibility Committee to conclude the initial Cross-reactive HLA Antigen Groups (CREG) alternative system study, the Joint Subcommittee discussed the next steps for evaluating use of CREGs in kidney allocation. Suggested options included extending the prior CREG study for an additional time period, creating a different generic alternative allocation system based on CREG, and not incorporating CREG into the allocation system. After further discussion, the Joint Subcommittee agreed to re-formulate a Committee-sponsored CREG alternative allocation system with an imposed time limitation. The intent is to further study the viability of CREG matching for deceased donor kidneys. Steve Takemoto, Ph.D., will chair a subgroup of the Joint Subcommittee to develop a first draft of the Committee-sponsored alternative allocation system. The Joint Subcommittee will review the draft during its next meeting.

The Joint Subcommittee subgroup on CREG convened on May 13, 2004, to continue the discussion of the next steps for CREG analysis. Participants of the subgroup agreed that the recent deceased donor kidney allocation policy change to eliminate points for B-locus matching incorporates one of the original goals of the CREG allocation variance, and that is to increase access to transplantation for minority candidates and those with uncommon HLA antigens. There was general consensus that it is premature to propose a new CREG alternative system because outcomes associated with the policy change are not yet fully known. It was suggested that a year of follow-up might be necessary for a more comprehensive evaluation of the data, including outcomes. It was proposed that the subcommittee design studies to develop preliminary data for a future alternative system proposal. Below is a framework for the initial analyses.

In a recent multivariate analysis completed by the SRTR, no benefit for avoiding mismatches of the 9 CREGs initially used for the OPTN/UNOS alternative system (0-CREG 0-DR mismatch) could be demonstrated over avoiding DR mismatches alone. The subcommittee generally agreed that before a new CREG alternative system could be proposed, there must be solid evidence that CREG matching improves graft outcome. Steve Takemoto presented data suggesting more complex models that included 18 or 36 CREGs may result in improved graft outcome. There is also emerging evidence that CREGs based on amino acid triplets, as proposed by Dr. Duquesnoy, may have increased clinical relevance. One task of this subgroup will be to elucidate the CREGs to be used in the future model.

Another recent analysis from the SRTR suggests patients with “advantaged” antigens; that is, antigens that were more common among historic donors compared to waiting list patients, had a higher probability of receiving a 0 A, B, DR mismatched transplant compared to those with “disadvantaged” antigens, i.e., those that were less common among donors than candidates.

In the previous CREG allocation study, the majority of 0 CREG, 0 DR mismatched transplants occurred in larger OPOs. One focus of the future alternative system could be to define minimal sharing units for adopting the system. The percentage of patients receiving a 0 DR mismatched transplant is expected to increase with

larger sharing areas (*e.g.*, with at least 2000 renal transplant candidates). The subgroup also expressed an interest in examining whether this expansion in the sharing area will increase transplantation of sensitized patients, and/or the availability of 0 DR mismatched transplants for pediatric candidates.

After further discussion, the CREG subgroup formulated a number of proposals to be modeled with KPSAM as follows:

1. Should patients with “advantaged” A and B locus antigens have decreased access to DR matching points to increase their dwell time and therefore the probability of receiving a 0 A, B, DR mismatched transplant (*i.e.*, when there are multiple 0 DR mismatched candidates identified for a donor)?
2. Should patients with “disadvantaged” DR antigens be given increased priority for 0 DR mismatched transplants (*i.e.*, to equalize median time to transplantation)?
3. What measure of phenotype diversity should be used to assess whether a candidate is phenotypically disadvantaged?
4. Should priority be given for 0 A,B CREG mismatched candidates over non-0 A,B CREG mismatched candidates within the 0-DR mismatched group?
5. Should the alternative system be implemented only in broader geographic areas?

Criteria for Prospective Crossmatching in Kidney and Pancreas Candidates

In November 2003, the Histocompatibility Committee submitted to the Board proposed modifications to the Bylaws addressing prospective crossmatching for transplantation of kidney and pancreas organs, but subsequently withdrew the proposal due to concerns expressed by the Kidney and Pancreas Transplantation Committee. The two Committees agreed to work together to develop appropriate language for a laboratory standard regarding crossmatching that would reside in the Bylaws, which govern laboratory membership criteria, as well as, a clinical practice policy on antibody screening and crossmatching that would reside in the OPTN/UNOS policies. The Joint Subcommittee considered the issue of prospective crossmatch criteria for kidney and pancreas transplant candidates during its January 13, 2004, meeting.

The current standard, expressed in H3.100, does not mandate crossmatches for all kidney and pancreas candidates, but requires laboratories to perform a prospective crossmatch if requested by the transplant center and dictated by clinical circumstances. The proposed modifications submitted to the Board in November 2003 by the Histocompatibility Committee would alter the current language to specifically require laboratories be capable of performing a prospective crossmatch and further require that laboratories perform such a crossmatch when requested by a physician or other authorized individuals. In addition, the proposal would require histocompatibility laboratories to develop a joint written policy with their transplant programs on candidate crossmatching strategies.

Some Members of the Joint Subcommittee felt the definition of an unsensitized candidate should be specified in the policy or elsewhere as guidance since transplant programs have differing notions and strategies for crossmatching such candidates. A more standard understanding of which patients truly are unsensitized and can be transplanted safely without a prospective crossmatch could help programs that are moving away from routinely crossmatching patients. Transplant programs could then determine whether to adopt the guidance on unsensitized candidates through their joint written policies with laboratories, or continue to prospectively crossmatch all transplant candidates. Possible explanations for differing crossmatching strategies include varying expertise and background among staff at transplant programs, lack of funding at programs for newer, more expensive techniques, and philosophical differences in crossmatching focus between acute accelerated rejection and long-term concerns.

The Joint Subcommittee agreed that requiring a joint written policy on crossmatching strategies between histocompatibility laboratories and transplant programs will be an important feature of any proposed policy modifications. The crossmatching strategies specified in the joint written policy should be based on data and should consider candidates with incomplete or unknown sensitization histories.

Three options for the OPTN/UNOS policy provision were discussed (**Exhibit TT**). First, the Joint Subcommittee could recommend the proposed language from the Histocompatibility Committee requiring crossmatching, either prospectively, unless the laboratory and transplant program provided otherwise in their joint written policy, or retrospectively. Members of the Joint Subcommittee expressed concern that this option might be too restrictive and lacks a provision for clarifying the meaning of unsensitized candidate.

The second option offered less restrictive language by requiring prospective crossmatching only for sensitized candidates, which would be defined by the joint written policy developed between the laboratory and transplant program. The joint written policy, however, would need to define crossmatching strategies for both sensitized and unsensitized candidates.

Finally, the third option would specifically detail how crossmatching should be performed, including the appropriate methods and patient sensitization histories needed. A subcommittee of the Histocompatibility Committee is currently developing a paper on such guidelines, which could be used in conjunction with the policy proposal.

Members agreed the second option represents the best starting point for developing policy. The alternative requires crossmatching for sensitized candidates and requires laboratories and transplant programs to discuss and develop criteria defining a sensitized individual. Option two concerned some Members as more restrictive than necessary. However, the proposed policy would only be as restrictive as the center and laboratory agreed to in their joint written policy. Though crossmatching is required for sensitized candidates under the proposal, transplant centers and laboratories would have the ability to define criteria for a sensitized candidate through their joint written policy. Members also suggested that unsensitized could be defined as no evidence of antibodies against HLA antigens and no history of sensitization. The Joint Subcommittee agreed that such provisions could be appropriately incorporated into the kidney allocation policy and applied to transplant centers and laboratories. Guidelines would also be drafted to provide parameters for centers and laboratories to develop their individual written policies and would be included as an appendix to the allocation policies referenced by the policy itself. The Joint Subcommittee agreed on the Histocompatibility Committee proposed modifications to H3.100, which would be used as histocompatibility laboratory OPTN/UNOS membership criteria.

After further discussion, the Joint Subcommittee agreed that a subgroup will draft and distribute the guidelines to the remaining Members of the Joint Subcommittee for review. The intent is to formulate a proposal that the Histocompatibility Committee would submit for public comment.

During its January 20-21, 2004, meeting, the Committee reviewed the Joint Subcommittee recommendations. Some Members stated that, in general, crossmatching should always be performed for kidney transplantation with few exceptions (*e.g.*, situations where a zero antigen-mismatched kidney is delayed several hours, therefore increasing cold ischemia time beyond a reasonable level, prior to arrival at the transplant center). Option one enforces this perspective as it requires crossmatching, either prospectively or retrospectively, for all kidneys. The less restrictive option two could result in fewer crossmatches performed on kidney transplant candidates and jeopardize patient care. However, other Members stated that unsensitized candidates do not require crossmatching if they are properly and thoroughly screened. Crossmatching is expensive and test results often confirm a negative crossmatch.

Members of the Committee suggested an expanded approach in which a white paper on crossmatching containing a model joint written policy could be adopted or modified by transplant centers and histocompatibility laboratories in the development of their own joint written policies. The intent is to ease the burden of policy development on the centers and laboratories.

After further discussion, the Committee agreed to recommend the development of a white paper with a model policy by a vote of 22 For; 0 Against; 0 Abstentions. The Committee also agreed to endorse the second policy option recommended by the Joint Subcommittee with the recognition that sensitized candidates would be defined by the white paper by a vote of 24 For; 0 Against; 0 Abstentions. Finally, the Committee agreed to endorse Bylaw provision H3.100, as recommended by the Joint Subcommittee, by a vote of 24 For; 0 Against; 0

Abstentions. See Item 14 (above) for the final proposal with respect to this issue and the Committee's endorsement of this final proposal.

Predicting Candidates Most Likely to Receive Zero Antigen Mismatched Kidney Offers

Lee-Ann Baxter-Lowe from UCSF presented an abstract at the 2003 ATC meeting describing a program developed to predict which patients would most likely receive a 0 mismatch kidney offer. Susan Saidman, Ph.D., discussed the subsequent presentation of the abstract to the OPTN/UNOS Histocompatibility Committee. The Joint Subcommittee noted that this predictive process may be useful as a tool for patient management but not as a factor in allocation or policy development. The model has been tested against a relatively small patient population. Ms. Baxter-Lowe would like now to use UNOS data to further test results of the UCSF model. The Joint Subcommittee noted that approximately 75% of 0 mismatch offers occur within 12-18 months of listing. In light of this percentage, it is even more difficult to understand why so few pediatric kidney candidates are receiving 0 mismatch transplants and if there are improvements in allocation priority that can be made at the local level to increase offers of well matched kidneys to pediatric candidates. It was noted by the Joint Subcommittee that regional and local differences in donor populations would also play a role in predicting which candidates would be most likely to receive 0 antigen mismatch kidney offers. The Joint Subcommittee agreed to follow up with Lee Ann Baxter-Lowe as to her availability to speak at the next meeting.

30. **Proposed Modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch).** Public comments on proposed amended OPTN/UNOS Policy 3.5.11.2 and the Committee's responses are set forth in **Exhibit UU**. The proposed modifications, originally developed by the OPTN/UNOS Joint Kidney and Pancreas, Pediatric Transplantation, Minority Affairs and Histocompatibility Subcommittee, would increase from 2 to 6 the total allocation points awarded to pediatric candidates who have a zero DR mismatch with a standard criteria deceased kidney donor. The additional points would not apply in determining priorities among zero antigen mismatched patients, prior living organ donors, or patients listed with OPOs receiving kidney payback offers. The modifications also would not apply to expanded criteria donor (ECD) kidney allocation. The intent is to increase the number of transplants of well-matched kidneys into pediatric candidates while maintaining relatively short pediatric candidate waiting time to transplant, and thus, minimize long-term sensitization in pediatric candidates who most likely will require subsequent transplants during their lifetimes.

Prior to the May 2004 Committee meeting, the OPTN/UNOS Joint Kidney and Pancreas, Pediatric Transplantation, Minority Affairs and Histocompatibility Subcommittee met to discuss the proposal and public comments received. The Joint Subcommittee reviewed the final data analysis from the SRTR, 5/7/04, evaluating the effect of DR matching on pediatric patient and graft survival and the effect in the pediatric population of prior mismatch level on subsequent sensitization. The study cohort for this analysis is comprised of pediatric kidney candidates (<18 years) who received their first deceased donor kidney transplant with at least one HLA mismatch during the study period of 3/6/1995 and 6/30/2001, with follow-up for the study extended until 12/31/01. Albin Gritsch, MD and Bill Harmon, MD, SRTR noted that it is difficult to reach a conclusive interpretation of the data due to the small numbers comprising the cohort. The data, as they are, do not show the graft survival advantage in pediatric patients when comparing 1 mismatch and 2 mismatch to 0 mismatch at the A, B, and DR loci that is seen in the entire group (adult and pediatric candidates combined). Ruth McDonald, MD further noted that, though the numbers may be further reduced, it may be of interest to separate out younger pediatric candidates (0-11 years) from the adolescent group (12-17 years) given the added complications of compliance, etc noted with adolescent recipients. Dr. Harmon noted that, for all kidney recipients (adult and pediatric) combined, there is an approximate 1.25 Relative Risk benefit with DR matching. Dr. Harmon further noted that the question this data analysis intended to address is whether there is a difference in advantage or disadvantage with DR matching, a biological histocompatibility difference, in the pediatric population. The Joint Subcommittee agreed that the small numbers in this study cohort do not allow for conclusive answers regarding this issue.

The Joint Subcommittee agreed that a continuing issue in pediatric kidney transplantation is balancing waiting for a well-matched kidney with the benefit of meeting time to transplant goals in order to prevent growth and development delays. Dr. Gritsch reviewed the SRTR analysis evaluating the effect on the pediatric recipient/candidate population of prior (1st transplant) mismatch level on subsequent sensitization levels. Susan Saidman, Ph.D., noted that, the PRA data reviewed would not include class II antibody information since

UNOS has started only recently to collect this information on the data forms. The Joint Subcommittee agreed that, with only the historical PRA data available for this analysis, DR matching at first transplant would be expected to show no impact upon subsequent sensitization. Results from this analysis are, therefore, difficult to interpret. Dr. Gritsch noted that in Table 1.2 of the final SRTR data analysis, the +10.6 increase in change in PRA for the category Time Since Failure of 1st Transplant (per year) suggests that the longer pediatric candidates wait from the time of failure of first transplant to the time of listing for 2nd transplant the more the rate of sensitization will increase. Karen Nelson, PhD suggested that during the time interval between transplants, candidates stop immunosuppression therapy/medications. Dr. Nelson further suggested that patients may be responding to tissue remnants (post-nephrectomy) from the first transplant during this time off of immunosuppressants. It was noted by the Joint Subcommittee that it is difficult to determine from this data whether pediatric candidates become increasingly sensitized the longer they wait for transplant, or if they wait longer for transplant because they are sensitized.

Dr. Gritsch reviewed the data on race/ethnicity, blood type, and sensitization in Tables 1.2 and 1.3 of the SRTR final analysis, 5/7/04. The Joint Subcommittee noted that the data suggest increased sensitization among black pediatric patients and pediatric patients in blood group B. Dr. Harmon noted that the increased risk may be attributed to longer waiting times on the transplant list for patients with blood type B; however, this analysis did not include data on time waiting on the list. Nathan Goodrich, SRTR noted that the small number of patients in the study cohort did not allow for clear interpretation of the analysis results. The Subcommittee noted that race/ethnicity was among the factors adjusted for in the SRTR data analysis. It was further noted by the SRTR that within the adult kidney transplant candidate population there was no apparent difference in change in PRA between blood types. Given that the number of pediatric patients in the cohort with blood type B is small (n=40), Hui-Hsing Wong, MD suggested reviewing the race/ethnicity of the patients in this group. Dr. Wong noted that if all the patients with blood type B in this study were of one race or ethnicity group, it would be difficult to adjust for this factor in the analysis. Dr. Harmon noted that children and adolescents are more than likely not different from adults in histocompatibility of blood type. Dr. Harmon suggested that the results from the analysis may be due to the lack of statistical significance with the small numbers of pediatric patients in the study cohort instead of a statistical trend specific to race or blood type.

The Joint Subcommittee discussed whether or not the data reviewed offered enough statistical evidence to move forward with the Joint Subcommittee developed public comment proposal to assign four additional points to pediatric kidney candidates based on 0 DR matching. Dr. Harmon noted that the intent of the proposal was to further balance the issue of matching and wait time for pediatric kidney candidates. Currently, pediatric candidates receive less well-matched kidneys. It is suggested that this is attributable at least in large part to assigned allocation priority at time of listing and then once time-to-transplant goals are surpassed. The proposal now out for public comment would allow pediatric kidney candidates increased opportunity to receive better-matched kidney offers and maintain time goal priority. Dr. Harmon noted that, given the small numbers of pediatric kidney candidates, there is currently no significant data to support the proposal based on biological advantage, however, there is also no data to suggest that pediatric candidates differ from adults in receiving benefit from DR matching. The Joint Subcommittee further noted that there may be limited studies on the benefit of DR matching in pediatric kidney candidates given the substantial number of parent living kidney donors. It was noted by the Joint Subcommittee that, in the case of parent living kidney donors, the laboratory protocol for transplant is different than for a deceased kidney donor, thus, there may not be the same data available for living kidney donor transplants. Moreover, previous data has suggested that recipients of living donor kidneys do better than recipients of deceased donor kidneys regardless of matching; therefore, this data may not be applicable to the analysis of the impact of DR matching in pediatric deceased donor kidney recipients.

Dr. Leichtman discussed whether pediatric kidney candidates would be better served by receiving additional priority for being < 18years and thus improving their access to a greater fraction of all kidney offers or would young children and adolescent candidates be better served by receiving assigned priority points for age and assigned priority points for matching. Dr. Leichtman suggested that as long as currently assigned pediatric priority is maintained, it would only be helpful for pediatric kidney candidates to be assigned additional priority for matching. The Joint Subcommittee agreed, given the discussion above and the 90% approval rate of public comment responses, to support the proposal to assign additional priority points to pediatric candidates for 0 DR matching and present the proposal to the Board of Directors in June 2004. The support of this proposal was

unanimous within the Joint Subcommittee with the exception of one individual who was opposed to this proposal moving forward and noted that there were not sufficient data to support the proposal in its presentation to the Board of Directors. Dr. Frank Delmonico further noted that supporting a proposal without sufficient evidence may set a difficult precedent for future policy development. Moreover, using HLA DR mismatch as a factor in allocation for children, could suggest to physicians that they should wait for DR matched organ offers before accepting organs for their pediatric patients. In the interim, they may miss opportunities for other younger, for example, donor kidney offers that actually are preferable to the DR matched organ offer. Dr. Gritsch noted that currently, given the small numbers of pediatric candidates, data on the effect of DR matching in pediatric kidney recipient survival and sensitization is not statistically significant, however, given the evidence and logic of DR matching benefit in adults the proposal to assign priority for pediatric matching should go forward.

There also was discussion regarding the benefit of assigning preference for children for HLA DR matching in light of the data showing no statistical significance upon graft survival, versus assigning a more absolute priority that would at least help address concerns regarding children waiting beyond their time goals to transplant. Again, there is trade-off between the two goals of improved matching, which may have clinical significance despite lack of statistical significance, and shorter waiting times for children.

Dr. Takemoto noted that Table 2 in the OPTN data analysis, *Pediatric Patients Who Have Surpassed Their Time to Transplant Goals*, seems to illustrate the issue of the small percentage of pediatric kidney candidates receiving 0 DR mismatch deceased donor kidneys. Only 7.4% (n=22) of pediatric patients who were transplanted between 1/1/02 and 12/31/03 (Total n=296), and had surpassed their time goals at time of transplant, received a 0 DR mismatch donor kidney.

The Joint Subcommittee also discussed the possibility of allocating adolescent donor kidneys preferentially to pediatric kidney candidates. Table 2.2 in the SRTR Final Data Analysis, 5/7/04, suggests that pediatric deceased donor kidney recipients have the best survival rate when transplanted with an adolescent donor kidney although the improvement is not statistically significant. Dr. McDonald suggested that pediatric candidates be prioritized for 0 DR matching and adolescent donors. Dr. Wong requested, for the next Joint Subcommittee meeting, the review of data on the number of times pediatric kidney candidates appeared on the match run but did not receive a 0 mismatch offer because an adult kidney candidate had greater priority for and accepted the offer. Dr. Delmonico also requested that an analysis of the number of times pediatric candidates bypassed an adult 0 mismatch candidate on a match run list be added to the above requested OPTN descriptive data analysis; the analysis will look at the trends in this data from the past five years.

Dr. McDonald suggested moving forward with the current proposal assigning four additional points to pediatric kidney candidates for 0 DR matching and, in addition, assign priority to pediatric kidney candidates for adolescent and young adult donor kidney offers. Dr. McDonald recommended that the proposal for additional assignment of priority to pediatric candidates for pediatric donor kidney be put forth separately in the August 2004 public comment cycle and that the current proposal regarding DR matching move forward to be presented to the Board of Directors at the June 2004 meeting. The SRTR Final Analysis of 5/7/04 included a graph following Table 3.3 that further illustrates that 11-17 year old deceased donor kidneys offer pediatric candidates the best graft survival rate. Dr. Wong suggested breaking out the age group of 18-34 years to see if younger adult donor kidneys offer the same survival benefit to pediatric candidates as adolescent donor kidneys. Dr. Leichtman requested the OPTN to prepare and distribute to the Joint Subcommittee a histogram of deciles of donors by age for further discussion of definition of 'ideal' donor for pediatric kidney candidates. Dr. Harmon noted that the risk of donors over 35 years compared with under 35 years for pediatric recipients is approximately 1.24 RR benefit for the pediatric candidate to receive an 18-34 year old deceased donor kidney as compared with a 35-49 year old deceased donor kidney. Dr. Harmon noted that this is the same benefit conferred, based on adult and pediatric (combined) recipient data, from a 0 DR mismatch compared with a 2 DR mismatch. Dr. McDonald and Dr. Leichtman recommended increasing priority for 0 DR mismatch offers to pediatric kidney candidates beginning at the local level.

Maureen McBride, PhD, OPTN reviewed the data analysis, *Pediatric Patients Who Have Surpassed Their Time to Transplant Goal*, with the Joint Subcommittee. Table 1 of the analysis shows the characteristics of pediatric

candidates who have surpassed their time to transplant goals and were still waiting for a kidney transplant on April 30, 2004. Dr. McBride outlined several of the results of the analysis including:

- With the exceptions of Regions 6 and 8, there are candidates in each age group who have surpassed their goals currently waiting for transplant. The majority of the patients are in Region 5 (CA, NV, AZ, UT), the region with the largest waiting list.
- The majority of the patients are blood type O. Specifically, 55% of the 0-5 year old candidates, 59% of the candidates aged 6-10, and 55% of the 11-17 year old candidates are blood type O.
- Over two-thirds of the youngest pediatric candidates are not sensitized (Peak and Current PRA 0-19%). However, among the adolescent candidates, 28% have a Peak PRA \geq 80%, and 19% have a current PRA \geq 80%.
- Twenty percent of the candidates aged 0-5 have had a previous transplant, compared with 32% of the candidates aged 6-10, and 46% of the 11-17 year old candidates who have surpassed their goals.
- Fewer than 40% of the candidates who surpassed their goals are white. Eighteen percent of the 0-5 year old candidates are Black and 25% are Hispanic. Among the 6-10 year old candidates, 26% are Black and 30% are Hispanic. Finally, among the adolescents, 35% are Black and 20% are Hispanic.
- Overall, 30 patients currently waiting have not received any offers. Most have received 1-10 offers. Over 20% of the adolescent candidates have received more than 40 offers.

The Joint Subcommittee noted that the Pediatric Committee has previously reviewed reasons/turndown codes for deceased donor kidney offers to pediatric candidates. Approximately one-third of the offers were turned down for donor quality, other turndown reasons included issues of size/weight. The Joint Subcommittee requested a histogram of turndown reasons, a descriptive analysis of number of offers and reasons for declining offers by OPO/Transplant Center/Region, and a comparative analysis of race/ethnicity of pediatric kidney candidates who have surpassed their time goals and race/ethnicity of the total waitlist. Dr. Leichtman recommended reconvening the Joint Subcommittee after the May Committee meetings but prior to the June 2004 Board of Directors meeting in order to review the data analyses requested.

At its May 20, 2004, meeting, the full Kidney/Pancreas Committee discussed the proposal in light of the public comments. Of the 44 individuals who commented on the proposal, 89% supported and 11% opposed the proposal. All 11 Regions supported the proposal, including 4 unanimously.

Albin Gritsch, M.D., summarized the efforts and findings of the Joint Subcommittee for the Committee. Since the Joint Subcommittee met, some Members had expressed concerns with the proposal going forward to the Board at the June 2004 meeting. First, the data could be viewed as tenuous. Second, the likelihood of this proposal being followed by a subsequent proposal with respect to pediatric priority at the fall Board meeting could diminish the real concern the Committee has with appropriately allocating kidneys to pediatric candidates. Perhaps the more beneficial option is to devise a more comprehensive approach to resolving the pediatric transplant access issues after assessing available data, and presenting the approach at one Board meeting.

Before a comprehensive approach is developed, some Members stated that the OPTN/UNOS Pediatric Transplantation Committee should determine and specify the goal(s) they want to achieve with respect to pediatric transplantation. One suggested goal was allocation of younger, more ideal donor kidneys (aged 18-34) to pediatric candidates.

One possible approach for consideration is to limit pediatric candidate access to local donors aged less than 35 years before reaching their time to transplant goals. The pediatric candidates would still retain six points for a zero DR mismatch to help ensure better-matched kidneys are offered to pediatric candidates. If the pediatric candidate surpasses their time to transplant goal, the donor pool could be expanded from local to Regional to provide additional organ offer opportunities.

After further discussion, the Committee agreed to withhold this proposal from the Board of Directors with the intent that a more comprehensive approach to pediatric allocation priority will be developed in the near future.

The Committee vote was unanimous. The Committee also agreed for the Joint Subcommittee to continue this discussion, and develop the goals for pediatric allocation and strategy for achieving those goals.

31. Report of the OPTN/UNOS Joint Kidney and Pancreas/OPO/Transplant Administrator Subcommittee. The first meeting of this new Joint Subcommittee was held on January 6, 2004. The Joint Subcommittee reviewed the November 2003 Board-approved resolutions with respect to islet transplantation and islet program criteria, as well as, explanations for low pancreas recovery rates.

Members of the Joint Subcommittee stressed that both the transplant center and the islet processing center must have an FDA Investigational New Drug (IND) in effect in order to isolate or transplant pancreatic islets. The OPTN/UNOS policy language approved by the Board for islet program criteria specifically acknowledges the IND requirements.

Some Members noted that part of the impetus behind the Board-approved modifications to pancreas and islet allocation policies was data indicating the overall relatively low rate of pancreas recovery, as well as, the low rate of utilization for whole pancreas transplant of pancreata from donors over 50 years and with BMIs greater than 30. A relevant issue for OPOs is how pancreata procured for islet transplantation are accounted for and whether they can justify reimbursement.

Strategies for increasing procurement of pancreata for both whole organ and islet transplantation were considered by the Joint Subcommittee. Some Members inquired as to whether the procurement goal should be a pancreas from every donor who consents, or a pancreas from every donor in which the liver is procured. It was suggested that one of the reasons more livers are procured relative to pancreata is due to demand from the transplant centers. In addition, some centers and OPOs do not receive information on a donor in adequate time to minimize cold ischemia, especially in relation to islet procurement. Finally, with respect to islet procurement, the common practice of procuring the liver before the pancreas presents some quality issues. Some Members commented that removal of the pancreas first is important and easier because it is more anterior than the liver.

Some Members of the Joint Subcommittee favored a standardized procurement procedure for every organ donor. Cooperation from all transplant centers, including those centers that lack a pancreas transplant program, is crucial to successful organ recovery. Some Members suggested that procurement teams should be required to procure the pancreas with the liver from all donors who have consented. However, other Members were concerned with this suggestion for several reasons. First, such a policy would require the OPTN to monitor organ procurement procedures in an unprecedented manner. Second, it was suggested that aligning people's interests through incentives, rather than unfunded obligations, is a better solution to the issue. Finally, requiring pancreas procurement from all donors could subvert clinical judgment as even pancreata not suitable for transplantation would need to be procured merely to maintain compliance with policy.

Members commented that in order to increase organ procurement rates, particularly pancreas rates, organ procurement programs need to be willing to travel and procure their own organs. Members stated that the Association of Organ Procurement Organizations (AOPO) reviewed this issue approximately one year ago. Some Members stated that some transplant programs are more willing to procure organs during the day compared to the night. This reality would perhaps be altered if surgeons and OPOs knew they would receive reimbursement for their efforts. However, some argued that the additional costs of transportation and procurement, which could amount to thousands of dollars, and OPO delays will prevent this suggestion from succeeding. Then again, as more islet and pancreas transplant programs develop, the likelihood of utilizing the organ locally will increase. Therefore, the cost of flying procurement teams to locales to procure pancreata is probably a short-term issue.

One suggested approach to resolve the pancreas reimbursement dilemma was the development of a dialogue with the Centers for Medicare and Medicaid Services (CMS) with the intent of establishing reimbursement protocols for all pancreata whether ultimately utilized for whole organ or islet transplantation. Reimbursement is currently a substantial barrier and disincentive to increasing pancreata procurement and islet transplantation to determine whether it is a viable medical treatment. Since Medicare does not currently reimburse the costs of pancreatic islet transplants, costs related to this procedure affect both OPOs and transplant centers. Appropriate

differentiation by OPOs on a Medicare cost report between a pancreas recovered for whole organ transplant and a pancreas recovered for islet cells would need to be discussed with CMS. In order for such differentiation to work, the reimbursement system would need to be outcome-based rather than intent-based. Some Members stated that, in general, the reimbursement system is based on intent at procurement in order to increase the count of extra-renal organs.

In relation to reimbursement, some Members stated as long as the technology for isolating the islet cells is in its infancy, consideration of islet cells as a tissue, rather than an organ, would probably be more beneficial and would reduce the cost allocation. If the pancreas used for islets is considered an organ for reimbursement purposes, it would be added to the total number of organs recovered and divided into the costs associated with the procurement.

After further discussion, the Joint Subcommittee unanimously agreed to draft a letter to CMS detailing the issues and recommendations with respect to islet transplantation. The letter would emphasize that whole pancreas transplantation is no longer experimental and ask that CMS acknowledge the value of whole organ pancreas transplantation by paying the costs associated with procurement and transplant. In addition, the letter would request CMS provide coverage for islet procurement and transplantation. After Board review and approval, the letter would be delivered to HRSA, which could then relay the letter to CMS.

32. **Report of the OPTN/UNOS Joint OPO Subcommittee.** The Committee considered several issues regarding disease transmission and HTLV- and HIV-positive donors, initially discussed by an OPTN/UNOS Joint OPO Subcommittee on January 8, 2004. The Joint OPO Subcommittee includes representatives from the OPTN/UNOS OPO, Kidney and Pancreas Transplantation, Pediatric Transplantation, and Liver and Intestine Transplantation Committees. The purpose of forming the Joint Subcommittee was to elicit multi-committee input on policies 4.0-4.5 that exclude recovery of organs from HIV- and HTLV-positive donors and individuals who have received human pituitary derived growth hormone (HPDG), and input on proposed policies 4.6-4.8 that outline a system for reporting cases where transmissible diseases or medical conditions, including malignancies, are detected by an OPO in a donor after organs are procured or detected by transplant centers either before or after organs are transplanted. The goal of the Joint Subcommittee is to further refine policy language with the intent that the organ specific and pediatric committees, as well as, an infectious disease specialist review and address these issues. The OPO Committee would then consider the Committee recommendations while developing proposed language.

The Joint Subcommittee agreed on a number of donor transmissible diseases and medical conditions (**Exhibit VV**) that should be reported by OPOs to UNOS and transplant recipient centers. The proposed policy should also include language addressing the necessity to report autopsy findings and culture results that pose potential risks for recipients. Representatives of the OPO Committee verified that receipt of pathology reports from donor autopsies is fairly standard and pertinent results should be disseminated to the recipient centers. The Joint Subcommittee also discussed the reporting mechanism outlined in the OPO Committee Report to the Board of Directors, November 20-21, 2003, and agreed that the UNetSM system should serve as the tool to collect and disseminate this information. Members of the Joint Subcommittee suggested that the information be reported as soon as possible by telephone or electronic mail to the appropriate transplant centers and entered into UNetSM within seven days of discovery.

The Joint Subcommittee agreed that the same list of transmissible diseases and medical conditions should be reported by the transplant recipient center to the OPO and UNOS if discovered in a recipient and thought to be of donor origin. Such diseases and conditions, including cancers, diagnosed in a recipient up to six months following transplantation and thought to be of donor origin, should be reported. Noting that some cancers of donor origin may not be detected in the recipient for a number of years post-transplantation, the Joint Subcommittee felt that the UNOS database for reporting all recipient cancers could serve as an avenue for reporting. It was confirmed that the reporting form provides a field to indicate if the cancer is thought to be of donor origin.

In policy section 4.7, the Joint Subcommittee agreed on the following modification to the proposed language:

- i. communication of the test results/diagnosis as soon as practicable to any transplant program and tissue bank ~~and the director of any other transplant program~~ that received tissue or an organ from the donor who is the subject of the investigation.

The Joint Subcommittee considered the policies related to HIV, HTLV and HPDG. The original OPTN/UNOS policies exclude the use of HTLV organs. It is recognized within the transplant community that a certain percentage of donor HTLV-positive test results are false positive as confirmed by Western Blot. Therefore, the data on recipients transplanted with HTLV-positive organs is likely flawed. The Joint Subcommittee concluded that OPTN/UNOS policy should not absolutely exclude HTLV-positive donor organs and supported policy modifications to remove the exclusionary language.

OPTN/UNOS policy also provides that use of organs from HIV-positive donors is not acceptable, though data suggests that some transplant centers accept HIV-positive organs for transplantation. Some Members stated that some transplant centers that list HIV-positive candidates would consider accepting organs under certain circumstances from HIV-positive donors. The Joint Subcommittee recognizes that advances have been made that allow for reconsideration of HIV-positive candidates and request the organ specific and pediatric committees provide direction on modifications to this policy. It was noted that the OPTN Final Rule currently requires the OPTN to adopt and use standards for preventing the acquisition of organs from individuals known to be infected with HIV and that discussions are in progress on this issue.

Finally, Members of the Joint Subcommittee questioned whether HPGH was still available and believed to be replaced by a synthetic version. Some Members were concerned that a patient may have received HPDG in the past but not converted, yet the likelihood of contracting Creutzfeldt-Jacob disease was probably minimal. Cases identified within the Joint Subcommittee related to a few tissue donors from 20 or more years earlier. The Donor Medical/Social History Form includes a question on HPDG. The Joint Subcommittee was not wholly supportive of eliminating this policy due to lack of information, but more supportive of language stating that acceptance of an organ from a patient that received HPGH should be at the discretion of the potential recipient and transplant surgeon. In the interim, the AATB will be contacted for further information to assist in upcoming deliberations.

Ken Andreoni, M.D., the Committee representative on the Joint Subcommittee, presented the Joint Subcommittee recommendations to the Committee during its January 20-21, 2004, meeting.

Some Members of the Committee expressed concern that the proposed policy language elimination with respect to HTLV and HIV organs, coupled with the Final Rule proclamation that OPOs should recover all useful organs, would effectively require OPOs to pursue all donors, including HIV and HTLV-positive donors. OPOs might be penalized under the proposed language for not pursuing such donors. Some Members also questioned the legality of recovering organs from HIV-positive donors given the Final Rule language addressing the prevention of acquiring such organs. In regards to transplantation of HTLV organs, some Members stated that this issue should be addressed with informed consent, particularly in locations where HTLV prevalence is likely to be elevated.

Members of the Committee noted that medical judgment is required in situations where it is recognized that a test yields a high rate of false positive results. The Committee was informed that the American Society of Transplantation (AST) and the Association of Organ Procurement Organizations (AOPO) are working with the Centers for Disease Control (CDC) to develop standardized nucleic tests that would distinguish the false positives from the actual test results.

After further discussion, a proposal was made to support the Joint Subcommittee policy recommendation on HTLV but not support the recommendation on HIV. The Committee agreed that additional work regarding the HIV provisions, including ensuring consistency in approach within the policy, is needed. However, recognizing that the Committee will have an additional opportunity to comment on the policy recommendations when they are submitted for public comment, the Committee agreed to withdraw the proposal.

Members of the Committee recommended the policy language for Policy 4.7 (Post Transplant Reporting of Potential Transmission of Disease or Medical Conditions, including Malignancies) be strengthened to require rather than recommend the reporting of these conditions. The policy should also stress a sense of urgency. The reporting mechanism should include UNetSM but provide for instantaneous updates on disease and medical conditions information. The system should generate a report notifying the OPOs and transplant centers immediately, rather than allowing days to input the information. The system should also be able to track occurrences and outcomes of these events. Finally, OPOs and transplant centers should be able to work together to convey the medical disease and condition information immediately to the appropriate parties.

33. Report of the OPTN/UNOS Joint Kidney and Pancreas and Organ Availability Subcommittee. The Joint Subcommittee reviewed a number of issues during its January 16, 2004, meeting.

Kidney Payback Policy

The Joint Subcommittee discussed and developed a proposal related to kidney payback thresholds, which was later approved by the Committee and distributed for public comment (See item 7 above).

Pancreas Procurement in the Presence of Hepatic Anomalies

During its January 16, 2004, meeting, the OPTN/UNOS Joint Kidney and Pancreas Transplantation and Organ Availability Subcommittee reviewed the issue raised by the OPTN/UNOS Organ Availability Committee (OAC) of incidents of pancreata discard related to hepatic anomalies. There is a perceived resistance by some organ procurement teams to procure both the pancreas and liver in the presence of a hepatic anomaly. The OAC requested the OPTN/UNOS Kidney and Pancreas Transplantation and Liver and Intestine Transplantation Committees work collaboratively with the OAC to establish a policy ensuring the procurement of pancreata with livers when recipients are identified for both organs.

Members of the Joint Subcommittee agreed that there is pancreata wastage each year resulting from hepatic anomalies. The current OPTN/UNOS policies require that all organs suitable for transplantation for which consent to donation is obtained be procured, but the difficulty is the fluctuation among OPOs as to what constitutes a suitable organ. UNOS does not currently monitor every instance where an organ is not procured from a donor; it is assumed that the OPO determined the organ not suitable for transplantation.

Some Members stated that additional measures should be developed to help increase pancreata procurement. For instance, allocation policies could require an OPO, in situations where it fails to procure all organs consented for transplantation by the donor or donor family, to provide an explanation for failure to procure all organs from the donor. Some of this information is currently collected in UNetSM as OPOs are required to enter the reason for not procuring a particular organ. The applicable reason used in cases of hepatic anomalies is usually "anatomy," though there is currently no reason specifically for hepatic anomaly. The Joint Subcommittee agreed to review data from the last six months on liver donors during their next meeting. The data will include whether the kidney and/or pancreas was recovered from the donor and the number of incidences in which "anatomy" is used as the explanation for not procuring the kidney and/or pancreas. In general, Members agreed that pancreata should be recovered with livers and that the data might illustrate whether a large number of otherwise usable pancreata are being discarded.

A second suggestion proposed policy language specifically requiring procurement of pancreata in the presence of hepatic anomalies. During its meeting on September 16, 2003, the OPTN/UNOS Organ Availability Committee (OAC) agreed on the following motion: *that in the event of hepatic vascular arterial variations such as replaced right-hepatic artery, the procurement of the liver and pancreas will occur if recipients are identified for each.* After further discussion, Members of the Joint Subcommittee representing the OAC agreed that the OAC would send the above language out for public comment as a policy modification recommendation.

A final suggestion proposed the development of a white paper on the techniques of pancreas and liver recovery in the face of vascular anomalies. The white paper could be a joint development between the OPTN/UNOS Kidney and Pancreas Transplantation and Liver and Intestine Transplantation Committees. The intent is to help

educate procurement professionals on the issue and increase the procurement of pancreata. Members supported the idea and agreed to forward the suggestion to the Liver and Intestine Committee for their consideration.

The Committee considered the Joint Subcommittee's recommendations during its January 20-21, 2004, meeting. The Committee supports efforts of the OPTN/UNOS Organ Availability intended to ensure procurement of both the liver and pancreas from donors. Though some Members were skeptical of the impact on pancreata procurement from educational efforts on hepatic anomalies, the Committee agreed to recommend development, in conjunction with the OPTN/UNOS Liver/Intestine Committee, of educational materials addressing how procurement of both organs is possible in the presence of hepatic anomalies. The vote of the Committee was 23 For; 0 Against; 0 Abstentions.

Time Limits for Offering Organs

The OPTN/UNOS Joint Kidney and Pancreas Transplantation and Organ Availability Subcommittee also reviewed an issue raised by the OPTN/UNOS Policy Compliance Department regarding situations where one OPO has offered zero mismatch kidneys at or near the 8-hour time limit after organ procurement on mandatory share zero antigen mismatched kidneys prescribed by OPTN/UNOS Policy 3.5.3.5 (Time Limit). OPTN/UNOS policy establishes a period of 8 hours after organ procurement for standard criteria donor (SCD) kidneys and 4 hours after organ procurement for expanded criteria donor (ECD) kidneys within which zero antigen mismatched kidneys must be offered through the UNOS Organ Center. For both standard and expanded criteria donor kidneys organ procurement is defined as cross clamping of the donor aorta. OPTN/UNOS policy does not establish time limits for offering kidneys shared in satisfaction of kidney payback obligations.

The issue before the Joint Subcommittee involves one OPO that has on several occasions offered zero antigen mismatched kidneys just prior to the expiration of the policy's time limits. These organs may then be difficult to place for zero mismatched candidates due to the length of cold ischemia time. Current review and analysis of OPO activities do not indicate a similar pattern among other OPOs presently or previously. The UNOS Policy Compliance Department offered several policy recommendations for the Joint Subcommittee to consider:

- Require OPOs to offer mandatory share kidneys within a set time frame after performing a match-run, not to exceed 8 hours.
- Shorten the current time limit of 8 hours after procurement for standard criteria donor kidneys to 4 hours, which is the same as for ECD kidneys.
- Require a written letter of inquiry from the UNOS Policy Compliance Department requesting an explanation on any cases in which kidneys are offered closely within the 8-hour time limit.
- Take no action and thereby affirm the current policy.

Another OPO also raised the issue of time limits for offering organs, but provided a different perspective at least in the case of donation after cardiac death (DCD) donors, pediatric donors, obese donors, and donors with bilateral groin lines. The OPO argued that the policy's time limits for making offers of kidneys from these donors are not adequate to provide typing material. The OPO suggested that DCD donors, pediatric donors, and donors where pre-nephrectomy typing materials are impossible or difficult to obtain be exempted from the current time limitations imposed by policy.

Some Members of the Joint Subcommittee were sympathetic to the OPO's perspective with regard to the difficulty of obtaining pre-nephrectomy typing materials for certain donors. However, other Members stated that OPOs should be able to pretype the vast majority of donors within the 8-hour time limit. Due to the fact that, to the Joint Subcommittee's knowledge, only one OPO has raised this concern, the Joint Subcommittee agreed to retain the current policy and not recommend an exemption for any classification of donor.

With respect to the particular issue raised by the UNOS Policy Compliance Department, Members of the Joint Subcommittee agreed that the transplant centers within the particular OPO should receive a letter from Policy Compliance informing them of the OPO's actions on these occasions. These actions do not appear consistent with general objectives for expediting organ procurement and placement. However, since only one OPO is known to have made such organ offers just prior to expiration of the policy time limits, the Joint Subcommittee agreed to retain the current policy as written.

The Committee considered the Joint Subcommittee recommendations during its January 20-21, 2004, meeting and agreed with the Joint Subcommittee.

Model to Predict Individual Patient Survival

At the request of the OAC, the Joint Subcommittee reviewed a model used in the United Kingdom to predict individual patient survival under different treatment assumptions, based on a patient's socio-demographic and comorbidity data. There was concern that such models may duplicate efforts underway with KPSAM. The ability to predict outcomes on an individual patient basis could be helpful, however, in counseling patients regarding treatment options if these predictions are reliable. The Joint Subcommittee made no recommendations.

Update on the Status of ECD Kidney Allocation

Due to time constraints, the OPTN/UNOS Joint Kidney and Pancreas Transplantation and Organ Availability Subcommittee was unable to review the updated data on the status of expanded criteria donor (ECD) kidney allocation during its January 16, 2004, meeting. The Joint Subcommittee intends to review the data at its next meeting.

During the January 20-21, 2004, meeting, Members of the Committee stated the importance of understanding ECD kidneys and ascertaining the most beneficial mechanisms for allocation. Some of the transplant community misunderstands the purpose of the ECD allocation system. Transplant centers currently list a wide range of their candidates, from 100% to 0%, for ECD kidney offers. Perhaps the transplant community needs further explanation of the ECD allocation system, expected outcomes from these organs, and the intent of allocating them by a separate protocol. The efforts of the Joint Subcommittee and Committee could help increase the community's awareness and understanding of ECD kidneys.

The critical issue with ECD kidneys, some Members stated, is the high discard rate of nearly 40%. Many of these kidneys are discarded due to the misunderstanding of ECD kidneys by the transplant community. The Committee agreed to review discarded ECD kidneys by comparing them to the allocation point scale utilized in Minnesota. Such a comparison would demonstrate whether a portion of the discarded ECD kidneys would likely have been used under the Minnesota system.

34. **ECD Mortality.** Dale Distant, M.D., presented a study conducted on the topic of ECD mortality during the Committee meeting of May 19-20, 2004 (**Exhibit WW**). The study was originally presented at the ATC Conference on May 16, 2004, and examined ECD mortality relative to OPO waiting time by race and age.

Since transplant candidates can now elect to be placed on the waiting list for an ECD kidney in addition to the waiting list for a standard criteria donor kidney, waitlisted candidates can be faced with a choice of an ECD kidney in the near future or a standard criteria donor kidney after, perhaps, a longer period of waiting. The hypothesis of the study was, on average, ECD transplantation is beneficial if the waiting time for a standard criteria donor kidney transplant is long. For the purposes of the study, benefit was measured by mortality risk. The evaluation of the ECD option was performed by comparing the mortality of two transplant options: (1) the candidate receiving an ECD kidney transplant now and (2) the candidate waiting some time longer and later receiving a standard criteria donor kidney transplant.

The study used national data from the OPTN and SRTR and examined candidates placed on the kidney waiting list between 1995 and 2002. The sample size included 114,602 waitlisted candidates, of which 38,470 received a deceased donor kidney transplant. Of those who received deceased donor transplants, 32,476 were performed with a standard criteria donor kidney and 5,994 were performed with an expanded criteria donor kidney. The study modeled time to death using time-dependent Cox regression models censored at either living donor transplant or the end of the study (June 30, 2003). Adjustments were made for candidate age, race, gender, year waitlisted, ethnicity, ESRD cause, peak PRA, organ procurement organization of listing, blood type, comorbidities present at waitlist, dialysis modality, and time from first dialysis to waitlist. Waiting time to transplant for the OPO of registration was divided between two categories, < 1,350 days and ≥ 1,350 days, and

was assigned as a patient-level covariate. Within the category of OPO with waiting time less than 1,350 days were 39 (66%) OPOs and 52,929 (46%) registrants, and within the category of greater than or equal to 1,350 days were 20 (34%) OPOs and 61,673 (54%) registrants.

The study found that among those registrants listed at OPOs with long waiting times, mortality risk reduction by ECD transplant was significant and of greater magnitude (RR = 0.82, $p < 0.01$). Among those listed at shorter waiting time OPOs, there was not a significantly lower mortality risk for any group (RR > 1.0). Candidates aged 18-39 years had a higher mortality risk with an ECD kidney at both short and long waiting time OPOs (RR = 1.36 and 1.55, respectively), though these elevated risks were not statistically significant. Candidates aged 40-59 years and 60+ and listed at OPOs with long waiting times had a mortality risk reduction by ECD transplant (RR = 0.77, $p = 0.03$; RR = 0.67, $p < 0.01$, respectively).

In conclusion, the study suggests that ECD kidneys should be offered to selected candidates in OPOs with long waiting times. Candidates listed at short waiting time OPOs, where rates of standard criteria donor kidney transplantation are higher, should be counseled that no survival benefit from ECD transplant can be demonstrated at this time.

Some Members of the Committee commented that a notice to the transplant community might be appropriate to educate about this study and inform about the ECD mortality risk. However, some Members stated release of this study at this time might be premature. For instance, the mortality risk might differ for each individual candidate based on a number of factors, including blood group and how much waiting time the individual has already accumulated. Additional versions of this study are planned for the future to gain increasing knowledge with respect to ECD kidneys.

35. Report of the OPTN/UNOS Joint Ad Hoc Living Donor and Kidney and Pancreas Transplantation Subcommittee. The Joint Subcommittee convened on April 29, 2004, in order to discuss 1) the criteria for living donor kidney programs and 2) “grand fathering” existing living donor programs. This joint subcommittee was formed in response to a proposal developed by the OPTN/UNOS Ad Hoc Living Donor Committee and withdrawn from consideration by the Board during the November 2003 meeting due to differences with the Committee. The proposal sought to specify criteria for a qualifying renal donor surgeon as part of a live kidney donor transplant center. The criteria differentiated between surgeons qualifying with open or laparoscopic nephrectomies.

With respect to the proposal, some of the issues of concern to the Committee included the following:

- Whether a single renal donor surgeon would need to meet the requirements for performing both open donor and laparoscopic nephrectomies if the program wishes to perform laparoscopic nephrectomies? Alternatively, could this expertise reside in two separate individuals?
- Whether deceased donor nephrectomy or removal of polycystic or diseased kidneys is appropriate to demonstrate experience toward open live donor nephrectomies? Additionally, whether the policy’s thresholds for time and volume of procedures to demonstrate experience are appropriate?
- Whether the distinction between hand-assisted and other laparoscopic nephrectomies is appropriate or necessary?

The Joint Subcommittee discussed the Committee’s concerns during the meeting. If laparoscopic nephrectomies are offered by a center, then surgical expertise to perform both open and laparoscopic nephrectomy procedures is required to ensure that emergency situations can be safely addressed. If a surgeon encounters complications while performing a laparoscopic donor nephrectomy, it may be necessary to convert to an open nephrectomy and a surgeon qualified to do this would be required. The Joint Subcommittee Members discussed whether open nephrectomy experience is a skill needed to handle a laparoscopic nephrectomy encountering such problems. Members stated it is acceptable to have the qualifying open nephrectomy surgeon on site to assist if necessary. They agreed that the qualifying expertise in open donor and laparoscopic nephrectomies could reside in two separate individuals as long as the program can demonstrate how both individuals will be available to the surgical team.

There was considerable discussion about whether or not deceased donor nephrectomies and nephrectomies performed for the “removal of polycystic and diseased kidneys, etc.” should count towards meeting the open nephrectomy requirements. There was agreement from the Members that these procedures are quite different from a live donor nephrectomy; however, there was concern that if these procedures did not apply then even busy transplant centers currently doing living donor work would not qualify in the near future. The Joint Subcommittee agreed to leave this section of the proposed guidelines unchanged, including the volume of cases and time period. They also agreed to add an additional pathway of “completing an ASTS fellowship with a certificate in kidney.” This addition obviated the issue of “grand fathering” existing living donor kidney programs.

The Members decided not to specify the surgical technique used for laparoscopic nephrectomies and agreed to eliminate the section addressing “hand-assisted laparoscopic nephrectomies.” They also wanted to clarify that in order to meet the requirements for a laparoscopic nephrectomy, the surgeon must act as the “primary surgeon or first assistant.” This language made the laparoscopic nephrectomy requirements consistent with the open nephrectomy requirements.

After further discussion, the Joint Subcommittee agreed unanimously to support a modified version of the Ad Hoc Living Donor Committee proposal (see Exhibit).

During its May 19-20, 2004, meeting, the Committee discussed the Joint Subcommittee proposal. The Committee was informed of the OPTN/UNOS Membership and Professional Standards Committee (MPSC) consideration of the proposal. The MPSC expressed concern with the proposal’s focus on criteria for becoming a live donor kidney transplant program on operations that have nothing to do with a live donor operation (*e.g.*, deceased donor nephrectomy and diseased kidney nephrectomy). In addition, the MPSC had reservations with the qualifying renal donor surgeon criteria of completion of an accredited ASTS fellowship. Some surgeons complete their renal fellowships having never seen or performed a live donor open nephrectomy. Finally, nearly half of the transplant programs are still performing their live kidney donor nephrectomies using the open technique. In summary, the MPSC felt that the proposal does not adequately ensure the safety of live donors.

Some Members were concerned that not allowing donor surgeons to qualify for open live donor nephrectomy based on non-living donor nephrectomies would result in the temporary shutdown of many living kidney donor programs. Surgeons performing these open nephrectomies and other surgical procedures still obtain the skill set and anatomical knowledge that could be used in an open live donor nephrectomy. The Committee recognized that the American Board of Surgery has not developed criteria for living donor surgeons. In addition, some Members indicated that no objective support exists justifying a specific number of open or laparoscopic nephrectomies that qualify a donor surgeon. Perhaps the use of numbers should be abandoned. However, some Members stated that if the Committees are unable to agree upon a number of nephrectomies as a baseline for qualification, some other agency or organization might develop and impose a standard more objectionable. Hospital credentialing, in general, continues to move toward surgeons justifying their qualifications based on quantifiable criteria.

Credentialing of live donor surgeons should be separated from credentialing of surgeons for any other disease state. Some Members stated that living donation is an inherently different operation and philosophical approach based on the fact that a surgeon is operating on a person who is not him/herself medically in need of such treatment. Other Members disagreed that a distinction should be drawn based on the patient upon whom the surgeon operates.

After further discussion, the Committee agreed to continue its discussion of live kidney donor program criteria with the Ad Hoc Living Donor Committee, as well as, representatives from the Membership and Professional Standards Committee to ensure its concerns are addressed.

36. Proposal for Priority for Candidates with Intermediate Sensitization Levels. This issue is a product of the recommendations from the National Conference to Analyze the Wait List for Kidney Transplantation held in Philadelphia, Pennsylvania, on March 4-5, 2002. Though the Committee deferred consideration of a proposal to prioritize candidates for mismatched kidney allocation with intermediate sensitization levels, defined as PRA

< 80%, during its January 2004 meeting, the Committee discussed the topic during its May 19-20, 2004, meeting.

Under the current OPTN/UNOS policy for zero antigen mismatched patients, after local allocation (and within blood group identity and compatibility), priority for sensitization level is stratified so that the highest priority is awarded to candidates with a PRA greater than or equal to 80%, next to children with PRA < 80%, next to candidates with a PRA between 21% and 79%, followed by candidates with a PRA of 20% or less. Priority is awarded to mismatched candidates on the waiting list with a PRA greater than or equal to 80%, but no other PRA distinction or priority is awarded for mismatched candidates.

The Committee was reminded of data on rates of transplantation by decile of PRA previously considered by the Committee. A candidate with a PRA of 10% has a relative rate of transplantation of 0.86, while a candidate with a PRA of 100% has a 0.36 rate of transplantation. It was noted that candidates with PRAs 30% or greater had a relative rate of transplantation less than 0.60, with the largest difference in relative rates occurring at PRAs of 20%.

If intermediate sensitization levels are to be developed into the mismatched portion of the kidney allocation system, the Committee agreed that additional data would be needed to support the proposal. Some Members stated that the Committee should review the various HLA procedures used to determine PRA levels if the allocation policies continue to provide allocation points for sensitization. The procedures used to determine sensitization vary widely across the nation and can even vary between transplant centers in the same OPO. Perhaps the same assay system should be used for tests that determine sensitization for allocation priority and final crossmatch to minimize any potential gaming of the system. In addition, transplant centers differ on whether peak or current PRA levels, which can vary widely, are used for antibody screening. Some Members stated that candidates who are truly sensitized will not experience wide fluctuations in PRA levels, and thus, perhaps current PRA is the most appropriate measure of sensitization.

However, some Committee Members were wary of the suggestion that one assay system should be mandated from the OPTN/UNOS. Some transplant centers and laboratories are likely to oppose such a mandate. The OPTN/UNOS Histocompatibility Committee is recommending that laboratories should use antibody screening and crossmatching assays with similar degrees of sensitivity.

The option of eliminating all allocation points for PRA was suggested by some Members. The intent is to minimize opportunities for gaming the allocation system and increase opportunities for the consistently sensitized candidates rather than those candidates who experience one high PRA result. In addition, the definition of panel reactive antibody (PRA) should be reviewed to determine which class titers are appropriate. The Committee agreed to defer these issues to the next meeting of the OPTN/UNOS Joint Kidney and Pancreas/Pediatrics/ Minority Affairs/Histocompatibility Subcommittee. Ken Andreoni, M.D., will join the Joint Subcommittee for this discussion.

Possible effects on pediatric candidates from increased allocation points for intermediate sensitization levels for mismatched candidates is a concern for some Members. In general, pediatric candidates are not sensitized and could be disadvantaged in terms of opportunities for organ offers under such a proposal. Members agreed that KPSAM may help predict the effects on pediatric candidates.

The Committee agreed that a dramatic overhaul of the sensitization allocation protocol is not yet warranted; however, a review of data on the impact of sensitization on the relative rate of transplantation with local mismatched and zero mismatched kidneys is in order. The Committee also elected to review data by transplant center on the number and percentage of candidates listed per PRA level. Finally, the Committee agreed to review at its next meeting draft language permitting candidates to have their PRAs assigned based on their historical peak PRA, but crossmatches based on their current PRA by a vote of 23 For; 0 Against; 0 Abstentions.

37. OPTN/UNOS OPO Committee Review of the Reuse of Disposable Transport Containers and Standardization of Organ Packaging Transport. The OPTN/UNOS ABO Joint Subcommittee, now the Ad Hoc Operations Committee, requested the OPO Committee review Policies 5.5 (Standard Organ Packaging Specifications) and

Policy 5.5.3.1 regarding the rigid container for housing the organ during transport. The ABO Joint Subcommittee opined that the reuse of disposable organ packages should be prohibited, and also found that the standardization of packaging organs would help to promote greater safety. In response to the request, the OPO Committee drafted proposed recommendations and requested review by the OPTN/UNOS Kidney and Pancreas Transplantation Committee (**Exhibit XX**). The proposed recommendations are as follows:

- The reuse of disposable transport boxes should be prohibited due to the integrity of the box being compromised during the removal of labels.
- Coolers should be allowed for non-commercial transporting when the organ recovery team is taking the organ with them from the donor hospital to the transplant center. The reuse of coolers should be allowed; all labels from the previous donor organ must be removed before reusing the cooler.
- If the organ is to be commercially shipped, such as with a courier service, commercial airline or charter service, the organ should be packaged in a disposable transport box, as outlined in Policy 5.5 (Standard Organ Package Specifications), to comply with OSHA and federal transportation regulations that would require a sealed, leak-proof container.

The Committee discussed this issue during its January 20-21, 2004, meeting. The Committee agreed to support these recommendations by a vote of 18 For; 0 Against; 0 Abstentions.

38. Request from the OPTN/UNOS OPO Committee Regarding Coordinating OPOs. The OPTN/UNOS ABO Joint Subcommittee, now the Ad Hoc Operations Committee, requested the OPO Committee consider the necessity of defining the role and responsibilities of the “coordinating OPO” in regards to when the organ is offered and accepted by a transplant center and then not transplanted into the candidate for whom the organ was accepted (**Exhibit YY**).

According to OPTN/UNOS Policy 3.2.3 (Match System Access),

For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a patient who ultimately is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local level must be done according to the match run.

The OPO Committee conducted a survey of the OPOs to determine the degree to which OPOs serve as the clearinghouse for organ offers/imports to patients at transplant programs within their donor service area. Of the 47 OPOs that responded to the survey, 30 responded that they act as the coordinating OPO, 4 OPOs responded that they did not, and 13 OPOs indicated that they act as the coordinating OPO for some of their transplant centers or for certain organs, such as kidneys. The OPO Committee conducted a subsequent survey asking OPOs to provide information on the impact, advantages and disadvantages of four different scenarios for managing organ offers/imports. The OPO Committee requested the OPTN/UNOS Kidney and Pancreas Transplantation Committee consider the charge of the OPTN/UNOS ABO Joint Subcommittee and survey results and provide recommendations to the OPO Committee for consideration in its deliberations.

The Committee reviewed this issue during its January 20-21, 2004, meeting. Members of the Committee noted that a majority of OPOs stated they serve as the clearinghouse for organs. If the organ is not used for the intended candidate and the sending OPO permits the kidney to be backed up locally, the receiving OPO will take over responsibilities of local OPO and ensuring appropriate organ allocation. Some Members questioned whether a kidney should become a local kidney for allocation policy purposes when it is backed up and cannot be used for the intended candidate. Current OPTN/UNOS policy provides that such kidneys are allocated according to the local donor service area waiting list, rather than the local transplant center waiting list. After further discussion, the Committee agreed to support current policy such that backed up kidneys not used for the intended candidate are allocated according to the standard local unit allocation protocol, by a vote of 19 For; 0 Against; 0 Abstentions. The responsibility for organ allocation should belong to the OPO rather than the transplant center.

39. Request from the OPTN/UNOS Operations Committee for Review of Required Listing Criteria to Assure More Accurate Patient Listing and Donor Acceptance Criteria. Dan Hayes, M.D., presented the issue to the Committee during its May 19-20, 2004, meeting. The issue was initially raised by the Joint ABO Subcommittee, which developed into the Operations Committee. The Operations Committee intends to review appropriate listing criteria in order to facilitate placement of organs on a more expedited basis to those candidates who are ready and suitable for transplantation. The primary focus of the Operations Committee will be on extra-renal organs, rather than kidneys and pancreata; however, the Committee is welcome to submit suggestions to the Operations Committee for consideration.

Some Members noted that a substantial portion of the pediatric candidate population is currently listed for an expanded criteria donor kidney transplant. Many of the pediatric candidates listed for an ECD transplant are listed at transplant centers that have listed all or most of their transplant candidates as willing to accept ECD kidneys. Though no ECD kidney has been accepted and transplanted into a pediatric candidate based on the ECD kidney allocation protocol since the ECD policy was implemented, offers are being made to pediatric candidates and delaying the ultimate placement of the ECD kidneys. Perhaps the Operations Committee should consider the listing of pediatric candidates for ECD kidneys during its discussion of listing criteria.

Placement of the heart and lungs from a particular donor can delay the recovery process of the other organs. Some Members stated that the kidneys, pancreas and liver organs are often placed from a given donor fairly quickly; however, placement of the heart and lungs often takes considerably longer and jeopardizes the procurement team from recovering the organs. One possible explanation for the increased time to place the heart and lungs is that transplant centers are listing candidates they do not intend to transplant. The Committee was informed the Operations Committee will consider this issue at its next meeting.

40. Aggressive Organ Placement Issues. The OPTN/UNOS Policy Compliance Subcommittee of the Membership and Professional Standards Committee previously requested that all organ specific committees define “aggressive” offers and placements for each organ. Under the current system, “aggressive” placements or expedited placements are discretionary to the OPO. There are instances when certain marginal organs are expeditiously placed with transplant centers that have a history of accepting such organs without following the match run. These events are followed by letters of inquiry from the UNOS Policy Compliance Department. The OPTN/UNOS Operations Committee is now taking up this issue.

The Bylaws Subcommittee previously considered this issue during its September 26, 2003, meeting. During that meeting the Subcommittee agreed that mechanisms for aggressive placements of kidneys and pancreata should probably be preserved and specified by guidelines. However, the Subcommittee felt that additional data was needed prior to developing such guidelines. For instance, the facilitated pancreas policy is currently in effect, but may not have had sufficient time to become fully utilized. The Subcommittee agreed to review data on the number of pancreata being placed under the facilitated system compared to the standard system during its next meeting.

Dan Hayes, M.D., Chair of the Bylaws Subcommittee, provided an update to the Committee during its May 19-20, 2004, meeting. Some Members expressed that aggressive organ offers are probably more prevalent among pancreas organs, though there are probably instances within expanded criteria donor kidneys. The Committee agreed that something should be done to minimize situations where transplant centers agree to accept, for instance, expanded criteria donor kidneys, but then reject most of the ECD offers made. These rejections increase cold ischemia time for kidneys that require minimal ischemic time.

The Committee was informed that the Operations Committee will develop guidelines for aggressive organ offers with respect to all of the organs, including kidney and pancreas.

41. Requested Clarification of Pancreas Donor Match Issue – Matching Includes Pancreas Donor to the Candidate and Previous Kidney Donor to the Candidate. The Committee, during its January 20-21, 2004, meeting, considered an inquiry regarding matching requirements for pancreas after kidney recipients (**Exhibit ZZ**). The Board approved a resolution in November 1994 modifying the UNOS system for pancreas allocation whereby mismatches shared between the kidney and pancreas donors will be considered as matches. Use of the modified

mismatch criteria is optional. Pancreata that do not meet the mismatch criteria for a particular recipient will not be offered to that candidate. The resolution was implemented in April 1996. The purpose of the modification is to enhance transplant opportunities for kidney recipients who require a sequential pancreas transplant, including opportunities for zero antigen-mismatched organ offers. Clarification was sought because this resolution, while approved by the Board and effective in the allocation system, is not codified within the OPTN/UNOS allocation policies.

Members of the Committee agreed to review this issue and request additional data. Data will include analyses of the frequency by which prior kidney donor antigens are used to establish the level of match for pancreas transplants. If there are adequate numbers, a survival analysis will be reviewed by the Committee during its next meeting.

42. Requested Review of P24 Antigen Screening for HIV Test. New Mexico Donor Services requested the organ-specific, OPO and Histocompatibility Committees review the issue of P24 antigen screening. The P24 antigen screen for the HIV test kit will be discontinued by the end of the year since the blood banking industry has transitioned to RNA testing, which is not a real-time test. Some OPOs perform the test as part of their prescreening serology panel at the request of transplant centers. The issue is whether, given the circumstances, the test needs to be performed, or whether there is interest in OPOs converting to RNA testing.

During its January 20-21, 2004, meeting, Members of the Committee stated that the Centers for Disease Control (CDC) and an infectious disease expert should be consulted on this issue. The Committee also agreed to convey to the OPO Committee the importance of the availability of a real-time test. Reliance on RNA testing, which can have a lag time of 36-72 hours is probably not acceptable.

43. Proposed Pancreatic Islet Conference. During the January 20-21, 2004, meeting, Mark Stegall, M.D., Vice Chair of the Committee, proposed the idea of assembling a group of professionals with expertise in pancreas and islet transplantation to discuss issues and obtain guidance relative to islet allocation and transplantation. The intent is to obtain a consensus among those with relevant expertise as to where the field of islet transplantation should be headed so as to best address issues under consideration by the OPTN/UNOS. Members from the OPTN/UNOS OPO Committee would also be invited to participate in the conference to share their perspectives with respect to issues of islet reimbursement, organ acquisition costs, and other issues that impact islet transplantation. The present plan is for Dr. Stegall and Bernard Herring, M.D. to co-chair the conference, which would occur over two days some time during the summer or fall of 2004, possibly in conjunction with either the OPTN/UNOS Kidney and Pancreas Transplantation or OPO Committee meetings. After further discussion, the Committee unanimously endorsed the concept of the islet conference by a vote of 23 For; 0 Against; 0 Abstentions.

During the May 19-20, 2004, meeting, Mark Stegall, M.D., provided an update on the proposed islet consensus conference. The goal is to hold the conference in conjunction with the AST Winter Symposium scheduled for January 23-25, 2005, in Miami Beach, FL, along with the full January Committee meeting. Possible additional topics for the conference include the pancreatic islet allocation system in general, and islet policy implementation. Members of the Committee were invited to suggest topics for the conference agenda.

44. Food and Drug Administration (FDA) Advisory Meeting on Islets. The Committee learned of the FDA Advisory Committee reviewing the status of islets during its meeting on January 20-21, 2004. HRSA and the FDA continue to work together on issues of islet allocation and procurement, but no consensus has been reached on specific donor criteria.
45. West Nile Virus. The Health Resources and Services Administration (HRSA) issued an alert on September 11, 2002, to organizations associated with organ transplantation about a suspected case of West Nile virus transmission through organ donation. Some Committee Members inquired as to HRSA's perspective on whether living donors should be screened for West Nile virus. Some Members stated that there is no documented case of West Nile virus transmission from a living donor to a transplant candidate, and thus, testing all living donors could be a waste of resources.

Laura St. Martin, M.D., stated that HRSA does not currently require testing for West Nile virus of living donors but strongly suggests such testing. The intent of the guidance statement was to inform transplant teams of the West Nile virus test and encourage blood banks to utilize the test for organ donors. Many factors persuaded HRSA to issue the guidance, including HRSA's desire to be proactive on the issue and the possibility of the Centers for Disease Control (CDC) issuing a much more restrictive testing requirement. The guidance is not a federal regulation, and thus, transplant centers and OPOs would not be in violation of a rule if they decide not to follow the recommendation.

46. **Organ Infection Request for Proposal.** During the May 19-20, 2004, meeting, Laura St. Martin, M.D., informed the Committee of the recent request for proposal (RFP) issued by the Centers for Disease Control. The RFP will study organ infection detection and prevention by focusing on organ transplant recipients. The intent is to develop a consortium of transplant centers that will help develop protocols for infectious disease monitoring and also develop a repository of specimens that would be used for possible National Institute of Health (NIH) funded research on infectious diseases. The NIH also intends to fund some epidemiological and risk factor studies aimed at determining risk factors associated with transplant recipients and the development of certain fungal infections.

47. **Double Kidney Allocation.** The conditions required of donors for double kidney allocation eligibility were raised as an issue during the May 19-20, 2004, meeting. There is a perception among some members of the transplant community that the conditions are too restrictive and prohibit good donor kidneys from being allocated under the double kidney provision. Current OPTN/UNOS Policy 3.5.7 specifies that adult donor kidneys must be offered singly unless the donor meets two of the following conditions and the OPO would not otherwise use the kidneys singly:

1. Donor age greater than 60 years;
2. Estimated donor creatinine clearance less than 65 ml/min based upon serum creatinine upon admission;
3. Rising serum creatinine (greater than 2.5 mg/dl) at time of retrieval;
4. History of medical disease in donor (defined as either longstanding hypertension or diabetes mellitus)
5. Adverse donor kidney histology (defined as moderate to severe glomerulosclerosis (greater than 15% and less than 50%))

Some Members suggested that the conditions in Policy 3.5.7 are not overly restrictive, but are perhaps somewhat complex. One suggestion offered would eliminate condition 3 and 4 and modify the policy to require the donor meet two of the three remaining conditions (age greater than 60 years, estimated donor creatinine clearance less than 65 ml/min based upon serum creatinine upon admission, or adverse donor kidney histology).

Other Members stated that the policy as written is simple to understand and not overly restrictive. After further discussion, the Committee agreed to maintain the current language of OPTN/UNOS Policy 3.5.7 by a vote of 23 For; 0 Against; 0 Abstentions.

48. **Review of Updated UNOS Travel Policy.** The Board approved modifications to the UNOS travel policies in November 2003, which were implemented on January 1, 2004. The modifications include increases in the per diem meal reimbursement level and the rate of reimbursement for mileage while traveling for UNOS business. The Committee was informed of Policy 8.2.4, which limits the reimbursement in situations where UNOS holds a meeting in the city where another organization is holding its own meeting.

49. **May Committee Meeting Schedule Change.** The Committee agreed to alter the scheduled date and location of the May 2004 meeting due to a scheduling conflict with the American Transplant Congress (ATC) conference. After further discussion, the Committee agreed to move the May meeting to Boston, Massachusetts in conjunction with the ATC conference by a vote of 22 For; 2 Against; 0 Abstentions. The Committee then agreed the meeting should be held after the ATC conference on May 19-20, 2004, by a vote of 13 For; 7 Against; 0 Abstentions.

50. **OPTN/UNOS Membership and Professional Standards Committee Metric Data and Analysis.** During its May 19-20, 2004, meeting, the Committee was informed that the OPTN/UNOS Membership and Professional

Standards Committee is developing metrics with the intent of evaluating transplant center and OPO compliance with OPTN/UNOS allocation policies. Since the metrics will be a comparative analysis, the hope is they could also serve as an educational tool for the centers and OPOs. There is currently no plan to present the metrics to the Committee, but a presentation could be made in the future if the Committee wishes.

Attendance at Kidney and Pancreas Transplantation Committee Meeting
Scottsdale, Arizona
January 20, 2004

Committee Members Attending:

Alan B. Leichtman, M.D.	Chairman
Mark D. Stegall, M.D.	Vice Chairman
Ernesto P. Molmenti, M.D.	Region 2
Thomas A. Gonwa, M.D.	Region 3
Benjamin D. Cowley, M.D.	Region 4
Gary K. Shen, M.D.	Region 5
Viken Douzdzjian, M.D.	Region 6
Allan M. Roza, M.D.	Region 7
Daniel Murillo, M.D.	Region 8
George A. Blessios, M.D.	Region 9
Mitchell L. Henry, M.D.	Region 10
Kenneth A. Andreoni, M.D.	Region 11
W. Ben Vernon, M.D.	At Large
Giacomo P. Basadonna, M.D., Ph.D.	At Large
Denise Y. Alveranga, M.D.	At Large
Francis L. Delmonico, M.D.	At Large
Marla Jill McMaster, MA	At Large
Dolly B. Tyan, Ph.D.	At Large
Daniel H. Hayes, M.D.	At Large
James J. Wynn, M.D.	At Large
Rob Kochik, RN, BSN	At Large
Trent Tipple, M.D.	At Large
Gabriel M. Danovitch, M.D.	At Large
Dale A. Distant, M.D.	At Large (via telephone)
Sharon C. Kiely, M.D., MPM	BOD Liaison
Laura St. Martin, M.D., M.P.H.	Ex Officio-Government Liaison

Members Unable To Attend:

Jeffrey S. Stoff, M.D.	Region 1
Peter G. Stock, M.D., Ph.D.	At Large
Ruth A. McDonald, M.D.	At Large
H. Albin Gritsch, M.D.	At Large
Kenneth L. Brayman, M.D., Ph.D.	At Large
Geoffrey A. Land, Ph.D.	At Large
Karen Keen Denton, RN, CPTC	At Large
Jill D. Maxfield, RN, CPTC	At Large
Kolleen E. Thompson, RN, BSN, CPTC	At Large

UNOS Staff Attending:

Cindy M. Sommers, Esq., UNOS Director of Allocation Policy
Jason R. Byrd, Esq., Policy Analyst, UNOS Department of Allocation Policy
Maureen McBride, Ph.D., Senior Biostatistician, UNOS Department of Research
Katrina Goodwin, Applications Engineer, UNOS Department of IT Development
Jeff Tongel, Applications Engineer, UNOS Department of IT Development

SRTR Staff Attending:

Randy Sung, M.D.
Mary Guidinger

Guests Attending:

Anthony M. D'Alessandro, M.D. (via telephone) and Martin F. Mozes, M.D. (via telephone)

Attendance at Kidney and Pancreas Transplantation Committee Meeting
Scottsdale, Arizona
January 21, 2004

Committee Members Attending:

Alan B. Leichtman, M.D.	Chairman
Mark D. Stegall, M.D.	Vice Chairman
Ernesto P. Molmenti, M.D.	Region 2
Thomas A. Gonwa, M.D.	Region 3
Benjamin D. Cowley, M.D.	Region 4
Gary K. Shen, M.D.	Region 5
Viken Douzdijan, M.D.	Region 6
Allan M. Roza, M.D.	Region 7
Daniel Murillo, M.D.	Region 8
George A. Blessios, M.D.	Region 9
Mitchell L. Henry, M.D.	Region 10
Kenneth A. Andreoni, M.D.	Region 11
W. Ben Vernon, M.D.	At Large
Giacomo P. Basadonna, M.D., Ph.D.	At Large
Denise Y. Alveranga, M.D.	At Large
Francis L. Delmonico, M.D.	At Large
Ruth A. McDonald, M.D.	At Large
Marla Jill McMaster, MA	At Large
Dolly B. Tyan, Ph.D.	At Large
Daniel H. Hayes, M.D.	At Large
James J. Wynn, M.D.	At Large
Rob Kochik, RN, BSN	At Large
Trent Tipple, M.D.	At Large
Gabriel M. Danovitch, M.D.	At Large
Dale A. Distant, M.D.	At Large (via telephone)
Sharon C. Kiely, M.D., MPM	BOD Liaison
Laura St. Martin, M.D., M.P.H.	Ex Officio-Government Liaison

Members Unable To Attend:

Jeffrey S. Stoff, M.D.	Region 1
Peter G. Stock, M.D., Ph.D.	At Large
H. Albin Gritsch, M.D.	At Large
Kenneth L. Brayman, M.D., Ph.D.	At Large
Geoffrey A. Land, Ph.D.	At Large
Karen Keen Denton, RN, CPTC	At Large
Jill D. Maxfield, RN, CPTC	At Large
Kolleen E. Thompson, RN, BSN, CPTC	At Large

UNOS Staff Attending:

Walter K. Graham, Esq., UNOS Executive Director
Cindy M. Sommers, Esq., UNOS Director of Allocation Policy
Jason R. Byrd, Esq., Policy Analyst, UNOS Department of Allocation Policy
Maureen McBride, Ph.D., Senior Biostatistician, UNOS Department of Research
Katrina Goodwin, Applications Engineer, UNOS Department of IT Development
Jeff Tongel, Applications Engineer, UNOS Department of IT Development

SRTR Staff Attending:

Randy Sung, M.D.	Robert Merion, M.D.
Mary Guidinger	
Keith McCullough	

Attendance at Kidney and Pancreas Transplantation Committee Meeting
Boston, Massachusetts
May 19, 2004

Committee Members Attending:

Alan B. Leichtman, M.D.	Chairman
Mark D. Stegall, M.D.	Vice Chairman
Thomas A. Gonwa, M.D.	Region 3
Benjamin D. Cowley, M.D.	Region 4
Allan M. Roza, M.D.	Region 7
George A. Blessios, M.D.	Region 9
Mitchell L. Henry, M.D.	Region 10
Kenneth A. Andreoni, M.D.	Region 11
W. Ben Vernon, M.D.	At Large
Peter G. Stock, M.D., Ph.D.	At Large
Jill D. Maxfield, RN, CPTC	At Large
H. Albin Gritsch, M.D.	At Large
Kenneth L. Brayman, M.D., Ph.D.	At Large
Giacomo P. Basadonna, M.D., Ph.D.	At Large
Denise Y. Alveranga, M.D.	At Large
Francis L. Delmonico, M.D.	At Large
Ruth A. McDonald, M.D.	At Large
Marla Jill McMaster, MA	At Large
Dolly B. Tyan, Ph.D.	At Large
Daniel H. Hayes, M.D.	At Large
James J. Wynn, M.D.	At Large
Trent Tipple, M.D.	At Large
Gabriel M. Danovitch, M.D.	At Large
Dale A. Distant, M.D.	At Large
Kolleen E. Thompson, RN, BSN, CPTC	At Large (via telephone)
Sharon C. Kiely, M.D., MPM	BOD Liaison
Laura St. Martin, M.D., M.P.H.	Ex Officio-Government Liaison

Members Unable To Attend:

Jeffrey S. Stoff, M.D.	Region 1
Ernesto P. Molmenti, M.D.	Region 2
Gary K. Shen, M.D.	Region 5
Viken Douzdijan, M.D.	Region 6
Daniel Murillo, M.D.	Region 8
Rob Kochik, RN, BSN	At Large
Geoffrey A. Land, Ph.D.	At Large
Karen Keen Denton, RN, CPTC	At Large

UNOS Staff Attending:

Walter K. Graham, Esq., UNOS Executive Director
Mary D. Ellison, Ph.D., UNOS Assistant Executive Director of Federal Affairs
Cindy M. Sommers, Esq., UNOS Director of Allocation Policy
Jason R. Byrd, Esq., Policy Analyst, UNOS Department of Allocation Policy
Maureen McBride, Ph.D., Senior Biostatistician, UNOS Department of Research
Katrina Goodwin, Applications Engineer, UNOS Department of IT Development

SRTR Staff Attending:

Randy Sung, M.D.
Laura Christenson

Guests Attending:

Henry Krakauer, M.D., Ph.D., Medical Officer, Division of Transplantation
Lawrence G. Hunsicker, M.D., Chair, OPTN/UNOS Data Working Group
Winfred W. Williams, M.D., Chair, OPTN/UNOS Minority Affairs Committee

Attendance at Kidney and Pancreas Transplantation Committee Meeting
Boston, Massachusetts
May 20, 2004

Committee Members Attending:

Alan B. Leichtman, M.D.	Chairman
Mark D. Stegall, M.D.	Vice Chairman
Thomas A. Gonwa, M.D.	Region 3
Benjamin D. Cowley, M.D.	Region 4
Allan M. Roza, M.D.	Region 7
George A. Blessios, M.D.	Region 9
Mitchell L. Henry, M.D.	Region 10
Kenneth A. Andreoni, M.D.	Region 11
W. Ben Vernon, M.D.	At Large
Peter G. Stock, M.D., Ph.D.	At Large
Jill D. Maxfield, RN, CPTC	At Large
H. Albin Gritsch, M.D.	At Large
Kenneth L. Brayman, M.D., Ph.D.	At Large
Giacomo P. Basadonna, M.D., Ph.D.	At Large
Denise Y. Alveranga, M.D.	At Large
Ruth A. McDonald, M.D.	At Large
Marla Jill McMaster, MA	At Large
Dolly B. Tyan, Ph.D.	At Large
Daniel H. Hayes, M.D.	At Large
James J. Wynn, M.D.	At Large
Trent Tipple, M.D.	At Large
Gabriel M. Danovitch, M.D.	At Large
Dale A. Distant, M.D.	At Large
Kolleen E. Thompson, RN, BSN, CPTC	At Large (via telephone)
Sharon C. Kiely, M.D., MPM	BOD Liaison
Laura St. Martin, M.D., M.P.H.	Ex Officio-Government Liaison

Members Unable To Attend:

Jeffrey S. Stoff, M.D.	Region 1
Ernesto P. Molmenti, M.D.	Region 2
Gary K. Shen, M.D.	Region 5
Viken Douzdijan, M.D.	Region 6
Daniel Murillo, M.D.	Region 8
Rob Kochik, RN, BSN	At Large
Geoffrey A. Land, Ph.D.	At Large
Karen Keen Denton, RN, CPTC	At Large
Francis L. Delmonico, M.D.	At Large

UNOS Staff Attending:

Cindy M. Sommers, Esq., UNOS Director of Allocation Policy
Jason R. Byrd, Esq., Policy Analyst, UNOS Department of Allocation Policy
Maureen McBride, Ph.D., Senior Biostatistician, UNOS Department of Research
Katrina Goodwin, Applications Engineer, UNOS Department of IT Development

SRTR Staff Attending:

Randy Sung, M.D.
Laura Christenson

Guests Attending:

Russell H. Wiesner, M.D., UNOS President

Proposed Modification to Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys**Summary**

The proposal would clarify a previous Committee proposal approved by the Board to create a generic alternative system that would provide priority in the kidney allocation system for original intended candidates (ICs) for living donor kidneys who are incompatible with their living donors due to crossmatch results or ABO blood type, when the living donors donate to candidates on the list of patients waiting for deceased donor kidneys. Under the proposal, ICs would be ranked, in situations where more than one IC appeared on a match run, in order of date of donation from the living donor. The term "time waiting" would be eliminated from this portion of the alternative system so as not to be confused with the standard meaning of candidate waiting time. The intent of the alternative system approved by the Board was to facilitate kidney donation by living persons and increase the availability of organs for transplantation overall. The present proposal is intended to assign priority among ICs when more than one in a manner that better reflects the alternative system's overall objectives.

I. Background

During its November 20-21, 2003, meeting, the OPTN/UNOS Board of Directors approved a prior Committee proposal to create a generic alternative system that would provide priority in the kidney allocation system for original intended candidates (ICs) for living donor kidneys who are incompatible with their living donors due to crossmatch results or ABO blood type, when the living donors donate to candidates on the list of patients waiting for deceased donor kidneys. The Committee, through its Subcommittee on Alternative Allocation and Distribution Systems, determined that the generic alternative system, rather than a modification to national allocation policy, is the best approach at this time to accomplish the Committee intent.

The Board-approved alternative system does not supercede the allocation algorithm (OPTN/UNOS algorithm or local alternative system) used by the participating OPO, but would be superimposed over their allocation algorithm. It only applies at the local level of organ allocation. The priority for original intended candidates for living donor organs follows the zero antigen mismatched combined kidney/pancreas patients who are highly sensitized (*i.e.*, panel reactive antibody (PRA) level $\geq 80\%$), zero antigen mismatched isolated kidney patients, prior living donors subsequently listed for kidney transplantation, UNOS paybacks (debts and credits), highest scoring high PRA candidates at the local level, and pediatric candidates who surpassed their transplant threshold goals at the local level. Existing exceptions within these various categories allowed for patients receiving kidneys with non-renal organs or emergency status patients for those OPOs that exercise the option to assign a patient emergency status continue to apply. The objective is to assign original intended candidates for living donor organs who meet the protocol's criteria sufficient priority in kidney allocation to get them transplanted expeditiously (i) without modifying priorities assigned for other candidates based upon demonstrated unique utility and/or medical benefit of the kidney transplant, and (ii) acknowledging the standard order of kidney paybacks (debts/credits) in the national system. Therefore, the priority for patients who are a zero antigen mismatch with their donor is maintained due to demonstrated improved transplant outcomes with receipt of a zero antigen mismatched kidney transplant. The priority for prior living donors is maintained due to compromised medical status of these patients in light of their sacrifice of a whole or partial organ. The priority for highly sensitized patients who have priority ahead of children who have waited their time goals to transplant is maintained due to unique issues of access for these patients. And, the priority for children who have waited beyond the time goals established in policy for them to be transplanted is maintained due to the unique problems pediatric patients experience with dialysis and disruption to expected growth and development processes due to renal failure. The Subcommittee and full Committee determined that these priorities based upon medical utility or benefit, as well as the historical priority for kidney paybacks, should be retained, and that the ICs should then follow in the next direct priority. In the event there is more than one IC, time waiting would be used to establish priority among ICs.

The Board-approved protocol does not direct how kidneys procured from living donors who elect to take part in the system shall be allocated. Instead, the Committee offered guidance with respect to this matter as an appendix to the protocol.

The generic alternative system requires any OPO operating with a different IC alternative system to review their system in light of the generic system. Such OPOs would then have the option to either adopt the generic system or continue with their own. If the OPO elects to continue its own alternative system, it could do so for a period of three years, at which time the OPO would be required to reapply with the Committee to extend the time frame for its system. The OPO also would need to follow data submission and other requirements applicable generally to alternative systems.

Finally, the Committee will review the generic alternative system on an annual basis to determine its impact on the Waiting List and the effectiveness of the system.

As previously noted, the OPTN/UNOS Board of Directors discussed the Committee recommendation during its November 20-21, 2003, meeting. Members of the Board were concerned with the use of the phrase "original intended recipient" in the proposal submitted by the Committee. The preferred term is "original intended candidate," which the Board agreed to incorporate into the proposal. The Board subsequently approved the Committee proposal as modified by the Board.

II. Policy Proposal

During the programming phase of the implementation process for the Board-approved system, an issue was raised regarding the intended meaning of "waiting time," used to prioritize ICs when there is more than one eligible IC, under the system. Two options were considered by the Committee during its meeting on January 20-21, 2004. First, ICs could be prioritized according to their accrued waiting time for kidney transplantation calculated using standard rules for determining waiting time. The language included in the Board-approved generic alternative system suggests this approach, which would apply the standard, current definition of waiting time.

Second, ICs could be prioritized based on the date of donation from their original intended living donor who was incompatible with the IC. The intent of the generic alternative system is to facilitate kidney donation by living persons. Some Members felt that prioritizing ICs based on the donation date of their original intended donor is more in line with the intent of the system. The priority among ICs would be determined by the time of the event establishing their rank order on the waiting list rather than length of overall waiting time, which may have no relationship to the time of their donor's donation. However, other Members expressed that ICs could be penalized under such a system if their original intended donor postpones the donation date due to any number of circumstances including work, school, or family obligations, and medical conditions. It was noted as well that, practically, differences between priority assignments using the two options most likely would be small since ICs often may not be listed on the deceased donor waiting list until incompatibility with their intended living donors is known.

After further discussion, the Committee proposed to prioritize ICs based on longest waiting time using standard calculations for candidate waiting time, but that proposal failed by a vote of 9 For; 10 Against; 0 Abstentions. The Committee then considered the proposal to prioritize ICs based on the date of the original intended donor living kidney donation, which was approved by a vote of 13 For; 8 Against; 0 Abstentions. The Committee believes that the latter option is most consistent with the objective of facilitating living donor donation.

The Committee agreed to eliminate the term "time waiting" from the language of the generic alternative system as it pertains to priority for ICs in order to prevent confusion over two meanings of "waiting time." Instead, the Committee would "rank" ICs in terms of the donation date of their original intended donors. The Committee agreed to submit the proposal for public comment.

*** RESOLVED, that the following modification to the local voluntary alternative system for assigning priority in kidney allocation to ICs shall be distributed for public comment:**

Goal

The primary goal of this prospective alternative system for kidney allocation is to facilitate kidney donation by living persons and increase the availability of organs for transplantation overall. Using live donor/paired candidate registries in situations where the original intended candidate for a living donor kidney is incompatible with his/her living donor has been problematic historically due to factors such as size of that subgroup of the living-donor pool and inability to match donors to transplant candidates. Assignment of priority for deceased donor kidney allocation to the original intended candidate (IC) when the patient's intended donor donates to a candidate on the list of patients waiting for a deceased donor kidney provides a mechanism to expand this pool of potential donors for the living donor's original intended candidate. The alternative system acknowledges the ABO or HLA antigen factor resulting in incompatibility between donor and candidate that prevented the intended live donor organ transplant to occur. It also acknowledges the difference in expected graft survival between a living donor kidney transplant and a deceased donor kidney transplant (*i.e.*, > 80% vs. > 70% 3-year graft survival¹). A primary principle of the system is, therefore, to get the original intended candidate transplanted expeditiously.

System Background and Rationale [No Proposed Changes to This Section]

System Design

The following allocation sequence will not supercede the allocation algorithm (OPTN/UNOS algorithm or local alternative system) used by the participating OPO, but will be superimposed on to their allocation algorithm. It will apply only at the local level of organ allocation. Transplant programs participating in the alternative system are required to provide appropriate guidance to living donors and patients who elect to take part in this system to enable understanding by these individuals of how the system works.

Allocation Sequence

- Zero antigen mismatched combined kidney/pancreas patients who are highly sensitized (*i.e.*, panel reactive antibody (PRA) level \geq 80%). See note 1 below.
- Zero antigen mismatched isolated kidney patients. See note 2 below.
- Prior living donors subsequently listed for kidney transplantation.
- UNOS Paybacks (Debits/Credits)
- Local Waiting List, Highest Scoring High PRA Candidates
- Local Waiting List, Surpassed Pediatric Goals
- Original intended candidates for living donor organs who meet the criteria for this priority as described below, **by time waiting in order of donation date of their respective original intended living donor** if more than one. See note 3 below.
- Other mismatched patients according to the standard algorithm.

Note 1: An exception to this priority exists for patients receiving kidneys with non-renal organs other than the pancreas.

Note 2: An exception to this priority exists for patients receiving kidneys with non-renal organs.

Note 3: An exception to this priority exists for patients receiving kidneys with non-renal organs. An exception to this priority may exist based upon preference assigned locally for patients considered medically urgent following a

¹ Terasaki PI, Cecka JM, Gjertson DW, Takemoto S. High Survival Rates of Kidney Transplants from Spousal and Living Unrelated Donors. *N Engl J Med* 1995; 333: 333.

cooperative medical decision of local kidney transplant centers under OPTN/UNOS Policy 3.5.11.4 (The Point System for Kidney Allocation – Medical Urgency).

The intent is to assign original intended candidates for living donor organs who meet the protocol's criteria sufficient priority in kidney allocation to get them transplanted expeditiously (i) without modifying priorities assigned for other candidates based upon unique utility and/or medical benefit of the kidney transplant, and (ii) acknowledging the standard order of kidney paybacks (debts/credits) in the national system.

Definition of Original Intended Candidate for Living Donor Kidney [No Proposed Changes to This Section]

Guidelines for Listing Patients as Original Intended Candidates for Living Donor Kidneys [No Proposed Changes to This Section]

Living Donor Considerations [No Proposed Changes to This Section]

Allocation of Living Donor Kidneys [No Proposed Changes to This Section]

Sign –up Process [No Proposed Changes to This Section]

Time Line [No Proposed Changes to This Section]

Analysis Plans [No Proposed Changes to This Section]

III. Public Comment Response

The proposal was issued to a mailing list of approximately 8,162 individuals and organizations for a comment period of 45 days beginning March 15, 2004, and ending April 29, 2004. As of April 29, 2004, 88 responses have been submitted to UNOS regarding this policy proposal. Of these, 43 (48.86%) supported the proposal, 1 (1.14%) opposed the proposal, and 44 (50.00%) had no opinion. Of the 44 who responded with an opinion, 43 (97.73%) supported the proposal and 1 (2.27%) opposed the proposal. Of the 11 Regions, each Region supported the proposal, including 6 Regions unanimously. Comments on the proposal received to date and the Committee's responses are set forth below.

Some of the public commentary received expressed concerns that the proposal might disadvantage ABO blood type O candidates otherwise listed for kidney transplantation since it would be expected that a substantial number of the intended candidates receiving higher priority under the proposal would be ABO blood type O. During its May 19-20, 2004, meeting, the Committee reaffirmed its previously stated position with respect to blood group O candidates. While it is acknowledged that blood type O patients might be disadvantaged by the proposal, these candidates face relatively long waiting times apart from this proposal. The intent of the proposal is to increase organs available for transplantation generally so that individuals may be transplanted and removed from the Waiting List freeing up deceased donor organs for other candidates on the list. Candidates are benefited overall, although individual candidates may not realize an advantage. It is hoped that implementation of the protocol as a generic alternative allocation system will permit collection of data sufficient to determine if the policy does disadvantage blood type O candidates. The protocol's analysis plan specifically requires that impacts of the system upon candidates by blood group be studied. Appropriate modifications could then be made to the generic alternative system.

Responses to the public comment also expressed that a candidate from the transplant center of the original intended candidate should receive the living donor kidney that was incompatible with the original intended candidate. Some Members of the Committee also questioned whether the alternative allocation system should specify the allocation algorithm to be used for the intended living donor organs in order to ensure equitable distribution of the kidneys. The alternative system presently permits OPOs to elect how best to allocate the incompatible living donor kidney. While the proposed system does not specify the allocation algorithm, the Committee offered guidance in Appendix 2 for the allocation of incompatible living donor kidneys. Though the guidance does not constitute a requirement, the Committee's recommendation is for OPOs to follow the local standard allocation system, but acknowledged the practical issues that might indicate living donor nephrectomy and transplantation should occur in the same transplant center so as to minimize cold ischemic time, costs, and accidental loss of or damage to the kidney.

Some Members expressed that discretion over allocation of the living donor kidneys should remain with the OPO, but OPOs, as part of the application process, should be required to submit documentation specifying how the living donor kidneys will be allocated under this original intended candidate system. The intent is to ensure these kidneys are allocated equitably and appropriately based on a defined protocol, rather than by random selection. After further consideration, the Committee agreed to amend the proposal to require documentation of the living donor kidney allocation protocol as part of the application to participate in the system by a vote of 24 For; 0 Against; 0 Abstentions. OPOs still would be permitted discretion in terms of the protocol developed, but they would be required to define the protocol as part of the application process.

After further discussion, the Committee unanimously agreed to offer the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modification to the local voluntary alternative system for assigning priority in kidney allocation to original intended candidates having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee with an amendment, shall be approved and implemented pending programming on the UNOS System:**

Goal

The primary goal of this prospective alternative system for kidney allocation is to facilitate kidney donation by living persons and increase the availability of organs for transplantation overall. Using live donor/paired candidate

registries in situations where the original intended candidate for a living donor kidney is incompatible with his/her living donor has been problematic historically due to factors such as size of that subgroup of the living-donor pool and inability to match donors to transplant candidates. Assignment of priority for deceased donor kidney allocation to the original intended candidate (IC) when the patient's intended donor donates to a candidate on the list of patients waiting for a deceased donor kidney provides a mechanism to expand this pool of potential donors for the living donor's original intended candidate. The alternative system acknowledges the ABO or HLA antigen factor resulting in incompatibility between donor and candidate that prevented the intended live donor organ transplant to occur. It also acknowledges the difference in expected graft survival between a living donor kidney transplant and a deceased donor kidney transplant (*i.e.*, > 80% vs. > 70% 3-year graft survival²). A primary principle of the system is, therefore, to get the original intended candidate transplanted expeditiously.

System Background and Rationale [No Proposed Changes to This Section]

System Design

The following allocation sequence will not supercede the allocation algorithm (OPTN/UNOS algorithm or local alternative system) used by the participating OPO, but will be superimposed on to their allocation algorithm. It will apply only at the local level of organ allocation. Transplant programs participating in the alternative system are required to provide appropriate guidance to living donors and patients who elect to take part in this system to enable understanding by these individuals of how the system works.

Allocation Sequence

- Zero antigen mismatched combined kidney/pancreas patients who are highly sensitized (*i.e.*, panel reactive antibody (PRA) level \geq 80%). See note 1 below.
- Zero antigen mismatched isolated kidney patients. See note 2 below.
- Prior living donors subsequently listed for kidney transplantation.
- UNOS Paybacks (Debits/Credits)
- Local Waiting List, Highest Scoring High PRA Candidates
- Local Waiting List, Surpassed Pediatric Goals
- Original intended candidates for living donor organs who meet the criteria for this priority as described below, **by time waiting in order of donation date of their respective original intended living donor** if more than one. See note 3 below.
- Other mismatched patients according to the standard algorithm.

Note 1: An exception to this priority exists for patients receiving kidneys with non-renal organs other than the pancreas.

Note 2: An exception to this priority exists for patients receiving kidneys with non-renal organs.

Note 3: An exception to this priority exists for patients receiving kidneys with non-renal organs. An exception to this priority may exist based upon preference assigned locally for patients considered medically urgent following a cooperative medical decision of local kidney transplant centers under OPTN/UNOS Policy 3.5.11.4 (The Point System for Kidney Allocation – Medical Urgency).

² Terasaki PI, Cecka JM, Gjertson DW, Takemoto S. High Survival Rates of Kidney Transplants from Spousal and Living Unrelated Donors. *N Engl J Med* 1995; 333: 333.

The intent is to assign original intended candidates for living donor organs who meet the protocol's criteria sufficient priority in kidney allocation to get them transplanted expeditiously (i) without modifying priorities assigned for other candidates based upon unique utility and/or medical benefit of the kidney transplant, and (ii) acknowledging the standard order of kidney paybacks (debts/credits) in the national system.

Definition of Original Intended Candidate for Living Donor Kidney [No Proposed Changes to This Section]

Guidelines for Listing Patients as Original Intended Candidates for Living Donor Kidneys [No Proposed Changes to This Section]

Living Donor Considerations [No Proposed Changes to This Section]

Allocation of Living Donor Kidneys

The proposed protocol does not direct how kidneys procured from living donors who elect to take part in the system shall be allocated. The committee does offer guidance with respect to allocation of these organs as set forth in Appendix 2 of this document [Appendix 2 is included as **Exhibit []** to this report for reference]. **Additionally, applications to participate in the system must include a description of the protocol that will be used to allocate living donor kidneys from donors who are incompatible with their original intended candidate.**

Sign-up Process [No Proposed Changes to This Section]

Time Line [No Proposed Changes to This Section]

Analysis Plans [No Proposed Changes to This Section]

[Please see **Exhibit []** for proposed modifications to Appendix 3, Application to Participate in the Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys, consistent with changes noted above.]

I. Individual Comments:

Comment 1:

vote: Oppose

The center goes through an enormous amount of work to work up the donor and convince the donor to donate a kidney to the pool even if the recipient on that center's waiting list cannot receive the related living donor kidney. Thus, it is abundantly reasonable to expect that the cadaveric kidney recipient chosen to receive this wonderful gift should be the recipient on top of the cadaveric waiting list at the same program of the intended living donor recipient. If this is not the case, we would certainly not go through all the extra work that is necessary to get this done.

Committee Response:

Some Members of the Committee also questioned whether the alternative allocation system should specify the allocation algorithm to be used for the intended living donor organs in order to ensure equitable distribution of the kidneys. The alternative system presently permits OPOs to elect how best to allocate the incompatible living donor kidney. While the proposed system does not specify the allocation algorithm, the Committee offered guidance in Appendix 2 for the allocation of incompatible living donor kidneys. Though the guidance does not constitute a requirement, the Committee's recommendation is for OPOs to follow the local standard allocation system, but acknowledged the practical issues that might indicate living donor nephrectomy and transplantation should occur in the same transplant center so as to minimize cold ischemic time, costs, and accidental loss of or damage to the kidney.

Some Members expressed that discretion over allocation of the living donor kidneys should remain with the OPO, but OPOs, as part of the application process, should be required to submit documentation specifying how the living donor kidneys will be allocated under this original intended candidate system. The intent is to ensure these kidneys are allocated equitably and appropriately based on a defined protocol, rather than by random selection. After further consideration, the Committee agreed to amend the proposal to require documentation of the living donor kidney allocation protocol as part of the application to participate in the system.

Comment 2:

vote: Support

Approve with comment. I support this proposal but when it is passed I suggest that you send out the description of the "Sign Up Process" that is referred to in the last lines (page 6 of the Public Comment Document) again. Most people will not remember that it was included as an Appendix in the previous Public Comment Document.

Committee Response:

The Committee appreciates the response; however, since the application information was previously submitted for public comment and approved by the Board of Directors, and since an additional public comment submission would dramatically delay the implementation of the proposal, the Committee agreed to submit the proposal to the Board for approval. The Committee would be pleased to redistribute notice of availability of the alternative system, along with the application.

Comment 3:

vote: Support

I support this proposal because it would go farther to make the waiting period less stressful on donor/family/recipient if the intended organ was not a good match, but a suitable replacement would be immediately available,

Committee Response:

The Committee appreciates the response.

Comment 4:

vote: Support

Let's get it programmed and begin. We are ready.

Committee Response:

The Committee appreciates the response.

Comment 5:

vote: No Opinion

I understand this proposal would give extra credit to those waiting if their intended living donor proved incompatible but went on to donate to the list. I am a little concerned about this and although the hope is to increase donation--I would be very careful about the potential donor feeling coerced to go on and donate to someone they do not know. This is a tough situation and there needs to be careful guidelines on how this is discussed with the donor. I donated to my sister but most likely, would have not felt compelled to donate to a stranger (until deceased.) The living donor is interested in the person who may be family or friend. As a family, we would have continued to find a donor. I doubt I would have given to the list. If someone willingly offers to still donate--this is like a non-directed donation. Fine and OK to give extra to the candidate.

Committee Response:

The Committee acknowledges concerns with living donors feeling coerced to donate in any situation. However, transplant centers and OPOs are capable of and responsible for educating the living donor and intended candidate and obtaining informed consent.

II. Comments from Other Committees:

Ethics Committee - The Committee found the proposal to be ethically acceptable based on current and historical practice.

Ad Hoc Living Donor Committee - The Committee supported the modifications. Committee vote: 19 in favor, 0 opposed, 0 abstentions.

Organ Availability Committee - The Committee unanimously supports this proposal as written.

Patient Affairs Committee - The Committee supports the proposed policy by a vote of 16-0-0.

III. Regional Comments:

REGIONAL COMMENT SUMMARY

PROPOSAL 1: Proposed Modifications to Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys (Kidney and Pancreas Transplantation Committee)

Sponsoring Committee: Kidney and Pancreas Transplantation

Description: The proposal would clarify a previous Committee proposal approved by the Board to create a generic alternative system that would provide priority in the kidney allocation system for original intended candidates (ICs) for living donor kidneys who are incompatible with their living donors due to crossmatch results or ABO blood type, when the living donors donate to candidates on the list of patients waiting for deceased donor kidneys.

Under the proposal, ICs would be ranked, in situations where more than one IC appeared on a match run, in order of date of donation from the living donor. The term “time waiting” would be eliminated from this portion of the alternative system so as not to be confused with the standard meaning of candidate waiting time. The intent of the alternative system approved by the Board was to facilitate kidney donation by living persons and increase the availability of organs for transplantation overall. The present proposal is intended to assign priority among ICs when more than one in a manner that better reflects the alternative system’s overall objectives.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	14 yes, 0 no, 0 no opinion			
2	5/7/04	29 yes, 2 no, 1 no opinion			
3	3/26/04	17 yes, 0 no, 0 no opinion			
4	4/2/04	21 yes, 4 no, 3 no opinion			
5	4/30/04	32 yes, 1 no, 3 no opinion			
6	4/2/04	52 yes, 0 no, 0 no opinion, 1 no vote			
7	4/23/04	16 yes, 0 no, 0 no opinion			
8	4/02/04	25 yes, 0 no, 0 no opinion			
9	4/21/04	18 yes, 0 no, 1 no opinion			
10	4/30/04	19 yes, 0 no, 0 no opinion			
11	3/26/04	19 yes, 0 no, 1 no opinion			

COMMENTS:

Region 2: Although the region approved the proposal, there was support for UNOS monitoring the blood type O candidates in area's where this system is implemented to make sure these candidates are not disadvantaged.

Committee Response:

The Committee reaffirmed its previously stated position with respect to blood group O candidates. While it is acknowledged that blood type O patients might be disadvantaged by the proposal, these candidates face relatively long waiting times apart from this proposal. The intent of the proposal is to increase organs available for transplantation generally so that individuals may be transplanted and removed from the Waiting List freeing up deceased donor organs for other candidates on the list. Candidates are benefited overall, although individual candidates may not realize an advantage. It is hoped that implementation of the protocol as a generic alternative allocation system will permit collection of data sufficient to determine if the policy does disadvantage blood type O candidates. The protocol's analysis plan specifically requires that impacts of the system upon candidates by blood group be studied. Appropriate modifications could then be made to the generic alternative system.

GUIDANCE FOR UNDIRECTED LIVING ORGAN DONATION

Developed by the OPTN/UNOS Kidney and Pancreas Transplantation Committee & Approved by the OPTN/UNOS Board of Directors, with an Amendment, on November 16 – 17, 2000

RECOMMENDATIONS:

1. Living donor nephrectomy and transplantation into the recipient should occur in the same transplant center. Rationale: Presently, any transportation from one center to another introduces logistic factors such as increased cold ischemic time, cost, accidental loss of or damage to the kidney. None of these factors improves outcome, and such risk should be avoided in the earliest development of undirected donor renal transplant.
2. None of the expenses of evaluation or donor nephrectomy should be borne by the donor or the donor's health insurer. The donor already shoulders the burden of time lost from employment or leisure. The recipient's insurer derives the benefit of reduced long-term expense for ESRD care achieved through transplantation.
3. In 1999, the overarching concept for the recommendations that follow recognizes undirected living kidney donation as a "Donor Driven Process". Each organization and the processes involved must support the donors' needs optimally. These needs include education, emotional & spiritual support, time away from work, time away from family, degree of anonymity requested, convenience and simplicity.

The committee members are impressed by the strength of character one must possess to volunteer as an undirected living kidney donor. Whether these donors will ever account for a substantial fraction of kidneys transplanted remains to be seen. But for our waiting recipients, even a single kidney is a significant contribution to our needs. At the beginning of this endeavor, we must be careful to avoid forcing these donors' broad altruism into narrow channels dug deeply by our preconceptions of how this process should work. These strong individuals will help teach us how to make this process work, if we are willing to listen.

Several committees have commented on the degree of anonymity which is desirable. The Pediatric Committee felt strongly that absolute anonymity should be the rule, as in blood banking, for instance. It is clear that the donor's wishes regarding the degree of anonymity desired **must** be respected. Each transplant center must develop policy and procedure to achieve the anonymity desired by the donor. Potential donors should be advised that, despite the transplant center's very best efforts, complete anonymity may not be possible in all circumstances.

4. Referral of an undirected living donor to a transplant center for evaluation will occur in one of two ways:
 - (A) The donor contacts someone or an organization which is not a transplant center {such as a primary care physician, a local (non-transplant center) hospital, an OPO, a blood bank, or an organization like the NKF, ADA or UNOS, etc}. The donor should be encouraged and politely, expeditiously and neutrally referred to the nearest transplant center(s). Such an individual or institution should defer counseling to the transplant center. UNOS may wish to assist OPO's in clearly defining the OPO's responsibilities, and encouraging the OPO's to disseminate these responsibilities to other local institutions likely to be approached by undirected living donors. For OPO's serving more than one transplant center, the donor should be encouraged to contact each of the centers, discuss the center's policies and procedures, and chose one of the centers to begin evaluation and counseling. For OPO's serving a single transplant center, it may be wise to provide the donor with at least one other nearby center to contact for additional opinions. This should be left to the discretion of the OPO based upon relevant circumstances. Neutral parties should remain neutral throughout this process.
 - (B) The donor contacts a transplant center {or a recipient they know on the list}, which begins the donor's education, counseling, evaluation and preparation for donor nephrectomy. Each transplant center should counsel the donor ethically without impediment to referral to other centers. In the process of education and

counseling, a donor may chose to donate to a recipient (based on matching or other criteria) listed at another center locally, regionally, or nationally. Recipient selection should be defined by center protocols that minimize any action that can be deemed discriminatory and are acceptable to the donor.

5. Evaluation of undirected living kidney donors. As soon as a transplant center meets and counsels a potential donor, then that donor becomes, to some degree, a directed donor. Certainly, donation may be directed to recipients listed at the evaluating center, or the donor may wish to consider the results of tissue typing, and transfer their care to another center in order to achieve directed donation to a particular well-matched recipient.

Transplant centers wishing to pursue undirected living donor kidney transplantation must develop protocols to evaluate and meet these donors needs for motivation, mental health, anonymity, convenience, simplicity, and success. Transplant centers should establish positions for a donor advocate to help counsel these individuals. The committee recommends leaving the details of psychological assessment and management of living donors to each program. However, the committee strongly recommends that each donor receive thorough mental health assessment by an experienced psychiatrist or clinical psychologist familiar with the unusual issues involved in these transplants. Additionally, living donors may experience changes in their ability to obtain health and life insurance as a result of the donation; this possibility should be discussed with potential donors.

6. Once the anonymous donor has been reasonably approved to proceed with kidney donation, allocation of the kidney to a recipient must be performed according to defined, written protocols in each center. Such protocols should consider the following issues (A) When feasible, zero mismatch allocation should be a priority. (B) The UNOS match run should be performed. (C) Allocation should be to the highest priority recipient with a prospective negative cross match. (D) The evaluating center should refer the donor to the recipient transplant center identified in (C) above if such referral is in keeping with the donor's wishes. (E) Allocation should **not** be driven by a donor's desire to benefit a specific class of individuals.

7. The Committee for Minority Affairs counsels that each transplant center review with greatest scrutiny: (a) the potential for exploitation of the donor; (b) the potential for financial compensation of the donor through the gift; (c) the allocation system; (d) maximizing the benefit of living donation through anonymous living donors; (e) elimination of all encouragement or suggestion of practices which may be potentially discriminatory.

8. The committee notes the recommendation of the Transplant Administrators Committee that charges may need to be passed through the donor's insurance first, for denial, before being appropriately billed to the recipient. The financial coordinators must pay detailed attention to prevent inappropriate charges to the donor and breaches of donor anonymity.

ANTICIPATED QUESTIONS:

Q. Shouldn't every possible kidney go to a 0 mis-matched recipient?

A. We don't do this for living directed donation. Some undirected donors' altruism may be tested beyond their limit by requiring travel to a distant center. For those whose altruism can embrace the hardships imposed by such a concept, a "Donor Driven Process" will permit these transplants to occur, despite the logistic problems.

Q. Can prisoners be undirected living kidney donors?

A. The committee believes, unanimously, that prisoners should be excluded.

Q. How does an OPO employee respond to a potential undirected living kidney donor who says, "Gee, I don't know which transplant center to choose. You decide." ?

A. "I've given you the names of all the transplant centers in town and the phone numbers of their coordinators who can help get you started on this decision. You can call these centers for further information, or you

may want to ask your personal physician about her opinion. Keep in mind that your gift involves medical care options for you as well as the individual you are helping. With medical treatment, in general, there can be more than one opinion about what is optimal. I want to be certain that you have all appropriate information in this process.”

- Q. What if the donor doesn't follow through on such a vague recommendation to contact all the local transplant centers?
- A. People who are truly committed to the idea of undirected living donation of a kidney are unlikely to be stopped by such a vague recommendation, and more likely to appreciate the unbiased information.
- Q. How on earth are we going to get the message to all the outfits that might be contacted by a potential donor?
- A. In fact, identifying and contacting these institutions will strengthen the relationships of our OPO's with many influential people, and provides an opportunity to educate about the importance of organ donation.
- Q. Come on now, shouldn't all these donors be going only to transplant centers that do laparoscopic nephrectomy? (Or sooper dooper immunosuppression?)
- A. Because technology is constantly evolving, it is very appropriate for one of the “neutral” third party institutions (such as OPO) to inform the potential donor that there are two approaches to removing a donor kidney (several approaches to immunosuppression), and they will want to inquire about each program's approach to the nephrectomy procedure (immunosuppression) without biasing the patient as to which program should be chosen.
- Q. We think we can work this out in our local allocation unit on a rotating basis.
- A. Good. But maybe these donors respond better by helping them explore and find what they want than by assignment. Nothing recommended above would absolutely preclude such a creative solution. A good test of alternative allocation solutions is whether the allocation is “donor driven” and responsive to the special needs and desires of each donor.

Model Transplant Service Humanitarian Living Donor Protocol

1. Prior to referral to transplant service: If donor referred by another agency, organ procurement service, blood bank, etc., they are supposed to have been referred impartially to all local transplant centers. At first contact, donors may simply be shopping for which center they will choose.
2. Potential donor calls to transplant service: Calls taken by social worker. Intake information obtained. Plan & process spelled out to potential donor by social worker.
3. Packet of information sent to donor, including print/audiotape/videotape information on living donation.
4. Preliminary (1st) Transplant Center visit.
 - A. Social worker visit & evaluation
 - B. Coordinator evaluation
 - C. Surgeon *or* Nephrologist evaluation
 - D. Items to be addressed: use videos and packet of literature as appropriate
 - i. Hypertension (BP), diabetes (GTT), urinalysis, 24 urine collection (?)
 - ii. Nature of kidney transplantation today
 - iii. Number of recipients waiting & list growth
 - iv. Why people are waiting longer
 - a. No live donor for some recipients
 - b. Sensitization of some recipients, some by disease process, transfusion, prior transplant
 - v. Risks to live donor
 - a. Nature of the procedure
 - b. Morbidity of procedure
 - c. Mortality of procedure
 - d. Future risk of renal failure
 - e. Risks of rejection and graft failure in recipient
 - vi. Ethics & logic of using live donors
 - a. No harm to donor
 - b. Better kidney for transplant to recipient
 - c. Procedure needs to be performed at the same hospital as recipient in order to achieve optimal benefit of live donation.
 - d. Therefore, transplant will be a directed donation
 - e. Nature of gift, not for sale, or exchange
 - E. Initial assessment of donor's values
 - i. Anonymity
 - ii. Willingness to travel. How far? How long?
 - iii. Time from work, lost income
 - iv. Time from family
 - (4.E.) v. Inconvenience
 - vi. Pain & possible morbid complications
 - vii. Unavoidable proximity to recipient & recipient family during hospitalization and clinic follow up.
 - F. Introduction to logistics
 - i. Next step is to refer donor to center for further evaluation and directed donation
 - ii. Need donor to direct us how to proceed in choosing a recipient (and therefore) which transplant center will do surgery.
 - iii. Options include:

- a. Donor wishes to visit the other center(s)
 - b. Donor wishes to stay with transplant center, implied consequences (how we will assign a donor)
 - c. Donor wishes more data, wants to donate based on match. Move to tissue typing & run list.
5. Psychiatry evaluation
 - A. Freedom from duress
 - B. Nature of altruism
 - C. Motivation, nature of gift
 - D. Post-donor depression
 - E. Review of potential (low-probability) events, acceptable reality testing (see attached list of events)
 6. Complete tests, assessments, immunology
 7. Identify directed recipient by running match list
 - A. Secure consent from directed recipient for living donation.
 - B. Introduction of donor and recipient, if desired by both.
 8. Follow-up (2nd) transplant center visit: Nephrologist *or* surgeon evaluation (whichever not done at first evaluation); ? follow-up social work evaluation
 9. Angiogram/MRA: to assess donor vascular anatomy
 10. Schedule surgery
 11. Follow protocol for living donor renal transplant for transplant event.

MAINTAIN ANONYMITY AS DESIRED BY DONOR

Low Probability Events to be Reviewed with Humanitarian Donors

What should we do if...?

1. Kidney has been removed but it is not wise to proceed with transplant into donor as originally planned?
2. Three months after transplant recipient is not doing well or has lost (rejected) the transplant?
3. You get kidney failure after 15 years and need dialysis?
4. It is 2 days post transplant and all the conversation is about how the kidney is doing in the recipient?
5. People from the media wish to talk to you? Can we (Should we) publicize this exciting form of transplant?

UNITED NETWORK FOR ORGAN SHARING (UNOS)

APPLICATION TO PARTICIPATE IN THE LOCAL
VOLUNTARY ALTERNATIVE SYSTEM FOR ASSIGNING
PRIORITY IN KIDNEY ALLOCATION TO ORIGINAL
INTENDED CANDIDATES FOR LIVING DONOR KIDNEYS

General Requirements

Applications to participate in the Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys may be submitted by OPOs, OPTN Members participating in an OPTN-approved Alternative Local Unit (ALU) or OPTN Members participating in an OPTN-approved sharing arrangement. In each case, the application must be supported by each OPO and transplant center that is to take part in the alternative system. If an OPO includes multiple local units (ALUs), all local units must agree to participate. Please mail completed applications to:

Director of Membership and Policy Development
United Network for Organ Sharing
700 North 4th Street
Post Office Box 2484
Richmond, Virginia 23218

Application Submission

For an application to be considered complete, it must include the following information:

1. Provide the name, mailing address, contact person, and telephone number for the transplant center(s) and OPO(s) that will participate in the alternative system.
2. The alternative system must be specified in writing and contain a statement of agreement that is signed and dated by the representative of the OPO(s) and transplant center(s) that will participate in the alternative system.
3. For those OPOs with multiple local units (ALUs), signatures must be obtained from each transplant center within the OPO indicating that they agree to participate in the alternative system.
4. Provide a description of the protocol that will be used to allocate living donor kidneys from donors who are incompatible with their original intended candidate. Please refer to Appendix 2 for guidance in this regard.

Members already operating with an approved alternative system for kidney allocation are advised to assess the implications of participating in multiple alternative systems and any expected impacts of the protocols, positive and negative, upon each other.

System Participation

Participation in the Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys shall be effective upon receipt of a completed application by UNOS; the alternative system will commence pending completion of computer programming.

Exceptions to Standard Alternative System Applications/Requirements

Pursuant to OPTN/UNOS Policy 3.1.9 (Alternate Point Assignments), an OPO, OPTN Members participating in an OPTN approved ALU or OPTN Members participating in an OPTN approved sharing arrangement may assign to each of the point system criteria set forth in OPTN/UNOS organ allocation policies 3.5 through 3.16 a number of points other than the number of points set forth in such policies for allocation of local organs with the prior approval by the OPTN/UNOS Board of Directors. Policy 3.1.9 stipulates several requirements for participation in an alternative system, including approval by the Board and data submission requirements. Pending final approval by the OPTN/UNOS Board of Directors it is agreed that local unit participants in the Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys are not required to: submit individual applications to participate in the study to OPTN/UNOS Committees; obtain approval of the Board to participate; obtain Region input; or submit additional alternative system data outside of the specific data submission requirements of the study. All other aspects of Policies 3.1.9 and 3.4.6 will still apply to participants in the original intended candidate alternative system. Participants are required, for example, to stay aware of all applicable provisions of the OPTN/UNOS organ allocation policies and any amendments thereto ("policy requirements") as well as all other OPTN/UNOS By-Laws and policies.

Study to Assess the Effects of A Proposed Alternative System to Calculate Kidney Waiting Time from the Earlier of the Dates of First Dialysis or GFR/CrCl < 20 ml/min

Kidney and Pancreas Transplantation Committee
 Minority Affairs Committee
 November 21, 2003

Hypotheses

- The proposed alternative system will
 - Increase access for minorities
 - Increase access for patients with ESRD whose only insurance is Medicare or Medicaid
 - Will not delay time to kidney transplant referral for patients with ESRD
 - Will not adversely effect case mix resulting in poorer post-transplant outcomes

Kidney Allocation

- Current: Earlier of the dates of waitlisting or GFR/CrCL < 20 ml/min
- Proposal: Earlier of the dates of first dialysis or GFR/CrCl < 20 ml/min

Methodology

- Time to event models
- Duration three years
- Adjusted for age, gender, cause ES RD, incidence year, race, ethnicity, comorbidities, dialysis unit type, DSA. Insurance
- Censored at death, living donor transplant, or end of study

Methodology

- Compare outcomes in participating DSAs before and after policy instituted
- Compare outcomes between participating and nonparticipating DSAs

Increase Minority Access

- Number of minority kidney transplants
- Ratio of minority kidney transplant recipients to the minority candidate pool
- Ratio of minority kidney transplant recipients to the minority ESRD populations
- Ratio of minority candidate pool to the minority ESRD populations

Increase Access for Patients with Medicare and Medicaid (M&M)

- Number of M&M kidney transplants
- Ratio of M&M kidney transplant recipients to the M&M candidate pool
- Ratio of M&M kidney transplant recipients to the M&M ESRD population
- Ratio of M&M candidate pool to the M&M ESRD population

Time to referral

- Trends in interval between date of first dialysis and waitlisting date for minority and non-minority populations
- Trends in preemptive listing

Survival

- Waitlist survival
- Post-transplant kidney allograft survival
- Post-transplant patient survival

Study to Assess the Effects of A Proposed Alternative System to Calculate Kidney Waiting Time from the Earlier of the Dates of First Dialysis Regardless of Listing Date or GFR/CrCl \leq 20 ml/min but no Earlier than Listing Date

Proposal

The current allocation system stipulates that waiting time begins at the earlier of the dates of First Dialysis/GFR/CrCl \leq 20 ml/min, provided that no time accrues prior to the date of listing. The proposed system would change this to permit kidney waiting time accrual to commence for primary transplant candidates, from the time of initiation of chronic maintenance dialysis once listed as an active transplant candidate even if this time pre-dates the date of listing, and for repeat transplant candidates, from the date the candidate returns to chronic maintenance dialysis after graft failure once re-listed even if this time pre-dates the date of re-listing. The system does not change current policy allowing a patient's waiting time to accrue upon attaining a creatinine clearance level or calculated GFR of 20 ml/min or less, with no time accrued based upon these criteria prior to the date of the patient's listing.

Statistical Methodology

Hypotheses

The primary endpoint of the study is time from dialysis until transplantation. The study is designed to minimize disparities in this time among ethnic groups, regardless of when patients are placed on the waiting list.

It is also hypothesized that the study will result in improvements in access to transplantation while not having deleterious effects on referrals to transplantation or transplant outcome.

Specifically, the hypotheses are that the system:

- Will increase likelihood of transplant for minorities
- Will increase likelihood of transplant for patients with ESRD whose only insurance is Medicare or Medicaid
- Will not delay time to kidney transplant referral for patients with ESRD
- Will not adversely effect case mix resulting in poorer post-transplant outcomes.

Enrollment Period

In order to minimize changes over time, consider having all DSA's that wish to participate enroll during the first year or some time period to be determined so that the comparison groups will be more similar. [Note: In the original proposal, DSA's were permitted to enroll during the entire initial three-year study period.]

Study Design

Each outcome will be compared between Donor Service Areas (DSAs) that elect to participate in the study (given 100% approval by all transplant programs in their service area) and those DSAs that choose not to participate. Outcomes within participating DSAs will also be compared before and after the policy is implemented. The initial study period will be three years.

Questions:

- 1) Should all non-participating DSAs be included, or only DSAs who use the “standard” national allocation system? Perhaps a comparison of only the “Standard” system DSAs should be considered as a subset analysis.
- 2) Do analyses need to be stratified by adult vs. pediatrics, or some perhaps limited to just adults?

Statistical Methods

Multivariate Cox regression and Logistic regression models will be used to assess the outcomes of the study. These models will be adjusted for important recipient characteristics, including, but not limited to, the following: age, gender, cause of ESRD, incidence year (year dialysis initiated and year added to the waiting list), race, ethnicity, comorbidities (such as: ...), dialysis unit type (private unit or hospital-related unit), DSA, insurance type. Time to event models will be censored at death, living donor transplant, or at the end of the study.

Definitions

Unless stated otherwise, the following definitions apply below:

Number of transplants refers to all transplants during the study period.

Number of candidates refers to all candidates ever on the waiting list during the study period.

ESRD population refers to all patients on dialysis (Are there any exclusions here to limit this population to so-called ‘potentially eligible’ transplant candidates, or is this truly all dialysis patients?)

Minimizing Waiting Time Disparities

Multivariate Cox regression models of time to transplant since dialysis initiation will be used to compare for differences among ethnic groups, while controlling for important risk factors as listed above.

Question:

- 1) Will competing risk models be used? Removals for other reasons, particularly death, may influence the probability of transplant if not considered in the competing risk framework.

Improving Access for Patients Regardless of Ethnicity

Endpoints include:

- Number of kidney transplants during the study period by ethnicity, overall and within DSA
- Ratio of kidney transplants to candidate pool by ethnicity, overall and within DSA
- Ratio of kidney transplant recipients to ESRD population by ethnicity, overall and within DSA
- Ratio of candidate pool to ESRD population by ethnicity, overall and within DSA

Question:

- 1) Are these factors to be compared statistically? If so, will adjustments be made, or will these be univariate comparisons?

Improving Access for Patients Regardless of Insurance

Endpoints include:

- Number of kidney transplants by insurance status, overall and within DSA
- Ratio of kidney transplants to candidate pool by insurance, overall and within DSA
- Ratio of kidney transplant recipients to ESRD population by insurance, overall and within DSA
- Ratio of candidate pool to ESRD population by insurance, overall and within DSA

Insurance status is categorized using standard definitions (e.g., Medicare only, Medicaid only, Medicare & Medicaid, Medicare & Group Health, HMO, Medicare & Other, Other)

Question:

- 1) Are these factors to be compared statistically? If so, will adjustments be made, or will these be univariate comparisons?

Time to Referral

Endpoints include:

- Trends in interval between date of first dialysis and waitlisting date by ethnicity
- Trends in pre-emptive listing

Question:

- 1) Are these factors to be compared statistically? If so, will adjustments be made, or will these be univariate comparisons?

Survival

Endpoints include:

- Waitlist survival
- Post-transplant kidney allograft survival
- Post-transplant patient survival

Multivariate Cox regression models of survival will be used to assess waiting list and post-transplant survival. All models will be adjusted for important recipient characteristics, and post-transplant models will also be adjusted for donor characteristics such as DCD and ECD status.

Questions:

- 1) What specific endpoints will be examined?
- 2) Any consideration of delayed graft function?
- 3) Will post-transplant analyses be limited to deceased donor kidney transplants?
- 4) What time periods will be considered, and how much follow-up will accrue prior to analysis?

Other (Intended and Unintended) Consequences of the Study

Endpoints include:

- Numbers (and percentages) of diabetic candidates receiving additional waiting time compared to non-diabetics, along with comparisons of appropriate measures of waiting time gained.

- Numbers (and percentages) of adult candidates receiving additional waiting time compared to pediatric candidates, along with comparisons of appropriate measures of waiting time gained.
- Numbers (and percentages) of pediatric candidates being transplanted by their time thresholds to transplant, broken down by deceased and living donor kidneys.
- Numbers (and percentages) of patients receiving additional waiting time, along with appropriate measures of waiting time gained, by ethnicity and socio-economic status (*need to define*).
- For transplants during the study period, profile of recipient characteristics that are factors in kidney allocation (e.g., HLA mismatch level, PRA, age) to see what impact the change of emphasis on waiting time has on allocation in general.
- For transplants during the study period, number (and percentage) of transplant recipients listed prior to policy implementation and those listed after policy implementation.

Global Questions:

- Need to specify which analyses will utilize OPTN or USRDS data?
- Power/Sample Size considerations?
- How will the bolus effect of grandfathering patients be considered?
- What about a “washout” period – how long is it expected to last?
- How far back will the pre-policy cohort extend?
- Will multi-organ transplants and candidates waiting for multi-organ transplants be excluded?
- Will all analyses be limited to local transplants, since this change will involve allocation only at the local level?
- Current OPTN/UNOS policy stipulates that waiting time begins at “initiation of dialysis,” and this is what is entered on the waiting list. The study protocol stipulates that waiting time will begin at the time of “initiation of chronic maintenance dialysis.” The definition of chronic maintenance dialysis, as stated by CMS, is “dialysis that is regularly furnished to an End-Stage Renal Disease (ESRD) patient in a hospital based, independent (non-hospital based), or home setting.” Will the standard policy be changed to reflect this definition as well, or will accommodations be made for the differing definitions?

System Design

The following study allocation protocol will apply only at the local level of organ allocation. Therefore, candidate waiting time will be calculated according to the study protocol design for purposes of local kidney allocation, and according to the standard national allocation system for purposes of non-local kidney allocation. Transplant programs participating in the study are required to provide appropriate guidance to their candidates to enable their understanding of how all provisions of the protocol work.

The study allocation protocol modifies when a candidate’s waiting time may commence. Under current OPTN/UNOS Policy 3.5.1.1 (Time of Waiting), “time of waiting” begins for candidates

aged 18 years and older as of the time an active candidate meets the following minimum criteria and this information is recorded on the UNOS Computer:

- measured (actual urinary collection) creatinine clearance level or calculated GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min; or
- initiation of dialysis

Under the study protocol, the initiation of dialysis criterion is modified to be initiation of chronic maintenance dialysis. For primary kidney transplant candidates, time of waiting does not precede the date of the candidate's listing in the case of qualification by measured creatinine clearance level or calculated GFR; however, time of waiting may precede the date of the candidate's listing in the case of qualification by initiation of chronic maintenance dialysis prior to the time of the candidate listing. In addition, time of waiting for candidates who experience graft loss and seek a subsequent kidney transplant begins when the candidate is re-listed for transplantation and as of the time the patient returns to or begins chronic maintenance dialysis following loss of the graft, or when measured (actual urinary collection) creatinine clearance level or calculated GFR (Cockcroft-Gault or other reliable formula) reaches 20 ml/min or less but not prior to the date of re-listing. Time of waiting for candidates aged less than 18 years old begins when the candidate is placed on the OPTN/UNOS Patient Waiting List; however, if such candidate began chronic maintenance dialysis prior to being placed on the waiting list, the candidate's time of waiting begins from the time of initiation of chronic maintenance dialysis. The system applies to both standard donor and expanded donor kidney allocation point systems.

Definition of Chronic Maintenance Dialysis

For purposes of this study, chronic maintenance dialysis is defined as dialysis that is regularly furnished to an End-Stage Renal Disease (ESRD) patient in a hospital based independent (non-hospital based), or home setting.

Sign-Up Process

This study protocol will allow any local unit that wishes to participate to do so simply by submitting a study enrollment application (Appendix 1) to the UNOS Membership and Policy Department. To participate in this study, individual local units are not required to submit data other than as specified in the study protocol and discussed in this document, or obtain Committee review, Board of Directors approval, or Region input prior to their participation. Documentation of relevant OPO Board approvals (signatures from UNOS OPO representatives) and unanimous approval by every renal and pancreas transplant center within the local unit wishing to participate (signatures from UNOS center representatives) must be submitted to UNOS staff as part of the application. As complete requests are received by UNOS, participants in the study will be added. Participants in the study are required to stay aware of and comply with all applicable provisions of the OPTN/UNOS organ allocation policies and any amendments thereto ("policy requirements") as well as other OPTN/UNOS By-Laws and policies. In addition, participants must comply with such other requirements as may be determined by the OPTN/UNOS Board of Directors.

OPOs or other local units that wish to participate in the system but do not have unanimous agreement among their affiliated organizations may apply to use the system or some derivation of it according to the standard requirements for requesting approval and implementation of an alternative allocation system, OPTN/UNOS Policies 3.1.9 (Alternate Point Assignment) and 3.4.6 (Application, Review, Dissolution, and Modification Processes for Alternative Organ Distribution or Allocation Systems).

UNITED NETWORK FOR ORGAN SHARING (UNOS)

APPLICATION TO PARTICIPATE IN THE STUDY TO PERMIT KIDNEY
WAITING TIME ACCRUAL TO COMMENCE FROM THE INITIATION
OF CHRONIC MAINTENANCE DIALYSIS

General Requirements

Applications to participate in the study to Permit Kidney Waiting Time Accrual to Commence from the Initiation of Chronic Maintenance Dialysis may be submitted by OPOs, OPTN Members participating in an OPTN-approved Alternative Local Unit (ALU) or OPTN Members participating in an OPTN-approved sharing arrangement. In each case, the application must be supported by each OPO and transplant center that is to take part in the study. If an OPO includes multiple local units (ALUs), all local units must agree to participate. Please mail completed applications to:

Director of Membership and Policy Development
United Network for Organ Sharing
700 North 4th Street
Post Office Box 2484
Richmond, Virginia 23218

Application Submission

For an application to be considered complete, it must include the following information:

1. Provide the name, mailing address, contact person, and telephone number for the transplant center(s) and OPO(s) that will participate in the study.
2. The study protocol must be specified in writing and contain a statement of agreement that is signed and dated by the representative of the OPO(s) and transplant center(s) that will participate in the study.
3. For those OPOs with multiple local units (ALUs), signatures must be obtained from each transplant center within the OPO indicating that they agree to participate in the study.

Members already operating with an approved alternative system for kidney and/or pancreas allocation are advised to assess the implications of participating in multiple alternative systems/algorithms and any expected impacts of the protocols, positive and negative, upon each other.

Study Participation

Participation in the study to Permit Kidney Waiting Time Accrual to Commence from the Initiation of Chronic Maintenance Dialysis shall be effective upon receipt of a completed application by UNOS; the study allocation protocol will commence pending completion of computer programming.

Exceptions to Requirements for Committee/Region/Board Consideration of Individual Applications

Local unit participants in the study to Permit Kidney Waiting Time Accrual to Commence from the Initiation of Chronic Maintenance Dialysis are not required to: submit individual applications to participate in the study to OPTN/UNOS Committees; obtain approval of the Board to participate; obtain Region input; or submit additional study data outside of the specific data submission requirements of the study. Participants are required to stay aware of and comply with all applicable provisions of the OPTN/UNOS organ allocation policies and any amendments thereto ("policy requirements") as well as all other OPTN/UNOS By-Laws and policies. In addition, participants must comply with such other requirements as may be determined by the OPTN/UNOS Board of Directors.

Proposed Modifications to OPTN/UNOS Policies 3.5.5 (Payback Requirements) and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals)

Summary

The proposed modifications, originally developed by the OPTN/UNOS Joint Kidney and Pancreas, Pediatric Transplantation, Minority Affairs and Histocompatibility Subcommittee, would elevate the priority at the local level of organ distribution assigned to high scoring high panel reactive antibody (PRA) candidates and pediatric candidates who surpassed their transplant goals ahead of payback debts and credits. This is supported by medical criteria justifying priority in allocation to highly sensitized patients and children versus no similar medical justification for payback offers specific to the patient group receiving the priority. The intent is to provide better opportunities for transplant for pediatric candidates who surpass their transplant goals as well as high PRA candidates who would rank ahead of these children but for the pediatric preference. The proposal was supported for public comment distribution by both the OPTN/UNOS Kidney and Pancreas Transplantation and Pediatric Transplantation Committees.

I. Background

Current OPTN/UNOS policy assigns four points to patients who are less than 11 years old and three points to patients who are 11 years old or older and less than 18 years of age. The purpose of these point assignments is to expedite access to deceased donor kidneys for pediatric transplant candidates. This is appropriate because young children and adolescents experience unique problems associated with dialysis and disruption to expected growth and development processes due to renal failure. Early reversal of the condition through transplantation can avoid the special problems of dialysis and ameliorate many of the adverse effects of end stage renal disease which confront these patients. Rapid treatment provides the best opportunity for reversing the growth and development deficits and preventing lifelong adverse consequences.

OPTN/UNOS policy expressly defines time thresholds to reach the objective of transplantation for children. These thresholds are listed in OPTN/UNOS Policy 3.5.11.5.2, and are as follows: within 6 months of listing for candidates 0-5 years old, within 12 months of listing for candidates 6-10 years old, and within 18 months of listing for candidates 11-17 years old. Pediatric candidates who surpass their transplant goal without receiving a transplant are assigned highest priority for kidney allocation, with exceptions for zero antigen mismatched patients, prior living organ donors, kidney payback offers, highly sensitized patients with higher priority, and patients in need of combined kidney/pancreas transplantation if preference is assigned to these multiple organ candidates locally. The spirit of the policies is to have pediatric patients transplanted before or by their respective time goals. If the goal date is exceeded, additional priority is assigned to increase their opportunity for timely transplantation.

The OPTN/UNOS Pediatric Transplantation Committee has for some time been studying impacts from the policy assigning additional priority in kidney allocation to children who have reached their time goals to transplant without receiving a transplant. Though the data demonstrate some improvement in overall transplant rates within pediatric time goals after implementation of the policy, this is largely due to increases in living donor kidney transplantation rather than deceased donor kidney transplantation and many pediatric candidates still are not receiving a transplant within their time goals. For example:

- Prior to the policy change in November 1998, 36 percent of all patients entering the national kidney waiting list between the ages of 0 and 5 years were transplanted (30% deceased donor, 6% living donor) within six months; 48 percent of this patient population was transplanted within 10 months.³ After the policy change, 43 percent of all patients entering the national kidney waiting list for this age group (since January 1, 2001) were transplanted (23% deceased donor, 20% living donor) within their time goal (6 months); 72 percent of all patients who had a

³ Four months beyond the time goal to transplantation was chosen for purposes of the study to provide a reasonable period of time to allow the additional allocation priority assigned under the policy to work.

chance to be transplanted within 4 months past their goal were transplanted (42% deceased donor, 30% living donor).

- Prior to the policy change, 53 percent of all patients entering the national kidney waiting list between the ages of 6 and 10 years were transplanted within 12 months (47% deceased donor, 7% living donor) and 63 percent were transplanted within 16 months (53% deceased donor, 9% living donor). After the policy change, 59 percent of all patients entering the national kidney waiting list for this age group (since July 1, 2000) were transplanted (36% deceased donor, 23% living donor) within their time goal (12 months); 77 percent of all patients who had a chance to be transplanted within 4 months past their goal were transplanted (51% deceased donor, 26% living donor).
- Prior to the policy change, 58 percent of all patients entering the waiting list between the ages of 11 and 17 years were transplanted within 18 months (47% deceased donor, 12% living donor) and 62 percent were transplanted within 22 months (50% deceased donor, 12% living donor). After the policy change, 71 percent of all patients entering the national kidney waiting list for this age group (since January 1, 2000) were transplanted (44% deceased donor, 27% living donor) within their time goal (18 months); 85 percent of all patients who had a chance to be transplanted within 4 months past their goal were transplanted (55% deceased donor, 30% living donor).

Percentage of Patients Entering the Waiting List Transplanted with Deceased Donor Kidneys		
Age	Prior to November 1998	After November 1998
0 – 5 Years (within Time Goal)	30%	23%
0 – 5 Years (within 10 Months)	36%	42%
6 – 10 Years (within Time Goal)	47%	36%
6 – 10 Years (within 16 Months)	53%	51%
11 – 17 Years (within Time Goal)	47%	44%
11 – 17 Years (within 22 Months)	50%	55%

II. Policy Proposal

The Pediatric Transplantation Committee also has examined why children are not getting transplanted once they reach their time thresholds even with the policy's additional allocation priority that is assigned for them. Based upon the same analysis referenced above, the most frequent reason for organ offer refusal 4 months past goal date for all pediatric age groups was listed as donor quality. Final organ disposition for organ offers refused for pediatric patients past their goal waitlist time was 79.4 percent (initial offers to 0-5year group), 85.4 percent (initial offers to 6-10year group), and 84.8 percent (initial offers to 11-17year group) to an adult patient at a different transplant center. For all age groups, at least 92 percent of all organ offers refused for pediatric patients past their goal waitlist time eventually transplanted are still surviving. It was noted that this is short or intermediate term graft outcome and does not measure how well the organ is functioning.

It also has been noted that pediatric physicians may be declining organ offers because they are looking for the best match possible for pediatric patients. Pediatric patients have more opportunity for multiple transplants over their lifetime than adult patients. Human leukocyte antigen (HLA) matching becomes extremely important in offering children the best match possible from the beginning to offer the best chance of survival, growth, and development. A separate proposal sponsored by the Kidney and Pancreas Transplantation Committee, also included in the public comment distribution, was submitted to further address issues of HLA matching for children in need of kidney transplantation. Expanded donor kidney offers also play a role in the number of organ offers declined on the basis of poor donor quality for pediatric candidates.

Another potential cause for pediatric candidates not receiving a transplant within their time goals is variations at the local level with respect to kidney payback debts owed by and credits due to be returned to OPOs. The Pediatric Transplantation Committee has commented that OPOs with relatively high kidney payback debts, at least historically, have had to offer a substantial number of suitable kidneys in satisfaction of these debts before offering them for children who had met or exceeded their time goals. This has made it difficult to get children transplanted

at all. When the priority for children who have waited their time thresholds without transplant was implemented, issues regarding kidney payback debts and particular imbalances between OPOs with relatively large numbers of debts and credits also were being discussed. The children's priority was placed after kidney payback debts acknowledging these other challenges and attempts in progress to address them. Policies placing limits on kidney payback debts have now been implemented and appear to have substantially reduced the debt accrued prior to the effective date of the new policies. Their impact upon current debt accrued also appears to be positive. It was suggested, therefore, that it may be time to re-consider the order of priorities assigned in kidney allocation policy for children who have reached their time thresholds to transplant and organ offers in satisfaction of kidney payback offers.

Under current policy, the top priorities in kidney allocation are assigned for patients who are a zero antigen mismatch with donors, prior living organ donors at the local level, offers for kidney payback, highly sensitized patients with priority higher than children who have met their time thresholds, and then the children at their time thresholds. For each of these patient groups, with the exception of patients receiving kidney offers in satisfaction of payback debts, there is justification for the allocation priority based upon medical criteria specific to the patient group receiving priority. In the case of zero antigen-mismatched patients, the justification is utility of the transplant based upon significantly improved post-transplant outcomes. In the case of prior living donors, the justification is to facilitate living organ donation. In the case of highly sensitized patients, the justification is access to transplantation based upon the difficulty of finding suitable matches for these patients. And, in the case of children, the justification is both utility and fairness of the transplant based upon the benefit of early transplantation for pediatric candidates in addressing unique problems associated with dialysis and disruption to expected growth and development processes due to renal failure. It can be argued, therefore, that children who have reached their time to transplant goals should be assigned priority ahead of kidney payback offers based upon medical factors, particularly now that challenges in addressing kidney payback imbalances may have been addressed at least in part.

The issue of whether pediatric candidates who have surpassed their time goals to transplant should receive priority ahead of payback offers was taken up by a Joint Subcommittee of the Kidney and Pancreas Transplantation, Pediatric Transplantation, and Minority Affairs Committees on September 26, 2003. Approximately 15% of organs transplanted are accepted for paybacks; thus, such a change in the allocation priority could result in additional transplants for pediatric candidates at least close to their time goals. Additionally, since these offers follow only those for zero antigen mismatched patients and prior living organ donors, it would be expected that they would result in a better quality of organ offer for children. After further discussion, the Joint Subcommittee agreed to recommend that children who reach time goals without a transplant be assigned priority ahead of kidney paybacks. Highly sensitized candidates (PRA \geq 80%) would keep their existing priority ahead of these children. Therefore, highly sensitized patients, who would have top priority if the children at goal time were not moved up in priority, would be ahead of children and paybacks.

Albin Gritsch, M.D., presented the Joint Subcommittee report to the full Committee during its October 1-2, 2003, meeting. The Committee agreed with the Joint Subcommittee recommendation to give priority to high scoring high PRA candidates and pediatric candidates who surpassed their transplant goals ahead of OPTN/UNOS payback debts and credits. This is supported by biologic reasons for the highly sensitized patient, who faces unique difficulties with respect to access to transplantation, and children, who face unique challenges with dialysis and disruption to expected growth and development processes due to renal failure, combined with the fact that pediatric kidney transplant candidates are not presently getting transplanted within the policy's goal times to transplantation. The Committee approved the proposal by a vote of 22 For; 0 Against; 0 Abstention, and will submit the proposal for public comment in the spring of 2004. The proposal was subsequently approved by a unanimous vote of the Pediatric Transplantation Committee during its October 3, 2003, meeting.

At the January 20-21, 2004, meeting, the Kidney and Pancreas Transplantation Committee affirmed its decision to submit the proposal for public comment.

* **RESOLVED, that the following modifications to Policies 3.5.5 (Payback Requirements) and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals) shall be distributed for public comment (additions and deletions recommended in this specific proposal are noted by bolded text):**

3.5.5 Payback Requirements. Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), **and** 3.5.5.2 (Exception for Prior Living Organ Donors), **and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals)**, when a kidney is shared pursuant to: (i) the mandatory zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor⁴, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

3.5.5.1 Kidney/Non-Renal Organ Sharing. [No Change]

3.5.5.2 Exception for Prior Living Organ Donors. Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.

3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered long-term debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (*i.e.*, incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3 (Mandatory Sharing).

[No Additional Proposed Changes until Policy 3.5.11]

3.5.11 The Point System for Kidney Allocation. When information about a standard donor is entered into the UNOS Match System, all patients who have an ABO blood type that is compatible with that of the donor and who are listed as active on the UNOS Patient Waiting List will be assigned points and priority as follows:

3.5.11.1 Time of Waiting. [No Changes]

3.5.11.1.1 Time of Waiting Points. [No Changes]

3.5.11.2 Quality of Antigen Mismatch. [No Changes]

3.5.11.3 Panel Reactive Antibody. [No Changes]

3.5.11.4 Medical Urgency. [No Changes]

3.5.11.5 Pediatric Kidney Transplant Candidates. Kidney transplant candidates who are less than 11 years old shall be assigned four additional points for kidney allocation. Candidates who are 11 years old or older but less than 18 years old will be assigned three additional points for kidney allocation. These points shall be assigned when the candidate is registered on the UNOS Patient Waiting List and retained until the candidate reaches 18 years of age.

3.5.11.5.1 Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals. Kidneys that are not shared mandatorily for 0 HLA mismatching, for renal/non-renal organ allocation, or locally for prior living organ donors pursuant to Policy 3.5.11.6 (Donation Status) shall be offered first for transplant candidates who are less than 18 years of age at listing and who have not received a kidney transplant within the time periods set forth in Policy 3.5.11.5.2 irrespective of the number of points assigned to the candidate relative to candidates 18 years old and older, with the exception of candidates assigned 4 points for PRA levels of 80% or greater under Policy 3.5.11.3 (Panel Reactive Antibody) who otherwise rank higher than all other listed patients based upon total points assigned under UNOS policy. When multiple pediatric transplant candidates are eligible for organ offers under this policy, organs shall be allocated for these patients in descending point sequence with the patient having the highest number of points receiving the highest priority. The priority assigned for pediatric patients under this policy does not supercede obligations to share kidneys as a result of a zero antigen mismatch pursuant to Policies 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys) and 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates) ~~or in satisfaction of payback debts pursuant to Policy 3.5.5 (Payback Requirements).~~

3.5.11.5.2 Pediatric Goals for Transplanting Kidney Transplant Candidates. The goals for transplanting pediatric kidney transplant candidates are as follows:

- (a) Candidates 0-5 years old at time of listing- within 6 months of listing.
- (b) Candidates 6-10 years old at time of listing- within 12 months of listing.
- (c) Candidates 11-17 years old at time of listing- within 18 months of listing.

3.5.11.6 Donation Status. [No Changes]

[No Further Changes]

III. Public Comment Responses

The proposal was issued to a mailing list of approximately 8,162 individuals and organizations for a comment period of 45 days beginning March 15, 2004, and ending April 29, 2004. As of April 29, 2004, 85 responses have been submitted to UNOS regarding this policy proposal. Of these, 44 (51.76%) supported the proposal, 0 (0.00%) opposed the proposal, and 41 (48.24%) had no opinion. Of the 44 who responded with an opinion, 44 (100.00%) supported the proposal and 0 (0.00%) opposed the proposal. Of the 11 Regions, each Region supported the proposal, including 6 Regions unanimously. All 11 Regions supported the proposal, including 4 Regions unanimously. Comments on the proposal received to date and the Committee's responses are set forth below.

After further discussion, the Committee agreed to approve the proposal as submitted for public comment by a unanimous vote of 24 For; 0 Against; 0 Abstentions. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modifications to Policies 3.5.5 (Payback Requirements) and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals) (see above) having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System (additions and deletions recommended in this specific proposal are noted by bolded text):**

I. Individual Comments:

Comment 1:

vote: Support

Approve - no comments.

Committee Response:

The Committee appreciates the response.

Comment 2:

vote: Support

ASHI supports this proposal to give elevated priority over payback debts and credits at the local level of organ distribution to high scoring high panel reactive antibody (PRA) candidates and pediatric candidates who surpassed their transplant goals.

Committee Response:

The Committee appreciates the response.

Comment 3:

vote: Support

We applaud the UNOS Committees' efforts to provide better opportunities for transplant for pediatric candidates who surpass their transplant goals.

Committee Response:

The Committee appreciates the response.

Comment 4:

vote: Support

We applaud the UNOS Committees' efforts to provide better opportunities for transplant for pediatric candidates who surpass their transplant goals.

Committee Response:

The Committee appreciates the response.

II. Comments from Other Committees:

Ethics Committee - The Committee found the proposals ethically acceptable based on current and historical practice.

Histocompatibility Committee - Support (14/0/0)

Patient Affairs Committee - The Committee supports the proposed policy by a vote of 13-0-0.

III. Regional Comments:

REGIONAL COMMENT SUMMARY

PROPOSAL 5: Proposed Modifications to OPTN/UNOS Policies 3.5.5 (Payback Requirements) and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals) (Kidney and Pancreas Transplantation Committee)

Sponsoring Committee: Kidney and Pancreas Transplantation

Description: The proposed modifications, originally developed by the OPTN/UNOS Joint Kidney and Pancreas, Pediatric Transplantation, Minority Affairs and Histocompatibility Subcommittee, would elevate the priority at the local level of organ distribution assigned to high scoring high panel reactive antibody (PRA) candidates and pediatric candidates who surpassed their transplant goals ahead of payback debts and credits. This is supported by medical criteria justifying priority in allocation to highly sensitized patients and children versus no similar medical justification for payback offers specific to the patient group receiving the priority. The intent is to provide better opportunities for transplant for pediatric candidates who surpass their transplant goals as well as high PRA candidates who would rank ahead of these children but for the pediatric preference. The proposal is supported by both the OPTN/UNOS Kidney and Pancreas Transplantation and Pediatric Transplantation Committees.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	13 yes, 0 no, 0 no opinion			
2	5/07/04	31 yes, 0 no, 1 no opinion			
3	3/26/04	11 yes, 2 no, 4 no opinion			
4	4/2/04	29 yes, 0 no, 1 no opinion			
5	4/30/04	33 yes, 0 no, 3 no opinion			
6	4/2/04	53 yes, 0 no, 0 no opinion			
7	4/23/04	16 yes, 0 no, 1 no opinion			
8	4/2/04	23 yes, 1 no, 2 no opinion			
9	4/21/04	19 yes, 0 no, 0 no opinion			
10	4/30/04	19 yes, 0 no, 0 no opinion			
11	3/26/04	8 yes, 7 no, 5 no opinion			

COMMENTS:

Proposed Modifications to and Implementation Protocol OPTN/UNOS Policy 3.8.1.5 (Islet Allocation Protocol)**Summary**

The proposal would determine how modifications to OPTN/UNOS Policy 3.8.1.5 recently approved by the OPTN/UNOS Board of Directors are to be implemented on the UNOS Computer. For pancreata identified for islet transplantation, waiting time would be used to designate the candidate for whom the first pancreatic islet offer would be made. The designated candidate's transplant center would then have the latitude in those situations where it is determined that the islet preparation is not medically suitable for that candidate, to determine the most medically suitable candidate from its waiting list. The islets would next be offered to the candidate with the longest waiting time at a transplant center(s) within the OPO (or other applicable local unit), if such candidate's transplant center shares an Investigational New Drug (IND) application with the center receiving the initial islet offer. If such a transplant center does not exist within the OPO (or other applicable local unit), the islets would be offered outside the local area to a transplant center(s) that shares in the IND. The intent of the policy is to better address the need for applying medical judgment in pancreatic islet transplantation decisions and avoid islet wastage.

I. Background

Transplantation of pancreatic islet cells, cells in the pancreas that produce insulin, has been regarded for decades as a possible cure for type 1 diabetes. It involves extraction of islet cells from the pancreas of a donor and infusion of these cells into the liver of a person with diabetes. This is a less invasive procedure than whole pancreas transplantation, which is an alternative treatment for halting or reversing complications from diabetes. Islet transplantation presents new challenges; however, as the cells are fragile making the transplant process difficult. Additionally, immunosuppressive drugs administered to prevent rejection of the cells can worsen the patient's diabetes and it may require multiple donor pancreases to obtain sufficient islet cells to transplant one patient.

The transplantation of isolated pancreatic human islets has become more successful in the past several years due to improvements in islet isolation, immunosuppressive regimens, and patient management. Studies in 1999 at the University of Alberta, Canada, demonstrated early success with new techniques. Efforts through the Immune Tolerance Network (ITN) and other islet transplantation trials are being undertaken to replicate and expand upon the success of protocols developed in the Canadian studies. Pancreatic islet transplantation remains an experimental procedure, however, requiring an IND from the Food and Drug Administration (FDA).

At its November 20-21, 2003, meeting, the OPTN/UNOS Board of Directors approved a recommendation from the OPTN/UNOS Kidney & Pancreas Transplantation Committee to modify OPTN/UNOS policies for allocating pancreata to direct organs generally more acceptable for whole organ use, first, for whole organ transplantation, and to direct organs generally more acceptable for islet use, first, for pancreatic islet transplantation. The intent was to facilitate the availability of pancreatic islets to assist in demonstrating the efficacy of islet transplantation as a treatment for diabetes. Under the revised policies, pancreata procured from donors greater than 50 years old or with body mass index (BMI) greater than 30 kg/m² that are not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch patient or pursuant to Policy 3.5.4 are allocated for islet transplantation (locally, then regionally, and then nationally).

The Committee had further proposed to modify the allocation protocol for pancreata identified for islet transplantation. Under this part of the proposal, islet transplant candidates would be prioritized by waiting time alone. Patients would maintain their waiting time following transplantation until they receive a maximum of three islet infusions or are removed from the waiting list, whichever is the first to occur, at which time their waiting time, if still listed or placed back on the list for islet transplantation, would begin anew.

The Board of Directors expressed concerns with this portion of the Committee's proposal during the Board's November 20-21, 2003, meeting. First, Members of the Board were concerned that waiting time may not be the

most appropriate means by which to allocate pancreatic islets. Instead, islets should be allocated to individuals with the most need, for instance, those candidates with hypoglycemic unawareness and severe life threatening hypoglycemic events. The allocation sequence should allow some discretion for surgeons to determine which of their candidates need the islet transplant the most. Additionally, islet candidates vary as to the islet yield required in order for the transplant to have its intended effect. However, the islet yield cannot be determined from a particular pancreas until it has been processed and the islets actually produced. Candidates designated for islet offers by waiting time alone may not be the most suitable recipients for the islets based upon final islet yield. Members of the Board were wary that islets would incur increased cold ischemic times as OPOs work their way through a list of potential candidates making offers based upon waiting time until the most medically suitable patient is reached. Instead, it was suggested that physicians need discretion to place islet offers for these ultimate candidates rapidly. Finally, there was concern that a transplant center's IND may not permit the center to share processed pancreatic islets with centers not covered under its IND.

After further discussion and in response to these concerns, the Board modified OPTN/UNOS Policy 3.8.1.5 to read as follows:

3.8.1.5 Islet Allocation. Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. If after islet processing is completed, the islet preparation is medically unsuitable for the candidate, the islets from that pancreas will be reallocated to the next most suitable candidate within the OPO that the Investigational New Drug (IND) application allows. The purpose of this policy is to allow for the application of medical judgment and to avoid islet wastage. The outcomes of this allocation policy will be reported to the OPTN/UNOS Board of Directors by the OPTN/UNOS Kidney & Pancreas Transplantation Committee within three years.

The Board modification to OPTN/Policy 3.8.1.5 was incorporated into the Committee proposal and approved by the Board pending programming. The Committee was charged with the task of how to implement the Board-approved modification to the proposal. The language of the policy, as approved, does not, for example, direct how the UNOS Computer would be programmed to prioritize candidates waiting for islet transplantation.

II. Policy Proposal

The Committee discussed the Board-approved modification to OPTN/UNOS Policy 3.8.1.5 and the Board intent during its January 20, 2004, meeting. Some Members questioned whether the objective of the Board modification was to require the Committee to develop a severity of disease score for islet transplantation. There was concern that pancreatic islet transplantation remains experimental and those with relative expertise still lack enough experience to develop such a system. Hypoglycemic unawareness is not the only indication for an islet transplant, for example. Some Members suggested that the decision of how to prioritize the waiting list for islet candidates should be left to the OPOs and islet transplant programs to agree among themselves. Other Members expressed the difficulty with such a system because it would not account for regional and national allocation of islets. Additionally, agreement at the local level of allocation may be difficult to reach depending upon the number of centers performing whole organ and/or islet transplantation.

It was noted that a primary objective of the Board was to allow more discretion for physicians to select the most medically suitable candidate for pancreatic islets based upon the condition of both the candidate and islet yield. Information regarding islet yield will not be known at the time of organ allocation. And, the means for determining candidate need in terms of urgency or islet yield required is still evolving. In general, the Board was concerned that the Committee proposed system could result in increased organ wastage due to increases in cold ischemia time as an OPO makes subsequent offers down the match run based on waiting time. The Board approved the changes to Policy 3.8.1.5 and is asking the Committee to resolve how best to implement the protocol.

Committee Members noted that this becomes most problematic when candidates from multiple transplant centers appear on a match run. The Committee agreed that if only one islet transplant center exists within an OPO (or other applicable local unit), that islet center should be able to proceed down their islet waiting list until the most appropriate candidate given the islet preparation is determined. The issue is more complicated for those OPOs who currently have more than one islet transplant center or will have multiple centers in the future.

The Committee agreed to convene a subgroup of the Committee headed by Giacomina Basadonna, M.D., to continue this discussion during the evening of January 20, 2004, and report a recommendation to the full Committee on January 21, 2004.

During its meeting on the evening of January 20, 2004, the islet subgroup agreed on the assumption that the Board's meaning of "need" as used in the Board's language for Policy 3.8.1.5 refers at least largely to the necessity for balancing islet yield needed by the candidate with medical urgency. Therefore, the subgroup agreed that in situations where the islet yield is deemed not suitable for the intended candidate, the transplant center should be given latitude to offer the islets to the candidate it determines to be most medically suitable on their waiting list. Waiting time would be used to designate the initial organ offer; the candidate's center would then use its medical judgment to select the most eligible candidate from its waiting list. This will help accomplish two goals, minimize organ wastage and provide medical latitude to the transplant centers, established by the Board resolution. The subgroup agreed that the Committee's original protocol for allowing candidate waiting time to continue to accrue for up to three islet infusions should be retained. This also corresponds with the concept of candidate "need" for additional infusions following the initial transplant.

With respect to the issue of allocation priority when multiple islet transplant centers exist within an OPO, the subgroup noted there is less flexibility. Islets cannot be distributed to any center within the OPO due to Food and Drug Administration (FDA) regulations. The transplant center wishing to obtain a particular islet preparation must have permission from the FDA to cross-reference the IND under which the pancreatic islets were produced. Transplant centers rather than OPOs obtain INDs. Therefore, a situation could exist where an OPO has multiple islet transplant centers each with permission to cross-reference different INDs. Members of the islet subgroup agreed, if the transplant center receiving the initial islet offer exhausts its own waiting list, the islets would then be offered to the longest waiting candidate at a transplant center within the OPO (or other applicable local unit) that shares the IND of the first center. If no such transplant centers exist within the OPO (or other applicable local unit), then the islets would be offered outside of the OPO for the longest waiting patient at a transplant center(s) that shares in the IND. The subsequent transplant centers would have the same latitude with regard to suitability as the center of the first offer. Members of the subgroup agreed that this proposal could help foster collaboration within OPOs so that additional transplant centers seek permission to cross-reference INDs for islet transplantation. In addition, OPOs would be permitted to request an alternative allocation system to address local (IND) issues.

Giacomo Basadonna, M.D., presented the islet subgroup recommendations to the full Committee during its meeting on January 21, 2004. Some Members of the Committee expressed their concern that the proposed system is susceptible to abuse. In theory, a transplant center could list a candidate on its islet waiting list who has a substantial amount of waiting time, but who the center does not intend to transplant. Since the proposed system designates the first candidate offer, and thus the transplant center, according to the candidate with the greatest amount of waiting time, the concern is that a large number of islets could be allocated to one particular transplant center. However, other Members noted that no system is completely free from opportunities for abuse. Patients listed for transplantation are presumed to be legitimate candidates for transplantation. Moreover, the OPTN/UNOS should monitor the islet waiting lists of the transplant centers and report situations that appear irregular to the Kidney and Pancreas Committee as well as the OPTN/UNOS Membership and Professional Standards Committee (MPSC) to determine if additional changes to the policy or other action is warranted.

One alternative suggestion considered by the Committee was to list islet candidates separately based on the islet yield required. Such a system would allow for less discretion among the transplant centers and curb any potential abuse. However, Members of the Committee pointed out that the islet yield from a particular pancreas is not known until after the pancreas is processed. Therefore, the pancreas could be allocated to a candidate and not yield the appropriate number of islet cells. The proposal offered by the islet subgroup accounts for such a situation and allows the center to allocate the islets to the most suitable candidate.

Some Members noted that the subgroup proposal does not account for severity of disease. Members of the islet subgroup stated that all candidates currently being listed for islet transplantation are type I diabetics with a certain degree of hypoglycemic unawareness; however, in general, the condition of these candidates is not life threatening. Therefore, severity of disease cannot be explicitly drafted into the policy language at least at this time. The transplant center latitude with respect to the most suitable candidate for a particular islet yield will allow the centers

to allocate as they deem most medically appropriate. Members agreed that future data could be examined to determine how often transplant centers use their discretion in allocating islet preparations or whether they usually proceed according to the waiting list.

Finally, it was re-emphasized that factors other than islet yield and time waiting can be used by physicians in making their allocation decisions. Committee Members felt that it was important, however, to explain that islet yield was viewed as an integral part of patient need in pancreatic islet transplantation.

After further discussion, the Committee agreed to submit the proposal for public comment by a vote of 23 For; 0 Against; 1 Abstention.

* **RESOLVED, that the following modifications to Policy 3.8.1.5 (Islet Allocation) and implementation plan described above shall be distributed for public comment:**

3.8 PANCREAS ALLOCATION. The following policies shall apply to the allocation of pancreata.

3.8.1 Pancreas Organ Allocation. For local pancreas allocation, recipients may be selected from candidates awaiting an isolated pancreas, kidney-pancreas combination, or a combined solid organ-islet transplant from the same donor, unless there is a patient on the UNOS Patient Waiting List who meets the requirements of Policy 3.5.4 or Policy 3.8.1.6 and for whom there is a zero antigen mismatch with the donor. Within each Patient Waiting List, length of time waiting shall be considered for the selection of organ recipients. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive. For combined kidney-pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.1, unless there is a zero antigen mismatch between the candidate and donor and the candidate is highly sensitized as defined in Policy 3.5. 4. If the pancreas is not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch patient or pursuant to Policy 3.5.4, the pancreas, if procured from a donor less than or equal to 50 years old and with body mass index (BMI) less than or equal to 30 kg/m², shall be allocated regionally and then nationally, or for patients listed for facilitated pancreas placement as described in Policy 3.8.1.3, in the following sequence. Pancreata procured from donors greater than 50 years old or with body mass index (BMI) greater than 30 kg/m² that are not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch patient or pursuant to Policy 3.5.4, shall be allocated according to Policy 3.8.1.4 below.

3.8.1.1 Regional Whole Pancreas Allocation. Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

- Isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2, and the kidney must be paid back as specified in Policy 3.5.5.

3.8.1.2 National Whole Pancreas Allocation. Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

- Isolated pancreas candidates; and

- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2, and the kidney must be paid back as specified in Policy 3.5.5.

3.8.1.3 Facilitated Whole Pancreas Allocation. In the event that the UNOS Organ Center has attempted, but has been unable, to place the pancreas for a period of at least five (5) hours, or upon notice to the Organ Center that organ retrieval is anticipated within one (1) hour, then irrespective of whether the entire regional and/or national Waiting List of patients has by that time been exhausted, the pancreas shall be offered through the UNOS Organ Center for patients listed with those transplant centers that have recorded in writing their desire, to participate in the UNOS system of facilitated pancreas allocation. A pancreas offered by this facilitated method shall be offered to patients who have not previously received an offer for that pancreas. The pancreas shall be offered, in the following sequence, based on the transplant candidate's length of waiting time within each of the enumerated categories below. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

- Isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is voluntarily being offered. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2, and the kidney must be paid back as specified in Policy 3.5.5.

Any transplant center desiring to participate in this system shall be allowed to do so provided that it (a) agrees to accept offers for pancreata that have been procured by institutions located outside of its OPO (b) agrees to accept offers for pancreata on a conditional basis pending tissue typing information and redistribution of the organs pursuant to UNOS Policy 3.8.1.6 in the event there is a patient on the Waiting List for whom there is a zero antigen mismatch with the donor, and (c) documents this agreement and its desire to participate in the system to UNOS in writing.

3.8.1.4 Islet Transplantation. If the donor is less than or equal to 50 years old and has body mass index (BMI) less than or equal to 30 kg/m² and a suitable recipient is not identified by the allocation criteria specified in Policies 3.8.1, 3.8.1.1, 3.8.1.2, or 3.8.1.3, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.

If the donor is greater than 50 years old or has BMI greater than 30 kg/m², and a suitable recipient is not identified at the local level of organ allocation by the criteria specified in Policy 3.8.1, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation., and then regionally followed by nationally for whole organ transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.

3.8.1.5 Islet Allocation Protocol. Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. If after islet processing is completed, the islet preparation is medically unsuitable for the candidate, the islets from that

pancreas will be reallocated to the next most suitable candidate within the OPO that the Investigational New Drug (IND) application allows. The purpose of this policy is to allow for the application of medical judgment and to avoid islet wastage. The outcomes of this allocation policy will be reported to the OPTN/UNOS Board of Directors by the OPTN/UNOS Kidney & Pancreas Transplantation Committee within three years. Two active status codes will be used, Status 1 (Urgent) and Status 2 (Non Urgent). At the regional and national level islet allocation shall be as follows:

- ~~Matching~~

0 HLA Mismatch	3 points
1 HLA Mismatch	2 points
2 HLA Mismatch	1 point
3-6 HLA Mismatch	0 points

~~Status 1 A patient that receives a clinical islet transplant becomes a Status 1 for a three week period. (Recipients need islets from four or more donors within three weeks). Status 1 islet candidates shall have priority over Status 2 candidates at each level of allocation, (i.e., local, regional, then national).~~

~~Status 2 All patients on the clinical islet transplant list who do not meet the Status 1 criteria.~~

- ~~Waiting Time~~

Waiting time shall begin when a patient is placed on the UNOS Patient Waiting List. Waiting time will accrue for a patient until he/she has received a maximum of three islet infusions or the transplant center removes the patient from the waiting list, whichever is the first to occur. If the patient is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew. Waiting time as a Status 1 begins when the patient becomes a Status 1 and continues until they are no longer a Status 1. If a patient returns to a Status 2, their entire waiting time continues. One point will be assigned to the patient waiting for the longest period with fractions of points assigned proportionately to all other patients, according to their relative waiting time. For example, if there are 75 patients waiting for islets, the patient waiting the longest would receive 1 point ($75/75 \times 1 = 1$). A person with the 60th longest time of waiting would be assigned 0.2 points ($(75-60)/75 \times 1 = 0.2$). The calculation of points is conducted separately for each geographic (local, regional and national) level of islet allocation. The local points calculation includes only patients on the local Patient Waiting List. The regional points calculation includes only patients on the regional list, without the local patients. The national points calculation includes all patients on the national list excluding all patients listed on the Host OPO's local or regional waiting list. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

[No further changes to Policy 3.8]

III. Public Comment Responses

The proposal was issued to a mailing list of approximately 8,162 individuals and organizations for a comment period of 45 days beginning March 15, 2004, and ending April 29, 2004. As of April 29, 2004, 81 responses have been submitted to UNOS regarding this policy proposal. Of these, 30 (37.04%) supported the proposal, 2 (2.47%) opposed the proposal, and 49 (60.49%) had no opinion. Of the 32 who responded with an opinion, 30 (93.75%) supported the proposal and 2 (6.25%) opposed the proposal. Comments on the proposal received to date and the Committee's responses are set forth below.

Of the 11 Regions, 10 Regions supported and 1 Region opposed the proposal. The 1 Region that opposed the proposal indicated that it would be inclined to support an amended version of the proposal requiring a detailed rationale when the intended candidate was bypassed in favor of another candidate. Some of the public comment suggested that the OPTN/UNOS should not have any policy on islet allocation since it is a developing field. The Committee reemphasized that the OPTN/UNOS should be involved in pancreatic islet transplantation precisely because it is a developing field within transplantation that requires some oversight to ensure patient safety. The present proposal is an attempt to balance need for flexibility in the process, allowing appropriate exercise of medical judgment and increased experience with islet transplantation, with equitable opportunities for organ offers for patients in need of both whole pancreas and pancreatic islet transplant therapy. The Committee determined that requiring submission of written justifications for selecting candidates to receive pancreatic islets under the proposal would be overly burdensome to transplant programs. Instead, the Committee anticipates review of program practices by UNOS Policy Compliance staff and investigation of any activity that appears inappropriate. Reports of such activity to the Committee could lead to further refinement of the policy if deemed necessary.

After further discussion, the Committee agreed to approve the proposed amended policy as submitted for public comment by a vote of 24 For; 0 Against; 0 Abstentions. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modifications to Policy 3.8.1.5 (Islet Allocation) and implementation plan described in Exhibit (see above) having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System:**

I. Individual Comments:

Comment 1:

vote: Oppose

UNOS should not have any policy on islet allocation until the field is developed. Even with this modification of policy with the intention of providing more leeway to the transplanting surgeons, it still creates bureaucracy at a time when bureaucracy could kill the field.

Committee Response:

The Committee reemphasized that the OPTN/UNOS should be involved in pancreatic islet transplantation precisely because it is a developing field within transplantation that requires some oversight to ensure patient safety. The present proposal is an attempt to balance need for flexibility in the process, allowing appropriate exercise of medical judgment and increased experience with islet transplantation, with equitable opportunities for organ offers for patients in need of both whole pancreas and pancreatic islet transplant therapy.

Comment 2:

vote: Support

Approve - no comments.

Committee Response:

The Committee appreciates the response.

II. Comments from Other Committees:

Patient Affairs Committee - There was discussion among the Committee as to how islet cells are spun down and pooled, that the islet cell yield cannot be determined prior to processing, and that individual candidates can require varying numbers of islet cells per injection. The Committee also discussed the fact that islet cell transplantation is still considered experimental, under FDA investigation and not covered by insurance. The Committee was very concerned about the possibility of abuse or even an innocent situation that could occur if a particular center has a candidate with a lengthy waiting time who needs a large islet yield. While that candidate might be constantly turned down due to unsuitable yields, the center would still pull all of the local blood type specific islet offers due to allocation based on waiting time alone.

In reference to the Board of Director's concerns that islets cells be allocated based on severity of medical need, the Committee felt that some standards should be in place as to the severity of hypoglycemic unawareness and life-threatening hypoglycemic events in candidates wait-listed for this procedure. Since allocation will occur based on waiting time, it was felt that diabetics only wishing to achieve insulin-free euglycemia but without severe hypoglycemic unawareness should not be listed for islet cell transplantation at this time.

The Committee strongly urges careful monitoring of this policy change by the Kidney and Pancreas Transplantation Committee and the Membership and Professional Standards Committee once implemented.

The Committee supports the proposed policy by a vote of 14-0-0.

III. Regional Comments:

REGIONAL COMMENT SUMMARY

PROPOSAL 7: Proposed Implementation Protocol for Modifications to OPTN/UNOS Policy 3.8.1.5 (Islet Allocation Protocol) (Kidney and Pancreas Transplantation Committee)

Sponsoring Committee: Kidney and Pancreas Transplantation

Description: The proposal would determine how modifications to OPTN/UNOS Policy 3.8.1.5 recently approved by the OPTN/UNOS Board of Directors are to be implemented on the UNOS Computer. For pancreata identified for islet transplantation, waiting time would be used to designate the candidate for whom the first pancreatic islet offer would be made. The designated candidate's transplant center would then have the latitude in those situations where it is determined that the islet preparation is not medically suitable for that candidate, to determine the most medically suitable candidate from its waiting list. The islets would next be offered to the candidate with the longest waiting time at a transplant center(s) within the OPO (or other applicable local unit), if such candidate's transplant center shares an Investigational New Drug (IND) application with the center receiving the initial islet offer. If such a transplant center does not exist within the OPO (or other applicable local unit), the islets would be offered outside the local area to a transplant center(s) that shares in the IND. The intent of the policy is to better address the need for applying medical judgment in pancreatic islet transplantation decisions and avoid islet wastage.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	13 yes, 1 no, 0 no opinion			
2	5/07/04	27 yes, 0 no, 5 no opinion			
3	3/26/04	17 yes, 0 no, 0 no opinion			
4	4/2/04	26 yes, 0 no, 6 no opinion			
5	4/30/04	25 yes, 3 no, 8 no opinion			
6	4/2/04	31 yes, 17 no, 5 no opinion	44 yes, 6 no, 3 no opinion		
7	4/23/04	3 yes, 12 no, 2 no opinion			
8	4/2/04	25 yes, 0 no, 1 no opinion			
9	4/21/04	13 yes, 1 no, 4 no opinion			
10	4/30/04	19 yes, 0 no, 0 no opinion			
11	3/26/04	17 yes, 0 no, 3 no opinion			

COMMENTS:

Region 7: The region voiced concerns that this policy sanctioned transplants centers to choose the patient who would receive the islets instead of the allocation being directed by the waitlist, as it is with all other organs. The region expressed that they would have been inclined to approve this proposals if language was added that

required documentation detailing the rationale when the intended recipient was bypassed in favor of another candidate.

Committee Response:

The Committee determined that requiring submission of written justifications for selecting candidates to receive pancreatic islets under the proposal would be overly burdensome to transplant programs. Instead, the Committee anticipates review of program practices by UNOS Policy Compliance staff and investigation of any activity that appears inappropriate. Reports of such activity to the Committee could lead to further refinement of the policy if deemed necessary.

Proposed Modifications to OPTN/UNOS Policy 3.8.1.6 (Mandatory Sharing of Zero Antigen Mismatch Pancreata)

Summary

The proposed modifications would eliminate requirements for sharing isolated pancreata for zero antigen mismatched patients except for highly sensitized candidates, defined as candidates with panel reactive antibody (PRA) levels of 80% or higher. The proposal arose out of concerns presented to the Committee over the lack of demonstrated survival benefit for isolated whole pancreas transplantation when compared to the demonstrated survival benefit for simultaneous pancreas-kidney transplantation. The Committee based its decision, in part, on data presented to the Committee showing only 50 zero antigen mismatched pancreata were transplanted between 1995 and 2002. The intent is to allow for increased simultaneous pancreas-kidney transplantation by not requiring sharing of zero antigen mismatched pancreata, except for highly sensitized candidates whose opportunities for an isolated pancreas offer are limited.

Please note that the exhibit submitted with the public comment proposal (Exhibit G) is not included with this briefing paper, but can be found in the March 15, 2004 OPTN/UNOS Public Comment Release.

I. Background

The Committee was requested to review OPTN/UNOS Policy 3.8.1.6, which requires that pancreata be offered to the appropriate OPTN member for any candidate waiting for an isolated pancreas transplant with a zero antigen-mismatch, first locally, then regionally, and then nationally based upon the length of time waiting. The policy exempts from the sharing requirements pancreata used locally for highly sensitized (PRA \geq 80%) patients in need of combined kidney-pancreas or isolated pancreas transplantation who are mismatched and have a negative preliminary crossmatch with the donor. Some members of the transplant community oppose the policy provision requiring sharing pancreata for zero antigen mismatched isolated pancreas candidates and suggest that data now demonstrate the limited benefit for pancreas after kidney (PAK), or pancreas transplant alone (PTA), relative to the substantial survival benefit for simultaneous pancreas-kidney transplantation (SPK). The concern is that OPTN/UNOS Policy 3.8.1.6 will effectively reduce the number of SPK transplants, thus contributing to increased patient mortality.

II. Policy Proposal

During its January 20-21, 2004, meeting, the Committee reviewed an analysis examining the number and outcome of zero antigen-mismatched isolated pancreas and simultaneous kidney-pancreas transplants. The analysis cohort included deceased donor pancreas and kidney-pancreas transplants between March 6, 1995, and December 31, 2002. Graft survival rates were calculated using Kaplan Meier methods for transplants performed between March 6, 1995, and December 31, 2001. Survival rates were stratified by human leukocyte antigen (HLA) mismatch level (0 versus other) and by peak PRA (< 80%, \geq 80%) for kidney-pancreas transplants and are shown only for known values of HLA mismatch. All analyses are based on OPTN data as of September 12, 2003.

Table 1 shows the distribution of pancreas and kidney-pancreas transplants by HLA mismatch level each year from March 6, 1995, through December 31, 2002. During this time period, 252 (3.6%) zero mismatch kidney-pancreas transplants and 50 (2.1%) zero mismatch pancreas transplants were performed. The greatest number of zero mismatch isolated pancreas transplants was 16 and occurred in 2002.

Table 2 shows the distribution of kidney-pancreas transplants by HLA mismatch level and by peak PRA at transplant each year from March 6, 1995, through December 31, 2002. During this time period, a total of 150 transplants were performed in recipients with a peak PRA 80% or greater. Of these recipients, 22 received a zero mismatch and 128 received a less well-matched kidney-pancreas. Of the 22 who received a zero mismatch, 8.7% were highly sensitized compared to 1.9% of those who received a less well-matched kidney-pancreas transplant.

Kaplan Meier graft survival rates are shown in Table 3 for deceased donor pancreas alone transplants performed between March 6, 1995, and December 31, 2001. The pancreas graft survival rates for zero mismatch pancreas transplants at 1 and 3 years post-transplant were 78.9% and 67.7% respectively, compared with 75.0% and 60.5% for less well-matched transplants. Table 4 shows Kaplan Meier graft survival rates for deceased donor kidney-pancreas transplants performed during the same time period by HLA mismatch level and peak PRA at transplant. At 1 and 3 years post-transplant, pancreas graft survival for unsensitized recipients (PRA <80%) was 81.9% and 76.4% for those receiving a zero mismatch kidney-pancreas transplant, and 83.7% and 77.0% for unsensitized recipients for those receiving a transplant with other degrees of mismatch. Only 16 highly sensitized (PRA ≥ 80%) recipients received a zero mismatch kidney-pancreas transplant during this time period. The 1-year graft survival for these recipients was 81.3%, but insufficient data prevented a 3-year graft survival computation.

Some Members observed that these data and other recent published studies show, in general, simultaneous kidney-pancreas transplants result in better pancreas graft outcomes than pancreas alone or pancreas after kidney transplants. The data do demonstrate a trend, without apparent statistical significance, in improved outcomes for recipients of zero antigen mismatched versus mismatched isolated pancreas transplants. In addition, only seven transplant programs in the nation imported more than 10 pancreata between 2000-2002. Since the majority of pancreata are used locally, eliminating national mandatory sharing for isolated pancreata would have a minimal impact on how pancreata are actually allocated.

However, some Members were concerned with the possible effects on highly sensitized candidates. A highly sensitized candidate presently has priority for a kidney-pancreas combination from a donor with whom he/she has a zero antigen mismatch in order to increase the opportunity for transplant. Members noted that the number of highly sensitized recipients of a kidney-pancreas transplant between March 6, 1995 and December 31, 2002, was only 150 (2.2%) out of 6,888 total kidney-pancreas transplants during the same time period. Thus, the impact on the pancreas allocation system for allowing such a priority for highly sensitized candidates is relatively minimal. It was suggested that the priority for receipt of a zero antigen mismatched isolated pancreas transplant also be maintained when the zero antigen mismatched candidate is highly sensitized (PRA ≥ 80%). Again, the objective would be to increase the opportunity for transplantation for these individuals who have such difficulty being matched with suitable donor organs due to the likelihood of rejecting these organs. Optimally (zero antigen mismatched) matched organs provide the best chance for avoiding rejection for these candidates and a large donor pool provides greater opportunities for locating such matches.

After further discussion, the Committee agreed to limit present requirements for sharing isolated pancreata for zero antigen mismatched candidates to only those candidates who are highly sensitized (PRA ≥ 80%). Existing exemptions from the sharing requirements for pancreata used locally for highly sensitized (PRA ≥ 80%) patients in need of combined kidney-pancreas or isolated pancreas transplantation who are mismatched and have a negative preliminary crossmatch with the donor would be maintained. Sharing requirements for zero antigen mismatched simultaneous kidney-pancreas transplants when the candidates are highly sensitized also would remain. The Committee also agreed to submit the proposal for public comment by a vote of 22 For; 0 Against; 0 Abstentions.

* **RESOLVED, that the following modifications to Policy 3.8.1.6 (Mandatory Sharing of Zero Antigen Mismatch Pancreata) shall be distributed for public comment:**

3.8 PANCREAS ALLOCATION. The following policies shall apply to the allocation of pancreata.

3.8.2 Pancreas Organ Allocation. [No Changes]

3.8.1.1 Regional Whole Pancreas Allocation. [No Changes]

3.8.1.2 National Whole Pancreas Allocation. [No Changes]

3.8.1.3 Facilitated Pancreas Allocation. [No Changes]

3.8.1.4 Islet Transplantation. [No Changes]

3.8.1.5 Islet Allocation Protocol. [No Changes]

3.8.1.6 Mandatory Sharing of Zero Antigen Mismatch Pancreata. In the event there is a patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the pancreas from that donor shall be offered, first, to the appropriate UNOS member for any highly sensitized patient waiting for a combined kidney/pancreas transplant with a zero antigen mismatch, pursuant to Policy 3.5.34 (first locally, then regionally, and then nationally, based upon length of time waiting). The pancreas shall then, be offered to the appropriate UNOS member for any highly sensitized (i.e., panel reactive antibody (PRA) level \geq 80%) patient waiting for an isolated pancreas transplant with a zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting, unless there is a patient listed on the Host OPO's local patient waiting list for combined kidney/pancreas or isolated pancreas transplantation who is mismatched with the donor and also has ~~panel reactive antibody (PRA)~~ level of 80% or greater based on historical or current serum samples, as used for crossmatch to determine suitability for transplant, and there is a negative preliminary crossmatch between the donor and that patient. In this event, for local allocation, the pancreas shall be offered for the mismatched patient(s) with PRA greater than or equal to 80% and a negative preliminary crossmatch (based upon length of time waiting if more than one patient meets these criteria) before being offered for highly sensitized zero antigen mismatched isolated pancreas transplant candidates regionally or nationally.

3.8.1.6.1 Time 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 the UNOS Organ Center. The UNOS Organ Center will attempt to place the organ(s) for zero antigen mismatched patients according to the national lists of patients waiting for combined kidney/pancreas or isolated pancreas 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 3.5.5 and pancreas allocation under Policy 3.8.1, as applicable (first locally, then regionally, and then nationally). 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 UNOS Organ Center shall continue to attempt to place the organ(s) for zero antigen mismatched patients according to the national lists of waiting patients. Acceptance of organs declined by the Host OPO will not generate an obligation to pay back the kidney pursuant to Policy 3.5.4 (Payback Requirements) even if accepted for a zero antigen mismatched patient. The UNOS Organ Center will document each offer and each response.

[No Further Changes]

III. Public Comment Responses

The proposal was issued to a mailing list of approximately 8,162 individuals and organizations for a comment period of 45 days beginning March 15, 2004, and ending April 29, 2004. As of April 29, 2004, 82 responses have been submitted to UNOS regarding this policy proposal. Of these, 38 (46.34%) supported the proposal, 2 (2.44%) opposed the proposal, and 42 (51.22%) had no opinion. Of the 40 who responded with an opinion, 38 (95.00%) supported the proposal and 2 (5.00%) opposed the proposal. Comments on the proposal received to date and the Committee's responses are set forth below.

Of the 11 Regions, 7 Regions supported, 1 Region supported with an amendment and 3 Regions opposed the proposal. Of the Regions in opposition to the proposal, the commentary stated that the proposal would further limit isolated pancreas transplantation and that the data did not justify the elimination of mandatory sharing for isolated zero antigen mismatched pancreata. Region 2 approved an amended proposal to eliminate priority for all zero antigen mismatch isolated pancreas candidates due to the difficulty of completing HLA typing on high PRA candidates prior to allocating the pancreas or kidney organ.

During its May 19-20, 2004, meeting, the Committee reiterated that the data do not demonstrate a statistically significant survival benefit with receipt of a zero antigen mismatched isolated pancreas transplant. Moreover, relatively few pancreata are accepted for transplantation from outside the local organ procurement organization (OPO) area. The proposal maintains the requirement to share the optimally HLA matched pancreata broadly only for highly sensitized candidates for whom the transplant can yield substantial benefit even absent expectations for improved outcomes. The proposal should facilitate pancreas placement and serve as a compromise among the positions articulated by the Regions.

After further discussion, the Committee agreed to approve the proposal as submitted for public comment by a vote of 24 For; 0 Against; 0 Abstentions. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

*** RESOLVED, that the following modifications to Policy 3.8.1.6 (Mandatory Sharing of Zero Antigen Mismatch Pancreata) (see above) having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System:**

I. Individual Comments:

Comment 1:

vote: Oppose

Outcomes evidence does not seem to support the policy of giving non-HLA matched sensitized candidates priority over regional or national HLA matched sensitized candidates nor unsensitized candidates in the local region.

Committee Response:

The proposed modifications would eliminate requirements for sharing isolated pancreata for zero antigen mismatched patients except for highly sensitized candidates, defined as candidates with panel reactive antibody (PRA) levels of 80% or higher. The proposal arose out of concerns presented to the Committee over the lack of demonstrated survival benefit for isolated whole pancreas transplantation when compared to the demonstrated survival benefit for simultaneous pancreas-kidney transplantation. The Committee based its decision, in part, on data presented to the Committee showing only 50 zero antigen mismatched pancreata were transplanted between 1995 and 2002. The intent is to allow for increased simultaneous pancreas-kidney transplantation by not requiring sharing of zero antigen mismatched pancreata, except for highly sensitized candidates whose opportunities for an isolated pancreas offer are limited.

Comment 2:
vote: Support

Approve - no comments.

Committee Response:

The Committee appreciates the response.

Comment 3:
vote: Support

ASHI has no objection to this proposal in view of the fact that number of zero antigen mismatched pancreata transplants is very low and it is unlikely that this proposed policy change will adversely affect patients.

Committee Response:

The Committee appreciates the response.

Comment 4:
vote: Support

The number of zero antigen mismatched pancreata transplants is very low and it is unlikely that this proposed policy change will adversely affect patients.

Committee Response:

The Committee appreciates the response.

II. Comments from Other Committees:

Ethics Committee - The Committee found the proposal ethically acceptable based on current and historical practice.

Histocompatibility Committee - Support (14/0/0)

Patient Affairs Committee - The Committee supports the proposed policy by a vote of 12-0-1.

III. Regional Comments:

REGIONAL COMMENT SUMMARY

PROPOSAL 8: Proposed Modifications to OPTN/UNOS Policy 3.8.1.6 (Mandatory Sharing of Zero Antigen Mismatch Pancreata) (Kidney and Pancreas Transplantation Committee)

Sponsoring Committee: Kidney and Pancreas Transplantation

Description: The proposed modifications would eliminate requirements for sharing isolated pancreata for zero antigen mismatched patients except for highly sensitized candidates, defined as candidates with panel reactive antibody (PRA) levels of 80% or higher. The proposal arose out of concerns presented to the Committee over the lack of demonstrated survival benefit for isolated whole pancreas transplantation when compared to the demonstrated survival benefit for simultaneous pancreas-kidney transplantation. The Committee based its decision, in part, on data presented to the Committee showing only 50 zero antigen mismatched pancreata were transplanted between 1995 and 2002. The intent is to allow for increased simultaneous pancreas-kidney transplantation by not requiring sharing of zero antigen mismatched pancreata, except for highly sensitized candidates whose opportunities for an isolated pancreas offer are limited.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	5 yes, 8 no, 1 no opinion			
2	5/07/04		26 yes, 3 no, 2 no opinion		
3	3/26/04	12 yes, 5 no, 0 no opinion			
4	4/2/04	17 yes, 3 no, 5 no opinion			
5	4/30/04	31 yes, 1 no, 4 no opinion			
6	4/2/04	53 yes, 0 no, 0 no opinion			
7	4/23/04	6 yes, 9 no, 3 no opinion			
8	4/2/04	24 yes, 0 no, 2 no opinion			
9	4/21/04	3 yes, 12 no, 5 no opinion			
10	4/30/04	19 yes, 0 no, 0 no opinion			
11	3/26/04	17 yes, 0 no, 3 no opinion			

COMMENTS:

Region 1: The region opposed this proposal due to a concern that such a policy change would further limit isolated pancreas transplantation. With improving graft survival, it was felt that there would be an increase in isolated pancreas transplantation. Supporters of the proposal felt that the need to share a zero antigen mismatched pancreas might create a problem related to timely recovery of the organ.

Region 2: The region opposed the current proposal and approved a proposal to eliminate priority for ALL 0 antigen mismatch isolated pancreas patients. Supporters of this proposal agreed that it was difficult to get typing completed on high PRA candidates prior to allocating the PA or KP.

Region 9 : The region opined that the data was very limited in quantity and therefore did not justify the elimination of mandatory sharing for isolated zero antigen mismatched pancreata.

Committee Response:

The Committee reiterated that the data do not demonstrate a statistically significant survival benefit with receipt of a zero antigen mismatched isolated pancreas transplant. Moreover, relatively few pancreata are accepted for transplantation from outside the local organ procurement organization (OPO) area. The proposal maintains the requirement to share the optimally HLA matched pancreata broadly only for highly sensitized candidates for whom the transplant can yield substantial benefit even absent expectations for improved outcomes. The proposal should facilitate pancreas placement and serve as a compromise among the positions articulated by the Regions.

Proposed Modifications to OPTN/UNOS Policies 3.5.5.1 (Kidney/Non-Renal Organ Sharing) and 3.5.5.2 (Deferment of Voluntary Arrangements)

Summary

The proposed modifications would increase the ABO blood group payback debt threshold from four to six in terms of an OPO's ability to retain local kidneys or receive shared kidneys to be used in a simultaneous kidney-pancreas transplant. The intent of the proposal is to provide additional flexibility in the payback system and enhance opportunities to use both kidneys and the pancreas from donors.

I. Background

Current Policy. OPTN/UNOS policy provides that OPOs receiving a kidney shared for zero antigen-mismatched patients, or with an extra-renal organ, or for a highly sensitized patient incur an obligation to pay back the kidney (*i.e.*, a debit or debt) to the national system. This debt must be repaid with offers of kidneys from the next suitable donors (six years old and older up to and including age 59) of the same ABO blood type as the donor of the shared organ (once the OPO has accumulated two such debts) until accepted by an OPO that is owed a debt from the system. OPOs acquire such "IOUs" (or credits) when they share a mandatory-shared kidney or a kidney shared with an extra-renal organ, or for a highly sensitized patient. Exceptions to the requirement for offering kidneys in satisfaction of payback obligations exist, including an exception to allow the debtor OPO to allocate a kidney otherwise subject to the payback rules for combined kidney/extra-renal organ transplants. The intent of this exception, at least in part, is to facilitate procurement and use of all suitable organs from a donor for human transplantation.

Over the years, the Committee has evaluated concerns that the kidney payback system was not working as intended. Certain OPOs were accumulating relatively high debt balances, while other OPOs were carrying relatively large credit balances including some IOUs that had been outstanding for long periods of time. There was concern that patients who were benefiting from receipt of the shared kidneys were doing so at the unintended expense of patients listed with the exporting OPOs due to differences throughout the country and among patient populations with respect to kidneys shared and available for payback. The payback policy is intended to ensure that no patient groups benefit from organ sharing policies to the disproportionate harm of any other patient group. It attempts to maintain overall system balance. After evaluating concerns that this balance was not being achieved, the Committee recommended and the OPTN/UNOS Board of Directors approved several policy modifications. These modifications include the following.

Effective January 1, 1998, Policy 3.5.5.1 was established to no longer permit an OPO with a debt of four or more payback kidneys owed within any blood group to retain a kidney of that blood group to use with a pancreas (except for zero mismatched patients) in lieu of offering the kidney in satisfaction of payback obligations. Similarly, such an OPO was no longer permitted to accept kidneys of this blood group shared voluntarily with a pancreas (except for zero mismatched patients) (Policy 3.5.5.2). Effective March 1, 2001, OPTN/UNOS policy was further modified to:

- Establish a kidney payback debt limit of nine (all blood groups combined) to be applied for debts incurred on and after implementation of the policy (*i.e.*, "short-term debt").
- Place all debts incurred up to implementation of the new policy into a "long-term debt" category, and require annual reduction of this debt.
- Stipulate that violation of either the limit for short-term debts, or the debt reduction thresholds for long-term debt shall result in:

- ❑ Referral of the OPO and all affiliated transplant centers to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) as a policy violation, and
- ❑ Re-prioritization of the OPO's non-highly sensitized adult patients for offers of zero antigen mismatched kidneys recovered regionally or nationally (*i.e.*, there was no change in priority for highly sensitized patients and when the kidney is recovered from a locally procured donor).

Issue Presented. During its October 1-2, 2003, meeting, the Committee reviewed a request from an OPO to reconsider the policy that limits the ability of an OPO owing four or more payback kidneys within any blood group to retain a kidney of that blood group to use locally with a pancreas (except for zero antigen mismatched candidates) in lieu of offering the kidney in satisfaction of payback obligations. The OPO's concerns include the following:

- The policy prevents maximizing the use of all donor organs. Pancreas placement is facilitated when the organs can be used with a donor kidney at the local level of allocation. The OPO argues that placement opportunities for pancreata alone, even within and particularly outside the Host OPO, are less certain, resulting in fewer pancreata procured.
- The policy disadvantages candidates in need of combined kidney/pancreas transplantation. This may be especially applicable if, for example, the OPO's policy assigns preference for the multiple organ candidate ahead of isolated pancreas candidates.
- The policy is not necessary to ensure prompt satisfaction of kidney payback debts. The OPO argues that any debt in excess of allowed limits is rapidly paid back from suitable donors where a kidney is not retained for use with the pancreas locally. Debt thresholds are exceeded only temporarily, while the OPO otherwise manages debt balances.

Some Members felt that it is reasonable to reassess the policy's limitations on use of kidney/pancreas combinations. However, other Members of the Committee stated that the policy was established to prevent OPOs from acquiring payback obligations with no practical means for repayment based on donor availability. Historically, certain OPOs have been shown to have a difficult time maintaining reasonable debt balances on their own. The policies implemented in response to these difficulties impose management mechanisms upon the OPOs. Expressed concerns regarding these policies are rare. Therefore, they should remain as currently written.

The Committee was provided with copies of recent Payback Debt Reports showing long-term debt status by OPO as of the date of implementation of the payback debt limits referred to above, along with short-term and long-term debt status as of May 1, 2003, and July 17, 2003. These reports reflect debt volume as of a particular day, rather than if and how this volume might fluctuate over time. Also provided to the Committee was a report showing instances in which patients have been re-prioritized for receipt of zero antigen mismatched kidney offers due to OPO payback debt balances in excess of allowed limits. In summary, for the period June 25, 2001 – April 16, 2003 (660 days), a total of 19,873 kidney matches were run. Of these, 1,645 had at least one candidate re-prioritized due to excessive paybacks. Overall, 2,137 candidates were affected. Therefore, while OPOs appear to be doing well in managing payback debt, both short-term and long-term, there is sufficient fluctuation over time that some OPOs do exceed short-term debt limits, resulting in re-prioritizing patients for receipt of zero antigen mismatched kidney offers.

After further discussion, the Committee denied the request to reconsider the limitations on use of donor pancreata with a kidney based upon kidney payback debt limits of four within blood group by a vote of 11 For; 2 Against; 2 Abstention. The Committee decision was communicated to the OPO. The OPO subsequently requested reconsideration of the issue based on its belief that the policy prevents the OPO from maximizing the use of all organ donors.

II. Policy Proposal

A Joint Subcommittee of the OPTN/UNOS Kidney and Pancreas Transplantation and Organ Availability Committees revisited the issue during its January 16, 2004, meeting via conference call. The Joint Subcommittee was reminded that the current policy allows for a total of nine short-term payback debts from all ABO blood groups. The policy's separate limit of four debts per ABO blood group, nearly half of the total debts allowed for all blood

groups combined, provides a fairly liberal limit. Additionally, the data reviewed by the full OPTN/UNOS Kidney and Pancreas Transplantation Committee show that 2,137 candidates were reprioritized for zero mismatch offers between June 25, 2001, and April 16, 2003, because their OPO exceeded the overall debt limit. This included approximately 8% of all kidney matches during the period. OPOs are not always maintaining debt balances on their own. Instead, the policies are imposing management protocols. Members of the Joint Subcommittee questioned whether the real issue behind the OPO request was concern regarding any limit on using kidneys with donor pancreata, or merely the debt threshold mandated by current policy.

Members of the Joint Subcommittee were sympathetic to the notion of enhancing candidate opportunities for a simultaneous kidney-pancreas transplant due to the demonstrated medical benefits of such an operation. Transplant programs may increasingly prefer to perform simultaneous kidney-pancreas transplants, rather than pancreas after kidney transplants; however, the current policy could make this more difficult when the debt threshold is exceeded. Members noted as well that while they may not have expressed concern regarding the policy limits in writing to the Committee, they do, in fact, encounter the same type of difficulties in dealing with these limits as described by the OPO raising the concerns. OPTN/UNOS kidney payback policy acknowledges that offering a donor kidney and the pancreas together may facilitate placement and use of these organs, and that offering the organs separately may result in additional placement difficulties and effort. The policy creates an exception, therefore, for use of the organs together, but with a limit that addresses the need for system balance as well as benefit from pancreas transplantation for patients in need of a solitary pancreas or pancreatic islets as well as those in need of combined kidney/pancreas transplantation. In the event the level of debt is sufficient that use of a donor kidney with the pancreas is not allowed, it is still expected that both kidneys from a donor, the pancreas, and any other organs deemed suitable for transplant would be procured (assuming consent is given). The OPO can and should offer the pancreas for patients in need of isolated pancreas or pancreatic islet transplantation, locally and outside the OPO area, according to the relevant algorithms. Again, however, challenges in trying to procure and place isolated pancreata, in practice, are understood.

Some Members felt that the policy should be modified to allow OPOs to offer kidneys for payback once they have one debt in the system. The current policy allows OPOs to payback when their debt reaches at least two in a particular blood group. An OPO can go from a debt of two to four for a particular ABO blood group in a relatively short amount of time depending on donor and patient availability. Some Members questioned whether OPOs would payback their debts sooner if policy allowed payback at the debt level of one. If an OPO incurred one payback debt and the next donor of the same ABO blood group was a high quality donor for example, the OPO may prefer to retain that kidney for local use. In addition, the original rationale for the provision allowing payback offers to commence at two debts rather than one was to minimize the number of organs that are shipped in order to satisfy payback obligations. Waiting until the OPO has obtained two debts for an ABO blood group allows for some self-cancellation of the debt. This occurs, for example, when a debtor OPO shares a kidney of the blood type owed for a zero antigen mismatched patient. A debt is cancelled without additional shipping of organs. The Joint Subcommittee agreed that paybacks should continue to be offered only after the OPO has obtained two debts in an ABO blood group.

The Joint Subcommittee also considered a proposal to eliminate the ABO blood group debt classifications, but establish a limit on the total number of payback debts. OPOs would have some additional flexibility in how they manage their payback obligations and the system would be simplified. However, the concern is such a system might disproportionately disadvantage certain ABO blood groups, such as blood group O for which debts tend to accumulate relatively rapidly.

In light of data showing overall good results with kidney payback debt management, coupled with concerns noted regarding pancreas utilization, the Joint Subcommittee discussed a proposal to increase the ABO blood group debt limits from four to six before an OPO would not be allowed to use a local kidney for simultaneous kidney-pancreas transplantation in lieu of offering the kidney to satisfy a payback obligation or accept a shared kidney for simultaneous kidney-pancreas transplantation. This would give OPOs additional flexibility in addressing their kidney payback debt, while still acknowledging the concerns resulting in these policy limits. The system would be monitored to determine whether OPO short-term paybacks increase inappropriately following the policy modification and whether the current limits should be restored or additional adjustments made to address these increases. After further discussion, the Joint Subcommittee unanimously agreed to recommend the proposal for

consideration by the OPTN/UNOS Kidney and Pancreas Transplantation Committee as the sponsoring Committee for the proposal.

The full Kidney/Pancreas Transplantation Committee considered the Joint Subcommittee recommendation during its January 20-21, 2004, meeting. Members of the Committee were also sympathetic to the proposal due to the demonstrated benefit of a simultaneous kidney-pancreas transplant relative to a pancreas alone transplant in candidates who need both organs. Under the current debt limit policy, some Members could envision a situation where a particular isolated pancreas is not acceptable for centers performing only isolated transplants. The same isolated pancreas may have been used by the local center for a simultaneous kidney-pancreas transplant, but they are unable to accept the kidney with the pancreas due to their ABO blood group debt level. Therefore, while the kidney may be used to satisfy a payback debt, the pancreas would be wasted under this possible scenario.

However, some Members were skeptical of the proposal noting that the core issue presented is an OPO's ability to manage its payback debt. There is no limit on use of kidney-pancreas combinations for OPOs that maintain debt levels within policy standards. Other Members reiterated the Joint Subcommittee observation that it can take a relatively short time to move from a debt of two, first permitting repayment of the debt, to a debt of four, the threshold for limiting use of kidney-combinations. This does not provide the OPO much flexibility. The proposal would reinstate some of this flexibility while maintaining reasonable limits. Additionally, results would be monitored to ensure no unintended consequences.

After further discussion, the Committee agreed to submit the proposal for public comment by a vote of 20 For; 2 Against; 0 Abstentions.

* **RESOLVED, that the following modifications to Policies 3.5.5.1 (Kidney/Non-Renal Organ Sharing) and 3.5.5.2 (Deferment of Voluntary Arrangements) shall be distributed for public comment (additions and deletions recommended in this specific proposal are noted by bolded text):**

3.5.5 Payback Requirements. Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), and 3.5.5.2 (Exception for Prior Living Organ Donors), when a kidney is shared pursuant to: (i) the mandatory zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor⁴, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

3.5.5.1 Kidney/Non-Renal Organ Sharing.

3.5.5.1.1 Deferment of the Kidney/Non-Renal Exception. OPOs that have accumulated ~~four~~**six** or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for kidneys allocated for a kidney-pancreas

transplant pursuant to UNOS Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The kidney/non-renal exception shall be deferred until the OPO has reduced its payback obligation to less than ~~four~~six.

3.5.5.1.2 Deferment of Voluntary Arrangements. OPOs that have accumulated ~~four~~six or more payback obligations within the same blood type shall not be offered, and, if offered, shall not accept kidneys shared with a non-renal organ from a donor of the same blood type as the accumulated payback obligations, except for kidneys allocated for a kidney-pancreas transplant pursuant to UNOS Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The offer/acceptance of kidneys voluntarily shared with non-renal organs shall be deferred until the OPO has reduced its payback obligation to less than ~~four~~six.

3.5.5.2 **Exception for Prior Living Organ Donors.** Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.

3.5.5.4 **Kidney Payback Debt Limit.** An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered long-term debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (*i.e.*, incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3 (Mandatory Sharing).

[No Further Changes]

III. Public Comment Responses

The proposal was issued to a mailing list of approximately 8,162 individuals and organizations for a comment period of 45 days beginning March 15, 2004, and ending April 29, 2004. As of April 29, 2004, 82 responses have been submitted to UNOS regarding this policy proposal. Of these, 32 (39.02%) supported the proposal, 6 (7.32%) opposed the proposal, and 44 (53.66%) had no opinion. Of the 38 who responded with an opinion, 32 (84.21%) supported the proposal and 6 (15.79%) opposed the proposal. Of the 11 Regions, 9 Regions supported and 2 Regions opposed the proposal. Comments on the proposal received to date and the Committee's responses are set forth below.

Public commentary varied between suggesting that (1) the proposal's increased flexibility for OPOs to manage kidney payback debt was too liberal and would allow inappropriate debt accumulation, to (2) the proposal does not go far enough to provide opportunities to use donor pancreata with a kidney. Region 2, for instance, supported the proposal, although the Region's kidney/pancreas transplant programs opined that the ABO blood group payback debt threshold should remain four. Region 5, which narrowly supported the proposal, stated the proposed modification would allow more leeway for OPOs that fail to monitor their payback debts. Region 9 opposed the proposal and stated the current policy should remain. Finally, Region 8 opposed the proposal because it would not solve the perceived problem, but merely increase by two the number of debts an OPO could accumulate with regard to kidney/pancreas transplants. Other public comments stated that OPOs should learn to manage their payback debts under the current system.

The OPO that submitted the original request to reconsider the policy that limits the ability of an OPO owing four or more payback kidneys within any blood group to retain a kidney of that blood group to use locally with a pancreas (except for zero antigen mismatched candidates) in lieu of offering the kidney in satisfaction of payback obligations, from which the Committee proposal was developed, presented their perspective to the Committee during its May 19, 2004, meeting.

In general, the OPO believed the Committee proposal is not flexible enough to ensure that opportunities for using pancreata shared with kidneys for simultaneous kidney and pancreas transplantation are realized. In addition, the continued restrictions imposed by the kidney payback system will result in decreased pancreas procurement, jeopardizing efforts to maximize organ procurement, due to challenges in placing pancreata without a donor kidney. Finally, the OPO was concerned that the policy requirement of offering both donor kidneys for payback once the OPO has reached a debt threshold requiring that both kidneys be offered, rather than one kidney offered for payback and the other shared locally for a combined kidney/extra renal transplant, becomes a de facto withholding of the extra renal organ (*e.g.*, pancreas) if the organ cannot be placed for an isolated transplant. Due to the limited number of pancreata transplanted within this OPO's Region as an isolated pancreas transplant, it is often difficult for this OPO to place isolated pancreata for transplant.

The OPO offered an alternative proposal to alleviate some of their concerns with the current policy and the proposed modifications to the policy. The OPO suggested an increase in the total payback debt limit (all blood groups combined) from 9 to 12 debts. In addition to the increased total debt limit, the OPO proposed a time delay of, for instance 12 months, before the restriction on retaining a kidney or importing a kidney for a simultaneous kidney-pancreas transplant would be enforced. Under this portion of the proposal, an OPO would be exempted from the payback requirements as it pertains to simultaneous kidney-pancreas transplants until that OPO exceeded the debt threshold longer than the specified time delay.

Some Members suggested that the core issue is an OPO's inability to manage its payback debt levels. The Committee is not aware that this is a significant concern for other OPOs. There is no limit on use of kidney-pancreas combinations for OPOs that maintain debt levels within policy standards. Members also emphasized that the current policies and proposed modifications do not preclude an OPO from procuring any organs. Resolution of the OPO's concern might better be accomplished by examining operational issues between the OPO and some of its recovery surgeons who may be reluctant to procure pancreata for isolated transplants. Additionally, OPOs and their transplant centers are not obligated to accept zero antigen mismatched kidney offers, placing them in jeopardy of reaching the payback thresholds. Instead, these offers may be declined removing the possibility of payback debt as a barrier to opportunities for use of kidney/pancreas combinations locally. Moreover, the OPO's proposal would merely establish a new baseline for payback debts and would not cause any OPO to review and improve its payback

debt management. Finally, the kidney payback system attempts to maintain system balance by ensuring that optimally HLA matched kidneys are not shared to the disproportionate disadvantage of any patient populations. Candidates waiting for a simultaneous kidney-pancreas transplant, in general, will wait a shorter time for transplant than candidates waiting for an isolated kidney transplant. If a candidate misses an opportunity due to the OPO's excessive debt threshold, the chances of a relatively quick subsequent transplant opportunity are very likely. Thus, it is expected that simultaneous kidney-pancreas candidates will not be disadvantaged by this policy.

Some Members moved that simultaneous kidney-pancreas transplants be exempted from the kidney payback system. However, other Members reiterated the views noted above and expressed additional concern that candidates on the isolated kidney transplant list, especially those listed with OPOs that operate separate kidney and kidney/pancreas waiting lists, would be disadvantaged and experience increased waiting times from such a proposal. As discussed above, in general, combined kidney/pancreas candidates wait for much shorter time periods for a transplant relative to isolated kidney transplant candidates. After further discussion, the motion was withdrawn for lack of support.

The alternative proposal offered by the OPO failed as no Committee Member was willing to offer the motion. After further discussion, the Committee agreed to approve the proposal as submitted for public comment by a vote of 23 For; 1 Against; 0 Abstentions.

The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modifications to Policies 3.5.5.1 (Kidney/Non-Renal Organ Sharing) and 3.5.5.2 (Deferment of Voluntary Arrangements) (see above) having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System (additions and deletions recommended in this specific proposal are noted by bolded text):**

I. Individual Comments:

Comment 1:

vote: Oppose

Before kidney paybacks are being contemplated, kidneys needed for combined liver/kidney, pancreas/kidney, and heart/kidney must receive priority over payback.

Committee Response:

The present proposal is an attempt to balance opportunities for use of kidney/pancreas combinations, while ensuring no patients are inappropriately disadvantaged by the sharing requirements for zero antigen mismatched patients. The existing policy already allows use of kidneys with hearts, lungs, or livers in lieu of offering them for payback.

Comment 2:

vote: Oppose

If OPOs manage their payback debt at the existing accumulated limit of four within each blood group there is no limit use of K/P combinations. I don't believe increasing the limit to six will be equitable to the OPOs who export the kidney mandatory shares. This is a slippery slope. Next the OPOs will be crying that they have too much debt accumulated and some of their long-term debt will be forgiven, like it has been in the past.

Committee Response:

The Committee reaffirmed its position that it can take a relatively short time to move from a debt of two, first permitting repayment of the debt, to a debt of four, the threshold for limiting use of kidney-combinations. This does not provide the OPO much flexibility. The proposal would reinstate some of this flexibility while maintaining reasonable limits. Additionally, results would be monitored to ensure no unintended consequences.

Comment 3:

vote: Support

Approve - no comments.

Committee Response:

The Committee appreciates the response.

Comment 4:

vote: Support

Firm time limits should be established for payback periods. Public notification is needed for centers failing to make paybacks.

Committee Response:

The Committee appreciates the response. The Committee reviews a snapshot of the payback debt report for each OPO during every Committee meeting; however, the report does not identify any of the OPOs. The intent is to minimize any opportunity for impartiality.

II. Comments from Other Committees:

Ethics Committee - The Committee found the proposals ethically acceptable based on current and historical practice.

Organ Availability Committee - The Committee unanimously supports this proposal as written.

Patient Affairs Committee - The Committee is highly supportive of Policy changes that discourage any waste of organs and supports this policy change. There was discussion among the Committee as to why the debt limit is being increased to six instead of eight. One member suggested that increasing the debt limit to six would give the OPOs increased flexibility in managing their paybacks, yet maintain reasonable limits. It was noted that this new system will be monitored and adjustments made if adverse consequences are noted.

The Committee supports the proposed policy by a vote of 14-0-0.

III. Regional Comments:

REGIONAL COMMENT SUMMARY

PROPOSAL 4: Proposed Modifications to OPTN/UNOS Policies 3.5.5.1 (Kidney/Non-Renal Organ Sharing) and 3.5.5.2 (Deferment of Voluntary Arrangements) (Kidney and Pancreas Transplantation Committee)

Sponsoring Committee: Kidney and Pancreas Transplantation

Description: The proposed modifications would increase the ABO blood group payback debt threshold from four to six in terms of an OPO's ability to retain local kidneys or receive shared kidneys to be used in a simultaneous kidney-pancreas transplant. The intent of the proposal is to provide additional flexibility in the payback system and enhance opportunities to use both kidneys and the pancreas from donors.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	13 yes, 0 no, 0 no opinion			
2	5/07/04	27 yes, 0 no, 5 no opinion			
3	3/26/04	11 yes, 4 no, 2 no opinion			
4	4/2/04	31 yes, 0 no, 2 no opinion			
5	4/30/04	16 yes, 15 no, 5 no opinion			
6	4/2/04	53 yes, 0 no, 0 no opinion			
7	4/23/04	16 yes, 0 no, 0 no opinion			
8	4/2/04	0 yes, 25 no, 0 no opinion			
9	4/21/04	0 yes, 16 no, 4 no opinion			
10	4/30/04	19 yes, 0 no, 0 no opinion			
11	3/26/04	14 yes, 3 no, 3 no opinion			

COMMENTS:

Region 2: The region approved this proposal, however, the K/P programs opined that Policy 3.5.5.1.2, should maintain a threshold of four.

Region 5: The members who opposed this proposal were concerned that this change would allow more leeway for OPO's who are not diligent in monitoring their paybacks.

Region 9: The region opined that increasing the debt threshold does not change the fundamental rationale for either utilizing a pancreas as an isolated transplant or combined with a kidney, and therefore opposed increasing the threshold from 4 to 6.

Region 8: The region voiced the opinion that the increase in the debt threshold would not solve the problem it would only allow for transplant centers to perform two additional kidney/pancreas transplants prior to reaching their debt limit.

January 7, 2004

James A. Cutler, CPTC
Executive Director & CEO
Southwest Transplant Alliance
Suite 1100
3710 Rawlins
Dallas, Texas 75219

Dear Mr. Cutler:

The OPTN/UNOS Kidney & Pancreas Transplantation Committee considered your concerns regarding OPTN/UNOS Policy 3.5.5.1.1 (Deferment of the Kidney/Non-Renal Exception) and declined to propose any modifications to the policy in response to these concerns. This letter is intended to provide some background regarding Policy 3.5.5.1.1 and to explain why the Committee determined that no change to the policy is warranted at this time. We appreciate very much you bringing your concerns to the attention of the Committee.

OPTN/UNOS Policy. OPTN/UNOS policy provides that OPOs receiving a kidney shared for zero antigen-mismatched patients, or with an extra-renal organ, or for a highly sensitized patient incur an obligation to pay back the kidney (*i.e.*, a debit or debt) to the national system. This debt must be repaid with offers of kidneys from the next suitable donors (six years old and older up to and including age 59) of the same ABO blood type as the donor of the shared organ (once the OPO has accumulated two such debts) until accepted by an OPO that is owed a debt from the system. OPOs acquire such "IOUs" (or credits) when they share a mandatory-shared kidney or a kidney shared with an extra-renal organ, or for a highly sensitized patient. Exceptions to the requirement for offering kidneys in satisfaction of payback obligations exist, including an exception to allow the debtor OPO to allocate a kidney otherwise subject to the payback rules for combined kidney/extra-renal organ transplants. The intent of this exception, at least in part, is to facilitate procurement and use of all suitable organs from a donor for human transplantation.

Over the years, the Committee has evaluated concerns that the kidney payback system was not working as intended. Certain OPOs were accumulating relatively high debt balances, while other OPOs were carrying relatively large credit balances including some IOUs that had been outstanding for long periods of time. There was concern that patients who were benefiting from receipt of the shared kidneys were doing so at the unintended expense of patients listed with the exporting OPOs due to differences throughout the country and among patient populations with respect to kidneys shared and available for payback. The payback policy is intended to ensure that no patient groups benefit from organ sharing policies to the disproportionate harm of any

G-11

President
Russell H. Wiesner, M.D.

Vice President
Robert A. Metzger, M.D.

Vice President
Patient & Donor Affairs
Paul B. Oldam, B.S.S.

Secretary
Marc I. Lorber, M.D.

Treasurer
Dean F. Kappel, M.S.W.

Immediate Past President
Clyde F. Barker, M.D.

Regional Councillors
George S. Lipkowitz, M.D. (1)
Andrew S. Klein, M.D. (2)
Shirley D. Schlessinger, M.D., FACP (5)
Kristene K. Gugliuzza, M.D. (4)
John P. McVicar, M.D. (5)
Douglas E. Wood, M.D. (6)

Christopher P. Johnson, M.D. (7)
Cass Franklin, M.D., FACS (8)
Frank S. Szmalec, M.D. (9)
Mark D. Pescovitz, M.D. (10)
P. R. Rajagopalan, M.D. (11)

At Large Board Members
Margo L. Akerman, M.S.
The Hon. Antonio Benedi
Ronald W. Busutil, M.D., Ph.D.
Anthony M. D'Alessandro, M.D.
John Davis
Richard J. DeSantis, M.D.

Melissa J. Doniger, J.D.
Barry S. Friedman, RN, BSN, MBA CPTC
Rose Marie Gray-Finnell, ARRT (R)
Jackie L. Johnson, MSW, LICSW
Lloyd H. Jordan, Jr., CPA
Bertram L. Kasiske, M.D.
Sharon C. Kiely, M.D., MPM
Helen W. Leslie, RN, CPTC
Donna L. Luebke, RN, MSN, CNP
Stephen M. Oelrich
Esther Padilla, M.S.W.
W. Steves Ring, M.D.
Sandra Rosen-Bronson, Ph.D.

Margaret I. Schaeffer, RN, CPTC
Nancy L. Senst, RN, BSN, CPTC
Charles F. Shield, M.D.
Judy J. Tisdale, Ph.D.
Adriana Zeevi, Ph.D.

Past Presidents
G. Melville Williams, M.D., 1984-85
Oscar Salvatierra, Jr., M.D., 1985-86
John C. McDonald, M.D., 1986-88
H. Keith Johnson, M.D., 1988-89
Robert J. Corry, M.D., 1989-90
James S. Wolf, M.D., 1990-91

Robert Mendez, M.D., 1991-92
R. Randal Bollinger, M.D., Ph.D., 1992-95
Douglas J. Norman, M.D., 1995-94
Margaret D. Allen, M.D., 1994-95
Bruce A. Lucas, M.D., 1995-96
James F. Burdick, M.D., 1996-97
Lawrence G. Hunsicker, M.D., 1997-98
William W. Pfaff, M.D., 1998-99
William D. Payne, M.D., 1999-2000
Patricia L. Adams, M.D., 2000-2001
Jeremiah G. Turcotte, M.D., 2001-2002

Executive Director Emeritus
Gene A. Pierce

other patient group. It attempts to maintain overall system balance. After evaluating concerns that this balance was not being achieved, the Committee recommended and the OPTN/UNOS Board of Directors approved several policy modifications. These modifications include the following.

Effective January 1, 1998, the policy you reference was established to no longer permit an OPO with a debt of four or more payback kidneys owed within any blood group to retain a kidney of that blood group to use with a pancreas (except for zero mismatched patients) in lieu of offering the kidney in satisfaction of payback obligations. Similarly, such an OPO was no longer permitted to accept kidneys of this blood group shared voluntarily with a pancreas (except for zero mismatched patients). Effective March 1, 2001, OPTN/UNOS policy was further modified to:

- Establish a kidney payback debt limit of nine (all blood groups combined) to be applied for debts incurred on and after implementation of the policy (*i.e.*, “short-term debt”).
- Place all debts incurred up to implementation of the new policy into a “long-term debt” category, and require annual reduction of this debt.
- Stipulate that violation of either the limit for short-term debts, or the debt reduction thresholds for long-term debt shall result in:
 - Referral of the OPO and all affiliated transplant centers to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) as a policy violation, and
 - Re-prioritization of the OPO’s non-highly sensitized adult patients for offers of zero antigen mismatched kidneys recovered regionally or nationally (*i.e.*, there was no change in priority for highly sensitized patients and when the kidney is recovered from a locally procured donor).

Current Payback Status. Enclosed with this letter are copies of recent Payback Debt Reports reviewed by the Committee. The first report shows long-term debt status by OPO as of the date of implementation of the payback debt limits referred to above, along with short-term and long-term debt status as of May 1, 2003. The second report shows short-term and long-term debt status as of a more recent date, July 17, 2003, but does not show the historical long-term debt column. These reports reflect debt volume as of a particular day, rather than if and how this volume might fluctuate over time. The Committee has been pleased with the progress of OPOs in reducing long-term debts. Based upon these reports, compliance with the short-term debt threshold also appears to be good. Enclosed is a third report reviewed by the Committee, showing instances in which patients have been re-prioritized for receipt of zero antigen mismatched kidney offers due to OPO payback debt balances in excess of allowed limits. In summary, for the period June 25, 2001 – April 16, 2003 (660 days), a total of 19,873 kidney matches were run. Of these, 1,645 had at least one candidate re-prioritized due to excessive paybacks. Overall, 2,137 candidates were affected. Therefore, while OPOs appear to be doing well in managing payback debt, both short-term and long-term, there is sufficient fluctuation over time that some OPOs do exceed short-term debt limits, resulting in re-prioritizing patients for receipt of zero antigen mismatched kidney offers.

Committee Deliberations. The Committee determined that the policies developed to ensure proper functioning of the kidney sharing and payback algorithms and balance in the system for

patients overall appear to be working well. The Committee further determined that these policies need to be continued to avoid returning to the imbalance that led to their creation. Moreover, the Committee has not received complaints from others similar to those you express regarding the protocol. In fact, OPOs have been very cooperative and successful in addressing the policy requirements.

It is important to note that the policies do not, as you suggest, prevent or preclude OPOs from recovering suitable organs for transplantation. OPTN/UNOS Policy, in fact, requires that OPOs offer all donor organs, for which consent is obtained, through the Match System unless there is a contraindication to organ procurement. It is expected that both kidneys from a donor, the pancreas, and any other organs deemed suitable for transplant would be procured (assuming consent is given) regardless of the OPO's kidney payback debt volume. In the event the level of debt is sufficient that use of a donor kidney with the pancreas is not allowed, then the OPO can and should offer the pancreas for patients in need of isolated pancreas or pancreatic islet transplantation, locally and outside the OPO area, according to the relevant algorithms. OPTN/UNOS kidney payback policy acknowledges that offering a donor kidney and the pancreas together may facilitate placement and use of these organs, and that offering the organs separately may result in additional placement difficulties and effort. The policy creates an exception, therefore, for use of the organs together, but with a limit that addresses the need for system balance as well as benefit from pancreas transplantation for patients in need of a solitary pancreas or pancreatic islets as well as those in need of combined kidney/pancreas transplantation. It also is important to note that the policy's limit of 4 debts by blood group allows considerable flexibility for the OPO since the total short-term debt an OPO is permitted to accrue, all blood groups combined, is 9.

You also suggest that offering a kidney in satisfaction of payback obligations rather than using it with the donor pancreas potentially violates your State's laws. This debt exists, however, because you accepted organs procured from outside your OPO. The policy resulting in these allocations presumes compliance with the payback criteria. Are you suggesting as well, therefore, that Texas law precludes you from accepting the shared organs in the first place? Your concerns regarding Texas law are difficult to understand as well because you seem to be comfortable offering organs to satisfy payback obligations except in the case of alternative offers for kidney/pancreas patients. It would be helpful to know specifically how you believe the policy of concern to you conflicts with Texas law.

We hope that this letter is useful in addressing the issues you have raised. In light of your ongoing concerns with the policy, we will be placing the matter back on the Kidney and Pancreas Committee's meeting agenda. If you have additional information, questions or concerns, therefore, please do not hesitate to let us know.

Very truly yours,

Alan B. Leichtman 

Alan B. Leichtman, M.D., Chair
OPTN/UNOS Kidney & Pancreas Transplantation Committee

Enclosures

cc: Robert A. Metzger, M.D., Chair
OPTN/UNOS Membership & Professional Standards Committee

Lloyd H. Jordan, Jr., CPA, OPO Representative
OPTN/UNOS Board of Directors

Helen W. Leslie, RN, CPTC, OPO Representative
OPTN/UNOS Board of Directors

John M. Holman, Jr., M.D., Ph.D., Chair
OPTN/UNOS OPO Committee

OPO	Short-Term Debts as of 5/1/03					Long-Term Debts as of 5/1/03					Long Term Debts as of 3/1/01				
	A	AB	B	O	TOTAL	A	AB	B	O	TOTAL	A	AB	B	O	TOTAL
1	0	1	1	2	4	0	0	0	0	0	0	0	2	1	3
2	0	0	0	0	0	0	0	0	0	0	2	0	0	1	3
3	1	0	0	0	1	0	1	0	0	1	0	1	0	0	1
4	2	2	0	0	4	0	1	0	0	1	0	1	1	0	2
5	0	0	0	1	1	0	0	0	0	0	0	0	0	3	3
6	1	0	0	1	2	0	0	0	0	0	6	0	0	0	6
7	1	0	0	2	3	0	0	1	0	1	3	0	1	1	5
8	0	1	0	0	1	0	0	0	0	0	0	0	1	0	1
9	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
10	0	0	1	0	1	0	1	0	0	1	NA	NA	NA	NA	NA
11	1	0	1	1	3	0	0	0	0	0	0	0	0	7	7
12	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
14	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0
15	1	0	0	4	5	0	0	0	0	0	0	0	1	1	2
16	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	1	0	0	1	0	1	1	0	2
18	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	3	0	0	0	3	0	0	0	0	0	1	0	0	0	1
20	0	1	0	0	1	0	1	0	0	1	0	1	0	3	4
21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
23	1	0	2	0	3	0	0	0	0	0	1	0	0	0	1
24	0	0	0	0	0	0	0	0	0	0	0	1	1	2	4
25	0	0	3	2	5	0	3	1	0	4	5	4	1	30	40
26	0	0	0	0	0	0	1	0	0	1	0	1	1	0	2
27	5	1	3	4	13	0	0	0	0	0	0	1	0	10	11
28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	1	0	0	1	0	1	0	0	1
30	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
32	2	0	1	0	3	0	0	0	0	0	3	0	0	0	3
33	0	0	1	2	3	0	0	0	0	0	0	0	1	3	4
34	1	0	0	5	6	0	0	0	0	0	1	0	0	6	7
35	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2
36	0	0	1	0	1	0	1	0	0	1	0	1	2	0	3
37	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1
38	0	0	1	5	6	0	0	0	0	0	1	0	0	0	1
39	1	0	0	1	2	0	1	0	1	2	22	1	1	35	59
40	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0
41	4	0	2	6	12	0	1	0	0	1	4	1	1	0	6
42	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0
44	1	0	0	5	6	0	1	1	0	2	0	1	1	1	3
45	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	6	6	0	0	0	0	0	1	0	3	2	6
48	0	1	1	0	2	0	0	0	0	0	0	1	0	0	1

OPO	Short-Term Debts as of 5/1/03					Long-Term Debts as of 5/1/03					Long Term Debts as of 3/1/01				
	A	AB	B	O	TOTAL	A	AB	B	O	TOTAL	A	AB	B	O	TOTAL
49	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2
51	0	0	1	0	1	0	0	0	0	0	0	0	0	3	3
52	0	0	0	0	0	0	0	0	0	0	12	0	0	8	20
53	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0
54	1	0	1	0	2	0	0	0	0	0	0	1	0	5	6
55	0	0	0	1	1	0	1	0	0	1	1	1	0	1	3
56	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
57	1	0	1	1	3	0	5	0	0	5	6	4	3	3	16
58	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
59	1	0	0	5	6	0	0	0	0	0	0	0	0	0	0
60	2	0	1	1	4	0	0	0	0	0	0	0	1	4	5

Short-Term Debts as of 7/17/03						Long-Term Debts as of 7/17/03					
OPO	A	AB	B	O	TOTAL	A	AB	B	O	TOTAL	OPO
49	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0
51	0	0	1	0	1	0	0	0	0	0	0
52	0	0	0	1	1	0	0	0	0	0	0
53	0	1	0	0	1	0	0	0	0	0	0
54	3	0	2	2	7	0	0	0	0	0	0
55	0	0	0	0	0	0	1	0	0	1	1
56	0	0	0	0	0	0	0	0	0	0	0
57	1	1	1	3	6	0	4	0	0	4	4
58	0	0	0	0	0	0	0	0	0	0	0
59	1	0	0	1	2	0	0	0	0	0	0
60	0	0	0	2	2	0	0	0	0	0	0
TOTAL	28	12	26	47	113	0	16	1	0	17	

Jason Byrd

From: Katrina Goodwin
Sent: Tuesday, April 22, 2003 1:18 PM
To: Joshua Czarda; Sandy Han; Shawn Wray
Cc: Jason Byrd; Cindy Sommers; Maureen McBride
Subject: Payback Issue

Category: 0 ABDR Mismatch: Low PRA and OPO has exceeded payback debt threshold. see Policy 3.5.3.3.2 - xi

On matches run by other OPOs, if an OPO currently exceeds the threshold, the Low PRA 0ABDR Mismatch candidates associated with this OPO fall into this category.

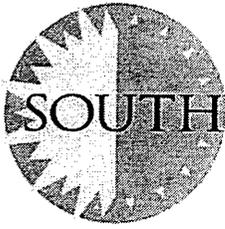
id	Descrip
20	0 ABDR Mismatch: ABO Ident Local
40	0 ABDR Mismatch: ABO Ident Payback, High PRA
60	0 ABDR Mismatch: ABO Ident Regional, High PRA
80	0 ABDR Mismatch: ABO Ident National, High PRA
100	0 ABDR Mismatch: ABO Ident Payback, Low PRA
120	0 ABDR Mismatch: ABO Ident Regional, Low PRA
140	0 ABDR Mismatch: ABO Ident National, Low PRA
160	0 ABDR Mismatch: ABO Compat Local
180	0 ABDR Mismatch: ABO Compat Payback, High PRA
200	0 ABDR Mismatch: ABO Compat Regional, High PRA
220	0 ABDR Mismatch: ABO Compat National, High PRA
240	0 ABDR Mismatch: ABO Compat Payback, Low PRA
260	0 ABDR Mismatch: ABO Ccompat Regional, Low PRA
280	0 ABDR Mismatch: ABO Ccompat National, Low PRA
283	0 ABDR Mismatch:Low PRA and OPO has exceeded payback debt threshold
288	UNOS Paybacks Debts
289	UNOS Paybacks Credits
300	Local List, Highest Scoring High PRA Candidates
340	Local List, Surpassed Pediatric Goals
390	Local List
500	Common OPO List, Highest Scoring High PRA Candidates
540	Common OPO List, Surpassed Pediatric Goals
590	Common OPO List
600	Regional List, Highest Scoring High PRA
640	Regional List, Surpassed Pediatric Goals
690	Regional List
700	National List, Highest Scoring High PRA
740	National List, Surpassed Pediatric Goals
790	National List

Between 6/25/01 and 04/16/03 (660 days) a total of 19,873 Kidney Matches were run. Of these, 1645 Matches had at least one candidate showing up in this category.

Overall, 2137 specific candidates were affected; with 11,224 instances of being classified in this category.

These candidates were associated with the following 11 OPOS:

opo ctr cd	A	AB	A1B	B	O	Candidates	Instances
	4	0	0	0	3	7	7
	5	14	0	0	1	20	28
	4	0	0	3	7	14	28
	23	2	0	7	33	65	114
	217	11	0	67	315	610	4850
	73	6	0	22	114	215	591
	145	13	1	69	237	465	2989
	24	2	0	11	31	68	289
	125	11	0	36	151	323	720
	115	9	0	36	136	296	1534
	27	1	0	6	20	54	74
Candidates	762	69	1	257	1048	Total: 2137	
Instances	4927	364	6	1124	4803	Total:11224	



SOUTHWEST TRANSPLANT ALLIANCE

A NONPROFIT CORPORATION

3710 Rawlins ■ Suite 1100 ■ Dallas, Texas 75219 ■ 214-522-0255 TEL ■ 214-522-0430 FAX

January 22, 2004

Alan B. Leichtman, M.D.
Chairman, OPTN/UNOS
Kidney & Pancreas Transplantation Committee
700 North 4th Street
Richmond, VA 25218

Dear Dr. Leichtman:

Thank you for your letter of January 7, 2004 regarding OPTN/UNOS Policy 3.5.5.1.1, regarding withholding placement of certain extra-renal organs on donors when an Organ Procurement Organization owes a kidney payback debt to the national system. You have indicated that one of the goals of the policy is to eliminate the "long-term" debt to the system, which is something that is laudable, and we are sympathetic to as well. Finally, you have indicated that the Kidney and Pancreas Transplantation Committee does not feel that any change is warranted in the policy at this time.

Additionally, your letter poses some questions for response, as well as other implied questions. I will try and address both your specific questions and implied inquiries.

First, we have made it clear in each correspondence on this issue that our goal is to fully comply with OPTN/UNOS policy. As you noted, we fully comply with our payback requirements, when those requirements do not force us to harm waiting patients by withholding viable organs for transplantation. For example, in each case where we have owed more than one payback debt, and placed one kidney with a pancreas for simultaneous kidney/pancreas transplant, we have always placed the contra-lateral kidney for payback. Also, on donors in whom recovery of transplantable pancreas is not possible, we offer both kidneys for payback, if both are owed to the system. Clearly, we are not suggesting that our debt should not be paid back; rather our concern is paying back a debt a few days or weeks earlier, at the expense of withholding transplantable organs from waiting patients.

Additionally, I have informed UNOS that I will comply with the policy, once UNOS has agreed to hold our organization harmless for the negative consequences of this policy. I have previously forwarded a hold harmless document to UNOS to accomplish this task, which UNOS has returned without execution. I have confirmed today with Deanna Sampson, Policy Compliance Director of UNOS that UNOS refuses to hold Southwest Transplant Alliance harmless for complying with this policy, which still leaves us with the negative risks of policy compliance.

G-20

Visit us on the web at www.organ.org

20

Regarding your question about our legal concerns they encompass four primary areas:

- 1) As you know, our federal mandate as an organ procurement organization (OPO) requires us to recover as many organs as possible for the purposes of organ transplantation. Therefore, it is our position that our federal designation as an OPO requires us to make every effort to recover and distribute every medically suitable viable whole organ for transplantation for which we have legal consent, and for which time and other logistical circumstances permit. Clearly, adhering to the policy in question, places us in contradiction to this requirement.
- 2) Based on the OPTN annual report, almost 70% of the pancreas transplants in this country are simultaneous kidney/pancreas transplants. Waiting kidney/pancreas patients probably believe that OPOs make every effort to recover organs for their transplant. I believe virtually all of these waiting patients are unaware that UNOS/OPTN has a policy that requires that certain medically suitable organs be withheld from them. Should these patients become aware of an instance when an OPO deliberately withholds an organ from them for transplant, a lawsuit could ensue.
- 3) Texas law mandates that qualified OPOs recover organs for which lawful consent has been obtained for the purposes of transplantation. This policy would require our OPO to violate this legal mandate under Texas law.
- 4) Organ donors, and/or their families grant legal consent for the recovery of organs and tissues for transplantation with the general understanding that we will make reasonable efforts to comply with their wishes, and facilitate the transplantation of the organs/tissues they wish to donate, so that the maximum good can come from their loved ones' demise. I know of many families that would be extremely distraught to learn that we deliberately did not follow their wishes, thereby not fulfilling our fiduciary responsibility if we did not recover and transplant viable organs, in order to comply with this policy.

Aside from these areas of legal concern, we have a public relations concern. The entire transplant community makes a large effort to proclaim that there are not enough organs being donated for the patients waiting, but in this instance we have a policy, that deliberately precludes the use of medically suitable viable organs. While you and I, as members of the transplant profession, can understand the reality of payback debts and credits, and that some centers might abuse such a system, it would be difficult to convince the public of a "barter" system of organs that prevents patients from transplant without their knowledge or consent. Also, our organization's mission is to recover organs for transplantation. When we are asked to not recover medically suitable organs for waiting patients, it violates our mission and value stream.

Regarding the data tables supplied with your letter, while they are interesting, they are not terribly helpful in the instance of our OPO. For example, based on a preliminary review, as of

December 17th our OPO had the following unresolved short-term debts with the UNOS system:

Southwest Transplant Alliance owes UNOS:

- 1) AB kidney for no-mismatch UNOS # NLR015 from WALC
- 2) AB kidney for no-mismatch UNOS # PIO014 from TXGC
- 3) A kidney for no-mismatch UNOS # QEB019 from NMMC
- 4) O kidney for no-mismatch UNOS QJB017 from PADU

UNOS has the following credits to Southwest Transplant Alliance:

UNOS owes Southwest Transplant Alliance the following credits:

- 1) O kidney for no-mismatch UNOS QGF011 to NCDU
- 2) O kidney for no-mismatch UNOS # QIE036 to NJBI
- 3) B kidney for no-mismatch UNOS # QJW018 to AZGS
- 4) O kidneys for no mismatch UNOS # QFR008 to KYJH/MNUM
- 5) O kidney for no-mismatch UNOS # QGY022 to COUC
- 6) A kidney for no-mismatch UNOS # QHL022 to MDUM
- 7) O kidney for no-mismatch UNOS # QHG035 to VAHD
- 8) O kidney for no-mismatch UNOS # QJV015 to TNVJ

Based on a recent conversation with the UNOS Organ Center staff, our OPO has no long-term debts with the UNOS system. As you can see, our OPO is not part of the problem with long-term debts. In fact, the UNOS system owes our OPO more credits than we owe debts.

You questioned in your letter if Texas law precludes our OPO from accepting shared organs. I have gone back and reviewed my correspondence on this issue and can find nothing that states or implies that Texas law precludes accepting organs for transplantation, and am confused as to what I may have written or said that would lead you to such a concern. Therefore, I am unable to answer your question without additional clarification.

Since your letter indicates that your Committee will be revisiting this issue, I would like to *formally request* to attend that Committee meeting, and answer any of the above considerations, or help in anyway I can during your deliberations on this matter.

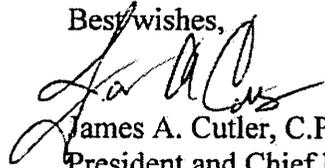
This policy clearly seems to have far reaching implications not only on kidney and pancreas transplantation, and the long-term debt of payback kidneys, but also on denying organs to waiting patients, OPO operations, and finally the UNOS principles of equitable organ allocation. I am curious to know what, if any, review this policy had by the OPO,

Patient Affairs, and Ethics Committees. As I understand the Department of Health and Human Services' OPTN Final Rule, the OPTN must consider organ wastage in its policies. If these Committees reviewed this policy prior to Board approval, I am surprised that none of these considerations arose during these reviews.

I am sure you understand that we are anxious to comply with UNOS policy, in a manner that will not unduly put our OPO at risk, since UNOS is not willing to hold Southwest Transplant Alliance harmless for compliance with this policy. I hope some of these clarifications are helpful.

In closing, I offer the following suggestion to ameliorate the situation, without routinely harming waiting patients by withholding transplantation of organs: A modification of the payback policy by placing qualifying criteria on the number and/or length of payback debts, before the mandatory placement of both kidneys from a single donor becomes necessary. For example, payback debts that are on the books for greater than 12 months, or the OPO owes greater than a net of 12 paybacks to UNOS, in excess of credits owed back to the OPO, could be the trigger before activating this policy. I also suggest exclusion for payback blood type AB kidneys, because the frequency of AB donors is so low, a natural consequence is a prolonged payback period.

Best wishes,



James A. Cutler, C.P.T.C.
President and Chief Executive Officer

cc: Robert Metzger, M.D., Chair
OPTN/UNOS Membership & Professional Standards Committee

Lloyd H. Jordan, Jr. CPA, OPO Representative
OPTN/UNOS Board of Directors

Helen W. Leslie, RN, CPTC, OPO Representative
OPTN/UNOS Board of Directors

John M. Holman, Jr. M.D., Ph.D., Chair
OPTN/UNOS OPO Committee

Ms. Deborah C Surlas, Chair
OPTN/UNOS Patient Affairs Committee

Mark Fox, M.D., Chair
OPTN/UNOS Ethics Committee

Virginia A. McBride, RN, BS, CPTC
Division of Organ Transplantation

Leichman.lt1 Admin UNOS 2004

G-24

24



Since 1984 — sharing organs, sharing data, sharing life.

700 North 4th Street, Richmond, VA 23219
P.O. Box 2484, Richmond, VA 23218
tel: 804-782-4800
fax: 804-782-4816
www.unos.org

Walter Graham, Executive Director

VIA FACSIMILE & REGULAR MAIL

April 2, 2004

James A. Cutler, CPTC
Executive Director & CEO
Southwest Transplant Alliance
Suite 1100
3710 Rawlins
Dallas, Texas 75219

Dear Mr. Cutler:

We are in receipt of your letter dated January 22, 2004, continuing the dialogue about OPTN/UNOS policy requiring, when OPOs exceed allowed kidney payback thresholds, that kidneys be shared in satisfaction of payback obligations in lieu of using them for combined kidney/pancreas transplantation. As noted, in our January 7th correspondence, we very much appreciate your interest in this matter and thank you for sharing your views and recommendations with us. As further noted in our earlier correspondence, the OPTN/UNOS Kidney & Pancreas Transplantation Committee reconsidered the policy in light of your concerns at its January 20-21, 2004, meeting. As a result of these deliberations, the Committee developed a proposal to increase the ABO blood group payback debt threshold impacting use of a kidney with the donor pancreas from four to six. This is proposal 4 in the group of policy proposals distributed for public comment on March 15, 2004. It can be found on the OPTN website, www.optn.org, by clicking on "Policies;" then "Public Comment;" and then "Proposals." We welcome your input on this proposal as well as your participation in our meeting on May 19-20 2004, when we will be discussing the proposal and all public comments related to it.

We all know the unfortunate truth that despite the substantial efforts devoted to increasing organ donation, we continue to work within a system where the need for organ transplants far exceeds the supply of organs available for transplantation. The allocation priority assignments do not withhold organs from patients, they establish rules for the ordering of organ offers after balancing the interests of all waiting patients. These rules (policies) are developed after circulation and discussion among, and with input from, organ transplant professionals and patient representatives. Contrary to your assertions, no OPTN/UNOS policy asks you or any OPO to not recover medically suitable organs. In fact, policy requires that OPOs offer all donor organs, for which consent is obtained, through the Match System unless there is a contraindication to organ procurement.

G-25

President
Russell H. Wiesner, M.D.

Vice President
Robert A. Metzger, M.D.

Vice President
Patient & Donor Affairs
Paul B. Oldam, B.S.S.

Secretary
Marc I. Lorber, M.D.

Treasurer
Dean F. Kappel, M.S.W.

Immediate Past President
Clyde F. Barker, M.D.

Regional Councillors
George S. Lipkowitz, M.D. (1)
Andrew S. Klein, M.D. (2)
Shirley D. Schlessinger, M.D., FACP (5)
Kristiene K. Gugliuzza, M.D. (4)
John P. McVicar, M.D. (5)
Douglas E. Wood, M.D. (6)

Christopher P. Johnson, M.D. (7)
Cass Franklin, M.D., FACS (8)
Frank S. Szmalc, M.D. (9)
Mark D. Pescovitz, M.D. (10)
P. R. Rajagopalan, M.D. (11)

At Large Board Members
Margo L. Akerman, M.S.
The Hon. Antonio Benedi
Ronald W. Busutil, M.D., Ph.D.
Anthony M. D'Alessandro, M.D.
John Davis
Richard J. DeSanto, MA

Melissa J. Doniger, J.D.
Barry S. Friedman, RN, BSN, MBA CPTC
Rose Marie Gray-Finnell, ARRT (R)
Jackie L. Johnson, MSW, LICSW
Lloyd H. Jordan, Jr., CPA
Bertram L. Kasiske, M.D.
Sharon C. Kiely, M.D., MPM
Helen W. Leslie, RN, CPTC
Donna L. Luebke, RN, MSN, CNP
Stephen M. Oelrich
Esther Padilla, M.S.W.
W. Steves Ring, M.D.
Sandra Rosen-Bronson, Ph.D.

Margaret J. Schaeffer, RN, CPTC
Nancy L. Senst, RN, BSN, CPTC
Charles F. Shield, M.D.
Judy J. Tisdale, Ph.D.
Adriana Zeevi, Ph.D.

Past Presidents
C. Melville Williams, M.D. 1984-85
Oscar Salvatierra, Jr., M.D. 1985-86
John C. McDonald, M.D. 1986-88
H. Keith Johnson, M.D. 1988-89
Robert J. Corry, M.D. 1989-90
James S. Wolf, M.D. 1990-91

Robert Mendez, M.D. 1991-92
R. Randal Bollinger, M.D., Ph.D. 1992-93
Douglas J. Norman, M.D. 1993-94
Margaret D. Allen, M.D. 1994-95
Bruce A. Lucas, M.D. 1995-96
James F. Burdick, M.D. 1996-97
Lawrence C. Hunsicker, M.D. 1997-98
William W. Pfaff, M.D. 1998-99
William D. Payne, M.D. 1999-2000
Patricia L. Adams, M.D. 2000-2001
Jeremiah C. Turcotte, M.D. 2001-2002

Executive Director Emeritus
Gene A. Pierce

25

James A. Cutler, CPTC

April 2, 2004

Page 2

In response to your specific questions regarding input on Policy 3.5.5.1.1 from the OPTN/UNOS OPO, Patient Affairs, and Ethics Committees, each of these as well as all other OPTN/UNOS Committees were provided opportunity to review and provide comments on the policy during its development, through the standard public comment process. We would be happy, at your request, to forward to you a copy of these and other comments received on the proposal, along with the Committee's responses.

We look forward to your input regarding the Kidney/Pancreas Transplantation Committee's current recommendations to modify Policy 3.5.5.1.1, as well as other proposals out for public comment or other matters about which you are interested.

Very truly yours,

Alan B. Leichtman 

Alan B. Leichtman, M.D., Chair
OPTN/UNOS Kidney & Pancreas Transplantation Committee

cc: Robert A. Metzger, M.D., Chair
OPTN/UNOS Membership & Professional Standards Committee

Lloyd H. Jordan, Jr., CPA, OPO Representative
OPTN/UNOS Board of Directors

Helen W. Leslie, RN, CPTC, OPO Representative
OPTN/UNOS Board of Directors

John M. Holman, Jr., M.D., Ph.D., Chair
OPTN/UNOS OPO Committee

Deborah C. Surlas, RN, Chair (w/ copy of January 7, 2004, letter to James C. Cutler, CPTC)
OPTN/UNOS Patient Affairs Committee

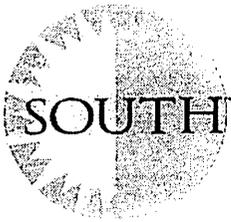
Mark D. Fox, M.D., Ph.D., Chair (w/ copy of January 7, 2004, letter to James C. Cutler, CPTC)
OPTN/UNOS Ethics Committee

Virginia A. McBride, RN, MPH, CPTC, OPTN Project Officer (w/ copy of January 7, 2004, letter to James C. Cutler, CPTC)
Division of Organ Transplantation

G-26

26

RECEIVED AIR 16 2004



SOUTHWEST TRANSPLANT ALLIANCE

A NONPROFIT CORPORATION

3710 Rawlins · Suite 1100 · Dallas, Texas 75219 · 214-522-0255 TEL · 214-522-0431 FAX

April 7, 2004

Alan B. Leichtman, M.D.
Chair, OPTN/UNOS Kidney and Pancreas Transplantation Committee
UNOS
700 North 4th Street
P.O. Box 2484
Richmond, VA 23218

RE: April 2, 2004 Correspondence

Dear Dr. Leichtman:

I am in receipt of your letter dated April 2, 2004 regarding clarification of UNOS Policy 3.5.5.1.1, and payback kidney requirements. I was initially heartened to read in your letter the UNOS position that it has no policy that asks any OPO to not recover medically suitable organs, and that UNOS also has a policy that requires OPOs to recover all medically suitable organs.

On further reflection, the statement that UNOS has no policy that "asks any OPO to not recover medically suitable organs" confuses me. My confusion stems from four observations, 1) the current practice of UNOS operational staff, 2) the current wording of UNOS policy, 3) the current practice of UNOS policy compliance staff, and 4) the actions of the UNOS Membership and Professional Standards Committee, which I will explain in more detail.

Unfortunately, what has been happening is that when our OPO determines that a donor is medically suitable (according to UNOS policy 3.3.1), and the kidney/pancreas from that donor has been accepted for transplant by numerous centers, it is the UNOS Organ Center staff who admonish our staff on a recorded line that we are in violation of UNOS policy. We subsequently receive a letter from the UNOS Policy Compliance Department Staff that we are in violation of the policy in question. Clearly, UNOS personnel's implementation of its policies are diametrically opposed to your clarifying statements, as they have determined that UNOS policy 3.5.5 precludes the procurement of kidney / pancreas (except for no-mismatch recipients) for transplantation when the payback limit is in place. As such, UNOS staff has operationalized this policy and given it meaning.

G-27

RECEIVED AIR 16 2004

Visit us on the web at www.organ.org

BEAUMONT · CORPUS CHRISTI · DALLAS · EL PASO · GALVESTON · TEMPLE · TYLER

27

One can understand how UNOS Staff would make this interpretation based upon UNOS policy 3.5.5.1.1, which states: **3.5.5.1.1 Deferment of the Kidney/Non-Renal Exception**: *OPOs that have accumulated four or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for kidneys allocated for a kidney-pancreas transplant pursuant to UNOS Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The kidney/non-renal exception shall be deferred until the OPO has reduced its payback obligation to less than four.*

Also, based upon the interpretation of the UNOS staff and the wording as listed above, the UNOS Membership and Professional Standards Committee has informed our OPO that our actions were in violation of UNOS Policy and thus we should not place a medically suitable pancreas for combined kidney/pancreas transplant, thereby withholding a viable whole organ for transplant.

Additional confusion exists with the statement that "UNOS has a policy that requires OPOs to offer all donor organs, for which consent is obtained, through the Match System unless there is a contraindication to organ procurement." I have reviewed what appears to be the pertinent UNOS policies, and the only policy that appears to come close to this statement is as follows: **3.2.3 Match System Access**. *The allocation of any and all organs from deceased donors must be made through the UNOS Match System. The Host OPO must enter required information about the donor (Policies 3.5.7, 3.6.9, 3.7.9 and 3.8.5) and execute the UNOS Match System computer programs which determine organ allocation priorities. Such information must be entered into the UNOS Match System for all deceased donors. For all renal deceased donors, UNOS Members must enter all donor data into the UNOS Match System within 15 hours after organ recovery.* Given the context of this issue the above policy is not aligned with the statement in your letter. If there is another policy that specifically states and deals with the issue contained in your letter, please provide the policy reference to me.

Based on the above facts, there are only a couple of conclusions that can be reached. One conclusion would be that UNOS staff has not been clear on the intent of this policy and have unfortunately not been implementing the policy correctly. Should this prove to be the case, it would seem a simple matter of re-educating the UNOS Organ Center and Policy Compliance staff that this policy does not preclude the recovery of all medically suitable organs. Once properly instructed as to the actual purpose of the policy, UNOS staff will no longer have to tell OPOs that they can not recover the pancreas for a simultaneous kidney/pancreas procedure, when payback kidney debts exceed the limit stated by policy. Furthermore, the UNOS Membership and Professional Standards Committee and the UNOS Policy Compliance department would not have to continue pursuing OPOs on this issue.

The second conclusion is that UNOS does have a policy that precludes the use of transplantable organs, which is in direct conflict with one of its own principles as delineated in UNOS' Rationale for Objective of Equitable Organ Allocation. The first of such Objective states that UNOS Policy should *maximize the availability of transplantable organs by:*

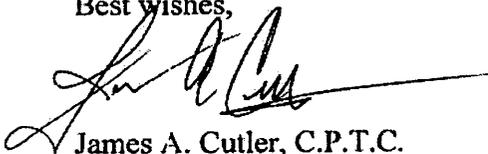
- *Promoting consent to donate;*
- *Enhancing procurement efficiency;*
- *Minimizing organ discards; and*
- *Promoting efficiency in organ distribution and allocation.*

Organ donation, procurement, distribution and allocation are all intrinsically linked together. Thus, organ allocation cannot be addressed in a vacuum without considering the impact of any allocation policy on the supply of transplantable organs. The policy should strive to avoid loss of organs, and it should also promote recovery of the maximum organs possible.

Finally, in your letter you state that the Kidney and Pancreas Committee reviewed my concerns at its January 20-21, 2004. However, following that Committee meeting the Committee forwarded me a letter with a series of clarifying questions. It is difficult to understand how the Committee could fully understand these issues, when it has to ask me clarifying questions after that Committee had met and made its decision. As I requested earlier, I feel this issue is critical, and I respectfully ask for an opportunity to come and speak before whatever Committee or Board is going to finally address this matter.

In conclusion, if the clarifying statements contained in your letter are accurate, and the problem has been one of incorrect staff implementation, I would be extremely appreciative if your Committee could notify both the Policy Compliance Department and Membership and Professional Standards Committee that we have never been in non-compliance with UNOS policy for our practice of attempting to recover and place a medically suitable organs for transplantation. Alternatively, if UNOS has interpreted and implemented the policy correctly, I continue to be confused, and am still awaiting an opportunity to address the appropriate Committee or Board to reach resolution on the numerous implications of the policy.

Best wishes,



James A. Cutler, C.P.T.C.
President and Chief Executive Officer

cc: Robert A. Metzger, M.D.
Chair OPTN/UNOS Membership and Professional Standards Committee

Lloyd H. Jordan, Jr. CPA, OPO Representative
OPTN/UNOS Board of Directors

Paul Schwab
Executive Director, AOPO

Helen Leslie, RN, CPTC, OPO Representative
OPTN/UNOS Board of Directors

John M. Holman, Jr. M.D., Ph.D.
Chair, UNOS OPO Committee

Deborah C. Surlas, RN
Chair, UNOS Patient Affairs Committee

Mark D. Fox, M.D., Ph.D.
Chair, UNOS Ethics Committee

Virginia A. Mc Bride RN, MPH, CPTC,
OPTN Project Officer,
Division of Organ Transplantation

Southwest Transplant Alliance Board of Directors

leicht: an.it2 admin unos coor

Proposed Modifications to OPTN/UNOS Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) (“Exemption of Kidneys Recovered from Donation after Cardiac Death (DCD) Donors from Sharing Requirements for Zero Antigen Mismatched Kidneys or Payback)

Summary

The proposal would exempt Donation after Cardiac Death (DCD) donor kidneys from the requirements of the zero antigen mismatch kidney sharing policy, except at the local level of organ distribution, as well as, kidney payback policy. OPOs would retain the option to offer DCD donor kidneys for payback, but would not be required to do so under the policy. The intent of the proposal is to place DCD donor kidneys as rapidly as possible to avoid adverse impacts from increased cold ischemia time, as well as, increase organ donation by providing an incentive for transplant centers to develop and enhance their DCD donor programs.

Please note that the exhibits submitted with the public comment proposal (Exhibits A-C) are not included with this briefing paper, but can be found in the March 15, 2004 OPTN/UNOS Public Comment Release.

I. Background

This proposal has been developed over time after the Committee considered several requests to operate with alternative systems for kidney allocation exempting organs recovered from Donation after Cardiac Death donors from sharing requirements for zero antigen-mismatched kidneys. The intent of those alternative system proposals is to place kidneys procured from DCD donors as rapidly as possible to avoid adverse impacts from increased cold ischemia time. It is argued that kidneys procured from these donors are not widely accepted beyond the local area. Therefore, requirements for making offers for zero antigen-mismatched patients regionally or nationally do no more than delay their ultimate placement. The Committee previously considered application of this idea to the national allocation system, but was initially reluctant due to insufficient data to make any evidence-based conclusions regarding the benefit in terms of number or outcomes of transplants that would be achieved by more local use of kidneys from DCD donors.

At its July 24, 2003, meeting, the Committee began reviewing analyses evaluating the recent experience with DCD donor transplantation overall. For analysis of donor characteristics, the study population included deceased donor kidneys procured between March 6, 1995, and June 30, 2001. For analysis regarding transplanted kidneys, the study population included first transplants using deceased donor kidneys performed between March 6, 1995, and June 30, 2001. The analysis calculated descriptive statistics regarding DCD kidneys including placement, share type, cold ischemia time, pump use, controlled vs. non-controlled, and warm ischemia time. The reasons for kidney turndown were tabulated. In addition, a Cox Model was used to analyze graft survival for DCD kidneys versus other deceased donor kidneys. A blinded histogram was generated to show programs accepting DCD kidneys, livers and (if any) hearts that are and are not procured at the transplanting center. Finally, the analysis described the demographics of recipients and used and discarded organs.

Tables 3.1 and 3.2 illustrate that when compared to deceased heartbeating donors (HBD), DCD donors had a higher rate of being discarded (20.4% compared to 13.3%), transplanted locally (64.2% compared to 59.3%), pumped (transplanted DCD accounted for 42.3% and discarded DCD accounted for 24.0% compared to transplanted HBD at 11.0% and discarded HBD at 9.0%) and cold ischemic time (mean time in hours of 22.7 compared to 20.4). Donation after Cardiac Death donor organs were used less frequently for payback when compared to deceased heartbeating donors. The tabulation of discard codes is documented in Table 3.3 and demonstrates that DCD donor organs were discarded due to no recipient being located, warm ischemic time being too long or too old on the pump more frequently than heartbeating donor organs. In contrast, heartbeating donor organs were discarded more frequently than DCD donor organs due to biopsy findings and diseased organ. The Committee noted that anoxia and CNS tumor are more prevalent causes of donor deaths for deceased DCDs than HBDs, as shown by Table 3.4a. In addition, DCD donors tend to be male and white when compared to heartbeating donors.

Table 3.5a and 3.5b show recipient characteristics of deceased DCD and HBD kidneys. A higher percentage of DCD kidneys compared with percentage of HBD kidneys were transplanted into Blacks. The opposite is true for Whites. A higher percentage of DCD recipients (42.6%) required dialysis in the first week after transplant than HBD recipients (23.3%). Finally, a lower percentage of DCD recipients (7.6%) received zero antigen-mismatched kidneys than HBD recipients (14.3%).

The Committee also reviewed an inferential analysis of graft failure. The study population consisted of transplants involving deceased renal donors to first-time transplant recipients between March 6, 1995 and June 30, 2001. Observations were censored at time of death or last expected follow-up. Additional graft failure data were obtained from the Centers for Medicare and Medicaid Services (CMS) data files. The donor models were adjusted for age, race, history of hypertension, history of diabetes, cold-ischemia time and creatinine > 1.5 mg/dl. The recipient models were adjusted for age, sex, ethnicity, panel reactive antibody (PRA), human leukocyte antigen (HLA) mismatch and cause of end stage renal disease (ESRD). The analysis concluded with statistical significance that DCD donor organs fail at a 36% higher rate than heartbeating donor organs.

The Committee next reviewed analyses targeted more directly to the question of whether DCD kidneys should be excluded from payback and zero antigen mismatch sharing policies. Specifically, during its October 1-2, 2003, meeting the Committee considered survival rates of DCDs compared to deceased donors, outcomes of shared DCD zero mismatch kidneys compared with standard mandatory shared kidneys and locally transplanted DCDs and the number of offers for local and shared DCD kidneys.

The study population consisted of 42,318 first transplants using deceased donor kidneys performed between March 6, 1995, and June 30, 2001. Due to incomplete data prior to July 2000, the offer data analysis included 178 DCD kidney recipients who received their first transplant between July 1, 2000, and June 30, 2001. The offer number (number of prior refusals + 1) at the time of acceptance of the kidney was determined for each transplant recipient.

Table 3.1 showed the 1, 3, and 5-year graft survival rates by donor status (recipients of their first, deceased donor kidney, March 6, 1995-June 30, 2001, followed through May 1, 2002). The analysis was adjusted for donor age, donor hypertension status, donor diabetic status, donor creatinine, donor ethnicity, recipient age, recipient sex, recipient ethnicity, recipient cause of ESRD, HLA matching, cold ischemia time, PRA, year of transplant, and ABO blood type compatibility. The results were as follows:

Donor Status	1-Year Survival	3-Year Survival	5-Year Survival
Heart Beating Donor	89.8	82.5	74.1
Donation after Cardiac Death Donor	83.5	77.3	70.9

A Cox regression model that was limited to a subset of 5,268 shared zero mismatch transplants compared graft survival outcomes for shared zero mismatch DCD transplants (n=51) to outcomes for shared zero-mismatch HBD transplants (n=5,217). The model was adjusted for donor age, donor hypertension status, donor diabetic status, donor creatinine, donor ethnicity, recipient age, recipient sex, recipient ethnicity, recipient cause of ESRD, cold ischemia time, PRA, year of transplant, and ABO blood type compatibility. Among shared zero mismatch transplants, recipients of DCD kidneys had a significantly higher rate of post-transplant graft failure compared to recipients of HBD kidneys (RR= 1.84; p-value= 0.048). The 95% confidence interval on the RR was [1.01, 3.35].

A second Cox regression model was limited to a subset of 641 DCD transplants. The graft survival outcomes for shared zero mismatch DCD transplants (n=51) were compared to outcomes for local DCD transplants (n=590). The model was adjusted for donor age, donor hypertension status, donor diabetic status, donor creatinine, donor ethnicity, recipient age, recipient sex, recipient ethnicity, recipient cause of ESRD, cold ischemia time, PRA, year of transplant, and ABO blood type compatibility. Among DCD transplants, recipients of shared zero mismatch kidneys did not have a significantly different rate of post-transplant graft failure compared to recipients of local DCD kidneys (RR= 1.26; p-value= 0.49). The 95% confidence interval on the RR was [0.66, 2.40]. Therefore, the expected benefit of zero mismatch HLA matching over local unmatched DCD is not shown; there actually is a slight decrease in graft survival.

Table 3.2 showed the counts and percent of DCD transplant recipients by offer number from July 2000-June 2001. Members of the Committee noticed that a substantial number of DCD kidneys receive either 1-5 offers or 20 or more offers. A possible explanation for this disparity is that such a kidney is either clearly suitable and accepted right away in the offer process, or ultimately is allocated to a transplant center with relatively liberal criteria after being offered to many other centers on the waiting list. Committee Members were interested in whether zero mismatch kidneys accepted within the first five offers have better outcomes than local mismatched kidneys. The data might be weighted with longer cold ischemia times due to the number of kidneys with 20 or more offers. Thus, the Committee was cautioned about drawing too many conclusions regarding zero mismatch-shared organs based on these data.

II. Policy Proposal

The Committee agreed that DCD kidneys are difficult to place, in general, as many transplant centers refuse such organs for transplant. The possible addition of several hours cold ischemia time while trying to place and transport a DCD kidney as a zero mismatch can make it even more difficult to use such a kidney. Additionally, the studies reviewed by the Committee demonstrate that the expected outcome benefit from receipt of a shared zero antigen mismatch DCD kidney compared with a local unmatched DCD kidney is not shown. Under the current system, approximately half of the DCD kidneys require 20 or more offers to be placed. The Committee considered placing a time limit on DCD zero mismatch offers, but recognized that the current time limit for zero mismatch offers is four hours. Imposing a more restrictive time frame on DCD zero mismatch offers might not be feasible. After further discussion, the Committee agreed to a proposal to exempt DCD kidneys from the requirements of the zero mismatch kidney mandatory sharing policy, as well as, kidney payback policy by a vote of 14 For; 6 Against; 0 Abstention. With respect to kidney payback policy, the Committee clarified that OPOs would retain the option to offer DCD kidneys for payback, but would not be subjected to the requirements imposed by the policy.

Following approval of the proposal, some Members of the Committee voiced concern about the effect the proposed modification would have on sensitized candidates. Such candidates have limited opportunities to receive an organ offer due to the likelihood that they will reject organs from substantial portions of the donor population. Indeed, perhaps one explanation for DCD kidneys being shared at all is that they are being used for transplantation into highly sensitized candidates. It was recognized that the analysis comparing shared and local DCD outcomes is adjusted for PRA. The motion was introduced to continue the application of the DCD zero mismatch mandatory sharing policy to those candidates with PRA of 21% or greater. Some Members were skeptical as to the frequency by which a zero mismatch DCD kidney is shared for a highly sensitized candidate. It was suggested that the Committee should avoid making national policy based on rare circumstances. However, other Members hypothesized that DCD donors could become a major resource for kidneys in the future. Some transplant programs are just beginning to implement their DCD protocols. Perhaps, based on the relatively minimal data now available, it is premature to change policy. The Committee agreed to postpone consideration of the motion regarding sensitized candidates pending review of data on the number of candidates offered and transplanted with a zero mismatch DCD kidney by PRA and the number zero mismatch DCD kidneys transplanted into a recipient other than the original candidate to whom it was allocated.

The analysis of sensitized candidates examined all kidney offers from DCD donors to zero antigen-mismatched candidates between January 1, 2001, and December 31, 2002 using OPTN data as of January 2, 2004. Offers refused for reasons of donor medical urgency, multi-organ placement, directed donation, military donor, alternative systems, extra-renal placed with kidney were excluded as these are similar to system refusals and do not reflect actual refusals by candidates and their transplant centers. Acceptance rates were computed as the number of kidneys accepted as zero mismatches divided by the total number of zero mismatch offers. Potential candidates were stratified by PRA level (missing, 0%-20%, or > 20%).

The total number of DCD donors in 2001 was 169, of which 51 had at least one offer made to a zero mismatch candidate. From these 51 DCD donors, a total of 181 offers were made to zero mismatch candidates and 22 were accepted, resulting in an overall acceptance rate of 12.2%. The acceptance rate varied depending on the PRA of the potential candidates ranging from 4% for those with unknown PRA to 21.9% for sensitized candidates with PRA > 20%. Of the 22 DCD kidneys accepted, 19 were transplanted. In most cases, the candidate who accepted the offer also received the transplant.

Data from 2002 yielded similar results. The total number of DCD donors in 2002 was 189, of which 56 had at least one offer made to a zero mismatch candidate. From these 56 donors, a total of 260 offers were made to zero mismatch candidates and 28 were accepted, resulting in an overall acceptance rate of 10.8%. The acceptance rate was highest (13.4%) for sensitized candidates with PRA > 20%. Of the 28 DCD kidneys accepted, 24 were transplanted.

In summary, between 2001 and 2002, 107 (30%) of the 358 DCD donors had at least one kidney offered to a zero mismatch candidate. A total of 441 offers to zero mismatch candidates resulted in 50 acceptances, or an acceptance rate of 11.3%. The acceptance rate for sensitized candidates with PRA > 20% was 16.2%. Of the 50 DCD kidneys accepted as a zero mismatch, 7 were ultimately not transplanted into the accepting candidate.

The Committee noted that during 2001 and 2002, a total of only 13 DCD kidneys were transplanted into sensitized candidates with PRA > 20% who had a zero mismatch with the donor.

With the current emphasis in the transplant community on transplanting more DCD kidneys, some Members were concerned that implementing a national policy at this point is not appropriate. Any policy implemented now could quickly become obsolete if DCD donation and utilization rates rise in the near future. The result could mean a more substantial impact on candidates including sensitized candidates with PRA > 20%. Other Members noted that a future where DCD donation and utilization rates increased substantially would be welcome in any event. A national policy exempting DCD donor kidneys from zero antigen mismatch sharing beyond the local level and payback requirements could help increase those rates as centers would be permitted to use more of these kidneys for their local candidates with less cold ischemia time. The exemption from sharing requirements for zero antigen mismatched patients also is supported by the outcomes data reviewed by the Committee.

After further discussion, the Committee agreed to submit the proposal for public comment by a vote of 23 For; 0 Against; 0 Abstentions.

- * **RESOLVED, that the following modifications to Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) shall be distributed for public comment (additions and deletions recommended in this specific proposal are noted by bolded text):**

3.5.3.3 Mandatory Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, **and deceased kidneys procured from Donation after Cardiac Death donors⁴** if there is any patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate ~~OPTN/UNOS~~ member for the patient with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, **and deceased kidneys procured from Donation after Cardiac Death donors²**, if there is any patient on the UNOS Patient Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate ~~OPTN/UNOS~~ member for the patient with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are

⁴ **For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a patient who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a patient who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.**

transplantable, the recipient center that was offered the kidney for a patient with a zero antigen mismatch does not have the implicit right to choose between the two kidneys. The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a patient with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all patients for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. **For kidneys procured from Donation after Cardiac Death donors, if there is any candidate on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to remaining zero antigen mismatched candidates according to the sequence set forth below.** When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

3.5.3.3.1 [No Changes]

3.5.3.3.2 [No Changes]

3.5.3.4 Kidney/Non-Renal Exception. [No Changes]

3.5.3.5 Time Limit. [No Changes]

3.5.4 **Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates.**
[No Changes]

3.5.4.1 Mandatory Sharing. [No Changes]

3.5.5 **Payback Requirements.** Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), and 3.5.5.2 (Exception for Prior Living Organ Donors), when a kidney is shared pursuant to: (i) the mandatory zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable standard donor **that does not meet the criteria for a Donation after Cardiac Death donor**², six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors **meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is** less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

[No Further Changes]

III. Public Comment Responses

The proposal was issued to a mailing list of approximately 8,162 individuals and organizations for a comment period of 45 days beginning March 15, 2004, and ending April 29, 2004. As of April 29, 2004, 83 responses have been submitted to UNOS regarding this policy proposal. Of these, 41 (49.40%) supported the proposal, 4 (4.82%) opposed the proposal, and 38 (45.78%) had no opinion. Of the 45 who responded with an opinion, 41 (91.11%) supported the proposal and 4 (8.89%) opposed the proposal. All 11 Regions supported the proposal, including 5 unanimously. Comments on the proposal received to date and the Committee's responses are set forth below.

Some of the public commentary suggested possible disadvantage to sensitized candidates, especially in the event DCD kidney usage increases measurably. There was particular concern for African American and other minority candidates due to relative likelihood of sensitization being an important issue for these populations. The Committee affirmed their previously stated position and noted that during the two-year period studied (2001 - 2002), a total of only 13 DCD kidneys were transplanted into sensitized candidates with PRA > 20% who had a zero mismatch with the donor. Of the total 441 DCD kidney offers to zero antigen mismatched candidates, only 50 were accepted. There simply is not broad use of these organs outside the local procurement area, at least at this time. A future where DCD donation and utilization rates increased substantially would be welcome as a means to increase overall organ procurement and transplantation. A national policy exempting DCD donor kidneys from zero antigen mismatch sharing beyond the local level and payback requirements could help increase those rates as centers would be permitted to use more of these kidneys for their local candidates with less cold ischemia time. The exemption from sharing requirements for zero antigen mismatched patients also is supported by the outcomes data reviewed by the Committee. That is, among shared zero mismatch transplants, recipients of DCD kidneys had a significantly higher rate of post-transplant graft failure compared to recipients of deceased heartbeating donor (HBD) kidneys (RR= 1.84; p-value= 0.048). The Committee will, however, continue to review the effects of the proposal to determine the future impact on various groups, including sensitized candidates and minorities.

After further discussion, the Committee approved the proposal as submitted for public comment by a unanimous vote of 24 For; 0 Against; 0 Abstentions. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modifications to Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) (see above) having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System (additions and deletions recommended in this specific proposal are noted by bolded text):**

I. Individual Comments

Comment 1:

vote: Oppose

ASHI is opposed to this proposal. While we recognize that at this time the number of cardiac death donors (DCD) is relatively low, if over time the use of DCD increases significantly, this policy is likely to have a negative impact on patients, particularly those who are highly sensitized (PRA > 80%) who may need a zero antigen mismatch donor in order to be successfully transplanted.

Committee Response:

The Committee affirmed their previously stated position and noted that during the two-year period studied (2001 - 2002), a total of only 13 DCD kidneys were transplanted into sensitized candidates with PRA > 20% who had a zero mismatch with the donor. Of the total 441 DCD kidney offers to zero antigen mismatched candidates, only 50 were accepted. There simply is not broad use of these organs outside the local procurement area, at least at this time. A future where DCD donation and utilization rates increased substantially would be welcome as a means to increase overall organ procurement and transplantation. A national policy exempting DCD donor kidneys from zero antigen mismatch sharing beyond the local level and payback requirements

could help increase those rates as centers would be permitted to use more of these kidneys for their local candidates with less cold ischemia time. The exemption from sharing requirements for zero antigen mismatched patients also is supported by the outcomes data reviewed by the Committee. That is, among shared zero mismatch transplants, recipients of DCD kidneys had a significantly higher rate of post-transplant graft failure compared to recipients of deceased heartbeating donor (HBD) kidneys (RR= 1.84; p-value= 0.048). The Committee will, however, continue to review the effects of the proposal to determine the future impact on various groups, including sensitized candidates and minorities.

Comment 2:

vote: Oppose

More education of the public is needed regarding transplant outcomes using donation after cardiac death donors. It is unclear why these should not be given in accordance to current policies. Further clarification is needed on the effect this change will have on minority and highly sensitized candidates.

Committee Response:

Please see Committee response to Comment 1.

Comment 3:

vote: Oppose

This proposal is not supported by data. Exempting these organs from the mandatory share rule would disadvantage sensitized patients, affecting African-Americans and women, disproportionately. The impact will be significant as the use of DCD donors increases.

Committee Response:

Please see Committee response to Comment 1.

Comment 4:

vote: Support

(Donation after Cardiac Death) - Approve with comment: It seems to me that allowing these kidneys to be offered for payback as an option would encourage programs to offer only lower quality organs so recovered for payback, further delaying the allocation of the organs most in need of rapid allocation. If OPOs were required to use all such organs locally, there would be no last minute delays due to conversations with local programs trying to determine whether or not a particular organ should be offered for payback. Incentive for their procurement could be enhanced by increasing the allowed debt before mandatory payoffs are required.

Committee Response:

The Committee appreciates the response. Of the total 441 DCD kidney offers to zero antigen mismatched candidates, only 50 were accepted. There simply is not broad use of these organs outside the local procurement area, at least at this time. A future where DCD donation and utilization rates increased substantially would be welcome as a means to increase overall organ procurement and transplantation. A national policy exempting

DCD donor kidneys from zero antigen mismatch sharing beyond the local level and payback requirements could help increase those rates as centers would be permitted to use more of these kidneys for their local candidates with less cold ischemia time. The exemption from sharing requirements for zero antigen mismatched patients also is supported by the outcomes data reviewed by the Committee. That is, among shared zero mismatch transplants, recipients of DCD kidneys had a significantly higher rate of post-transplant graft failure compared to recipients of deceased heartbeating donor (HBD) kidneys (RR= 1.84; p-value= 0.048). The Committee will, however, continue to review the effects of the proposal to determine the future impact on various groups, including sensitized candidates and minorities.

II. Comments from Other Committees:

Ethics Committee - The Committee found the proposals ethically acceptable. However, there was some concern voiced that a possibility exists for abuse of this proposal. Some potential donors, who were in the process of being declared brain dead, could conceivably be recovered as DCD donors in an effort to keep the kidneys for local use.

Histocompatibility Committee - Support (Committee vote: 14 For, 0 Against, 0 Abstentions). The committee made the following comment: "That the number of Donation after Cardiac Death (DCD) donors be monitored at least annually, and if the numbers become substantial, that the policy would be re-evaluated." The committee requested that UNOS provide the number of DCD donors by OPO to the committee at all of its face-to-face committee meetings, beginning in July 2004.

Organ Availability Committee - The Committee unanimously supports this proposal as written.

Patient Affairs Committee - The Committee supports the proposed policy by a vote of 16-0-0.

III. Regional Comments:

REGIONAL COMMENT SUMMARY

PROPOSAL 2: Proposed Modifications to OPTN/UNOS Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) (“Exemption of Kidneys Recovered from Donation after Cardiac Death (DCD) Donors from Sharing Requirements for Zero Antigen Mismatched Kidneys or Payback) (Kidney and Pancreas Transplantation Committee)

Sponsoring Committee: Kidney and Pancreas Transplantation

Description: The proposal would exempt Donation after Cardiac Death (DCD) donor kidneys from the requirements of the zero antigen mismatch kidney sharing policy, except at the local level of organ distribution, as well as, kidney payback policy. OPOs would retain the option to offer DCD donor kidneys for payback, but would not be required to do so under the policy. The intent of the proposal is to place DCD donor kidneys as rapidly as possible to avoid adverse impacts from increased cold ischemia time, as well as, increase organ donation by providing an incentive for transplant centers to develop and enhance their DCD donor programs.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	14 yes, 0 no, 0 no opinion			
2	5/07/04	29 yes, 2 no, 1 no opinion			
3	3/26/04	17 yes, 0 no, 0 no opinion			
4	4/2/04	26 yes, 1 no, 1 no opinion			
5	4/30/04	36 yes, 0 no, 0 no opinion			
6	4/2/04	51 yes, 2 no, 0 no opinion			
7	4/23/04	16 yes, 0 no, 0 no opinion			
8	4/2/04	24 yes, 1 no, 1 no opinion			
9	4/21/04	17 yes, 1 no, 0 no opinion			
10	4/30/04	19 yes, 0 no, 0 no opinion			
11	3/26/04	19 yes, 0 no, 1 no opinion			

COMMENTS:

Proposed Modifications to OPTN/UNOS Policy 3.5.5 (Payback Requirements) (“ECD Kidney Exemption from Payback Sharing Requirements”)

Summary

The proposed modifications would exempt expanded criteria donor (ECD) kidneys from the requirements of the kidney payback policy. OPOs would retain the option to offer expanded criteria donor kidneys for payback, but would not be required to do so under the policy. The Committee based its proposal on data previously reviewed and discussed by the Committee, including data showing that approximately only 10% of ECD payback offers have been accepted since the implementation of the ECD kidney policy in November 2002. The intent of the policy is to minimize cold ischemia time and maximize use of the ECD kidneys.

I. Background

The OPTN/UNOS Membership and Professional Standards Committee requested the Committee to review the issue of whether expanded criteria donor (ECD) kidneys should be exempt from the payback policy requirements. OPTN/UNOS Policy 3.5.5 (Payback Requirements) currently states the following:

Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), and 3.5.5.2 (Exception for Prior Living Organ Donors), when a kidney is shared pursuant to: (i) the mandatory zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable donor, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

The kidney payback system was developed as a mechanism to address imbalances created by the policy for sharing zero antigen mismatched kidneys as well as kidneys shared voluntarily with a non-renal organ or for highly sensitized patients, ensuring that no patient population benefits from the sharing rules to the disproportionate harm of any other patient population. The payback policy is intended to put the system back into balance.

The Committee considered exempting ECD kidneys from payback requirements when it first developed the ECD kidney allocation system, but decided to give the system some time to operate before creating such an exemption. A creditor OPO to whom an ECD kidney is offered in satisfaction of a kidney payback obligation has the discretion to accept or reject the offer. While there is no duty to accept the kidney, the creditor OPO may have broad organ acceptance criteria and be willing to accept the kidney. Provided that there is general or reasonable acceptance of these organs for payback, debtor OPOs should be required to make them available.

Recently, the OPTN/UNOS Policy Compliance Staff has initiated inquiries as to why some OPOs are not offering certain kidneys for payback pursuant to OPTN/UNOS Policies. The OPOs have explained that ECD kidneys generally are not accepted for payback and thus not offered to expedite and maximize placement.

II. Policy Proposal

The Committee discussed this issue during its October 1-2, 2003, meeting. Between November 2002 and April 2003, 51 ECD kidneys were transplanted into recipients. Of these 51 ECD kidneys, 39 were offered for payback; however, only 4, or approximately 10.3%, of the ECD payback offers were accepted for payback. Based on these data, Members of the Committee were supportive of the notion to exempt ECD kidneys from the mandatory payback policy. However, some Members were reluctant to recommend such a modification because the data includes only small numbers and the ECD protocol has been in place for a relatively short period of time. Transplant centers are still developing guidelines for which ECD kidneys are acceptable for their program and candidates. It may be premature to expect centers to accept ECD kidneys regionally, or for payback on any large scale.

After further discussion and based upon experience with acceptance of ECD kidneys in satisfaction of payback debts to date, the Committee agreed to the proposal to exempt ECD kidneys from the mandatory payback policy, while retaining the option for OPOs to volunteer ECD kidneys for payback, by a vote of 21 For; 1 Against; 0 Abstention. This would allow greatest flexibility for OPOs in determining best use of ECD kidneys and appropriate management of payback debt. The Committee affirmed its decision to submit the proposal for public comment during its January 20-21, 2004, meeting.

- * **RESOLVED, that the following modifications to Policy 3.5.5 (Payback Requirements) shall be distributed for public comment (additions and deletions recommended in this specific proposal are noted by bolded text):**

3.5.3.3 Mandatory Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors² if there is any patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate ~~OPTN~~**UNOS** member for the patient with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors², if there is any patient on the UNOS Patient Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate ~~OPTN~~**UNOS** member for the patient with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a patient with a zero antigen mismatch does not have the implicit right to choose between the two kidneys. The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a patient with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all patients for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after Cardiac Death donors, if there is any candidate on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to remaining zero antigen mismatched candidates according to the sequence set forth below. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

3.5.3.3.1 [No Changes]

3.5.3.3.2 [No Changes]

3.5.3.4 Kidney/Non-Renal Exception. [No Changes]

3.5.3.5 Time Limit. [No Changes]

3.5.4 **Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates.**
[No Changes]

3.5.4.1 Mandatory Sharing. [No Changes]

3.5.5 **Payback Requirements.** Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), and 3.5.5.2 (Exception for Prior Living Organ Donors), when a kidney is shared pursuant to: (i) the mandatory zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable **standard** donor **that does not meet the criteria for a Donation after Cardiac Death donor²**, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors **meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older** may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

[No Further Changes]

III. Public Comment Responses

The proposal was issued to a mailing list of approximately 8,162 individuals and organizations for a comment period of 45 days beginning March 15, 2004, and ending April 29, 2004. As of April 29, 2004, 81 responses have been submitted to UNOS regarding this policy proposal. Of these, 41 (50.62%) supported the proposal, 2 (2.47%) opposed the proposal, and 38 (46.91%) had no opinion. Of the 43 who responded with an opinion, 41 (95.35%) supported the proposal and 2 (4.65%) opposed the proposal. All 11 Regions supported the proposal, including 5 unanimously. Comments on the proposal received to date and the Committee's responses are set forth below.

After further consideration, the Committee approved the proposal as submitted for public comment by a vote of 24 For; 0 Against; 0 Abstentions. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

- * **RESOLVED, that the following modifications to Policy 3.5.5 (Payback Requirements) (see above) having been distributed for public comment, and subsequently recommended by the OPTN/UNOS Kidney and Pancreas Transplantation Committee, shall be approved and implemented pending programming on the UNOS System (additions and deletions recommended in this specific proposal are noted by bolded text):**

I. Individual Comments:

Comment 1:

vote: Support

(Extended Criteria Donors)- Approve with comment: It seems to me that allowing these kidneys to be offered for payback as an option would encourage programs to offer only lower quality organs so recovered for payback, further delaying the allocation of the organs most in need of rapid allocation. If OPOs were required to use all such organs locally, there would be no last minute delays due to conversations with local programs trying to determine whether or not a particular organ should be offered for payback. Increasing the allowed debt before mandatory payoffs are required could enhance incentive for their procurement.

Committee Response:

Between November 2002 and April 2003, 51 ECD kidneys were transplanted into recipients. Of these 51 ECD kidneys, 39 were offered for payback; however, only 4, or approximately 10.3%, of the ECD payback offers were accepted for payback. Based on these data, Members of the Committee were supportive of the notion to exempt ECD kidneys from the mandatory payback policy. However, some Members were reluctant to recommend such a modification because the data includes only small numbers and the ECD protocol has been in place for a relatively short period of time. Transplant centers are still developing guidelines for which ECD kidneys are acceptable for their program and candidates. It may be premature to expect centers to accept ECD kidneys regionally, or for payback on any large scale.

II. Comments from Other Committees:

Ethics Committee - The Committee found the proposal ethically acceptable based on current and historical practice.

Organ Availability Committee - The Committee unanimously supports this proposal as written.

Patient Affairs Committee - The Committee supports the proposed policy by a vote of 15-0-0.

III. Regional Comments:

REGIONAL COMMENT SUMMARY

PROPOSAL 3: Proposed Modifications to OPTN/UNOS Policy 3.5.5 (Payback Requirements) (“ECD Kidney Exemption from Payback Sharing Requirements”) (Kidney and Pancreas Transplantation Committee)

Sponsoring Committee: Kidney and Pancreas Transplantation

Description: The proposed modifications would exempt expanded criteria donor (ECD) kidneys from the requirements of the kidney payback policy. OPOs would retain the option to offer expanded criteria donor kidneys for payback, but would not be required to do so under the policy. The Committee based its proposal on data previously reviewed and discussed by the Committee, including data showing that approximately only 10% of ECD payback offers have been accepted since the implementation of the ECD kidney policy in November 2002. The intent of the policy is to minimize cold ischemia time and maximize use of the ECD kidneys.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	14 yes, 0 no, 0 no opinion			
2	5/7/04	31 yes, 1 no, 0 no opinion			
3	3/26/04	17 yes, 0 no, 0 no opinion			
4	4/2/04	27 yes, 4 no, 2 no opinion			
5	4/30/04	33 yes, 0 no, 3 no opinion			
6	4/2/04	53 yes, 0 no, 0 no opinion			
7	4/23/04	16 yes, 0 no, 0 no opinion			
8	4/2/04	24 yes, 1 no, 1 no opinion			
9	4/21/04	17 yes, 1 no, 0 no opinion			
10	4/30/04	19 yes, 0 no, 0 no opinion			
11	3/26/04	19 yes, 0 no, 1 no opinion			

COMMENTS:



December 22, 2003

UNOS Kidney/Pancreas Committee:

The UNOS extended cadaver donor (ECD) allocation algorithm supersedes local variances/ALU's. For years, the Midwest Transplant Network OPO has had a UNOS-approved variance to allocate A₂/A₂B kidneys into B and O patients from all local donors, which included ECD as well as non-ECD donors. Since the ECD algorithm supersedes all local variances, our OPO can no longer allocate kidneys from A₂ or A₂B ECD donors to our B and O patients, reducing the access they would have to those kidneys.

Therefore this letter requests that our OPO be allowed to continue (as we had until the ECD algorithm was implemented) allocating A₂ and A₂B kidneys from ECD donors to B and O recipients on our OPO waiting list. All of the transplant centers in the OPO (see signatures enclosed) feel this is warranted since until the ECD allocation system was implemented, our A₂/A₂B allocation variance included kidneys from ECD.

Enclosed for your review is a copy of our most recent (2002) report to UNOS on our A₂ variance so you can see that it (and every annual report we have sent to UNOS over that last few years) included all A₂ & A₂B donors (ECD as well as non-ECD). Finally, we enclose signatures from an appropriate representative of each of the six renal transplant programs in our OPO demonstrating their support for our request. From the UNOS computer programming standpoint, it would just mean "laying our current A₂ variance on top of the ECD algorithm," allowing A₂ and A₂B ECD donors to be allocated in accord with our long-standing UNOS-approved A₂ allocation variance.

Thank you for your consideration of this request. Please feel free to contact either of us with any comments or questions.

Sincerely,

Rob Linderer
Executive Director

Christopher F. Bryan, Ph.D., HCLD
Laboratory Director

RL/CFB:ncm

Enclosures

J-1

Transplant Center Signature Page

Each of the following transplant centers in the Midwest Transplant Network OPO support the request to return to our variance to allocate ECD kidneys from blood group A₂ and A₂B donors to B and O recipients.



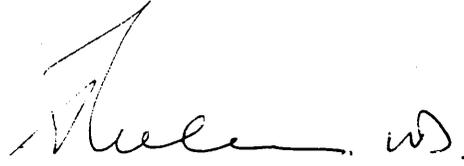
Dennis A. Diederich, M.D.
University of Kansas Hospital
Kansas City, KS



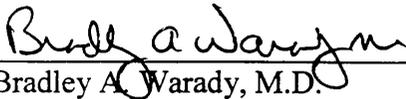
Charles F. Shield, III, M.D.
Via Christi-St. Francis Regional Medical
Center, Wichita, KS



Thomas T. Crouch, M.D.
Saint Luke's Hospital
Kansas City, MO



Paul W. Nelson, M.D.
Saint Luke's Hospital
Kansas City, MO



Bradley A. Warady, M.D.
The Children's Mercy Hospital
Kansas City, MO



Daniel Murillo, M.D.
Research Medical Center
Kansas City, MO



Nicolas A. Muruve, M.D.
University Hospital
Columbia, MO

**Midwest Transplant Network
Organ Procurement Organization**

2002 Annual Report to UNOS on the Midwest Transplant
Network OPO A₂/A₂B Kidney Allocation Variance

2002 Annual Report to UNOS on the Midwest Transplant Network OPO
A₂/A₂B Kidney Allocation Variance

TABLE OF CONTENTS

Section	Title
I.	Textual Responses to UNOS Questions
A.	Introduction to 2002 Midwest Transplant Network Variance Report
B.	Issues Addressed
C.	Specific Data Elements
II.	Tables (1-11)
III.	Figures (1 & 2)
IV.	Attachments

- I. Textual Responses to UNOS Questions
 - A. Introduction to 2002 Midwest Transplant Network
Variance Report
 - B. Issues Addressed
 - C. Specific Data Elements

I.A. Introduction to 2002 Midwest Transplant Network
Variance Report

1.A.

As with last year's variance report to UNOS, we will focus our discussion on data generated from A₂ and A₂B into B kidney transplants done from 1994 to 2002, and present data for 2002. Long-term graft survival for A₂ and A₂B into B patients is equivalent to ABO compatible transplants (Table 7 and attachment 2). In 2002, the transplant centers in our service area performed three A₂ into B deceased donor renal transplants, one A₂ into O deceased donor kidney + pancreas transplant, and one A₂ into O kidney transplant. To date, we have now done four kidney + pancreas A₂ into B transplants and two A₂ into O kidney+ pancreas transplants. Overall (1994 – 2002), 31% of the transplants done in B candidates were kidneys from A₂ donors.

In 2002, only 14% (3/21) of the deceased donor B transplants done were A₂ into B transplants, and each is still functioning. Of interest, 67% (2/3) of the blood group B patients who received an A₂ kidney were in minority groups (1 Asian and 1 black). In 2001, Research Medical Center began routinely performing A₂ into B deceased donor transplants, so all centers in our OPO now routinely perform these transplants.

I.B. Issues and Data Elements to be Addressed in
Member's Report on Alternative Organ
Allocation/Distribution System to UNOS

1. What are the advantages of the alternative system over the current OPTN allocation policy for this organ type? How is equitable organ allocation facilitated under the system?

Midwest Transplant Network OPO Response:

The most important rationale for continuing our OPO's A₂/A₂B kidney allocation variance (see attachment 1 for our allocation algorithm) is to be able to continue the increased access to kidneys for our blood group B ESRD waiting list candidates. Since 1994, we have transplanted 162 blood group B ESRD patients with deceased donor kidneys; of those, 31% (51/162) received A₂ or A₂B kidneys (Table 2a). In 2002 alone, 14% (3/21) of the B recipients of deceased donor kidneys received either A₂ or A₂B kidneys (Table 2a). The continued use of this variance allows our OPO to maintain the increased access to kidneys of the patients on our B waiting list by providing them with kidneys they would not normally have access to without this type of allocation variance (see attachments 2-5 for recent publications on this subject).

A further impact this variance has had is on our OPO-wide B waiting list (Figures 1a & 1b). Our B waiting list has been reduced by one-third, whereas, over the last two years our O and A lists (Figure 1a) have remained relatively constant. However, in just the last two years our B list increased slightly with the addition of B candidates, possibly due to lower numbers of kidneys transplanted locally from B donors in 1999 and 2000 (Table 2b) and fewer A₂ or A₂B to B transplants.

An additional important aspect to the use of this variance is the impact that removal of access to A₂ kidneys has had on our A waiting list. First, as shown in national perspective (Table 3), the A waiting list candidates have a distinct advantage with access to 39.6% of the donor population, but they comprise only 28.2% of the candidates on the national waiting list. In marked contrast, B candidates have access to 10.2% of the donors, but they comprise 17.4% of the candidates on the waiting list. Thus, based on national data, A candidates would be disadvantaged to a lesser degree if a small proportion of A

kidneys were allocated to B waiting list candidates compared to the degree B patients would be advantaged. As can be seen from the data in Figure 2, only 47 of the 722 A kidneys that were transplanted, 6.5%, were taken from the A waiting list candidates and allocated to B waiting list candidates, which increased the blood group B transplant rate by 31% from 1994 to 2002 (Table 2a), with 51 of the 162 transplant recipients receiving A₂ or A₂B kidneys. Thus, local A candidates are disadvantaged to a smaller degree than the degree to which B candidates are advantaged.

In summary, we believe the above discussion of our data demonstrate that this allocation variance has facilitated more equitable kidney allocation to candidates on our B waiting list with minimal detrimental effects on our A waiting list. Only 6.5% of the A kidneys from 1994 to 2002 were used by this variance, and we were able to increase the transplant rate of our B candidates by 31%. That resulted in our ability to reduce our OPO-wide B waiting list by that many B patients over a 9-year period (Figure 1a).

Our experience with A₂/A₂B into B and O deceased donor transplants is shown in Tables 2a and 2c and with living-donor transplants in Table 4. It should be pointed out that Table 2c was added to this report to show the kidney + pancreas A₂ into B and O transplants that were done. The demographic data are shown in Table 5. As seen from the data in Table 6, three of the transplantable kidneys from local A₂ donors in 2002 were transplanted into B patients by using our variance. The one-month function rate in the patients transplanted since 1994 is 93% (64/69) (Table 5). We therefore believe that the clinical success of these transplants and the increased rate of transplantation for our B patient waiting list justify continued approval of our variance. Please see the publications in attachments 2 - 5 for further documentation. Finally, we should note that 6 of the A₂ into B and O deceased donor transplants done in 1999, 2000, 2001, and 2002 (Table 2c) were kidney + pancreas transplants. All organs in the kidney + pancreas patients continue to function as of January, 2003.

2. *If the alternative system includes an ALU, what is the effect of the ALU in relation to each of the six principles for defining local?*

Midwest Transplant Network OPO Response:

Our OPO A₂/ A₂B kidney allocation variance does not involve an ALU nor is there any subdivision of the OPO with regard to kidney allocation. We allocate kidneys only in accord with the variance and the standard UNOS renal algorithm to our single OPO-wide renal waiting list.

3. *How does the alternative system affect organ allocation, waiting times and mortality for highly sensitized transplant candidates?*

Midwest Transplant Network OPO Response:

Our A₂/ A₂B kidney allocation variance allocates first to the highly sensitized A patients before kidneys are allocated to the B or O candidates (*see allocation steps 1 & 2 in attachment 1*). Since we first offer these kidneys to any high PRA blood group A patients (80% or higher PRA), no negative effects on waiting times or mortality occur. In fact, one high PRA patient (A₂→B) was transplanted in 1997 (Table 1) and two high PRA patients were transplanted in 2002 (one of which was a simultaneous kidney + pancreas recipient).

Secondly, within each of the allocation steps 3 and 4 (see attachment 1) where we allocate A₂ or A₂B kidneys to B and O patients, the standard UNOS renal algorithm operates. Thus, high PRA patients who have a negative crossmatch with historic and current sera are assigned the 4 points by the standard UNOS allocation algorithm. (Our OPO-wide choice is to use the historic PRA/serum to assign the 4 points.) Thus, in each of the first 4 steps of our variance allocation algorithm we use the UNOS standard system, which gives preference to high PRA patients.

4. *How is HLA typing used and what is the impact of HLA typing under the alternative system?*

Midwest Transplant Network OPO Response:

HLA typing as used in this allocation variance is no different from our standard UNOS algorithm. The standard UNOS algorithm with the standard HLA point system operates within each of the six tiers of our allocation variance. Therefore, no impact of HLA typing would be seen with this variance. Furthermore, since we use the typical UNOS allocation point system, blood group A₂/A₂B kidneys with zero mismatches are shared before those kidneys may be used in our allocation scheme.

5. *What are the demographic impacts of the alternative system, e.g., its effect on organ allocation, waiting times (wait times are addressed in our response to question 7), and mortality among minority, female, and pediatric transplant candidates?*

Midwest Transplant Network OPO Response:

Minority Transplant Candidates: During 2002, 2 of the 5 (40%) A₂ and A₂B transplants were performed in ethnic minority candidates (Table 1). Since 1994, 39% (20/51) of the B recipients of A₂ or A₂B kidneys transplanted were minority candidates. Whereas the minority transplant rate of all B recipients of B or O kidneys is 36% (Table 8).

Female Transplant Candidates: Of the five A₂ transplants done in 2002, 3 (60%) were to females (Tables 1 and 5). Table 5 shows that since 1994, of our A₂/A₂B into B and O transplants, 39% went to females. That approximates the one-third incidence of females on our waiting list historically and currently. The A₂/A₂B variance therefore transplants females at a rate comparable with their waiting list composition.

Pediatric Transplant Candidates: None of the patients who received an A₂ kidney in 2002 were pediatric candidates. The A₂/A₂B algorithm utilizes the

standard UNOS kidney allocation algorithm, which includes the point system for age, so that system operates within each of the variance's allocation steps. We have transplanted two A₂ kidneys into pediatric candidates since implementing the variance and 4 pediatric patients with cadaveric A₂ kidneys prior to implementation of our variance (Table 9). Those data, as well as the NAPRTCS ABO-incompatible data are shown in the enclosed article (attachment 5). Offering A₂ or A₂B kidneys to B and O pediatric candidates increases their access to kidneys, which they would lack without this variance. Finally, the data in Table 9 show that graft outcomes in B and O pediatric patients who receive A₂ kidneys are good. Of the 7 pediatric patients transplanted, 3 (43%) still have functioning kidneys with a mean follow-up of 11.6 years. Of the four that failed, one functioned well for 23 months before failure due to non-compliance, and two functioned for over ten years before being lost to rejection. In summary, A₂/ A₂B pediatric transplants do well and expand donor access for B and O pediatric patients.

6. *How does the alternative system affect transplant outcomes (e.g., transplant recipient and graft survival)?*

Midwest Transplant Network OPO Response:

Early Function:

One of the important components implemented has been to perform quarterly anti-A titer measurements in B and O candidates who are eligible for A₂/ A₂B transplants (*see the last requirement of our A₂ variance regarding performing anti-A titers, attachment 1*). This has reduced the likelihood that these kidneys will have early non-function. By performing these measurements on most patients, we now have a titer history or profile (*Transplantation Proceedings* 28:221, 1996), in much the same way that we also have a PRA history on patients by monthly or quarterly PRA testing. The anti-A titer profiles allow us to use these data at the time of kidney allocation to determine whether a patient should or should not be considered for transplant.

Our current one-month deceased donor kidney function rate for A₂/A₂B kidneys is 93% (64/69) (Table 5). A low titer history/profile existed for 95% of the 66 patients transplanted with A₂/ A₂B kidneys. We relate the good early function rate to the use of more complete anti-A titer histories in our transplant selection criteria.

Longer-Term Function:

As shown earlier in this report (question 1), as well as in past publications (attachments 2 – 5), long-term graft survival (5-year) in these patients is comparable with that of ABO-compatible transplants (Table 7). The actual survival is shown in Table 1 and the survival curve was not re-calculated since there were only 3 more A₂ or A₂B to B transplants performed in 2002.

Cold Ischemic Time:

Another important contribution of having the anti-A titer history of each candidate for A₂/ A₂B kidneys available before transplantation is that we have been able to maintain a low cold ischemia time (CIT) on A₂/ A₂B kidneys we transplant into B and O patients. Since 1994, the mean CIT is 13.7 ± 5.3 hours (n=69).

7. *How does the alternative system affect organ allocation, waiting times and mortality among transplant candidates of different blood types?*

Midwest Transplant Network OPO Response:

Organ Allocation in Candidates of Different Blood Types: By design, our-A₂/ A₂B allocation variance preferentially directs A₂/A₂B kidneys (A₂B kidneys only go to B candidates) first to blood group B candidates and then to O candidates, in accord with the six-step allocation algorithm (see attachment 1). As seen in steps 1 and 2 of that variance, we give first priority to **highly sensitized** patients who are blood group A₂ and A₂B (see attachment 1, allocation step 1) and who are blood group A₁ or A₁B (see attachment 1, allocation step 2). We then allocate A₂ and A₂B kidneys to B patients (see attachment 1, allocation step 3) followed by allocating A₂ kidneys to O patients

(allocation step 4). Finally, allocation of A₂ and A₂B kidneys goes to A₂ and A₂B candidates with a current PRA < 80% (allocation step 5, attachment 1) and then to A₁ and A₁B candidates with a PRA < 80% (allocation step 6, attachment 1).

Since one of the objectives of the allocation variance was to preferentially allocate A₂ and A₂B kidneys to B and then to O patients, since 1994 we have allocated 74% (51/69) of the A₂ and A₂B kidneys (Table 5), that get transplanted into B and O patients, into blood group B patients. The percentage of B patients receiving A₂ and A₂B kidneys (of all B deceased donor transplants) is now 31% of all the kidneys that went to B patients (Table 2a). We thus feel that using a proportion of the blood group A kidneys we procure from deceased donors in B patients, who have less access to kidneys than A patients, is equitable since A patients wait a much shorter time and have relatively greater access to kidneys (Table 3).

The data in Table 10 show that we are currently (1994 to 2002) identifying close to the expected proportion of A₂ and A₂B subgroups of A and AB donors. A₂ donors constitute 15% of A blood group donors and A₂B donors constitute 27% of the AB donors. Those values are close to the 20% expected for Caucasian A and AB individuals. In the years before 1994, the frequency of A₂ donors was around 12% of A donors. We feel that the chief reason we now approach the expected incidence of A₂ and A₂B donors is due to ***purposeful ABO typing using pre-transfusion blood from our OPO's local donors, when possible, since post-transfusion blood from A₂ and A₂B donors would likely type as A₁ and A₁B due to being transfused with A₁ or A₁B blood. For quality assurance, the A₂ subtype is always confirmed by another lab.*** Finally, as an additional quality assurance component, our lab has established an anti-A titer proficiency-testing program with the University of Texas in Galveston, Southwestern Immunodiagnostics, and Inland Northwest Blood Center, Spokane, WA. This program assures that our anti-A titer measurements are precise and accurate.

Waiting Time in Candidates of Different Blood Types: The data in Table 11 show median and mean waiting times of all of our OPO's recipients by blood groups. Of note is the observation that waiting times for B patients who received A₂ or A₂B kidneys (median=181 days; n=51) were lower than that of B patients who received O or B kidneys (median=291 days; n=109). A similar trend was noted for O patients who received A₂ kidneys compared with O patients who received O kidneys.

A second important observation is that the median waiting time for B patients who received A₂ or A₂B kidneys (median=181 days; n=51) is less than that of A patients (median=296 days; n=528).

Mortality in Candidates of Different Blood Types:

8. *If the alternative system is for allocation of hearts, livers, intestinal organs or pancreas-islets, how does it affect organ allocation, waiting times and mortality among the various categories of medical urgency?*

Midwest Transplant Network OPO Response:

The A₂/ A₂B allocation variance is only for deceased donor kidney allocation.

I.C. Specific Data Elements Requested by UNOS

1. *Total number of patients transplanted (and as % of Waiting List)*

Midwest Transplant Network OPO Response:

Five patients received A₂ deceased donor kidneys in 2002. In total, since 1994, of 69 B and O patients transplanted with A₂ and A₂B kidneys, 74% (51/69) were B patients and 26% (18/69) were O recipients. The data showing our B, A and O waiting lists are shown in Figures 1a and 1b. However, in January of 2000, the B waiting list started to increase for two reasons. First, we have had fewer B donors in our OPO than would normally be expected. The data in Table 2b show that in 2000, we had only 4.8% (5/104) B donors, and in 1999, 7.2% (8/110) of the donors were B. Normally the proportion of B donors would be closer to 10%, as we saw in 2001 and 2002. Furthermore, 29% (18/62) of the kidneys from those donors were exported. Also, this year we have only done three A₂ → B transplants.

Since 1994, 26% (18/69) of the transplants done under our variance were A₂ → O transplants, with two being done in 2002. Our blood group O waiting list (Figure 1a) has remained fairly constant, until the increase in 2000. A total of 557 deceased donor transplants into O recipients were done between 1994 and 2002, and of those, 3.2% (18/557) were with A₂ kidneys.

2. *Number of pediatric patients transplanted (and as % of Waiting List)*

Midwest Transplant Network OPO Response:

One pediatric patient was transplanted in 2000 and between 1994 and 2002, two were done. Please review Table 9 and the manuscript in attachment five. It should be pointed out that the standard UNOS algorithm giving points for pediatric patients operates in each component of our A₂ allocation variance, so they are not disadvantaged.

3. *Number of minority patients transplanted (and as % of Waiting List)*

Midwest Transplant Network OPO Response:

Two minority patients were transplanted in 2002 with A₂ kidneys. From 1994 to 2002, of the 160 blood group B candidates transplanted with deceased donor kidneys in our OPO service area, 37% (59/160) were minority patients (Table 8). When that group is broken down to the percent of minority recipients transplanted by donor blood groups, 36% (39/109) of the blood group B recipients of O or B kidneys were minority patients. The blood group B recipients of A₂ or A₂B kidneys had a minority transplant rate of 39% (20/51).

4. *Number of highly sensitized patients transplanted (and as % of Waiting List)*

Midwest Transplant Network OPO Response:

Only one high PRA patient has received an A₂ kidney between 1994 and 2002 and that transplant was done in 1997 (Table 1). However, it is important to keep in mind that high PRA patients get first access to A₂/A₂B kidneys in each allocation tier of our algorithm (attachment 1) and this year (2002) two high PRA blood group A patients received A₂ kidneys, one of which received a simultaneous kidney and pancreas transplant (Table 6).

5. *Percentage of patient survival greater than 12 months.*

Midwest Transplant Network OPO Response:

Of the 5 patients transplanted in 2002, 5 (100%) are alive (Table 1). Of the 69 patients transplanted since 1994, 59 are alive (86%) (Table 1). Of those ten who have died, eight died with functioning kidneys and one died of vascular complications (Table 1).

6. *Percentage of patients transplanted by status code*

Midwest Transplant Network OPO Response:

All active kidney patients on our renal waiting list are status 1.

7. *The average distance the organ traveled (miles)*

Midwest Transplant Network OPO Response:

The kidneys transplanted in these recipients were from locally procured donors (within our OPO service area).

8. *The median distance organ traveled (miles)*

Midwest Transplant Network OPO Response:

The kidneys transplanted in these recipients were from locally procured donors (within our OPO service area).

9. *Percentage of ABO identical transplanted*

Midwest Transplant Network OPO Response:

This question is not relevant since we are doing ABO mismatched transplants.

10. *Number of pre-transplant deaths*

Midwest Transplant Network OPO Response:

No pre-transplant deaths occurred.

11. *Number of post-transplant deaths*

Midwest Transplant Network OPO Response:

No post-transplant deaths occurred in 2002 for patients transplanted in 2002.

12. *Median waiting time (days from arrival to transplant)*

Midwest Transplant Network OPO Response:

The median waiting time was 260 days for the 5 transplants done in 2002. The median waiting time for the 69 blood group B and O patients transplanted since 1994 was 210 days (Table 5). Median waiting times for recipients of deceased donor kidneys between 1994 and 2002 stratified by blood group are shown in Table 11 and show that B recipients of A₂ or A₂B kidneys have shorter median waiting times than all other blood groups, except AB.

II. Tables (1-11)

J-22

125

TABLE 1 Clinical Followup for A2 to B O Transplants : 1984 to 2002

Organs Txed	Tx Ctr	Tx Date	Rejection Date	Death Date	Kidney Func at 1 month	Func at Rej	Reason	Wait Time (days)	Gen Race	Tx #	Recip ABO	Don ABO	Anti-A Titer	PRA Current	PRA Peak	A,B,DR mm	Age	Follow Up (mo)
Kidney	KSFW	8/6/1984		5/17/1988	Yes	DWFG		373 F	Black	1 B	A2	A2	Low	5	8	6	33	22
Kidney	KSFW	8/6/1984			Yes	Functioning 3/03		778 M	White	1 B	A2	A2	Low	0	0	5	43	102
Kidney	KSFW	12/23/1984			Yes	Functioning 3/03		317 M	Hispan	1 B	A2	A2	Low	0	5	4	65	98
Kidney	KSFW	12/23/1984			Yes	Functioning 3/03		519 M	White	1 B	A2	A2	Low	0	5	5	33	98
Kidney	MOLH	12/30/1984	3/1/2001		Yes	Rejection		270 F	White	2 O	A2	A2	Low	5	10	4	57	98
Kidney	MOLH	12/30/1984	10/2/2001		Yes	Rejection		210 M	White	1 O	A2	A2	Low	0	0	5	35	98
Kidney	KSUK	3/25/1985	12/18/2000		Yes	Rejection		641 F	White	1 B	A2	A2	Low	0	3	6	19	88
Kidney	KSFW	3/25/1985	4/7/1985	8/22/96	No	Rejection		277 M	White	1 O	A2	A2	Low	0	3	3	53	0.5
Kidney	MOLH	6/3/1985			Yes	Functioning 3/03		207 M	Black	1 O	A2	A2	Low	0	0	5	68	90
Kidney	KSFW	8/27/1985	7/18/1988		Yes	Rejection		191 F	Black	1 B	A2	A2	Low	0	0	6	48	35
Kidney	MOLH	12/17/1985		1/23/1988	Yes	DWFG		75 M	White	1 B	A2	A2	ND	0	0	4	56	1
Kidney	MOLH	12/17/1985			Yes	Functioning 3/03		601 F	White	2 O	A2	A2	Low	35	40	5	22	87
Kidney	KSUK	1/17/1986			Yes	Functioning 3/03		238 M	White	1 B	A2	A2	Low	0	4	5	55	84
Kidney	KSFW	9/25/1986	5/14/1988		Yes	Rejection		425 F	White	1 O	A2	A2	Low	0	5	3	34	20
Kidney	MOUM	3/28/1987			Yes	Functioning 3/03		161 F	White	1 B	A2B	A2B	ND	0	3	2	64	60
Kidney	MOLH	3/28/1987	11/14/2001		Yes	Rejection		279 M	White	1 B	A2B	A2B	Var	0	0	5	36	60
Kidney	KSFW	4/19/1987		8/27/1987	Yes	DWFG		1066 F	White	2 B	A2	A2	Var	57	84	3	38	59
Kidney	KSFW	4/19/1987			Yes	Functioning 3/03		201 M	White	1 B	A2	A2	Low	0	3	4	40	59
Kidney	KSFW	5/17/1987			Yes	Functioning 3/03		109 F	White	1 O	A2	A2	Low	0	2	4	37	58
Kidney	MOUM	5/27/1987	5/3/2001		Yes	Rejection		280 F	White	1 O	A2	A2	Low	0	12	5	57	58
Kidney	MOUM	7/24/1987		9/14/1987	Yes	DWFG		1201 F	White	2 B	A2	A2	Low	28	67	5	58	56
Kidney	KSFW	7/24/1987			Yes	Functioning 3/03		71 F	White	1 B	A2	A2	Low	0	0	4	56	56
Kidney	MOLH	9/1/1987			Yes	Functioning 3/03		62 M	White	1 B	A2	A2	ND	0	0	5	43	54
Kidney	KSUK	9/1/1987			Yes	Functioning 3/03		102 M	White	3 B	A2	A2	ND	0	0	5	36	54
Kidney	KSUK	9/1/1987			Yes	Functioning 3/03		80 M	White	3 B	A2	A2	Low	0	3	3	50	53
Kidney	KSUK	10/8/1987		7/7/2002	Yes	DWFG		602 M	White	2 O	A2	A2	Low	15	40	6	45	53
Kidney	KSFW	10/8/1987		8/8/2000	Yes	Functioning 3/03		81 M	White	2 B	A2	A2	Low	0	0	3	42	52
Kidney	KSUK	11/23/1987			Yes	DWFG		106 F	White	2 B	A2	A2	Low	0	0	3	52	52
Kidney	MOUM	11/23/1987			Yes	Functioning 3/03		224 M	White	1 O	A2	A2	Low	0	7	3	51	62
Kidney	MOLH	12/2/1987			Yes	Functioning 3/03		276 M	White	2 O	A2	A2	Low	0	0	5	46	62
Kidney	KSFW	12/2/1987			Yes	Functioning 3/03		224 M	White	1 O	A2	A2	Low	0	0	5	46	62
Kidney	MOLH	6/10/1988			Yes	Functioning 3/03		659 F	Black	1 B	A2	A2	Low	16	41	5	57	55
Kidney	KSFW	8/10/1988	7/2/1988	1/23/1988	No	Rejection/vascular problem		105 M	Black	1 B	A2	A2	Low	0	2	5	80	55
Kidney	KSFW	8/20/1988			Yes	Functioning 3/03		207 M	White	2 B	A2B	A2B	Low	0	2	5	50	57
Kidney	MOUM	6/20/1988			Yes	Functioning 3/03		94 F	White	1 B	A2B	A2B	ND	0	0	5	56	57
Kidney	KSUK	7/11/1988			Yes	Functioning 3/03		410 M	White	1 O	A2	A2	Low	0	0	3	48	56
Kidney	KSFW	7/11/1988			Yes	Functioning 3/03		221 M	White	1 O	A2	A2	Low	0	0	2	48	56
Kidney	KSUK	9/18/1988			Yes	Functioning 3/03		79 F	White	1 B	A2	A2	Low	0	0	5	30	52
Kidney	KSUK	9/19/1988	10/18/1988		No	Rejection		72 F	Black	1 B	A2	A2	Low	0	0	5	33	52
Kidney	MOLH	10/2/1988		5/22/2000	Yes	DWFG		31 M	White	1 B	A2	A2	Low	0	4	4	67	19
Kidney	KSFW	10/2/1988			Yes	Functioning 3/03		62 M	Indian	2 B	A2	A2	Low	9	9	4	54	53

Clinical Followup for A2 to B O Transplants : 1994 to 2002

TABLE 1

Organs Txed	Tx Ctr	Tx Date	Rejection Date	Death Date	Kidney Func at Rej 1 month Reason	Wait Time (days)	Gen Race	Tx #	Recip ABO	Don ABO	Anti-A Titer	PRA Current	PRA Peak	A,B,DR mm	Age	Follow Up (mo)
.....
Kidney	KSUK	11/3/1998		2/13/1998	Yes DWFG	35 F White	1 O	A2	A2	ND	0	0	5	57	52	
Kidney	MOLH	11/3/1998			Yes Functioning 3/03	536 M White	1 O	A2	A2	Var	0	9	5	27	52	
SPK	KSUK	2/14/1998			Yes Functioning 3/03	90 M White	1 B	A2	A2	Low	0	0	5	29	49	
Kidney	MOLH	3/10/1998			Yes Functioning 3/03	125 M White	1 B	A2	A2	Low	0	0	4	58	48	
SPK	KSUK	3/10/1998	10/15/2001		Yes Non-Compliance/RD	47 M Black	1 B	A2	A2	Low	0	0	5	29	48	
SPK	KSFV	4/12/1998			Yes Functioning 3/03	2314 M White	1 B	A2	A2	Low	0	5	5	48	47	
Kidney	KSUK	4/12/1998			Yes Functioning 3/03	131 M Viet	1 B	A2	A2	Low	0	0	4	30	47	
Kidney	MOUM	7/25/1998			Yes Functioning 3/03	131 M White	1 B	A2	A2	ND	2	2	5	42	44	
Kidney	MOUM	7/28/1998	5/18/2000		Yes Rejection	220 F Black	1 B	A2	A2	ND	3	13	5	38	10	
Kidney	MOLH	9/15/1998	9/17/1998		No Rejection	184 F White	1 B	A2	A2	Low	0	0	6	24	0.1	
Kidney	KSFV	3/30/2000			Yes Functioning 3/03	252 F AI	1 B	A2	A2	Low	0	0	5	67	36	
Kidney	KSFV	3/30/2000			Yes Functioning 3/03	171 M White	1 B	A2	A2	Low	0	2	4	43	36	
Kidney	KSUK	7/24/2000			Yes Functioning 3/03	81 F White	1 B	A2	A2	Low	0	0	3	50	31	
Kidney	KSUK	7/24/2000			Yes Functioning 3/03	47 F White	1 B	A2	A2	Low	0	0	3	43	31	
Kidney	KSUK	7/24/2000			Yes Functioning 3/03	166 M Cambo	1 B	A2	A2	Low	0	0	4	16	30	
Kidney	MOCM	8/30/2000			Yes Functioning 3/03	284 M White	1 B	A2	A2	Low	0	0	4	45	29	
SPK	KSUK	11/10/2000			Yes Functioning 3/03	380 F White	1 O	A2	A2	Low	0	0	3	50	24	
SPK	KSUK	3/24/2001			Yes Functioning 3/03	140 M Hispan	1 B	A2	A2	Low	0	7	6	63	22	
Kidney	KSFV	5/25/2001			Yes Functioning 3/03	121 M White	1 B	A2	A2	Low	0	0	5	54	22	
Kidney	KSUK	5/25/2001			Yes Functioning 3/03	389 M Black	2 B	A2	A2	Low	0	0	5	61	20	
Kidney	MOLH	7/31/2001			Yes Functioning 3/03	398 M Black	1 B	A2	A2	Low	0	0	5	42	20	
Kidney	MOLH	7/31/2001			Yes Functioning 3/03	374 M Black	1 B	A2	A2	Low	0	0	5	48	19	
Kidney	MORH	8/10/2001			Yes Functioning 3/03	255 M White	1 B	A2	A2	Low	0	0	5	55	19	
Kidney	MORH	8/10/2001			Yes Functioning 3/03	235 M Hispan	1 B	A2	A2	Low	0	0	5	51	16	
Kidney	KSUK	11/4/2001			Yes Functioning 3/03	260 F Asian	1 B	A2	A2	Low	0	0	6	54	14	
Kidney	MORH	1/10/2002			Yes Functioning 3/03	146 M White	1 O	A2	A2	Low	0	0	5	45	14	
SPK	KSUK	1/10/2002			Yes Functioning 3/03	143 F Black	1 B	A2	A2	Low	9	9	5	68	14	
Kidney	MOUM	1/13/2002			Yes Functioning 3/03	389 F White	1 O	A2	A2	Low	0	0	6	60	0.5	
Kidney	MOLH	1/13/2002	1/23/2002		No Never functioned	278 M White	1 B	A2	A2	Low	0	0	6	51	8	
Kidney	MORH	7/1/2002			Yes Functioning 3/03											

Table 2a

**DISTRIBUTION OF DECEASED DONOR KIDNEYS FOR B RECIPIENTS
TRANSPLANTED FROM 1994 to 2002**

<u>ABO Groups</u> Donor → Recipient	1994 to 2002	2002 Only
B & O → B	69% (111/162)	86% (18/21)
A ₂ & A ₂ B → B	31% (51/162)	14% (3/21)
Totals	162	21

Table 3

UNOS Data for 1996 by ABO¹

ABO	% Patients on Waiting List^a	% Cadaveric Kidney Donors^b	% Cadaveric Transplants^c	ABO Frequency (White)
O	52.0%	46.6%	44.1%	45.0%
A	28.2%	39.6%	39.8%	40.0%
B	17.4%	10.2%	10.8%	11.0%
AB	2.4%	3.5%	5.3%	4.0%

¹ Data from 1997 Annual Report of the U.S. Scientific Registry of Transplant Recipients and The Organ Procurement and Transplantation Network.

^a see page 204

^b see page 38

^c see page 67

Table 4

**Graft Outcome of Living-Related A₂ Transplants
1986 – 2002**

Transplant Date	Donor → Recipient ABO	HLA Haplotype Match	Anti-A IgG Titer At Transplant	Graft Status¹
3-3-86	A ₂ → O	0	0	Functioning
9-6-89	A ₂ → O	1	8	Functioning
9-19-92	A ₂ → O	1	<2	Functioning
7-24-95	A ₂ → B	2	2	Functioning
6-21-99	A ₂ → O	1	2	Functioning
8-1-00	A ₂ → O	0	<2	Functioning
12-28-01	A ₂ → O	1	<2	Functioning

¹ Graft Status as of February, 2003.

Table 5

Demographic Data for MTN A₂/A₂B → B and O Patients Variance 1994 – 2002

Demographics	Cumulative Summary of Variance Data ¹	
	Since 1994	2002
Recipients of A ₂ /A ₂ B Kidneys ABO:		
B	51	3
O	18	2
Total	69	5
Wait Time (days) for B and O Recipients of A ₂ /A ₂ B Kidneys		
Mean	294 ± 344 (n=69)	239 ± 95 (n=5)
Median	210	260
Recipient Age (years)	47.7 ± 12.4 (n=69)	55.6 ± 8.8 (n=5)
HLA Mismatches	4.5 ± 1.0 (n=69)	5.6 ± 0.5 (n=5)
Peak PRA	5.9 ± 14.8% (n=69)	1.8 ± 4% (n=5)
Percent Kidney + Pancreas Transplants	8.7% (6/69)	20% (1/5)
Percent with Low Titer History	95% (63/66)	100% (5/5)
Percent Female	39% (27/69)	60% (3/5)
Percent Minority (non-white)	29% (20/69)	40% (2/5)
Percent Primary Transplants	81% (56/69)	100% (5/5)
Percent Patients with Functioning Kidney at 1 month	93% (64/69)	80% (4/5)

¹ Some data presented as mean ± 1 SD.

Table 6

Disposition of Kidneys from A₂ and A₂B Donors in 2002

#	DATE	UNOS NUMBER	DONOR ABO	LOCAL TX	DISPOSITION OF KIDNEYS		
					Recipient ABO	EXPORTED	OTHER
1	1/10/02	PAI026	A ₂	MORH KSUK	B		
2	1/13/02	PAL007	A ₂	MOLH MOUM	O*		
3	3/07/02	PCF025	A ₂		B		NYMS
4	3/19/02	PCR004	A ₂	KSUK	A ₁ *		NYMS
5	4/27/02	PDZ014	A ₂				OHCC ILSF
6	5/05/02	PED012	A ₂ B				OHOH MDJH
7	6/23/02	PFV012	A ₂				MDJH
8	7/01/02	PGA011	A ₂	MORH MOUM	B		NO KIDNEYS RECOVERED
9	8/01/02	PHI018	A ₂		A ₁ *		
10	9/10/02	PIJ018	A ₂	KSUK	A ₂ *		NO KIDNEYS RECOVERED
11	10/03/02	PJC003	A ₂	MOUM MOUM	A ₁		TXHH

*A₂ → O kidney + pancreas transplant.

* High PRA kidney + pancreas transplant

* High PRA patient

* SPK

Table 7

**Graft Outcome in B Recipients of A₂/ A₂B Compared with B/O → B
Cadaveric Donor Kidneys: 1994 – 2002**

ABO Combination	DWFG Censored	Graft Survival (Years)					Wilcoxon Log-rank
		1	2	3	4	5	
A ₂ /A ₂ B → B (n=48)	YES	93% (34)	93% (26)	84% (18)	84% (13)	74% (5)	0.30
B, O → B (n=91)	YES	90% (67)	84% (54)	82% (47)	76% (33)	71% (20)	0.58
A ₂ /A ₂ B → B (n=48)	NO	86% (34)	80% (26)	70% (18)	70% (13)	61% (5)	0.62
B, O → B (n=91)	NO	84% (67)	76% (54)	73% (47)	66% (33)	59% (20)	0.88

Table 8

**Transplantation Rate of Minority Patients by Blood Group:
1994 to 2002**

ABO Group of Donor → Recipient	White	Minority¹
B and O → B	64% (70/109)	36% (39/109)
A ₂ and A ₂ B → B	61% (31/51)	39% (20/51)
A ₂ , A ₂ B, B & O → B	63% (101/160)	37% (59/160)

¹ This group contains all minorities.

Table 9

Summary of Midwest Transplant Network Pediatric A₂ → B and O Transplants 1986 through 2002

- 1 Pediatric (16 yrs) A₂ → B Transplant in 2000 (Cambodian)
 - 6 Pediatric A₂ → B and O Transplants 1986 – 2000
(Mean Age = 15.3 years)
 - 6 (86%) Cadaveric Transplants
 - 1 (14%) Living-Related Transplant
 - 4 (58%) Minority Transplants
 - 2 Black (29%)
 - 2 Asian (29%)
 - 4 (57%) A₂ → O
 - 3 (43%) A₂ → B
 - 4 of 7 (57%) cadaveric transplants were done before our variance was implemented (September, 1991).
 - 3 grafts (43%) functioning as of January, 2003
 - 4 grafts (67%) failed
 - 1 failed at 23 months (non-compliance) (Low anti-A titer history)
 - 1 hyperacute rejection (anti-A titer = 1:8) (also had anti-endothelial antibody)
 - 2 were rejected after each functioned for over 10 years (1 due to non-compliance)
 - Most of these data and NAPRTCS ABO-incompatible data were published in *Pediatric Transplantation*, 2:1, 26-29, 1998, which is included in the attachments section.
-

Table 10

**Distribution of Midwest Transplant Network A and AB
Cadaveric Donors by Subgroup: 1994 – 2002**

YEAR	Blood Group and Subgroup					
	A	A ₁	A ₂	AB	A ₁ B	A ₂ B
2002	57	47 (82%)	10 (18%)	3	2 (67%)	1 (33%)
2001	45	39 (87%)	6 (13%)	2	1 (50%)	1 (50%)
2000	50	45 (90%)	5 (10%)	5	4 (80%)	1 (20%)
1999	58	51 (89%)	7 (12%)	1	1 (100%)	0 (0%)
1998	54	45 (83%)	9 (17%)	6	5 (83%)	1 (17%)
1997	43	33 (77%)	10 (23%)	4	3 (75%)	1 (25%)
1996	40	33 (82%)	7 (18%)	4	2 (50%)	2 (50%)
1995	54*	47 (87%)	6 (11%)	4	2 (50%)	2 (50%)
1994	36	30 (83%)	6 (17%)	4	4 (100%)	0 (0%)
Totals	437	370 (85%)	66 (15%)	33	24 (73%)	9 (27%)
Expected Blood Group Frequency	—	80%	20%	—	80%	20%

* One A donor was not subgrouped.

Table 11

Waiting Times for Recipients of Cadaveric Transplants: 1994 – 2002

ABO: Donor → Recipient	Number	Waiting Time (Days)		
		Median	Mean ± 1 SD	
A, O → A	528	296	409 ± 486	
A ₂ /A ₂ B → B	51	181	312 ± 391	
B, O → B	109	291	461 ± 545	
O → O	539	430	468 ± 387	
A ₂ → O	18	274	299 ± 137	
A, B, AB → AB	35	87	154 ± 197	

III. Figures (1 - 2)

J-35

100

Figure 1a

Midwest Transplant Network OPO Deceased Donor Waiting List: 1994 to 2002

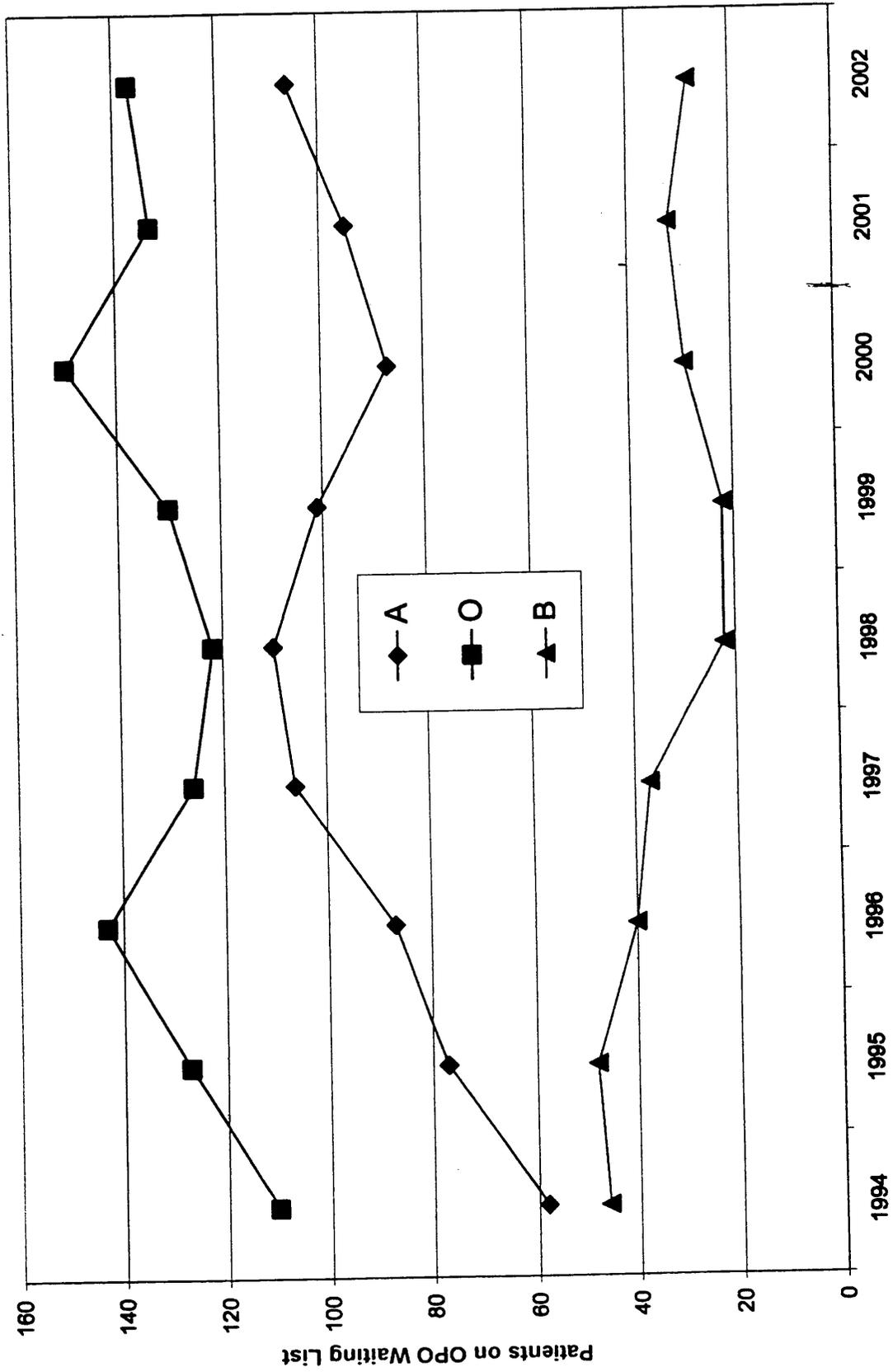
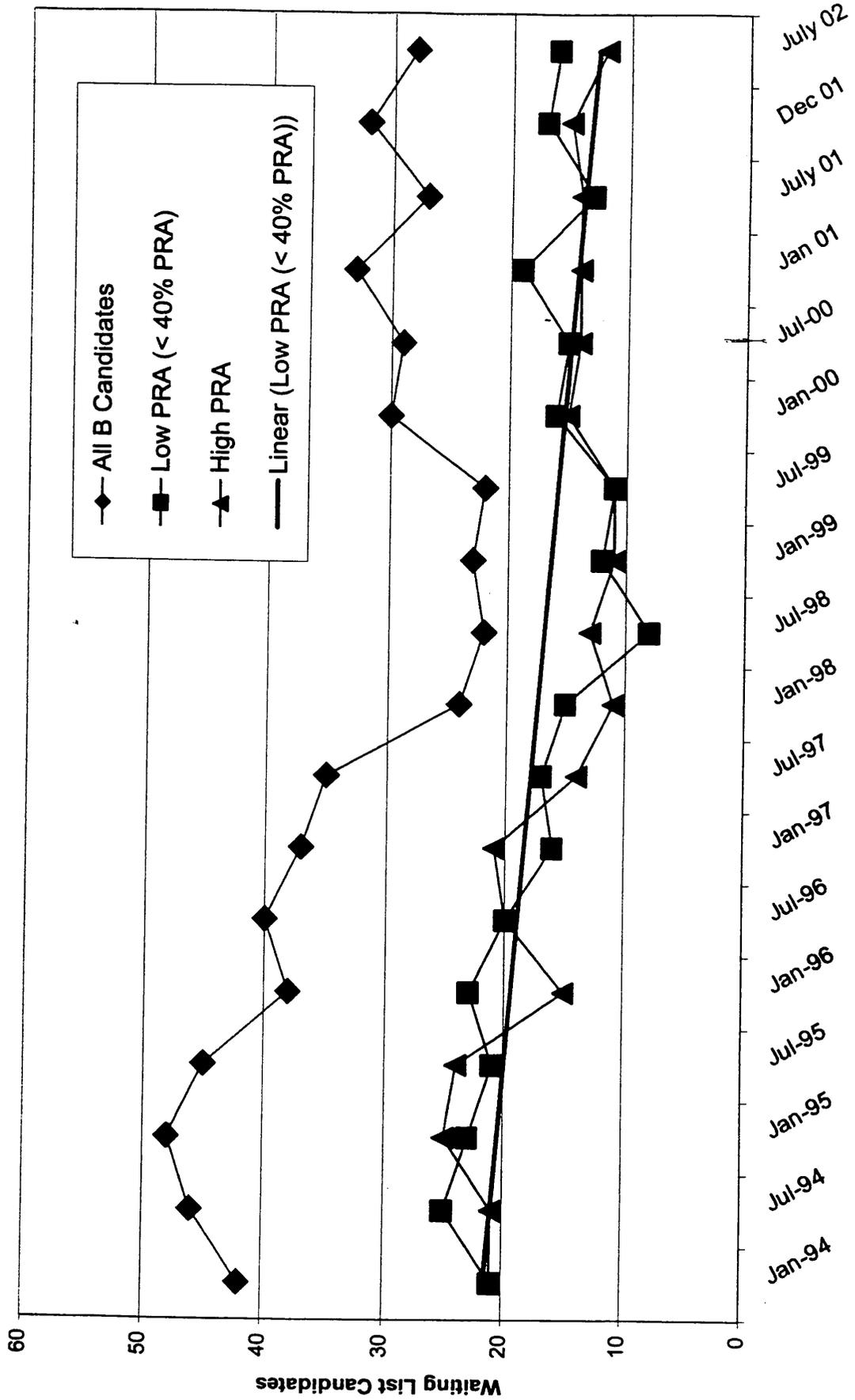


Figure 1b

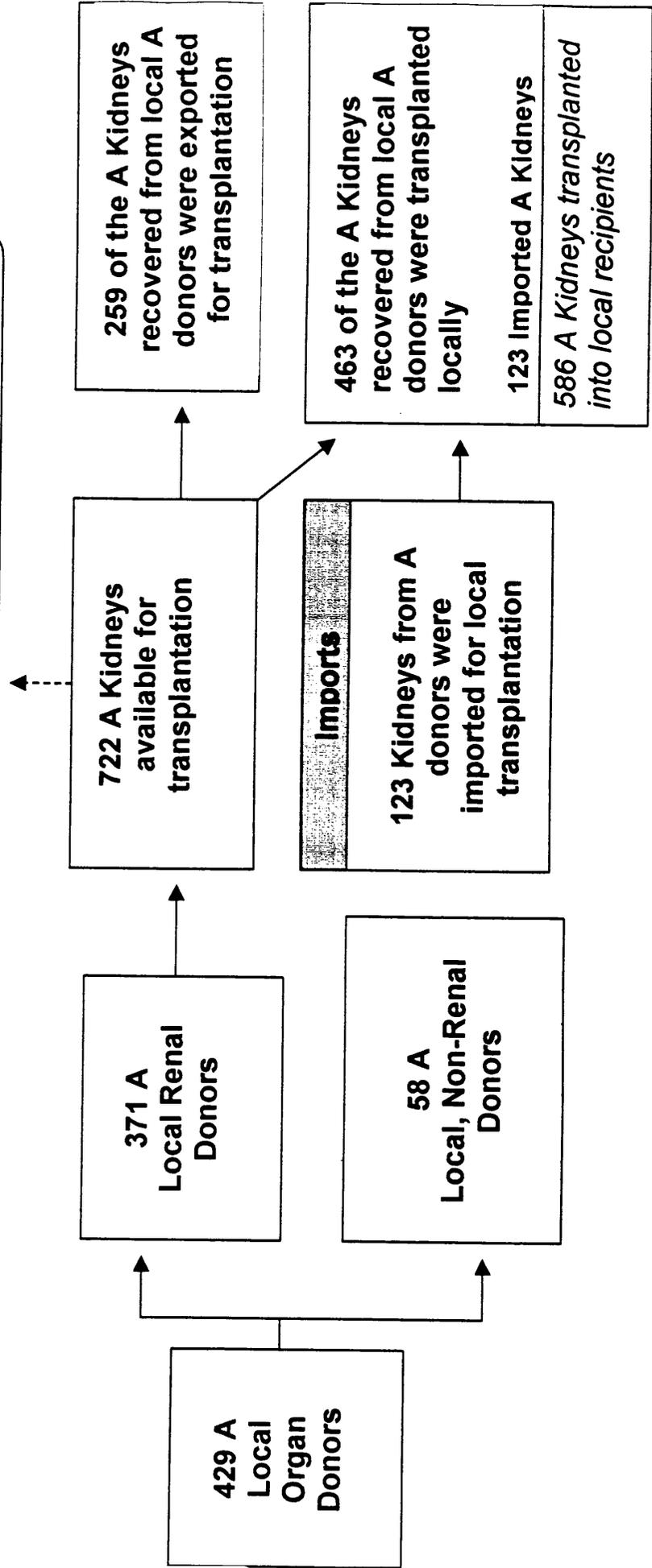
MTN B Waiting List 1994 to 2002



Availability of Kidneys from Locally-Recovered Blood Group A Deceased Donors: 1994 – 2002

From 1994 to 2002:

- 6.5% (47/722) of the A kidneys transplanted were A₂ kidneys that were transplanted into B patients, thus increasing the transplant rate of B patients by one-third (see Table 2a).



IV. Attachments

J-39

11a

2.6 A₂ Renal Policy (As amended by the Midwest Transplant Network Board of Directors on October 18, 1994 and approved by UNOS on June 28, 1995.)

A₂ (A₂B) cadaveric kidneys will be allocated in accordance with existing Midwest Transplant Network and UNOS allocation rules, and in accordance with the following order of priority:

- 1. Blood group A₂ and A₂B recipients (of A₂ kidneys) or A₂B recipients (of A₂B kidneys) with a current and/or historical PRA of 80% or greater and/or antibodies to the blood group A (A₁) antigen;**
- 2. Blood group A₁ and A₁B recipients (of A₂ kidneys) or A₂B recipients (of A₂B kidneys) with a current PRA of 80% or greater;**
- 3. Blood group B recipients (of A₂ or A₂B kidneys);**
- 4. Blood group O recipients (of A₂ kidneys only);**
- 5. Blood group A₂ and A₂B recipients (of A₂ kidneys) and A₂B recipients (of A₂B kidneys) with a current PRA of less than 80%; and,**
- 6. Blood group A₁ and A₁B recipients (of A₂ kidneys) and A₁B recipients (of A₂B kidneys) with a current PRA of less than 80%.**

All prospective cadaveric renal transplant recipients who are blood group B and O, must have quarterly anti-A RBC titers performed to be eligible for A₂ kidneys allocated through this system.

Increased Access to Transplantation for Blood Group B Cadaveric Waiting List Candidates by Using A₂ Kidneys: Time for a New National System?

Paul W. Nelson^a, Charles F. Shield III^b,
Nicolas A. Muruve^c, Daniel Murillo^d,
Bradley A. Warady^e, Mark I. Aeder^f and
Christopher F. Bryan^{g,*}

^a Saint Luke's Hospital and the University of Missouri,
Kansas City, MO, USA

^b Via-Christi St. Francis Regional Medical Center, Wichita,
KS, ^c University Hospital, Columbia, MO, USA

^d Kansas University Medical Center, Kansas City, KS, USA

^e The Children's Mercy Hospital, Kansas City, MO, USA

^f Research Medical Center, Kansas City, MO, USA

^g Midwest Transplant Network, Westwood, KS, USA

* Corresponding author: Christopher F. Bryan PhD,
cbryan@mwob.org

Since blood group B end-stage renal disease (ESRD) patients have less access to donor kidneys and a higher minority composition than any other blood group, the United Network for Organ Sharing (UNOS) approved a voluntary national kidney allocation variance to allow organ procurement organizations (OPOs) to preferentially allocate A₂ and A₂B kidneys to B candidates.

The Midwest Transplant Network OPO has preferentially allocated and transplanted kidneys from blood group A₂ and A₂B donors to our blood group B waiting list candidates for more than 7 years to increase access to kidneys for the B candidates on our OPO-wide waiting list. Between 1994 and 2000, a total of 121 blood group B ESRD patients from our OPO-wide cadaveric kidney waiting list were transplanted. Thirty-four per cent (41/121) of those B candidates received either an A₂ or an A₂B kidney. One- and 5-year graft survival rates for the group of B recipients of A₂ or A₂B kidneys were 91 and 85% (died with functioning graft [DWFG] censored), respectively, which were not significantly different from those of 91 and 80% for the 80 B recipients of B or O kidneys (Wilcoxon = 0.48; log-rank = 0.55).

These data support the national trial for additional OPOs to voluntarily allocate A₂ and A₂B kidneys preferentially to B waiting list candidates, thus increasing access of blood group B patients to renal transplantation.

Key words: A₂ to B, access, kidney transplant, UNOS variance

Received 26 July 2001, revised and accepted for publication 13 September 2001

Introduction

Blood group B end-stage renal disease (ESRD) patients have longer waiting times prior to cadaveric renal transplantation

compared with other blood groups (Table 1) (3). In 1996, the median national waiting time for B kidney candidates was 1426 d, compared with 641 d for A candidates (Table 1) (2). There are multiple reasons why B patients may wait longer before cadaveric kidney transplantation, but 65.9% of the national B waiting list comprises minority recipient candidates (Table 1), and African-Americans have historically had longer waiting times (3). The high minority composition of the national B waiting list is not unexpected, as the nation's donor population is predominantly white (75.9% in 1999), a population with a blood group B incidence of 9%, far lower than the 19% and 25% incidence seen in African-American and Asian populations (2) (Table 1).

Another reason is that blood group B candidates have less access to cadaveric kidneys than blood group A candidates. United Network for Organ Sharing (UNOS) data from 1999 show that 16.8% of the national waiting lists were B candidates and they received 13% of the cadaveric transplants (Table 1) (2). By contrast, 28.2% of the national lists were A candidates and they received 38.2% of the cadaveric kidney transplants (Table 1) (2). The transplant rate approximates the ABO frequency in the predominantly white donor population (Table 1).

This study focuses on the experience of our Midwestern OPO in preferentially allocating and successfully transplanting kidneys from A₂ and A₂B donors into B patients (4,5), a practice that has increased the transplantation rate of blood group B candidates in our OPO by one-third (6). These data provide support for the implementation of a similar national trial of A₂ allocation to the B cadaveric kidney waiting list. The Organ Procurement Transplant Network (OPTN)/UNOS Board of Directors, at the request of the UNOS Minority Affairs Committee, released this allocation proposal for Public Comment on March 15, 2001, and approved it on June 28-29, 2001. It is the intention that this national allocation policy will, at least partially, alleviate some of the access problems experienced by blood group B candidates and increase their transplantation rate while minimizing any effect on the A waiting list. This report demonstrates to kidney transplant programs in OPOs across the United States how implementation of transplantation of A₂ and A₂B kidneys into B candidates can impact their B waiting list.

Materials and Methods

Study design

The time-frame for this analysis and review was from January 1, 1994, to December 31, 2000, and included all consecutive cadaveric donors and

each quarter. For the 41 blood group B recipients of A₂ or A₂B kidneys, 73.1% (30/41) had a consistently low anti-A titer history; 22% (9/41) had one pretransplant titer that was low (≤ 4); and 4.9% (2/41) had a low titer history except for one high titer (8). Since 1998, for B waiting list candidates who were eligible to receive A₂ or A₂B kidneys, anti-A titers were done monthly for the first 6 months following activation, and then quarterly. That was done to establish more rapidly a titer history for these patients, since in 21% (9/41) of the cases, only a single pretransplant titer was available. Our current policy is to transplant only patients whose entire anti-A titer history is low. If a patient does not have a current anti-A titer available at the time an A₂ kidney is offered (one done in the last 3 months), the patient is bypassed since we have shown that the cold ischemia time is increased by an average of 6h when current titers are performed [see Table 2 in Nelson et al. (5)]. For that reason, it is important to establish and maintain a sufficient and current anti-A titer history for each blood group B patient so that, at the time of an A₂ kidney offer, the decision whether or not to transplant can be made without additional testing.

Statistical analysis

The Lifetest procedure in Statistical Analysis Systems was used to determine actuarial statistics, and the Kaplan–Meier method was applied to compute univariate survival estimates. The Wilcoxon and log-rank tests were used to determine the statistical significance of differences between survival curves. The chi-square (χ^2) test was used to compare distribution differences. Student's *t*-test was used to compare group mean differences.

Results

The data in Table 3 show that, of the 121 B cadaveric transplants performed by the seven kidney transplant programs in our OPO, 34% (41/121) of the patients received either an A₂ (29%) or an A₂B (3%) kidney, including four of six SPK patients who received their organs from an A₂ donor.

Table 4 shows that 1- and 5-year graft survival rates (censored for patient death with a functioning graft, DWFG) of the blood group B recipients of A₂ or A₂B kidneys (91 and 85%, respectively) were not significantly different from those of the B recipients of B or O kidneys (91 and 80%, respectively) (Wilcoxon = 0.48; log-rank = 0.55). Even when patients were not censored for DWFG, the 1 and 5-year graft survival rates of the B recipients of A₂ or A₂B kidneys (84 and 72%, respectively) were not significantly different from the group that received B or O kidneys (84 and 64%) (Wilcoxon = 0.78; log-rank = 0.75). All four SPK A₂ into B recipients have func-

tioning kidney and pancreas grafts, with an average follow-up of 17 months (range: 3–23 months) (Table 5).

An important component of safely performing A₂ transplantation into B and O recipients has been to evaluate the titer of the A IgG isoagglutinins in B and O patients, as 95.1% (39/41) of the B patients transplanted with A₂ kidneys consistently had low anti-A titers (≤ 4), or had a single low titer before transplantation. The incidence of blood group B patients who have a consistent (at least 1 year) history of low anti-A titers is 77% in white patients (54/70) and 69% in black patients (23/35), not a statistically significant difference ($p = 0.2$, χ^2).

The incidence of minority patients transplanted with A₂ or A₂B kidneys was 22% (9/41) and the incidence of blood group B minority patients transplanted with B or O kidneys was 39% (31/80), a nonstatistically significant difference ($p = 0.06$, χ^2). However, the minority rate of blood group B recipients, 33% (40/121), was significantly higher than that of blood group A recipients, 12% (48/413) ($p = 0.000001$, χ^2). Furthermore, the median waiting time for the 41 blood group B recipients of A₂ or A₂B kidneys or SPKs (166d) was less than that of B recipients of B or O kidneys (308d), and was even less than that of A recipients (288d).

Since this allocation algorithm has increased the transplantation rate of patients on our OPO-wide blood group B cadaveric renal waiting list, it is important to monitor the composition of our OPO waiting list over time. Table 6 shows that from 1994 to 1997, our OPO-wide active B waiting list candidates ranged from 38 to 45 patients, with 16–23 low PRA ($\leq 40\%$) B candidates, and from 1998 to 2000, the list range decreased to 24–30 patients, with 12 to 16 low PRA B candidates. It is important to note that the low PRA minority patient group is declining at a rate similar to the entire low PRA group.

Since one of the criticisms of this allocation policy is that A candidates are denied a portion of blood group A kidneys, we have routinely monitored the OPO-wide A waiting list and number of A transplants performed (Table 7). Between 1994 and 2000, we transplanted 37 A₂ kidneys into B patients, comprising 8.8% (37/416) of the total number of local blood group A cadaveric kidney transplants. Our data have also shown that the number of patients on the A waiting list started to decline in 1999 and the number of both blood group A donors and transplant recipients has gradually increased.

Discussion

Recent attention has focused on racial disparities in organ accessibility and survival following renal transplantation (3,7–11). One of the accessibility problems discussed by Young and Gaston (11) associated the disparity with the distribution of blood groups in different race groups (as illustrated in

Table 3: Distribution of blood group B patients transplanted from 1994 through 2000 by centers within the Midwest Transplant Network (MTN) organ procurement organization

Organs transplanted	Donor ABO → recipient ABO	Incidence of B patients transplanted
Kidney	B and O → B	68% (78/115)
	A ₂ → B	29% (33/115)
	A ₂ B → B	3% (4/115)
Simultaneous kidney + pancreas	B → B	33% (2/6)
	A ₂ → B	67% (4/6)
Totals	B and O → B	66% (80/121)
	A ₂ and A ₂ B → B	34% (41/121)

Table 7: Characteristics of organ procurement organization (OPO)-wide blood group A waiting list candidates and cadaveric transplants

Year	Month	A		Kidneys transplanted from OPO A donors	Local A transplants (includes imports)	A ₂ → B (% of local A transplants)
		waiting list	donors			
1994	January	58	36	61	46	4 (8.7%)
1995	January	77	54	90	67	3 (4.4%)
1996	January	87	40	60	46	1 (2.1%)
1997	January	106	43	66	41	9 (21.9%)
1998	January	110	54	94	63	6 (9.5%)
1999	January	101	58	98	79	8 (10.1%)
2000	January	87	50	86	74	6 (8.1%)
Totals			335	555	416	37 (8.8%)
Mean			47	79	59	

*Note: a portion of these kidneys are transplanted outside the OPO (zero mismatches and exported kidneys) but most are transplanted locally.

supported this endeavor as one possible way to influence accessibility for the blood group B patients and to increase their renal transplantation rate. Furthermore, since 65.9% of the B waiting list comprises minority patients (the highest for any blood group) (Table 1), allocation of A₂ or A₂B kidneys to B patients is one way to increase minority access to transplantation. The success of this allocation scheme will be measured by the increase in blood group B patient transplantation and a concomitant decrease in B recipient waiting time.

A major consideration in A₂ or A₂B to B transplantation is that the function of those kidneys is significantly affected by the anti-A titer in the recipient prior to transplantation. In our earlier study, we found that a high anti-A titer (≥ 8) was associated with a 1-month nonfunction rate of 55%, whereas, in recipients whose titers were 4 or less, all the A₂ or A₂B kidneys were functioning at 1 month (4,5). Norman's group has also shown that high levels of IgG anti-A are associated with early rejection in A₂ to B and O kidney transplants (12). Since the anti-A antibody level is clinically relevant, the relative level of expression of the A antigen on the transplanted A₂ kidney is similarly likely to be important. Expression of the immunodominant A antigen, N-acetylgalactosamine, is much lower on the red cells (13) and kidney endothelium (14) of A₂ compared with A₁ individuals, which is likely due to the fact that the A₂ glycosyltransferase is 10% as active as the A₁

(15). In addition to a one-amino acid difference at position 156, the A₂ glycosyltransferase compared with the A₁ has an extra 21-amino acid domain at the carboxyl terminus of the enzyme due to a frameshift in the DNA which makes the stop codon disappear and likely explains in large part its reduced enzymatic activity and the lower level of A antigen expression on A₂ kidneys (16). One final question that should be considered is whether or not transfusion(s) of blood/blood products from A₁ donors into A₂ donors influences the antigenicity or clinical outcome of A₂ kidneys after transplantation into B patients. That is unlikely, since Bariéty et al. (14) demonstrated that A antigen expression is due to cell antigen expression, not to plasma circulating A antigen by showing that when O kidneys were transplanted into A recipients, no endothelial or tubular epithelial A antigen was identified.

Another important point regarding IgG anti-A titer levels is that the incidence of patients with low titer histories is equivalent in blood group B white and black patients: 77 and 69%, respectively. Thus, access to A₂ or A₂B kidneys with respect to titer history should not be an obstacle for black patients. That is in contrast to other immunologic characteristics that may cause black patients to wait longer for renal transplantation (1,3,17). Furthermore, based on our experience, between 23 and 31% of the B waiting list candidates are not eligible for an A₂/A₂B kidney because of having one or more high titers (≥ 8) in their

Table 8: Possible changes to national (UNOS) blood group A and B waiting lists and transplants if A₂ kidneys were routinely allocated to B patients^a

Group	Blood group A			Number of kidneys used	Blood group B		
	Before	After	(% change)		Before	After	(% change)
% UNOS waiting list	28.2%	29.3%	(3.8%↑)	510 ^b →	16.8%	15.6%	(6.5%↓)
(n)	13117	13627			7801	7291	
% kidney transplants	38.2%	31.8%	(16.6%↓)	510 ^b →	13.0%	19.3%	(49%↑)
(n)	3061	2551			1039	1549	

^a2000 UNOS Kidney Scientific Registry Data (2).

^bA total of 510 A₂ kidneys were deducted from As and added to Bs since we assume that 20% of the 2995 A kidneys will be A₂ (n = 599), and since 15% of these 599 will be zero mismatches, an estimated 510 A₂ kidneys could be transplanted into B patients.

TRANSPLANTATION RATE OF THE BLOOD GROUP B WAITING LIST IS INCREASED BY USING A₂ AND A₂B KIDNEYS¹

CHRISTOPHER F. BRYAN,^{2,3} CHARLES F. SHIELD, III,⁴ PAUL W. NELSON,⁵ GEORGE E. PIERCE,⁶ GILBERT ROSS,⁷ ALAN M. LUGER,⁷ BRADLEY A. WARADY,⁸ THOMAS S. HELLING,⁵ MARK I. AEDER,⁹ JOHN MARTINEZ,¹⁰ TERRY M HUGHES,¹¹ MALCOLM L. BECK,¹² AND KEVIN M. HARRELL²

Midwest Organ Bank, Inc., Westwood, Kansas; Via Christi-St. Francis Regional Medical Center, Wichita, Kansas; University of Missouri-Kansas City, Kansas City, Missouri; University of Kansas Medical Center, Kansas City, Kansas; University of Missouri Hospital and Clinics, Columbia, Missouri; Children's Mercy Hospital, Kansas City, Missouri; Research Medical Center, Kansas City, Missouri; St. John's Regional Medical Center, Joplin, Missouri; Midwest Organ Bank, Inc., Wichita, Kansas; Community Blood Center of Greater Kansas City, Missouri

Background. We have increased the transplantation rate for blood group B cadaveric waiting list candidates by transplanting them with A₂ and A₂B kidneys.

Methods. Since 1991, five of the seven renal transplant programs in our organ procurement organization service area have preferentially transplanted blood group A₂ and A₂B cadaveric kidneys to B blood group waiting list candidates with histories of low anti-A isoagglutinin titers.

Results. Between 1991 and 1997, these five centers performed transplantations on 71 patients from the B cadaveric waiting list. Of those 71 patients, 29% (21 of 71) underwent transplantation with either A₂ (n=18) or A₂B (n=3) cadaveric kidneys. In 1997 alone, 48% (11 of 23) of the B patient transplant recipients received A₂ or A₂B kidneys.

Conclusions. Transplantation of A₂ and A₂B kidneys to B waiting list patients has successfully increased access of B patients to kidneys. Such an allocation algorithm implemented nationally may similarly increase the transplantation rate of B waiting list candidates.

Blood group B end-stage renal disease candidates wait longer before cadaveric transplantation than candidates of any other blood group (1). The key factor that most likely influences that extended waiting time is the lower availability of B cadaveric donors relative to A and O cadaveric donors. In 1996, 10.2% (513 of 5036) of cadaveric donors in the United States were blood group B compared with 39.6% (1996 of 5036) that were blood group A and 46.6% (2349 of 5036) that were blood group O (1). The percentages of cadav-

eric kidney transplants performed from those donors were as follows: 10.8% (921 of 8558) went to B recipients; 39.8% (3405 of 8558) went to A recipients; and 44.1% (3775 of 8558) went to O recipients. Since 1991, our organ procurement organization (OPO*) has preferentially allocated blood group A₂ and A₂B cadaveric kidneys to the OPO-wide B waiting list candidates before offering them to the O list (2-5).

METHODS

Between September 1991 and December 1997, five of the seven transplant centers in our OPO performed 34 cadaveric kidney transplants into B (n=21) and O (n=13) recipients using kidneys from either A₂ (n=31) or A₂B (n=3) organ donors in accord with our OPO United Network of Organ Sharing (UNOS)-approved variance (6). Donor to recipient combinations consisted of the following: 62% (21 of 34) were A₂/A₂B into B recipients and 38% (13 of 34) were A₂ into O recipients. The demographics of the A₂/A₂B into B group are compared with the ABO-compatible group in Table 1. Most of those transplantations (88%; 30 of 34) were performed after 1994. For graft survival comparison with our A₂/A₂B into B and O groups, a control group of 497 consecutive ABO-compatible cadaveric transplants performed from 1994 to 1997 was included.

Cadaveric-donor kidneys were flushed in situ and preserved in ViaSpan (Belzer UW, Dupont Pharma, Wilmington, DE). Posttransplant treatment protocols for recipients of A₂ and A₂B kidneys did not differ from those used for other ABO-compatible patients. All patients received methylprednisolone, cyclosporine or tacrolimus, and azathioprine. No patients underwent plasmapheresis or splenectomy as part of this protocol. Throughout the period under study, most cadaveric kidney recipients received induction therapy with either ATG or OKT3.

ABO grouping, anti-A titer performance, and definition of patients' anti-A titer histories were done as previously described (3-6). Our OPO's practice regarding the frequency of anti-A titer testing and clinically acceptable levels is based on the requirement that anti-A isoagglutinin (IgG) titers be performed quarterly for all B and O waiting list candidates who are eligible to receive A₂ or A₂B kidneys (only B candidates receive A₂B kidneys). When patients are added to our

* Abbreviations: DWFG, died with a functioning graft; IgG, isoagglutinin; OPO, organ procurement organization; UNOS, United Network for Organ Sharing.

¹ Presented in abstract form at the 17th Annual Meeting of the American Society of Transplant Physicians, May 9-13, 1998, Chicago, IL.

² Midwest Organ Bank, Inc., Westwood, KS.

³ Address correspondence to: Christopher F. Bryan, Ph.D., HCLD, Midwest Organ Bank, Inc., 1900 West 47th Place, Suite 400, Westwood, KS 66205-1801.

⁴ Via Christi-St. Francis Regional Medical Center, Wichita, KS.

⁵ University of Missouri-Kansas City, Kansas City, MO.

⁶ University of Kansas Medical Center, Kansas City, KS.

⁷ University of Missouri Hospital and Clinics, Columbia, MO.

⁸ Children's Mercy Hospital, Kansas City, MO.

⁹ Research Medical Center, Kansas City, MO.

¹⁰ St. John's Regional Medical Center, Joplin, MO.

¹¹ Midwest Organ Bank, Inc., Wichita, KS.

¹² Community Blood Center of Greater Kansas City, MO.

TABLE 3. Waiting time data for cadaveric renal transplants performed before (1988 to 9/14/91) and since (9/15/91 to 1997) implementing A_2/A_2B variance

Blood group of donor→recipient	Waiting time (days)			
	Median		Mean ± 1 STD	
	Before	Since	Before	Since
A, B and AB→AB	160 (n=13)	96 (n=19)	212±265 (n=13)	210±258 (n=19)
A and O ^c →A	126 (n=153)	200 (n=303)	167±160 (n=153)	306±363 (n=303)
B				
A_2/A_2B →B	—	194 (n=21)	—	338±341 (n=21)
B and O ^c →B	241 (n=35)	353 (n=67)	319±256 (n=35)	520±536 (n=67)
O				
A_2 →O	262 (n=7)	280 (n=13)	279±120 (n=7)	327±130 (n=13)
O→O	211 (n=166)	330 (n=370)	282±227 (n=166)	403±341 (n=370)

^c These O→B and A transplants were predominantly zero antigen mismatched.

who underwent transplantation with B or O kidneys (22 of 69) and 24% (5 of 21) of the B patients who underwent transplantation with A_2 or A_2B kidneys. Because the incidence of minority candidate transplant recipients was not significantly different between those two groups, access of blood group B minority candidates to A_2 or A_2B kidneys is commensurate with their composition on our waiting list.

The minority composition of our OPO B waiting list in March of 1997, before we performed transplantations of 11 A_2 and A_2B kidneys into B patients, compared with November of 1997, after all those transplants occurred, did not significantly change (42% [14 of 33] to 50% [15 of 30]; $P>0.25$). It should be pointed out that a large portion of the minority blood group B candidates before (n=14) and after (n=15) transplantation of A_2/A_2B kidneys had high percent reactive antibody levels or were listed with one of the centers that do not transplant B patients with A_2 or A_2B kidneys (75% [9 of 12] in March and 93% [13 of 14] in November).

The potential impact of allocating A_2 and A_2B kidneys to B and O candidates on reducing access to kidneys by blood group A candidates is an important consideration. During the variance, 400 blood group A kidneys were recovered and transplanted from our OPO. Of those A kidneys, 4.5% (18 of 44) were A_2 kidneys transplanted into B candidates, and 3.2% were A_2 kidneys transplanted into O candidates. The median waiting time for A patient transplant recipients between September 1991 and 1997 was 200 days (n=303; mean, 306±363), which was not significantly different from A waiting times from 1994 to 1997 (229 days; n=199; mean, 333±405) ($P=0.4$).

Graft outcome for the 30 B and O recipients of A_2 and A_2B cadaveric kidneys compared with 497 ABO-compatible transplants done since 1994 is shown in Figure 1. The 3-year graft survival of B and O recipients of A_2 and A_2B kidneys (96% for patients who died with a functioning graft [DWFG]-censored and 76% for DWFG-not censored) was not significantly different from that of the concurrent ABO-compatible transplants (88% for DWFG-censored and 78% for DWFG-not cen-

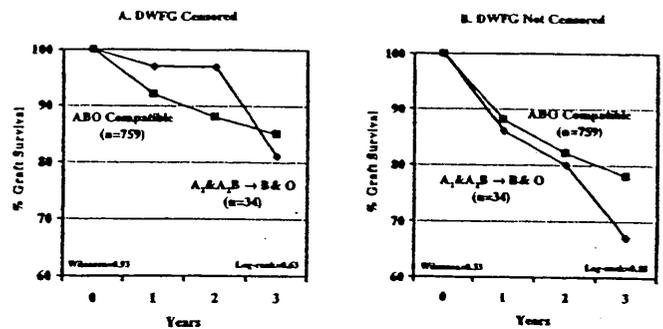


FIGURE 1. Graft outcome for B and O recipients of A_2 and A_2B kidneys (♦) compared with that for ABO-compatible concurrent transplants (■) done from 1994 through 1997. A and B analyze patients who died with a functioning graft (DWFG) and were censored (A) or not (B).

sored) (log-rank=0.45 for DWFG-censored and 0.55 for DWFG-not censored). Of the 30 B and O recipients of A_2 and A_2B cadaveric kidneys since 1994, 25 (83%) have a functioning kidney, four (13%) died with a functioning kidney, and only one (blood group O patient) rejected an A_2 kidney 14 days after transplantation. Mean follow-up was 16.9±16.6 months (minimum, 1 month; median, 9.5 months; maximum, 72 months). Furthermore, of the 6 minority transplant recipients, four (66%) have functioning kidneys, one died with a functioning kidney 21 months after transplantation, and one adolescent recipient (who was suspected of noncompliance) rejected his kidney 2 years after transplantation.

These data show that by allocation of A_2 and A_2B kidneys to patients on our OPO-wide B waiting list, we have increased their access to kidneys by 29.3%. The median waiting times of B recipients of A_2 and A_2B cadaveric kidneys (194 days) were less than those of B recipients of B and O cadaveric kidneys (353 days) and more consistent with those of our OPO-wide A waiting list candidates (200 days) (Table 3).

DISCUSSION

The clinical success of A_2 and A_2B transplants into recipients with low anti-A IgG titer histories (3–6) has the potential to favorably influence the blood group B national transplant rate. Applied conservatively, between 20 and 30% more B waiting list candidates may receive transplants each year with A_2 and A_2B kidneys, a potential increase of at least 100 more B candidate transplant recipients annually. This allocation policy, applied nationally, would potentially decrease the waiting times for B recipients of A_2 or A_2B kidneys. Based on our data, the percent drop in median waiting time for B recipients of A_2 or A_2B kidneys (194 days) compared with B recipients of B or O kidneys (353 days) was 45%. UNOS waiting time data for B candidates in 1994 was 1329 days. A conservative estimate of a 30% reduction in waiting times for that portion of the national B waiting list who received A_2 or A_2B kidneys would lower waiting times to a median of 931 days. That more closely approaches the 1994 national median waiting time for O patients, which was 1007 days.

Allocation of A_2 and A_2B kidneys to blood group B patients may also help equalize waiting times for black candidates. The frequency of blood group B is 20% in blacks and 11% in whites. Thus, blacks should have a disproportionately higher

TEN-YEAR EXPERIENCE IN TRANSPLANTATION OF A₂ KIDNEYS INTO B AND O RECIPIENTS¹

PAUL W. NELSON,^{2,3} MICHAEL D. LANDRENEAU,⁴ ALAN M. LUGER,⁵ GEORGE E. PIERCE,⁶
GILBERT ROSS,⁷ CHARLES F. SHIELD III,⁸ BRADLEY A. WARADY,⁹ MARK I. AEDER,¹⁰
THOMAS S. HELLING,² TERRY M. HUGHES,¹¹ MALCOLM L. BECK,¹² KEVIN M. HARRELL,¹³ AND
CHRISTOPHER F. BRYAN¹³

Department of Surgery, University of Missouri, Kansas City; Department of Surgery, St. John's Regional Medical Center, Joplin; Department of Pathology and Department of Surgery, Section of Urology, University of Missouri Hospital & Clinics, Columbia; Department of Nephrology, Children's Mercy Hospital, Kansas City; Department of Surgery, Research Medical Center, Kansas City, and Community Blood Center of Greater Kansas City, Kansas City, Missouri; and Department of Surgery, University of Kansas Medical Center, Kansas City; Department of Surgery, Via Christi St. Francis Campus, Wichita; and Midwest Organ Bank, Inc., Wichita and Westwood, Kansas

Background. This article summarizes our 10-year multicenter experience with transplantation of 50 blood group A₂ and A₂B kidneys into B and O patients.

Methods. Since 1986, we have transplanted kidneys from 46 cadaver donors and 4 living donors who were blood group A₂ (47 donors) or A₂B (3 donors) into 19 B and 31 O patients. In 1991, we began allocating these kidneys preferentially to B and O recipients who were selected based on a history of low (≤ 4) anti-A IgG isoagglutinin titers. Immunosuppression was no different from that used in ABO-compatible grafts.

Results. The 1-month function rate before thus selecting the patients was 68% (19/28), but is now 94% (17/18). Two-year cadaver-donor graft survival with this selection method is 94%, compared with 88% for 640 concurrent and consecutive ABO-compatible transplants (log-rank, 0.15). All four living-related transplants are still functioning, with a mean follow-up of 71 months. Since we began allocating A₂ kidneys preferentially to B and O recipients, the percentage of the B patients who received A₂ or A₂B kidneys has increased from 29% (8/28) to 55% (10/18).

Conclusions. Transplantation of A₂ or A₂B kidneys into B and O patients is clinically equivalent to that of ABO-compatible transplantation when recipients are selected by low pretransplant anti-A titer histories. This approach increases access of blood group B recipients to kidneys.

It is generally agreed that there is a shortage of organ donors for transplantation, and that waiting times are too long. It is also known that patients with blood groups B and O wait longer for kidney transplants than do patients with blood group A (1). Increasing the pool of donor kidneys available to B and O recipients would be expected to decrease waiting time. We have been interested in transplantation of kidneys from subgroup A₂ donors. Based on the work of Brynger and others (2-4), we have previously published our early experience with this subgroup and have shown that blood group B and O recipients can, in many instances, undergo uneventful transplantation with subgroup A₂ kidneys (5). We have also shown (5-7) that the early non-function rate of these kidneys is higher when the recipient's serum is high in antibody against the A blood group antigen (isoagglutinin). In this article, we present our cumulative experience 10 years after performing our first A₂ to non-A kidney transplant.

PATIENTS AND METHODS

Midwest Organ Bank A₂/A₂B transplants. Between March 1986 and December 1996, the transplant centers in our organ procurement organization (OPO*) performed 50 kidney transplants using kidneys from either A₂ (n=47) or A₂B (n=3) donors (Table 1). Ninety-two percent (46/50) were done with kidneys from cadaveric donors, and 8% (4/50) were with kidneys from living-related donors. The donor to recipient combination, A₂ into O (n=31) was the most frequent, 62%, followed by 32% (16/50) A₂ into B, and 6% (3/50) A₂B into B transplants.

Midwest Organ Bank A₂/A₂B kidney allocation variance. In September 1991, our OPO implemented a United Network for Organ Sharing-approved allocation variance that allowed preferential allocation of A₂ kidneys first to B and then O patients. Originally, A₂ kidneys were first allocated to A₂ and A₂B patients with low panel-reactive antibodies (PRAs) and then to high PRA A₁ and A₁B patients. In October 1994, we modified that variance so as to not allocate A₂ kidneys first to low PRA A₂ or A₂B patients, because most of our A₂ kidneys were not being transplanted into B and O patients. We first allocate A₂ kidneys to high PRA (>79%) A₂ or A₂B patients, followed by high PRA (>79%) A₁ and A₁B patients before proceeding to B and then O patients. Since implementing the variance, 18 A₂ or

* Abbreviations: DWFG, died with a functioning graft; OPO, organ procurement organization; PCR, polymerase chain reaction; PRA, panel-reactive antibody.

¹ Presented at the 23rd Annual Meeting of the American Society of Transplant Surgeons, May 14-16, 1997, Chicago, IL.

² Department of Surgery, University of Missouri.

³ Address correspondence to: Paul W. Nelson, 308 Medical Plaza Building, 4320 Wornall Road, Kansas City, MO 64111.

⁴ Department of Surgery, St. John's Regional Medical Center.

⁵ Department of Pathology, University of Missouri Hospital & Clinics.

⁶ Department of Surgery, University of Kansas Medical Center.

⁷ Department of Surgery, Section of Urology, University of Missouri Hospital & Clinics.

⁸ Department of Surgery, Via Christi, St. Francis Campus.

⁹ Department of Nephrology, Children's Mercy Hospital.

¹⁰ Department of Surgery, Research Medical Center.

¹¹ Midwest Organ Bank, Inc., Wichita.

¹² Community Blood Center of Greater Kansas City.

¹³ Midwest Organ Bank, Inc., Westwood.

survival analysis, based on the recommendation of Matas (12). First, patients who DWFG were considered to be lost to follow-up at the time of death and were censored from further actuarial analysis. A second analysis was done in which patients who DWFG were not censored, and they were considered in the actuarial analysis as having lost their graft (clinical method of analysis). Both analyses are shown in the graft survival data (Table 3). The chi-square test was used to compare distribution differences. Student's *t* test was used to compare group mean differences.

RESULTS

Demographics. Table 2 compares demographics of the patient groups who received A₂ or A₂B kidneys before and after implementation of the allocation variance in 1991. As can be seen, the percentage of B patients who received A₂ or A₂B kidneys has increased from 29% (8/28) to 55% (10/18) since implementation of the variance. The cold ischemia time has declined significantly (*P*=0.002) from 22.2±6.2 hr (n=28) to 16±6.7 hr (n=18) since 1991. This decrease is likely due to our current practice (since 1991) of performing prospective anti-A titers on B and O candidates for A₂ or A₂B transplants. When an A₂ or A₂B kidney is available for allocation, patients are selected to receive the kidney based on their anti-A IgG titer history being low (each titer in their history ≤4). Before 1991, only a current sample was tested for the titer, and that was performed at the time the A₂ or A₂B donor was identified, thus adding to the cold ischemic time.

Anti-A titers and early graft function. Our current practice of using the anti-A titer history to select patients for transplantation is associated with a trend toward lower anti-A titers at transplant (Table 2), but importantly is also associated with a trend (*P*<0.1) toward higher 1-month kidney function rate since 1991 of 94% (17/18), compared with 68% (19/28) before 1991. The only other significant difference in demographics between the two groups is a higher degree of HLA mismatch in the current group (*P*=0.012).

Graft survival. Graft survival in the recipients of cadaver A₂ or A₂B kidneys since implementing our new patient selection criteria based on a patient's anti-A IgG titer history is shown in Table 3. It should be noted that at 2 years, the actuarial graft survival is 94% in the A₂ group compared with 88% in the overall concurrent and consecutive ABO-compatible group (n=640; log-rank, 0.15). Of the 18 cadaver grafts done since the variance took effect in 1991, 4 grafts were lost to rejection. The intervals to graft loss in these four patients were 27, 41, 21, and 0.5 months. The last of these four patients was a 53-year-old man with no anti-HLA antibody receiving his first graft. Serial anti-A titers during his 333 days on the waiting list were all in the low (≤4) range. Two patients died with functioning allografts at 21 months and 1 month after transplantation. The cause of death in the patient who died at 1 month was bacterial endocarditis, but the patient had normal renal function until shortly before death.

TABLE 2. Demographics of B and O recipients of A₂ or A₂B kidneys stratified according to implementation of the United Network for Organ Sharing-approved variance

Demographics	Cumulative summary of variance data			P
	Before variance	Since variance	Total	
Recipients of A ₂ /A ₂ B kidneys ABO				
B	29% (8/28)	55% (10/18)	39% (18/46)	
O	71% (20/28)	45% (8/18)	61% (28/46)	<0.25
Wait time (days) for B and O recipients of A ₂ /A ₂ B Kidneys				
Mean	276±137 (n=11)	352±203 (n=18)	323±182 (n=29)	0.29
Median	262	325	317	
Cold ischemic time (hr)	22.2±6.2 (n=28)	16.0±6.7 (n=18)	19.8±7.0 (n=46)	0.002
Recipient age (yr)	37±15 (n=28)	42±16 (n=18)	39±15 (n=46)	0.24
HLA mismatches	3.6±1.4 (n=28)	4.6±1.0 (n=18)	4.0±1.3 (n=46)	0.012
Current PRA	8.4±19.1 (n=22)	2.1±4.2 (n=18)	5.5±14.6 (n=40)	0.21
Anti-A titer at transplant	14.5±29.6 (n=24)	2.9±3.5 (n=18)	9.5±27.1 (n=42)	0.1
Number with low titer history	ND ^a	94% (15/16)	ND	
Percent female	32% (9/28)	39% (7/18)	35% (16/46)	<0.75
Percent minority (nonwhite)	32% (9/28)	33% (6/18)	33% (15/46)	<0.75
Percent primary transplants	79% (22/28)	89% (16/18)	83% (38/46)	<0.75
Percent patients with functioning kidney at 1 mo	68% (19/28)	94% (17/18)	78% (36/46)	<0.1

^a ND, not determined.

actuality be some other subtype of A and trigger a brisk antibody response in the recipient. We are now using molecular ABO genotyping, using PCR with sequence-specific primer mixes to confirm the result of ABO serology for A₂ donors (Fig. 1). Of four donors tested thus far, including the one in Figure 1, all had the A²O¹ genotype. It may be useful to apply such methods to type A₂ donors. However, this still does not provide an explanation for the disparate clinical results between our series and other case reports.

We report in this article a series of cadaver and living-related kidney transplants from A₂ and A₂B donors in which the recipients were selected by the presence of multiple serial low titers of anti-A and show that graft survival at 2 years is equivalent to a traditional ABO-compatible population.

Further data are needed to explain the variable anti-A antibody response seen in these recipients and to characterize those recipients who will not reject an A₂ graft. Further study is needed to explain why some recipients with elevated anti-A titers do not reject grafts whereas a few with low anti-A titers do. Routine subtyping of A donors is not widely done. Technical differences between laboratories in determining A subgroup status may lead to the performance of unsuccessful A₂ transplants. Routine transplantation of A₂ donors into non-A recipients should be done only after careful examination of the multiple factors involved. A national registry of these transplants could provide more answers to this clinical problem.

Acknowledgments. The authors thank Norma Melton for help in preparing the manuscript, Stanley Mitchell for statistical analyses, and each laboratory technologist who performed the testing. The authors also thank the following renal transplant coordinators who provided the clinical outcome data: Mark Blackmore, R.N., Via Christi, St. Francis Campus; Brenda Brewer, R.N., St. Luke's Hospital; Julie Green, R.N., St. John's Regional Medical Center; Diana Layes, R.N., University of Kansas Medical Center; Leslie Reed, R.N., Children's Mercy Hospital; Clay Pickens, B.M.E., University of Missouri Hospital & Clinics; and Karen Vandeputte, R.N., Research Medical Center.

REFERENCES

1. United Network for Organ Sharing. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients (OPTN/SR)1996 annual report: transplant data 1988-1995. Richmond, VA: United Network for Organ Sharing, 1997: 231.
2. Brynager H, Rydberg L, Samuelsson B, Blohme I, Lindholm, Sandberg L. Renal transplantation across a blood group barrier: A₂ kidneys to O recipients. Proc Eur Dial Transplant Assoc Eur Ren Assoc 1982; 19: 427.
3. Breimer ME, Brynager H, Rydberg L, et al. Transplantation of blood group A₂ kidneys to O recipients: biochemical and immunological studies of blood group A antigens in human kidneys. Transplant Proc 1985; 17: 2640.
4. Brynager H, Rydberg L, Samuelsson B, et al. Experience with 14 renal transplants with kidneys from blood group A (subgroup A₂) to O recipients. Transplant Proc 1984; 16: 1175.
5. Nelson PW, Helling TS, Pierce GE, et al. Successful transplantation of blood group A₂ kidneys into non-A recipients. Transplantation 1988; 45: 316.
6. Nelson PW, Helling TS, Shield CF, et al. Current experience with renal transplantation across the ABO barrier. Am J Surg 1992; 164: 541.
7. Nelson PW, Aeder MI, Beck ML, et al. An association of anti-A RBC titer in ESRD patients with clinical outcome in transplantation of blood group A₂ kidneys into B and O recipients. Hum Immunol 1991; 32: 55.
8. Gassner C, Schmarada A, Nussbaumer W, Schönitzer D. ABO glycosyltransferase genotyping by polymerase chain reaction using sequence-specific primers. Blood 1996; 5: 1852.
9. Olerup O. HLA-B27 typing by group-specific PCR amplification. Tissue Antigens 1994; 43: 253.
10. Smith KT, Long CM, Bowman B, Manos MM. Using cosolvents to enhance PCR amplification. Amplifications 1990; 16.
11. Hoppe BL, Conti-Tronconi BM, Horton RM. Gel-loading dyes compatible with PCR. BioTechniques 1992; 12: 679.
12. Matas AJ, Gillingham KJ, Sutherland DER. Half-life and risk factors for kidney transplant outcome: importance of death with function. Transplantation 1993; 55: 757.
13. Rydberg L, Breimer ME, Brynager H, Samuelsson BE. ABO-incompatible kidney transplantation (A₂ to O): qualitative and semi-quantitative studies of the humoral immune response against different blood group A antigens. Transplantation 1990; 49: 954.
14. Schachter H, Michaels MA, Tilley CA, Crookston MC, Crookston JH. Qualitative differences in the N-acetyl-D-galactosaminyltransferases produced by human A₁ and A₂ genes. Proc Natl Acad Sci USA 1973; 70: 220.
15. Mendez R, Sakhrani L, Chaballout A, Mendez RG. ABO incompatible transplants involving A₂ donors. Transplant Proc 1991; 23: 1738.
16. Slapak M, Digard N, Ahmed M, Shell T, Thompson F. Renal transplantation across the ABO barrier: a 9 year experience. Transplant Proc 1990; 22: 1425.
17. Hanto DW, Brunt EM, Goss JA, Cole BR. Accelerated acute rejection of an A₂ renal allograft in an O recipient: association with an increase in anti-A₂ antibodies. Transplantation 1993; 56: 743.
18. Pins MP, Saidman SL, Cosimi AB, Jennings LD, Stowell CP. Accelerated acute rejection of an apparent A₂ renal allograft in an O recipient. Transplantation 1997; 63: 984.

Received 8 May 1997.

Accepted 9 September 1997.

Patients and methods

Using the NAPRTCS (1987–1995) and MOB (1986–1996) databases, all pediatric ABO-mismatched kidney transplants and their outcome were identified. In each case, the patient's age, gender, race and primary renal disorder were determined. Additional factors assessed included recipient and donor blood types, donor source, use of pre-transplant preparations (e.g. donor-specific transfusions, plasmapheresis/immunoabsorption, splenectomy or anti-platelet aggregation therapy), initial and post-transplant day 30 immunosuppression and the recipient anti-A titer (only for MOB patients) at time of transplant.

The anti-A titer was determined in the laboratories of the MOB. Briefly, the procedure for determination of anti-A RBC IgG and IgM titers consisted of making several dilutions of the recipient's sera in saline and testing for agglutinating activity towards A₁ and A₂ RBC following a 10-min incubation at 22 °C. Titers were read macroscopically. To differentiate between IgM- and IgG-agglutinating activity, sera were treated with the sulfhydryl component dithiothriitol (DTT) at 0.01 M. Agglutination of sera treated with DTT was attributed to IgG. The anti-A titer reported is based on the anti-A₁ RBC and not the anti-A₂ RBC because of the greater reactivity of the former.

Results

A total of 11 pediatric patients registered in the NAPRTCS and/or MOB databases received ABO-mismatched kidney transplants between 1986–1996. The patient profiles, clinical and laboratory data are listed in Table 1. The mean (± SD) age at transplant was 14.7±3.0 yr. There were 6 male and 5 female recipients: 2 were black, 8 were white and 1 was Asian. The primary renal diagnoses were as follows:

obstructive uropathy (3 pts), membranoproliferative glomerulonephritis (MPGN) (2 pts), cystinosis (1 pt), renal dysplasia (1 pt), reflux nephropathy (1 pt), focal segmental glomerulosclerosis (FSGS) (1 pt), Bartter's syndrome (1 pt) and rapidly progressive glomerulonephritis (RPGN) (1 pt).

Eight A₂ kidneys were transplanted into O recipients, 2 A₂ kidneys into B recipients and 1 A₂B kidney into a B recipient. Seven kidneys were from cadaveric donors while 4 were from living-related donors (2 from parents and 2 from siblings). All but 2 transplants were index transplants. In the case of the 6 patients from the MOB region, the mismatched transplants were proposed following a UNOS-approved variance for the MOB which allowed allocation of A₂ kidneys preferentially to B and O recipients to increase their access to kidney transplantation. No data were available on the reasons mismatched transplantation was pursued in the remaining cases. Two of the 11 patients underwent splenectomy as part of their pre-transplant preparation. No additional data were available as to whether plasmapheresis or any other special donor or recipient pre-transplant management was performed.

Induction and initial immunosuppression consisted of corticosteroids (7.8±4.0 mg/kg/d) in 11 patients, azathioprine (2.6±1.3 mg/kg/d) in 11 patients, anti-lymphoblast globulin (ALG)/anti-thymocyte globulin (ATG) (17.6±4.3 mg/kg/d) in 6 patients, OKT3 (0.13±0.0 mg/kg/d) in 3 patients, and cyclosporine (11.7±3.7 mg/kg/d initiated from day 0 to day 15 post-transplant) in 10 patients (Table 2).

At day 30 post-transplant, the mean cyclosporine dose was 10.6±4.0 mg/kg/d, prednisone was 0.8±0.7 mg/kg/d and azathioprine 1.7±0.9 mg/kg/d in all patients with functioning grafts (Table 2).

Eight of the 11 patients (72%) had at least 1 acute rejection episode (Table 3). In 7 patients, the initial rejection occurred during the first 31 d post-trans-

Table 1. Patient characteristics and ABO blood type mismatch

Patient no.	Age at transplant (yr)	Year of transplant	Gender	Race	Blood type Recipient/donor	Donor source	Primary renal diagnosis
1	14	1994	F	W	O/A ₂	CAD ¹	renal dysplasia
2	17	1989	M	B	O/A ₂	LRD ¹	cystinosis
3	11	1990	M	W	O/A ₂	CAD	obstructive uropathy
4 ²	20	1991	F	B	B/A ₂	CAD	Bartter's syndrome
5 ³	15	1989	F	W	O/A ₂	LRD	MPGN ⁴
6	14	1987	M	W	O/A ₂	CAD	MPGN
7	15	1991	F	W	B/A ₂ B	CAD	reflux nephropathy
8	9	1987	M	W	O/A ₂	LRD	obstructive uropathy
9 ³	17	1993	M	W	O/A ₂	LRD	FSGS ⁵
10 ²	14	1986	F	W	O/A ₂	CAD	obstructive uropathy
11	16	1987	M	Asian	B/A ₂	CAD	RPGN ⁶

¹Cadaveric (CAD) or living related (LRD) kidney donor. ²Second transplant. ³Pretransplant splenectomy. ⁴Membranoproliferative glomerulonephritis. ⁵Focal segmental glomerulosclerosis. ⁶Rapidly progressive glomerulonephritis.

Brynger and colleagues were among the first to demonstrate that A₂ kidneys can function well in some recipients with blood group O without the development of the hyperacute rejection that has long been known to accompany ABO-mismatched transplantation (1, 4). It is believed that this tolerance on the part of the recipient may be related to the low level antigenicity of the A antigen expressed on the endothelium of A₂ blood group kidneys compared to A₁ kidneys. Nelson et al. (5–7) and Bryan et al. (8) have previously demonstrated that ABO-mismatched kidney transplantation with A₂ donors can be performed successfully without modification of the patient's immune status prior to transplantation. These authors have suggested that successful graft outcome of A₂ kidneys transplanted into O and B patients is associated with the presence of a low (≤ 4) pre-transplant anti-A titer history. In contrast, a titer of ≥ 8 appears to be associated with a worse clinical outcome. The latter result appears to reflect a higher level of A isoagglutinin of the recipient with respect to the A antigen on the endothelium of the A₂ kidney. Even though Welsh et al. also found that high pre-transplant anti-A titers correlated with failure of A₂ to O transplants, low titers in their patients did not always predict success (9).

Eleven pediatric A₂ to O or B kidney transplants have been identified in the period 1986–1996 from the NAPRTCS and MOB data. The fact that the NAPRTCS registry alone includes >5000 pediatric kidney transplants makes ABO-mismatched renal transplantation in children a rare event (10). Overall, the graft outcome of this combined LRD and CAD recipient population was slightly worse than that experienced by pediatric patients in general, with actual 1- and 2-yr graft survival rates of 73%. However, it is noteworthy that in 3 of the failed grafts, no anti-A titer was performed prior to the transplant. In those cases where the transplant was successful, it is likely that the success was secondary to reduced levels of A antigen on the graft endothelium of the A₂ kidney coupled with the low titer of natural ABO isoagglutinins in the recipient. While our results suggest that the association between low pre-transplant anti-A titer history and graft survival in pediatric patients is especially promising, the assessment of additional A₂ to O and B donor–recipient pairs will be necessary to validate this clinical finding further.

Although the A₂ pool of kidney donors is only approximately 20% of the A donors, it may offer a substantial source of kidneys for pediatric and adult recipients with blood types O and B, who have the longest waiting time for kidney transplantation (11–13). The median waiting times for O and B recipients for a kidney transplant are 912 and 1178 d, respectively, as compared to a median 288 d for AB

and 551 d for blood group A patients. Preferential allocation of A₂ kidneys into O and B recipients has already resulted in an 19% increase in the MOB transplantation rate of blood group B patients (2).

In summary, pediatric kidney transplantation across the ABO barrier is an uncommon practice. However, our preliminary experience and that of the adult transplant population suggests that the application of the routine assessment of anti-A titers in potential O and B recipients of A₂ kidneys, and the performance of transplants only in those patients whose anti-A titer history has been low (≤ 4), are associated with good graft outcome and are well deserving of further study.

References

1. BRYNGER H, RYDBERG L, SAMUELSSON B, BLOHME I, LINDHOLM A, SANDBERG L. Renal transplantation across a blood group barrier – 'A₂' kidneys to 'O' recipients. *Proc EDTA* 1982; 19: 427–430.
2. NELSON PW, LANDRENEAU MD, LUGER AM, et al. Ten year experience in transplantation of A₂ kidneys into B and O recipients. *Transplantation* 1997; 64: 1–5.
3. KERMAN RH. The role of crossmatching in organ transplantation. *Arch Pathol Lab Med* 1991; 115: 255–259.
4. ALEXANDRE GPL, SQUIFFLET JP, DE BRUYÈRE M, LATINNE D, MORIAU M, IKABU N, et al. Splenectomy as a prerequisite for successful human ABO-incompatible renal transplantation. *Transpl Proc* 1985; 17: 138–143.
5. NELSON PW, HELLING TS, PIERCE GE, et al. Successful transplantation of blood group A₂ kidneys into non-A recipients. *Transplantation* 1988; 45: 316–319.
6. NELSON PW, HELLING TS, SHIELD CF, BECK M, BRYAN C. Current experience with renal transplantation across the ABO barrier. *Ann Surg* 1992; 164: 541–545.
7. NELSON PW, HUGHES TM, BECK ML, WARADY BA, AEDER MI, HELLING TS, et al. Stratification and successful transplantation of patients awaiting ABO-incompatible (A₂ into B and O) transplantation by A-isoagglutinin-titer phenotype. *Transpl Proc* 1996; 28: 221–223.
8. BRYAN CF, NELSON PW, AEDER MI, BECK ML, HELLING TS, HUGHES TM, et al. Current experience with renal transplantation across the ABO blood group barrier. *Transpl Proc* 1992; 24: 2527–2529.
9. WELSH KI, VAN DAM M, KOFFMAN CG, BERWICK M, RUDGE C, TAUBE D. Transplantation of blood group A₂ into O or B recipients: the effect of pretransplant anti-A titers on graft survival. *Transpl Proc* 1987; 19: 4565–4567.
10. WARADY BA, HEBERT D, SULLIVAN EK, ALEXANDER SR, TEJANI A. Renal transplantation, chronic dialysis, chronic renal insufficiency in children and adolescents. The 1995 Annual Report of the North American Pediatric Renal Transplant Cooperative Study. *Pediatr Nephrol* 1997; 11: 49–64.
11. ISSITT PP. *Applied blood group serology*. Miami: Montgomery Scientific, 1985.
12. Organ Procurement and Transplantation Network/Scientific Registry 1996 Annual Report. *Transplant Data 1988–1995 United Network for Organ Sharing*. p.231.
13. PORT F, HELD P, WOLFE R. The impact of non-identical ABO cadaveric renal transplantation on waiting times and graft survival. *Am J Kidney Dis* 1991; 17: 519–523.

LifeLink Foundation

RECEIVED MAY 14 2004

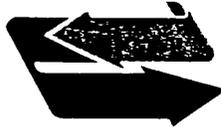


Exhibit K

A not-for-profit corporation dedicated to serve patients in need of transplantation therapy.

May 10, 2004

Mr. Doug A. Heiney, Liaison
Membership Services and Policy Development
United Network for Organ Sharing
1100 Boulders Parkway, Suite 500
P.O. Box 13770
Richmond, VA 23225-8770

RE: Application for Variance to Current Florida Alternate Local Unit (ALU) for Pancreas and Kidney-Pancreas Allocation

Dear Mr. Heiney:

The following information is provided to address the current Florida alternate local unit for pancreas and kidney-pancreas allocation and to request a variance to the same. Dr. Thomas Gonwa has agreed to present this at the upcoming Kidney/Pancreas (K/P) Committee meeting and will be referencing the information contained in this packet. At the direction of Cindy Sommers, liaison to the (K/P) Transplantation Committee, copies of this application have been forwarded to Dr. Alan Leichtman, Chair of the K/P Transplantation Committee, Dr. Thomas Gonwa, Region 3 Representative, and to Cindy for inclusion in the agenda packet for the upcoming meeting.

Information included in this packet was also sent to all Region 3 pancreas and kidney-pancreas transplant centers as well as Region 3 OPOs.

Communication with the Executive Directors of all OPOs in Region 3, specifically Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, and Puerto Rico, shows broad, unanimous support for a change in the current UNOS sharing algorithm, which calls for a single state-wide list as the local center, regional and then national distribution. All of the pancreas transplant centers in Florida support the implementation of a new strategy for sharing which would mirror our long-standing renal allocation system, i.e. local, state, regional, and then national.

We anticipate unanimous support from Florida transplant centers and will provide documentation to that end prior to the May 19th Kidney/Pancreas Transplantation Committee Meeting.

The attached data shows that each of the states in our region recovered more donors and have more pancreata available than are used locally (Attachment VIII) as evidenced by the rare "distant" recovery of K/P or isolated pancreas. It is our belief that if approved this alternate local unit would provide increased local use with increased pancreas utilization overall resulting in shorter ischemic times, potentiating better patient outcomes.

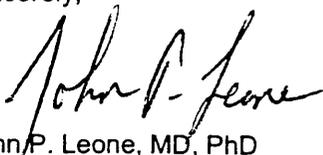
K-1

Page two
Mr. Doug A. Heiney, Liaison
Membership Services and Policy Development
United Network for Organ Sharing

RE: Application for Variance to Current Florida Alternate Local Unit (ALU) for Pancreas and Kidney-Pancreas Allocation

Included for your review is the completed application. If there are any questions please do not hesitate to contact me, 813-251-8017, extension 1094.

Sincerely,



John P. Leone, MD, PhD
Director, Pancreas Transplant Program
LifeLink Healthcare Institute

Enclosures

cc: Alan B. Leichtman, MD
Chair, Kidney/Pancreas Transplantation Committee

Thomas Gonwa, MD
Region 3 Representative

Cindy Sommers
Liaison, Kidney/Pancreas Transplantation Committee

APPLICATION FOR VARIANCE TO CURRENT FLORIDA ALTERNATE LOCAL UNIT FOR PANCREAS AND KIDNEY-PANCREAS ALLOCATION

- Attachment I:** Proposed Variance to Pancreas and Kidney-Pancreas Allocation
Alternate Local Unit for Florida
- Attachment II:** Referenced UNOS Policies and Current Florida ALU
- Attachment III:** Florida Transplant Center Signatures for Proposed Variance
To be sent under separate cover
- Attachment IV:** Florida Organ Procurement Organization Signatures for Proposed Variance
To be sent under separate cover
- Attachment V:** Justification for Proposed Variance to Pancreas and Kidney-Pancreas Allocation
Alternate Local Unit for Florida
- Attachment VI:** Region 3 Transplant Centers with Active, Inactive and No Pancreas Programs
- Attachment VII:** Region 3 Organ Procurement Organizations
- Attachment VIII:** Supporting Data
Table A: UNOS 01/2000 – 12/2003 - Florida Pancreas and Kidney-Pancreas Transplant Data
Table B: 2003 Region 3 Pancreas and Kidney-Pancreas Recovery and Transplant Data
Table C: 2002 Region 3 Pancreas and Kidney-Pancreas Recovery and Transplant Data
Table D: Current Pancreas and Kidney-Pancreas Waiting List by Transplant Center for Region 3 as
of April 02, 2004
- Attachment IX:** Region 3 / Non-Florida Responses to Variance Proposal
To be sent under separate cover

Attachment I: Proposed Variance to Pancreas and Kidney-Pancreas Allocation Alternate Local Unit for Florida

The following represents a draft proposal for Florida pancreas and kidney-pancreas allocation incorporating the proposed amended pancreas ALU language into current UNOS pancreas allocation policy (UNOS Policy 3.8 – Pancreas Allocation).

This draft defines pancreas and kidney-pancreas allocation to include local in the current state, regional and national allocation scheme.

For the purpose of this document “local” is defined as the OPO service area per UNOS policy.

In accordance with UNOS Policy 3.8, Pancreas Allocation, the following variance to the current alternate local unit for Florida is proposed:

Proposed Local Whole Pancreas Allocation: For local pancreas allocation, recipients may be selected from candidates awaiting an isolated pancreas, kidney-pancreas combination, or a combined solid organ-islet transplant from the same donor, unless there is a patient on the UNOS Patient Waiting List who meets the requirements of Policy 3.5.4 or Policy 3.8.1.6.

Proposed State Whole Pancreas Allocation: Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

- Isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.

Proposed Regional Whole Pancreas Allocation: Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.

- Isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.

National Whole Pancreas Allocation and Facilitated Pancreas Allocation shall remain as stated in UNOS Policy 3.8.1.2 and 3.8.1.3 respectively.

Proposed Local Islet Allocation Protocol according to policy 3.8.1.4 and 3.8.1.5.

Proposed State Islet Allocation Protocol according to policy 3.8.1.4 and 3.8.1.5.

Regional and National Islet Transplantation shall remain as stated in policy 3.8.1.4 and 3.8.1.5.

April 16, 2004

Attachment II: Referenced UNOS Policies and Current Florida Pancreas ALU

- 3.5.2** ABO "O" Kidneys into ABO "O" Recipients and ABO "B" Kidneys into ABO "B" Recipients. Blood type O kidneys must be transplanted only into blood type O patients except in the case of zero antigen mismatched patients (as defined in Policy 3.5.3.1) who have a blood type other than O. Additionally, blood type B kidneys must be transplanted only into blood type B patients except in the case of zero antigen mismatched patients (as defined in Policy 3.5.3.1) who have a blood type other than B. Therefore, kidneys from a blood type O donor are to be allocated only to blood type O patients and kidneys from a blood type B donor are to be allocated only to blood type B patients, with the exception for zero antigen mismatched patients noted above. This policy, however, does not nullify the physician's responsibility to use appropriate medical judgment in an extreme circumstance.
- 3.5.3** Mandatory Sharing of Zero Antigen Mismatched Kidneys. The following policies apply to allocation of any deceased expanded criteria or standard donor kidney for which there is a patient on the UNOS Patient Waiting List with a zero antigen mismatch:
- 3.5.3.1** Definition. A zero antigen mismatch is defined as occurring when a patient on the UNOS Waiting List has an ABO blood type that is compatible with that of the donor and the patient and donor both have all six of the same HLA-A, B, and DR antigens. A zero antigen mismatch is also defined as a match occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B, and DR antigens when at least one antigen is identified at each locus. Phenotypic identity means that the donor and patient each has the same antigens identified at each pair of A, B, and DR HLA loci. Patients with only one antigen identified at an HLA locus (A, B, or DR) are presumed "homozygous" at that locus (i.e. homologous chromosomes are presumed to code for identical antigens at that locus). For example, a donor or patient typed as A2, A- (blank) would be considered A2, A2. A zero antigen mismatch would also include cases where both antigens are identified at a locus in the patient but the donor is typed as being homozygous for one of the patient's antigens at that locus. For example, there would be a zero antigen mismatch if the recipient were typed as A1, A31, B8, B14, DR3, DR4 and the donor were typed as A1.A- (blank), B8, B14, DR3, DR-(blank). If the donor is homozygous at any A, B, or DR locus, the match can be said to be a zero antigen mismatch, as long as none of the identified A, B, or DR donor antigens are different from those of the recipient.
- 3.5.3.2** Computer Entry. Information regarding each and every deceased kidney donor must be entered into the UNOS computer system prior to kidney allocation, to determine whether there is a zero antigen mismatch between the donor and any patient on the UNOS Patient Waiting List. Pre-procurement tissue typing is expected consistent with Policy 2.7 (Expedited Organ Procurement and Placement) in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to patient waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to UNOS.
- 3.5.3.3** Mandatory Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, if there is any patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate UNOS member for the patient with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, if there is any patient on the UNOS Patient Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate UNOS member for the patient with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a patient with a zero antigen mismatch does not have the implicit right to choose between the two kidneys. The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a patient with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all patients for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:
- 3.5.3.3.1** First to identical blood type zero antigen mismatched patients in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as follows:
- i local patients; then to
 - ii 80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
 - iii 80% or higher PRA patients on the regional waiting list; then to
 - iv 80% or higher PRA patients on the national waiting list; then to
 - v less than 80% PRA patients who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
 - vi less than 80% PRA patients who are less than 18 years old on the regional waiting list; then to
 - vii less than 80% PRA patients who are less than 18 years old on the national waiting list; then to
 - viii 21%-79% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
 - ix 21%-79% PRA patients on the regional waiting list; then to
 - x 21%-79% PRA patients on the national waiting list; then to
 - xi less than or equal to 20% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for patients on the list of OPOs that owe ten or

more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

- xii less than or equal to 20% PRA patients on the regional waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to
- xiii less than or equal to 20% PRA patients on the national waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to

3.5.3.3.2

Next (1) in the case of blood type O donor kidneys, to blood type B zero antigen mismatched patients, first, in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i) – (viii) below, and then, to blood type A and AB zero antigen mismatched patients, also in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i) – (viii) below, and (2) in the case of blood type A, B, and AB donor kidneys, to all compatible blood type zero antigen mismatched patients in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)– (viii) below:

- i local patients; then to
- ii 80% or higher PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
- iii 80% or higher PRA patients on the regional waiting list; then to
- iv 80% or higher PRA patients on the national waiting list; then to
- v less than 80% PRA patients who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
- vi less than 80% PRA patients who are less than 18 years old on the regional waiting list; then to
- vii less than 80% PRA patients who are less than 18 years old on the national waiting list; then to
- viii 21%-79% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
- ix 21%-79% PRA patients on the regional waiting list; then to
- x 21%-79% PRA patients on the national waiting list; then to
- xi less than or equal to 20% PRA patients on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to
- xii less than or equal to 20% PRA patients on the regional waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to
- xiii less than or equal to 20% PRA patients on the national waiting list, except for patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to
- xiv less than or equal to 20% PRA patients on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt), ranked by OPO in inverse order of the highest number of payback obligations owed by the OPO if more than one OPO is in this category.

3.5.3.4 Kidney/Non-Renal Exception. When kidneys are procured for the purpose of simultaneous kidney and non-renal organ transplantation, only one of the kidneys procured must be shared as a zero antigen mismatch. In the event the kidney/non-renal organ transplant is not performed, the kidney retained for that transplant must be immediately offered for zero antigen mismatched patients. This exception does not apply to kidney-islet combined transplants or kidney-pancreas combined transplants for zero antigen mismatched highly sensitized patients as defined in Policy 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).

3.5.3.5 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 the UNOS 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). The UNOS Organ Center will attempt to place standard donor organ(s) for zero antigen mismatched patients according to the national lists of patients 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). 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 UNOS Organ Center shall continue to attempt to place the organ(s) for zero antigen mismatched patients according to the national lists of waiting patients. 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 patient. The UNOS Organ Center will attempt to place expanded criteria donor organ(s) for zero antigen mismatched patients according to the national lists of patients 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 patients 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 UNOS Organ Center will document each offer and each response.

3.5.4 Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates. An offer of a donor kidney to a highly sensitized candidate for whom there is a zero antigen mismatch with the donor, who is also a candidate for a combined kidney-pancreas transplant, must be accompanied by an offer of the pancreas from the donor. For purposes of this policy, "highly sensitized" is defined as panel reactive antibody (PRA) level of 80% or greater regardless of preliminary crossmatch results.

3.5.4.1 Mandatory Sharing. When kidneys are procured with the option of simultaneous kidney and pancreas transplantation, if there is any highly sensitized patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the kidney and pancreas from that donor shall be offered to the appropriate UNOS member for the patient with the zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting.

3.5.5 Payback Requirements. Except as otherwise provided in UNOS Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatch Pancreata - Time Limit), and 3.5.5.2 (Exception for Prior Living Organ Donors), when a kidney is shared pursuant to: (i) the mandatory zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a patient with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the UNOS Organ Center a kidney from the next suitable donor, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

3.5.5.1 Kidney/Non-Renal Organ Sharing.

3.5.5.1.1 Deferment of the Kidney/Non-Renal Exception. OPOs that have accumulated four or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for kidneys allocated for a kidney-pancreas transplant pursuant to UNOS Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The kidney/non-renal exception shall be deferred until the OPO has reduced its payback obligation to less than four.

3.5.5.1.2 Deferment of Voluntary Arrangements. OPOs that have accumulated four or more payback obligations within the same blood type shall not be offered, and, if offered, shall not accept kidneys shared with a non-renal organ from a donor of the same blood type as the accumulated payback obligations, except for kidneys allocated for a kidney-pancreas transplant pursuant to UNOS Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The offer/acceptance of kidneys voluntarily shared with non-renal organs shall be deferred until the OPO has reduced its payback obligation to less than four.

3.5.5.2 Exception for Prior Living Organ Donors. Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.

3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered long-term debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (i.e., incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3 (Mandatory Sharing).

3.8 PANCREAS ALLOCATION. The following policies shall apply to the allocation of pancreata.

- 3.8.1 Pancreas Organ Allocation.** For local pancreas allocation, recipients may be selected from candidates awaiting an isolated pancreas, kidney-pancreas combination, or a combined solid organ-islet transplant from the same donor, unless there is a patient on the UNOS Patient Waiting List who meets the requirements of Policy 3.5.34 or Policy 3.8.1.6 and for whom there is a zero antigen mismatch with the donor. Within each Patient Waiting List, length of time waiting shall be considered for the selection of organ recipients. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive. For combined kidney-pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.1, unless there is a zero antigen mismatch between the candidate and donor and the candidate is highly sensitized as defined in Policy 3.5.34. If the pancreas is not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch patient or pursuant to Policy 3.5.34 the pancreas, if procured from a donor less than or equal to 50 years old and with body mass index (BMI) less than or equal to 30 kg/m², shall be allocated regionally and then nationally, or for patients listed for facilitated pancreas placement as described in Policy 3.8.1.3, in the following sequence: Pancreata procured from donors greater than 50 years old or with body mass index (BMI) greater than 30 kg/m² that are not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch patient or pursuant to Policy 3.5.4, shall be allocated according to Policy 3.8.1.4 below:
- 3.8.1.1 Regional Whole Pancreas Allocation.** Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.
- Isolated pancreas candidates; and
 - Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.42 and the kidney must be paid back as specified in Policy 3.5.7.5.
- 3.8.1.2 National Whole Pancreas Allocation.** Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.
- Isolated pancreas candidates; and
 - Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.42 and the kidney must be paid back as specified in Policy 3.5.7.5.
- 3.8.1.3 Facilitated Pancreas Allocation.** In the event that the UNOS Organ Center has attempted, but has been unable, to place the pancreas for a period of at least five (5) hours, or upon notice to the Organ Center that organ retrieval is anticipated within one (1) hour, then irrespective of whether the entire regional and/or national Waiting List of patients has by that time been exhausted, the pancreas shall be offered through the UNOS Organ Center for patients listed with those transplant centers that have recorded in writing their desire, to participate in the UNOS system of facilitated pancreas allocation. A pancreas offered by this facilitated method shall be offered to patients who have not previously received an offer for that pancreas. The pancreas shall be offered, in the following sequence, based on the transplant candidate's length of waiting time within each of the enumerated categories below. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.
- Isolated pancreas candidates; and
 - Combined kidney-pancreas candidates if the kidney is voluntarily being offered. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.42 and the kidney must be paid back as specified in Policy 3.5.45.
- Any transplant center desiring to participate in this system shall be allowed to do so provided that it (a) agrees to accept offers for pancreata that have been procured by institutions located outside of its OPO (b) agrees to accept offers for pancreata on a conditional basis pending tissue typing information and redistribution of the organs pursuant to UNOS Policy 3.8.1.6 in the event there is a patient on the Waiting List for whom there is a zero antigen mismatch with the donor, and (c) documents this agreement and its desire to participate in the system to UNOS in writing.
- 3.8.1.4 Islet Transplantation.** If the donor is less than or equal to 50 years old and has body mass index (BMI) less than or equal to 30 kg/m² and suitable recipient is not identified by the allocation criteria specified in Policies 3.8.1, 3.8.1.1, 3.8.1.2, or 3.8.1.3, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.
- If the donor is greater than 50 years old or has BMI greater than 30 kg/m², and a suitable recipient is not identified at the local level of organ allocation by the criteria specified in Policy 3.8.1, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation, and then regionally followed by nationally for whole organ transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.
- 3.8.1.5 Islet Allocation Protocol.** Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. If after islet processing is completed, the islet preparation is medically unsuitable for the candidate, the islets from that pancreas will be reallocated to the next most suitable candidate within the OPO that the IND allows. The purpose of this policy is to allow for the application of medical judgment and to avoid islet wastage. The outcomes of this allocation policy will be reported to the OPTN Board by the KPTC within three years. Two active status codes will be used,

~~Status 1 (Urgent) and Status 2 (Non Urgent). At the regional and national level islet allocation shall be as follows:~~

- ~~• Matching 0 HLA Mismatch _____ 3 points~~
- ~~1 HLA Mismatch _____ 2 points~~
- ~~2 HLA Mismatch _____ 1 point~~
- ~~3-6 HLA Mismatch 0 points _____~~

~~Status 1 A patient that receives a clinical islet transplant becomes a Status 1 for a three week period. (Recipients need islets from four or more donors within three weeks). Status 1 islet candidates shall have priority over Status 2 candidates at each level of allocation, (i.e., local, regional, then national).~~

~~Status 2 All patients on the clinical islet transplant list who do not meet the Status 1 criteria.~~

- ~~• Waiting Time—Waiting time shall begin when a patient is placed on the UNOS Patient Waiting List. Waiting time will accrue for a patient until he/she has received a maximum of three islet infusions or the transplant center removes the patient from the waiting list, whichever is the first to occur. If the patient is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew. Waiting time as a Status 1 begins when the patient becomes a Status 1 and continues until they are no longer a Status 1. If a patient returns to a Status 2, their entire waiting time continues. One point will be assigned to the patient waiting for the longest period with fractions of points assigned proportionately to all other patients, according to their relative waiting time. For example, if there are 75 patients waiting for islets, the patient waiting the longest would receive 1 point ($75/75 \times 1 = 1$). A person with the 60th longest time of waiting would be assigned 0.2 points ($(75-60)/75 \times 1 = 0.2$). The calculation of points is conducted separately for each geographic (local, regional and national) level of islet allocation. The local points calculation includes only patients on the local Patient Waiting List. The regional points calculation includes only patients on the regional list, without the local patients. The national points calculation includes all patients on the national list excluding all patients listed on the Host OPO's local or regional waiting list. Candidates shall continue to accrue waiting time while registered on the UNOS Patient Waiting List as inactive.~~

NOTE: The amendment to Policy 3.8.1 (Pancreas Organ Allocation), above shall be implemented following programming on the UNOS system.

3.8.1.6 Mandatory Sharing of Zero Antigen Mismatch Pancreata. In the event there is a patient on the UNOS Patient Waiting List for whom there is a zero antigen mismatch with the donor, the pancreas from that donor shall be offered, first, to the appropriate UNOS member for any highly sensitized patient waiting for a combined kidney/pancreas transplant with a zero antigen mismatch, pursuant to Policy 3.5.3 (first locally, then regionally, and then nationally, based upon length of time waiting). The pancreas shall then, be offered to the appropriate UNOS member for any patient waiting for an isolated pancreas transplant with a zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting, unless there is a patient listed on the Host OPO's local patient waiting list for combined kidney/pancreas or isolated pancreas transplantation who has panel reactive antibody (PRA) level of 80% or greater based on historical or current serum samples, as used for crossmatch to determine suitability for transplant, and there is a negative preliminary crossmatch between the donor and that patient. In this event, for local allocation, the pancreas shall be offered for the patient(s) with PRA greater than or equal to 80% and a negative preliminary crossmatch (based upon length of time waiting if more than one patient meets these criteria) before being offered for zero antigen mismatched isolated pancreas transplant candidates.

3.8.1.6.1 Time 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 the UNOS Organ Center. The UNOS Organ Center will attempt to place the organ(s) for zero antigen mismatched patients according to the national lists of patients waiting for combined kidney/pancreas or isolated pancreas 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 3.5.5 and pancreas allocation under Policy 3.8.1, as applicable (first locally, then regionally, and then nationally). 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 UNOS Organ Center shall continue to attempt to place the organ(s) for zero antigen mismatched patients according to the national lists of waiting patients. Acceptance of organs declined by the Host OPO will not generate an obligation to pay back the kidney pursuant to Policy 3.5.4 (Payback Requirements) even if accepted for a zero antigen mismatched patient. The UNOS Organ Center will document each offer and each response.

3.8.2 Waiting Time Adjustment. Waiting time accrued by a transplant candidate for one or more organs shall be transferred as follows if it is determined that the patient requires another organ or organ combination:

- (i) Waiting time accrued by a kidney transplant candidate while registered on the UNOS Patient Waiting List shall be assigned also to the listing for a combined kidney-pancreas transplant if it is determined that the patient requires a combined kidney-pancreas transplant.
- (ii) Waiting time accrued by a kidney transplant candidate while registered on the UNOS Patient Waiting List shall be assigned also to the listing for an isolated pancreas transplant if it is determined that the patient requires a pancreas transplant.

- (iii) **Waiting time accrued by a kidney-pancreas transplant candidate while registered on the UNOS Patient Waiting List shall be assigned also to the listing for an isolated pancreas transplant if it is determined that the patient is suitable for a pancreas alone transplant.**
- (iv) **Waiting time accrued by a kidney-pancreas transplant candidate while registered on the UNOS Patient Waiting List shall be assigned also to the listing for an isolated kidney transplant if it is determined that the patient is suitable for a kidney alone transplant.**
- (v) **Waiting time accrued by an isolated pancreas transplant candidate while registered on the UNOS Patient Waiting List shall not be assigned to the listing for a combined kidney-pancreas transplant.**
- (vi) **Waiting time accrued by an isolated pancreas transplant candidate while registered on the UNOS Patient Waiting List shall not be assigned to the listing for an isolated kidney transplant.**

3.8.3 Inclusion of HLA Data. Recipient HLA information must be included when listing a potential pancreas or combined kidney-pancreas candidate on the UNOS Patient Waiting List.

3.8.4 Regional or National Allocation to Alternate Recipients. For a pancreas that is shared regionally or nationally, the UNOS Organ Center will advise the OPO for the transplant center for the patient who has the highest number of points at that center to seek alternate patients on the OPO's waiting list to receive the pancreas in the event that the pancreas cannot be used by that patient. Selection of alternate patients must be according to the UNOS pancreas allocation policy.

3.8.5 Minimum Information for Pancreas Offers.

3.8.5.1 Essential Information Category. The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:

- (i) Donor name and OPTN Donor I.D. number, age, sex, race and weight;
- (ii) Date of admission for the current hospitalization;
- (iii) Diagnosis;
- (iv) Blood type;
- (v) Current history of abdominal injuries and operations including pancreatic trauma;
- (vi) Pertinent past medical or social history including pancreatitis;
- (vii) Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;
- (viii) Indications of sepsis;
- (ix) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
- (x) Current medication and transfusion history;
- (xi) Blood glucose;
- (xii) Amylase;
- (xiii) Insulin protocol;
- (xiv) Alcohol use (if known);
- (xv) Familial history of diabetes.

3.8.6 Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists When Transplanted or Deceased. If a pancreas transplant candidate on the UNOS Patient Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the patient is multiple listed, shall immediately remove that patient from all pancreas waiting lists and shall notify UNOS within 24 hours of the event. If the pancreas recipient is again added to a pancreas waiting list, waiting time shall begin as of the date and time the patient is relisted. If the recipient is waiting for a combined kidney-pancreas transplant and receives only an isolated pancreas transplant, the recipient's accrued waiting time while listed for the combined organ transplant shall automatically be transferred to the isolated Kidney Waiting List.

3.8.7 Waiting Time Reinstatement for Pancreas Recipients. In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor pancreas, the patient may be reinstated to the waiting list and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non-function shall be defined as pancreas graft failure resulting in removal of the organ within the first two weeks of transplant. Waiting time will be reinstated upon receipt by the Organ Center of a completed Pancreas Waiting Time Reinstatement Form and documentation, including but not limited to, the patient operative report. UNOS will notify the OPO serving the recipient transplant center of the relisting and forward a copy of the relisting form to that OPO.

CURRENT FLORIDA PANCREAS ALU

1. Local High PRA
2. State O ABDR
3. Regional O ABDR
4. National O ABDR
5. Statewide List
6. Regional
7. National

**Attachment III: Signatures for Proposed Variance to Pancreas and Kidney-
Pancreas Allocation Alternate Local Unit for Florida**

Florida Transplant Centers With Active Pancreas Programs

We, the undersigned, wish to modify the current Florida alternate local unit (ALU) for pancreas and kidney-pancreas allocation. We are in support of a new Florida ALU for pancreas and kidney-pancreas that would follow UNOS Policy 3.8 for allocation of pancreas and kidney-pancreas to the local center, a Florida statewide list, then to the region followed by the nation.

See Attachment I: Proposed Variance to Pancreas and Kidney-Pancreas Allocation Alternate Local Unit for Florida dated April 16, 2004.

George W. Burke, III, MD
Director, Pancreas Transplant
Jackson Memorial Hospital
Miami, FL

Date

Thomas A. Gonwa, MD
Medical Director, Transplant Center
St. Luke's Hospital
Jacksonville, FL

Date

Jeffery L. Steers, MD
Chair, Department of Transplantation
St. Luke's Hospital, Mayo Clinic
Jacksonville, FL

Date

John P. Leone, MD, PhD
Director, Pancreas Transplant
LifeLink Healthcare Institute
Tampa, FL

Date

Shiro Fujita, MD
Surgical Director, Pancreas Transplant
Shands Hospital at the University of Florida
Gainesville, FL

Date

Bruce Kaplan, MD
Medical Director, Pancreas Transplant
Shands Hospital at the University of Florida
Gainesville, FL

Date

Fax signed document to 813-348-0571 and mail the original in the enclosed envelope before 05/05/04.

**Attachment III: Signatures for Proposed Variance to Pancreas and Kidney-
Pancreas Allocation Alternate Local Unit for Florida**

Florida Kidney Transplant Centers With Active Pancreas Programs

We, the undersigned, wish to modify the current Florida alternate local unit (ALU) for pancreas and kidney-pancreas allocation. We are in support of a new Florida ALU for pancreas and kidney-pancreas that would follow UNOS Policy 3.8 for allocation of pancreas and kidney-pancreas to the local center, a Florida statewide list, then to the region followed by the nation.

See Attachment I: Proposed Variance to Pancreas and Kidney-Pancreas Allocation Alternate Local Unit for Florida dated April 16, 2004.

Joshua Miller, MD
Director, Kidney Transplant
Jackson Memorial Hospital
Miami, FL

Date

Thomas A. Gonwa, MD
Medical Director, Transplant Center
St. Luke's Hospital
Jacksonville, FL

Date

Jeffrey Steers, MD
Chair, Department of Transplantation
St. Luke's Hospital, Mayo Clinic
Jacksonville, FL

Date

Victor D. Bowers, M.D
Director, Kidney Transplant
LifeLink Healthcare Institute
Tampa, FL

Date

Richard Howard, MD
Director, Kidney Transplant
Shands Hospital at the University of Florida
Gainesville, FL

Date

David Foley, MD
Director, Kidney Transplant
Shands Hospital at the University of Florida
Gainesville, FL

Date

**Fax signed document to 813-348-0571 and mail the original in the enclosed envelope
before 05/05/04.**

Attachment IV: Florida Organ Procurement Organization Signatures for Proposed Variance to Pancreas and Kidney-Pancreas Allocation Alternate Local Unit for Florida

We, the undersigned, wish to modify the current Florida alternate local unit (ALU) for pancreas and kidney-pancreas allocation. We are in support of a new Florida ALU for pancreas and kidney-pancreas that would follow UNOS Policy 3.8 for allocation of pancreas and kidney-pancreas to the local center, a Florida statewide list, then to the region followed by the nation.

See Attachment I: Proposed Variance to Pancreas and Kidney-Pancreas Allocation Alternate Local Unit for Florida dated April 16, 2004.

Liz Lehr, BSN, MHA
VP, Executive Director
LifeLink of Florida/LifeLink of Southwest Florida
Tampa, FL

Date

Mr. Timothy Jankiewicz, RN, CPTC
Director, Transplant Programs
TransLife
Orlando, FL

Date

Leslie Cortina, CPA
Executive Director
Life Alliance Organ Recovery Agency
Miami, FL

Date

Danielle L. Cornell, RN, CPTC
Executive Director
LifeQuest Organ Recovery Services
Gainesville, FL

Date

Fax signed document to 813-348-0571 and mail the original in the enclosed envelope before 05/05/04.

**Attachment III: Signatures for Proposed Variance to Pancreas and Kidney-
Pancreas Allocation Alternate Local Unit for Florida**

Florida Kidney Transplant Centers With Inactive or No Pancreas Programs

We, the undersigned, wish to modify the current Florida alternate local unit (ALU) for pancreas and kidney-pancreas allocation. We are in support of a new Florida ALU for pancreas and kidney-pancreas that would follow UNOS Policy 3.8 for allocation of pancreas and kidney-pancreas to the local center, a Florida statewide list, then to the region followed by the nation.

See Attachment I: Proposed Variance to Pancreas and Kidney-Pancreas Allocation Alternate Local Unit for Florida dated April 16, 2004.

Bobby Narasimha Nibhanupudy, MD
Director, Kidney Transplant
Bert Fish Medical Center
New Smyrna Beach, FL

Date

Michael Angelis, MD
Director, Kidney Transplant
Florida Hospital Medical Center
Orlando, FL

Date

Sajid Latif, MD
Director, Kidney Transplant
Bert Fish Medical Center
New Smyrna Beach, FL

Date

Daniel Shoskes, MD
Director, Kidney Transplant
Cleveland Clinic Hospital
Weston, FL

Date

Thomas G. Peters, MD
Director, Kidney Transplant
Shands - Jacksonville
Jacksonville, FL

Date

Nicolas A. Muruve, MD
Director, Kidney Transplant
Cleveland Clinic Hospital
Weston, FL

Date

Gordon D. Burtch, MD
Director, Kidney Transplant
Southwest Florida Regional Medical
Center
Fort Myers, FL

Date

**Fax signed document to 813-348-0571 and mail the original in the enclosed envelope
before 05/05/04.**

Attachment V: Justification for Proposed Variance to Pancreas and Kidney-Pancreas Allocation Alternate Local Unit for Florida

This variance seeks to dissolve the existing alternate local unit (ALU) in the state of Florida for pancreas and kidney-pancreas sharing. Currently, pancreas and kidney-pancreas are shared per the alternate local unit to a single statewide pancreas list as the local center, then to Region 3, then to the national list.

Alternatively we would like to establish a new alternate local unit (ALU), which would mirror our renal allocation system, i.e. local, statewide list, regional, and then national.

According to UNOS' Application Requirements for Variances, we are requested to address the following:

a. What are the advantages of the proposed variance over the current UNOS allocation policy for this organ type? Explain how equitable organ allocation will be facilitated through the variance.

- The advantages of the proposed variance over the current UNOS allocation policy for this organ type are that the proposed variance would provide increased local use with increased pancreas utilization overall resulting in shorter ischemic times, potentiating better patient outcomes.
- We also anticipate recovery and utilization of a greater number of available donor pancreata by allowing us to utilize marginal or borderline pancreata that may have otherwise been lost to the system. This process would be facilitated by having local transplant surgeons on site for rapid evaluation of said organs. The attached data shows that each of the states in our region recovered more donors and have more pancreata available than are used locally (See Attachment VIII). Therefore there is little to no impact on other transplant centers in our region by utilization of the proposed variance vs. the current process.
- The proposed allocation variance policy would maintain consistency amongst the kidney-pancreas and pancreas transplant centers within Region 3 as all other Region 3 programs allocate pancreas and kidney-pancreas utilizing similar allocation schemes.

b. How will the variance affect organ allocation and waiting times for highly-sensitized transplant candidates?

- The proposed variance will have no impact on organ allocation and waiting times for highly sensitized transplant patients as UNOS policy 3.8.1 will continue to be followed.

c. How will HLA typing be utilized for determining organ allocation through the variance?

- The proposed variance will have no impact on organ allocation in regards to HLA typing, as current policies will be followed.

d. What is the anticipated effect on recipient and graft survival?

- The proposed variance is anticipated to provide improved recipient outcomes with an increase in graft survival and reduction in patient morbidity due to shorter ischemic times if more organs are used at the local center.

e. How will the variance affect organ allocation and waiting times for transplant candidates who are pediatric, female, or represent racial minorities?

- The proposed variance should have no expected impact on pediatric, female, or minority transplant candidates.

f. How will the variance affect organ allocation and transplant candidate waiting times among different blood types?

- The proposed variance should have no expected impact on waiting times among different blood types.

g. If the variance is proposed for heart, liver, intestinal organ, or pancreatic-islet allocation, how will it affect allocation and waiting times among the various categories of medical urgency for these organ types?

- The proposed variance should have no expected impact on allocation and waiting times on other organs (including kidneys allocated to patients at centers with and without pancreas transplant programs).
- The proposed variance will have no affect on allocation and waiting times as current islet allocation policies will continue to be followed as outlined in UNOS policy 3.8.1.4 and 3.8.1.5.

April 16, 2004

Attachment VI: REGION 3 TRANSPLANT CENTERS – Inactive and No Pancreas Programs

Per UNOS, the following centers have either pancreas transplant programs that are currently inactive or no pancreas program.

INACTIVE PANCREAS PROGRAMS

<p>ALAM University of South Alabama Medical Center 2451 Fillingim Street - 3rd Floor Mobile, AL 36617-2293</p> <p>Thelma Scantlebury, M.D. (K) 251-471-7542</p> <p>vscantlebury@usouthal.edu</p>	<p>FLBF Bert Fish Medical Center 401 Palmetto Street New Smyrna Beach, FL 32168</p> <p>Bobby Narasimha Nibhanupudy, M.D. (K) Sajid Latif, M.D. (K) 386-424-6445</p> <p>bobby.nibhanupudy@bfmc.halifax.org</p>	<p>FLJT Shands Jacksonville 580 W. 8th Street Jacksonville, FL 32209</p> <p>Thomas G. Peters, M.D. (K) 904-366-7900</p> <p>thomas.peters@jax.ufl.edu</p>
<p>LASU Louisiana State University Medical Center Shreveport 1501 Kings Highway PO Box 33932 Shreveport, LA 71130-3932</p> <p>Gazi Zibari, M.D. (K) 318-675-6100</p> <p>gzibari@lsuhsc.edu</p>		
<p>NO PANCREAS PROGRAMS</p>		
<p>ARBH Surgical Clinic of Arkansas 9500 Kanis Road Suite 501 Little Rock, AR 72205</p> <p>John F. Dunn, MD (K) 501-227-9080</p>	<p>FLFH Florida Hospital Medical Center/TransLife 2501 N. Orange Avenue Suite 514 Orlando, FL 32804</p> <p>Michael Angelis, MD (K) 407-303-2474</p> <p>michael.angelis@translife.org</p>	<p>FLFR Hagan, Bacon, Burtch and Sweeney Southwest Florida Regional Medical Center 3596 Broadway Ft. Myers, FL 33901-8018</p> <p>Gordon D. Burtch, MD (K) 239-936-8555</p> <p>KAWParker@ewol.com</p>
<p>FLCC Cleveland Clinic Hospital 2950 Cleveland Clinic Boulevard Weston, FL 33331</p> <p>Nicholas A. Muruve, MD (K) 954-659-5188</p> <p>muruven@ccf.org</p>	<p>FLCC Cleveland Clinic Hospital 2950 Cleveland Clinic Boulevard Weston, FL 33331</p> <p>Daniel A. Shoskes, MD (K) 954-659-5188</p> <p>dshoskes@mac.com</p>	<p>MSUM University of Mississippi Medical Center 2500 North State Street Jackson, MS 39216</p> <p>W. Henry Barber, IV, MD (K) 601-984-5083</p>
<p>PRSJ Auxilio Mutuo Hospital PO Box 191227 Hato Rey, PR 00919-1227</p> <p>Eduardo A. Santiago Delpin, MD (K) 787-765-7650</p> <p>prtp@coqui.net</p>		

Attachment VI: REGION 3 TRANSPLANT CENTERS – Active Pancreas Programs

<p>ALUA University of Alabama 618 S. 20th Street Birmingham, AL 35233</p> <p>Carlton J. Young, M.D. (P) 205-934-1391 Mark H. Deierhoi, M.D. (K) 205-934-7714</p> <p>carlton.young@ccc.uab.edu</p>	<p>FLUF Shands Hospital at The University of Florida 1600 Archer Road. SE Gainesville, FL 32611</p> <p>Bruce Kaplan, M.D. (P) Shiro Fujita, MD (P) Richard Howard, M.D. (K) David Foley, M.D. (K) 352-395-0254</p> <p>fujita@surgery.ufl.edu kaplab@medicine.ufl.edu</p>	<p>LAOF Ochsner Foundation Hospital 1514 Jefferson Highway – BH 313 New Orleans, LA 70121</p> <p>George Loss, M.D., PhD (P) James D. Eason, MD (K) 504-842-5764</p> <p>gloss@ochsner.org lhernn@ochsner.org (asst.)</p>
<p>ARUA University Hospital of Arkansas 4301 W. Markham – Slot 520-4 Little Rock, AR 72205-7199</p> <p>Gary W. Barone, M.D. (P) (K) 501-686-6644</p> <p>baronegary@uams.edu</p>	<p>GAEM Emory University Hospital 1364 Clifton Road, NE Atlanta, GA 30322</p> <p>Christian Larsen, M.D., PhD. (P) 404-727-8466 Thomas C. Pearson, M.D., PhD (K) 404-727-8464</p> <p>clarsen@emoryhealthcare.org tpearson@emoryhealthcare.org</p>	<p>LASB Memorial Medical Center 301 N. Jefferson Davis New Orleans, LA 70119</p> <p>J. Philip Boudreaux, M.D. (P) 504-488-8121 Daniel J. Frey, M.D. (K) 504-488-8121</p> <p>philip.boudreaux@tenethealth.com</p>
<p>FLJM Jackson Memorial Hospital University of Miami School of Medicine 1611 NW 12th Avenue East Tower 2169 Miami, FL 33136</p> <p>George W. Burke, III, M.D. (P) 305-355-5111 Joshua Miller, M.D. (K) 305-355-5080</p> <p>gburke@med.miami.edu</p>	<p>GAMC Medical College of Georgia 1120 15th Street Augusta, GA 30912-7700</p> <p>James Wynn, M.D. (P) (K) 706-721-2874</p> <p>jwynn@mail.mcg.edu</p>	<p>LATU Tulane University Medical Center 1430 Tulane Avenue New Orleans, LA 70112</p> <p>Douglas P. Slakey, M.D. (P) (K) 504-584-2972</p> <p>douglas.slakey@hcahealthcare.com</p>
<p>FLSL St. Luke's Hospital 4205 Belfort Road, Suite 1100 Jacksonville, FL 32216</p> <p>Thomas Gonwa, M.D. (P) (K) Jeffery Steers, MD (P) (K) 904-296-5876</p> <p>gonwa.thomas@mayo.edu steers.jeffery@mayo.edu</p>	<p>GAPH Piedmont Hospital 1968 Peachtree Road, NW Atlanta, GA 30309</p> <p>John Whelchel, M.D. (P) (K) 404-605-4600</p> <p>john.whelchel@piedmont.org</p>	<p>LAWK Willis Knighton Medical Center 2751 Virginia Avenue, Suite 4A Shreveport, LA 71130</p> <p>Gazi Zibari, M.D. (P) 318-212-4676 Donnie F. Aultman, M.D. (K) 318-212-4676</p> <p>gzibari@lsuhsc.edu</p>
<p>FLTG Tampa General Hospital 2 Columbia Drive Tampa, FL 33606</p> <p>John Leone, M.D., PhD (P) 813-253-2640 Victor D. Bowers, M.D. (K)</p> <p>leone@lifelinkfound.org bowers@lifelinkfound.org</p>		

K = Kidney
P = Pancreas

Attachment VII: REGION 3 ORGAN PROCUREMENT ORGANIZATIONS

<p>ALOB Alabama Organ Center 500 22nd Street South, Suite 102 Birmingham, AL 35233</p> <p>Charles H. Patrick III, M.H.A., CPTC 205-731-9200</p> <p>charles.patrick@ccc.uab.edu</p>	<p>AROR Arkansas Regional Recovery Center 1100 N. University Avenue, Suite 200 Little Rock, AR 72207-6344</p> <p>Boyd Ward 501-907-9150</p> <p>bward@arora.org</p>
<p>FLFH TransLife 2501 N. Orange Avenue Suite 514 Orlando, FL 32804</p> <p>Tim Jankiewicz, RN, CPTC 407-303-2474</p> <p>tim.jankiewicz@translife.org</p>	<p>FLMP Life Alliance Organ Recovery Agency University of Miami School of Medicine Highland Building-JMH 1801 NW 9th Avenue, Suite #150-A Miami, Florida 33136</p> <p>Leslie Cortina 305-243-7588</p> <p>lcortina@med.miami.edu</p>
<p>FLSW LifeLink of Southwest Florida 12623 New Brittany Blvd Building 17 East Fort Myers, FL 33907-3631</p> <p>Liz Lehr, BSN, MHA 239-936-2772</p> <p>lizl@lifelinkfound.org</p>	<p>FLUF LifeQuest Organ Recovery Services 720 SW 2nd Avenue North Tower, Suite 570 Gainesville, FL 32601</p> <p>Danielle Cornell, BSN, CPTC 352-338-7133</p> <p>cornedl@lifegquest.ufl.edu</p>
<p>FLWC LifeLink of Florida 4069 Bayshore Blvd Tampa, FL 33606</p> <p>Liz Lehr, BSN, MHA 813-253-2640</p> <p>lizl@lifelinkfound.org</p>	<p>GALL LifeLink of Georgia 2875 Northwoods Parkway Norcross, GA 30071</p> <p>Kathleen Lilly, BSN, CPTC 770-225-5465</p> <p>kathleen@lifelinkfound.org</p>
<p>LAOP Louisiana Organ Procurement Agency 3501 N. Causeway Blvd. Suite 940 Metairie, LA 70002-3626</p> <p>Kelly Ranum, BSN, CPTC 504-837-3355</p> <p>kraum@lopa.org ftapani@lopa.org</p>	<p>MSOP Mississippi Organ Recovery Agency 12 River Bend Place Jackson, MS 39232</p> <p>Kevin Stump, RN, BSN 601-933-1000</p> <p>kstump@msora.org</p>
<p>PRLL LifeLink of Puerto Rico Daimler Chrysler Building Suite 100 Calle 1, #1 Metro Office Park Guaynabo, PR 00968</p> <p>Marien Saade, RN, MSN, CNN 787-277-0900</p> <p>lifelink2@prtc.net</p>	

Attachment VIII: Supporting Data

Table A: UNOS 01/2000 – 12/2003 - Florida Pancreas and Kidney-Pancreas Transplant Data**

		Organ Transplanted											
		Kidney-Pancreas				Pancreas				Total			
		Allocation Type				Allocation Type				Allocation Type			
		Local	Florida Share	Other Non-Florida Sh	Total	Local	Florida Share	Other Non-Florida Sh	Total	Local	Florida Share	Other Non-Florida Sh	Total
		N	N	N	N	N	N	N	N	N	N	N	N
Year of Transplant	Recovering OPO												
2000	FLFH-IO1	0	9	2	11	0	5	1	6	0	14	3	
	FLMP-OP1	24	1	0	25	1	0	0	1	25	1	2	
	FLSW-OP1	0	0	1	1	0	2	2	4	0	2	3	
	FLUF-IO1	8	0	3	11	2	1	1	4	10	1	4	
	FLWC-OP1	0	1	0	1	0	2	3	5	0	3	3	
	Total		32	11	6	49	3	10	7	20	35	21	13
2001	Recovering OPO												
	FLFH-IO1	0	4	2	6	0	3	2	5	0	7	4	
	FLMP-OP1	27	2	0	29	9	0	0	9	36	2	0	
	FLSW-OP1	0	0	0	0	0	2	0	2	0	2	0	
	FLUF-IO1	21	2	2	25	3	1	0	4	24	3	2	
	FLWC-OP1	18	0	0	18	4	0	1	5	22	0	1	
Total		66	8	4	78	16	6	3	25	82	14	7	
2002	Recovering OPO												
	FLFH-IO1	0	3	0	3	0	4	2	6	0	7	2	
	FLMP-OP1	25	2	5	32	1	0	0	1	26	2	5	
	FLSW-OP1	0	0	0	0	0	3	1	4	0	3	1	
	FLUF-IO1	18	1	0	19	2	1	1	4	20	2	1	
	FLWC-OP1	20	0	2	22	2	5	1	8	22	5	3	
Total		63	6	7	76	5	13	5	23	68	19	12	
2003	Recovering OPO												
	FLFH-IO1	0	3	1	4	0	3	5	8	0	6	6	
	FLMP-OP1	24	0	0	24	6	0	0	6	30	0	0	
	FLSW-OP1	0	2	0	2	0	1	3	4	0	3	3	
	FLUF-IO1	13	2	0	15	6	1	0	7	19	3	0	
	FLWC-OP1	18	0	0	18	0	3	5	8	18	3	5	
Total		55	7	1	63	12	8	13	33	67	15	14	
Total	Recovering OPO												
	FLFH-IO1	0	19	5	24	0	15	10	25	0	34	15	
	FLMP-OP1	100	5	5	110	17	0	0	17	117	5	5	
	FLSW-OP1	0	2	1	3	0	8	6	14	0	10	7	
	FLUF-IO1	60	5	5	70	13	4	2	19	73	9	7	
	FLWC-OP1	56	1	2	59	6	10	10	26	62	11	12	
Total		216	32	18	266	36	37	28	101	252	69	46	

Based on OPTN data as of March 12, 2004. Data subject to change based on future data submission or correction.

**In a separate survey conducted of Florida OPO's (TransLife, Life Alliance Organ Recovery Agency, LifeQuest Organ Recovery Services and LifeLink of Florida / LifeLink of Southwest Florida) data provided showed no pancreata or kidney-pancreata went to other Region 3 Centers.

April 16, 2004

Table B: 2003 Region 3 Pancreas and Kidney-Pancreas Recovery and Transplant Data

	Organ Donors – 2003			Transplants Performed - 2003		Combined Total
	Organ Donors	Pancreas Recovered	Pancreas Transplanted	Pancreas	Kidney/ Pancreas	
U.S.	6455	1774	1380	502	867	1369
Region 3	1016	258	216	50	139	189
Alabama	89	31	25	3	19	22
Arkansas	44	9	5	0	1	1
Florida	444	116	97	31	64	95
Georgia	197	46	43	7	27	34
Louisiana	119	31	28	9	28	37
Mississippi	55	18	12	0	0	0
Puerto Rico	68	7	6	0	0	0

SUMMARY: For 2003, OPO's in Region 3 have had 216 pancreata transplanted from local donors, but only 189 were transplanted at Region 3 transplant centers. Region 3 was a net exporter of pancreata in 2003. Florida was a net exporter of 2 pancreata.

Table C: 2002 Region 3 Pancreas and Kidney-Pancreas Recovery and Transplant Data

	Organ Donors – 2002			Transplants Performed - 2002		Combined Total
	Organ Donors	Pancreas Recovered	Pancreas Transplanted	Pancreas	Kidney/ Pancreas	
U.S.	6187	1872	1459	553	905	1458
Region 3	1008	251	215	58	142	200
Alabama	100	20	18	2	15	17
Arkansas	54	21	10	1	4	5
Florida	439	111	99	39	71	110
Georgia	182	47	43	5	27	32
Louisiana	111	33	31	11	25	36
Mississippi	60	15	10	0	0	0
Puerto Rico	62	4	4	0	0	0

SUMMARY: For 2002, Region 3 is a net exporter of pancreata. Florida is a net importer of 11 pancreata.

Table D: Current Pancreas and Kidney-Pancreas Waiting List by Transplant Center for Region 3 as of April 02, 2004

Center Code	Center Name	Pancreas	Kidney / Pancreas
ALUA – TX1	University of Alabama Hospital	29	41
ARUA – TX1	The University Hospital of Arkansas	5	17
FLJM – TX1	Jackson Memorial Hospital	9	29
FLSL – TX1	St. Luke's Hospital	0	3
FLTG – TX1	Tampa General Hospital	0	7
FLUF – TX1	Shands Hospital at University of Florida	6	23
GAEM – TX1	Emory University Hospital	4	20
GAMC – TX1	Medical College of Georgia Hospital	0	6
GAPH – TX1	Piedmont Hospital	4	6
LAOF – TX1	Oschsner Foundation Hospital	0	10
LASB – TX1	Memorial Medical Center	5	11
LATU – TX1	Tulane University Medical Center	5	28
LAWK – TX1	Willis Knighton Medical Center	2	21

Based on OPTN data as of April 02, 2004. Data subject to change based on future data submission or correction

RECEIVED APR 16 2004



April 12, 2004

Alan Leichtman, MD, Chair
Kidney and Kidney Pancreas Transplantation Committee
United Network for Organ Sharing
P.O. Box 2484
Richmond, VA 23218

Dear Dr. Leichtman:

Attached is LifeGift's application to modify LifeGift's current variance that allows LifeGift to allocate kidneys based solely on waiting time¹. Currently, the Houston and Fort Worth transplant centers allocate kidneys according to this UNOS approved variance. LifeGift desires to modify this variance by having this variance apply to all LifeGift affiliated transplant centers, which would include the two transplant centers in Lubbock, Texas. This variance has allowed LifeGift to achieve equal waiting times for minorities and non-minorities in Houston and Fort Worth long ago since the variance has been in place for a decade.

In order to serve our patients most effectively and equitably, LifeGift is requesting this minor modification to its variance, adding Lubbock to LifeGift's existing variance. Attached are the details of the request. If you have any questions, please do not hesitate to call.

Sincerely,

A handwritten signature in black ink that reads "Samuel M. Holtzman".

Samuel M. Holtzman
President and Chief Executive Officer

¹ No points added for HLA match with exception of the mandatory share 6 antigen match / 0 mismatch kidneys.

RECEIVED APR 16 2004

UNITED NETWORK FOR ORGAN SHARING

Application for a Modification to LifeGift Kidney Allocation Variance
(No assignment of points for degree of HLA match)

BY

LIFEGIFT ORGAN DONATION CENTER
Houston, Texas

April 9, 2004

LifeGift Organ Donation Center
Application for a Modification to LifeGift Kidney Allocation Variance
(No assignment of points for degree of HLA match)

Variance Summary Statement:

The LifeGift Board of Directors request permission to modify (extend) LifeGift's existing variance which already applies to transplant centers in Houston and Fort Worth to transplant programs in Lubbock.

There are three regions and nine renal transplant centers in the LifeGift service area:

1. **Southeast (Houston)**
 - a. Memorial Hermann Hospital
 - b. St. Lukes Episcopal Hospital
 - c. Texas Children's Hospital
 - d. The Methodist Hospital
2. **North (Fort Worth)**
 - a. Baylor All Saints Medical Center
 - b. Cook Children's Medical Center
 - c. Harris Methodist Fort Worth
3. **West (Lubbock)**
 - a. Covenant Medical Center
 - b. University Medical Center

LifeGift's current variance for renal allocation assigns 0 points for HLA matching in the Houston and Fort Worth areas. In the Lubbock area, points are assigned as per the current UNOS allocation system for degree of match (2 points for no DR matches or 1 point if there is a 1 DR mismatch.)

LifeGift requests that the Lubbock region be added to LifeGift's current variance, which would mean that OPO-wide, there are no points given for the degree of HLA match.

1. Contact information for Transplant Centers and OPOs:

LifeGift Organ Donation Center
5615 Kirby, Suite 900
Houston, TX 77005
713-523-4438
Samuel M. Holtzman, President and Chief Executive Officer

Memorial Hermann Hospital

6411 Fannin

Houston, TX 77030

713-704-6891

Jim Salyer, Chief Executive Officer, Memorial Hermann Children's Hospital

St. Luke's Episcopal Hospital

P.O. Box 20269

Houston, Texas 77225-0269

713-791-4614

John J. Lynch, Executive Vice President and Chief Executive Officer

Texas Children's Hospital

6621 Fannin, Mail Code 1-4460

Houston, Texas 77030

(832) 824-1159

Randall Wright, Vice President

The Methodist Hospital

6565 Fannin, MS 101

Houston, TX 77030

713-441-6762

Judy Spinella, Vice President of Operations

Harris Methodist Fort Worth

1301 Pennsylvania Avenue

Fort Worth, TX 76104

817-882-2106

Barclay Berdan, Chief Executive Officer

Cook Children's Medical Center

801 Seventh Avenue

Fort Worth, TX 76107

817-885-4340

Nancy Cychol, Chief Executive Officer

Baylor All Saints Medical Center

1400 Eight Avenue

Fort Worth, TX 76104

817-922-4650

Marlon Levy, MD, Medical Director

Covenant Medical Center

3615 19th Street

Lubbock, TX 79408

806-725-0569

Baird Helfrich, MD

University Medical Center

602 Indiana Avenue
Lubbock, TX 79415
806-743-3515
Kim Judd, Vice President

2. Statement of Variance and Statement of Agreement

Statement of Variance:

Kidneys in all regions of LifeGift Organ Donation Center shall be allocated with zero points allocated for degree of HLA match. This allocation scheme has been in place for a decade in two of the three LifeGift regions (Southeast - Houston and North - Fort Worth) and this variance modification will simply apply the current variance to the remainder of the LifeGift service area, namely, the West Region (Lubbock). The West Region of LifeGift serves two renal transplant centers: Covenant Medical Center and University Medical Center.

Statement of Agreement:

The LifeGift Board of Directors and the LifeGift Medical Advisory Committee desire to modify LifeGift's current UNOS approved Renal Variance, which currently applies to Houston and Fort Worth, to extend also to the remainder of the OPO service area – the West Region - which includes the two transplant centers in Lubbock.



Samuel M. Holtzman, President and Chief Executive Officer

3. Responses to Application Questions:

- a. What are the advantages of the proposed variance over the current UNOS allocation policy for this organ type? Explain how equitable organ allocation will be facilitated through the variance.**

It is well known that LifeGift has had a variance in place for a decade now in its four renal transplant centers in Houston and its three centers in Fort Worth which causes kidneys to be allocated primarily based on waiting time alone. Because of this, LifeGift is one of the few OPOs in the U.S. with no difference in waiting times between minorities and non-minorities. LifeGift desires to extend the benefits of its current UNOS approved variance to the remainder of the LifeGift system – the two transplant centers in Lubbock.

This proposed variance modification (and LifeGift's current variance which is in place in Houston and Fort Worth) is the allocation system that was proposed by the UNOS Kidney Pancreas committee to the UNOS board of directors in November of 2001. It was voted down by the board of directors. Subsequently, another proposal was passed which reduced points for degree of HLA match with a subsequent increase in the number of minorities transplanted.²

The LifeGift Variance to not award points for HLA matching, to make time waiting the primary determinant of a patient's relative position on the kidney list, has been extremely successful in eliminating differences between the amount of time minorities wait for a kidney transplant versus Caucasians – *waiting times for African Americans, Hispanics and Caucasians are virtually equal in LifeGift's service area.* LifeGift's variance removes any discriminatory impact of HLA matching on racial minorities within the regions where these minority populations represent a significant percentage of patients waiting for kidney transplants.

LifeGift's racial/ethnic demographics are as noted in Table 1.

Table 1. LifeGift African American Demographics
Percentage in General Population and Percentage on Waiting List

Region	Percentage of African Americans in General Population	Percentage of African Americans on Local Kidney Transplant Lists
Southeast ALU	13%	34%
North ALU	9%	25%
West ALU	4%	23%

LifeGift has had the variance to not award points for degree of HLA match in the allocation of cadaveric kidneys since 1993. LifeGift believes that the current national system of giving points for degree of match is not justified by the extremely small increase in graft survival versus the very real injustice of much longer waiting times for African Americans and Hispanics that is caused by using the current national system of awarding points for HLA matching that often outweighs the points that can be accrued by waiting.³

Waiting times between minorities and non-minorities, African Americans, Hispanics and Caucasians, are essentially equal. This can be contrasted with the frequent reports of African Americans waiting two to five times longer than Caucasians in other parts of the

² Roberts JP, Wolfe RA, Bragg-Gresham JL, Rush SH, Wyinn JJ, Distant DA, Ashby VB, Held PJ, Port FK. Effect of changing the priority for HLA matching on the rates and outcomes of kidney transplantation in minority groups. NEJM. Feb 5, 2004; 350:545-551.

³ 2 points for a 0 DR mismatch; 1 point for a 1 DR mismatch.

country. For the period, 1993-2001, one can see that a situation of equity exists when looking at the difference between minorities and non-Hispanic Caucasians. (Figure 2)

Figure 1: Minority Kidney Transplant Candidates

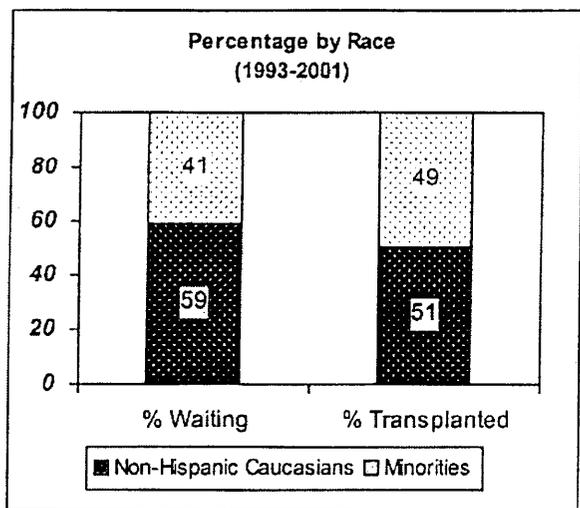
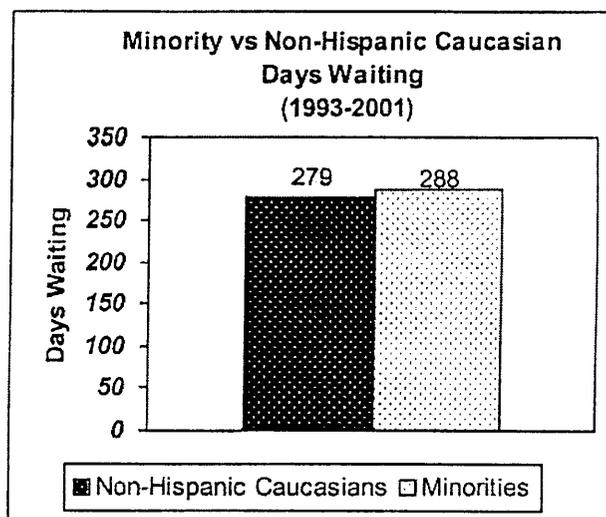


Figure 2: Median Waiting Time in Days . Minorities vs. Non-Hispanic



This parity continues into the current period, 2001-2003. (Both sets of dates are used to demonstrate the new data since the most recent report by LifeGift to UNOS on this variance.)

Figure 3: Minority Kidney Transplant Candidates

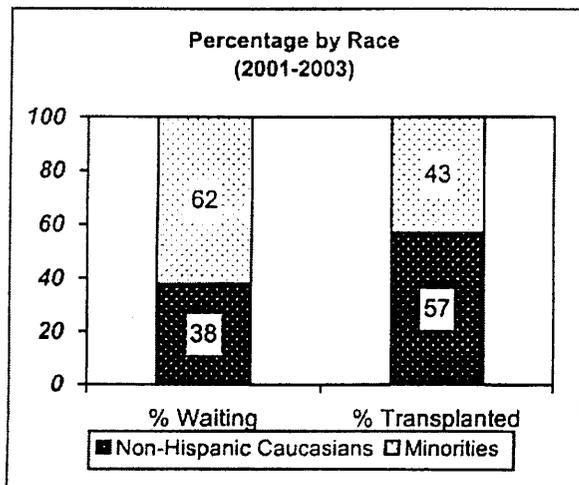
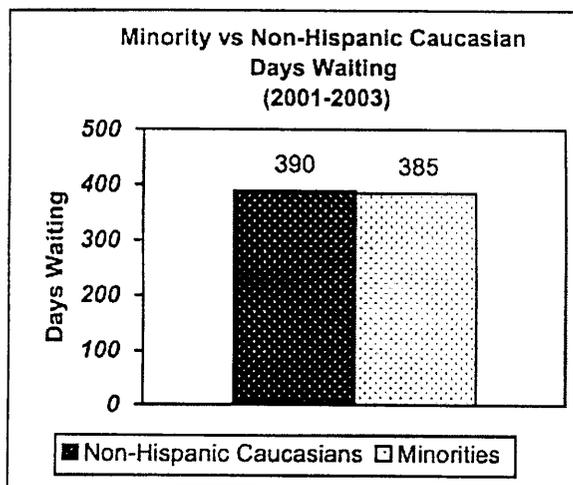


Figure 4: Median Waiting Time in Days Minorities vs. Non-Hispanic



The policy of mandatorily sharing kidneys to perfectly matched recipients is justified because of the results⁴, however, there is little evidence to support giving priority to lesser degrees of matches⁵. According to Held et al., the increase in graft survival nationally from a maximal matching policy would likely be 2 to 4 percent with the number of non-Caucasian patients receiving transplants decreasing by one third to 17.7 percent, and the percentage of African Americans receiving kidneys decreasing to 15 percent.⁵ Takemoto et al. documented that cadaveric renal allograft recipients who receive less than perfectly HLA matched kidneys have little difference in long term outcome when contrasting "one HLA mismatch" recipients and "six HLA mismatched" recipients. There is only one year difference in half life of recipients receiving "one HLA mismatch" kidneys and recipients receiving "six HLA mismatched" kidneys.⁴

Additionally, African Americans are also disadvantaged by the current UNOS HLA matching points system because donor kidneys that are a six antigen match / zero antigen mismatch (about 13% of the pool of available kidneys⁴), are directed away from the general list of all of those waiting and are mandatorily shared to a smaller group of patients who are a "perfect" match. Only 8 percent of this smaller group of patients are African American⁴. Thus, from the total pool of kidneys transplanted (8011 in 1999)⁴, it is likely that slightly over a thousand of those kidneys were removed from the national pool and redirected to a smaller group of patients, of whom only 8 percent were African American, despite the fact that African Americans comprise 35% of the national kidney waiting list. In LifeGift's case, of 53 kidneys that were shared nationwide in Calendar Year 2003 as a mandatory share for 6 antigen match/ zero antigen mismatches, only 3.7% of those kidneys were allocated to African Americans.

UNOS provided data in 1999 to a Texas Task Force that examined median waiting times of kidney transplant patients throughout the state. Median Waiting Time data was collected for all Texas transplant centers and the kidney median waiting time difference between races mirrored the national experience. Only LifeGift, which has a variance to not award HLA matching in kidney allocation, showed nearly equal waiting times between all race/ethnicities. Whether the MWT was measured for all patients transplanted (Figure 5) or for all patient registrations by Kaplan Meier estimates (Figure 6), the differences between LifeGift and its two neighboring OPOs was striking when it came to minority waiting times.⁶ (See Figures 5 and 6)

LifeGift does not have current data because it is not readily available by OPO, by ethnicity/race, however, this situation has likely not changed greatly since UNOS's new system of allocation with less emphasis on matching has not been in place very long.

⁴ Takemoto SK, Terasaki PI, Gjertson DW, Cecka JM. Twelve years' experience with national sharing of HLA-matched cadaveric kidneys for transplantation. *New England Journal of Medicine*. 2000 Oct 12;343(15):1078-84.

⁵ Held PH, Kahan BD, Hunsicker LG et al. The impact of HLA mismatches on the survival of first cadaveric kidney transplants. *New England Journal of Medicine*. 1994 Sep 22; 331(12):765-770.

⁶ Texas task force, Department of Health, Austin Texas. *Task Force Data: Kidney TransplantPatients*, April, 2000.

We include these graphs to demonstrate that HLA matching does make a difference in waiting times for minorities.

Figure 3: Median Waiting Time in Days, Kidney Transplant Recipients
Texas OPOs: 1/1/95 – 6/30/99

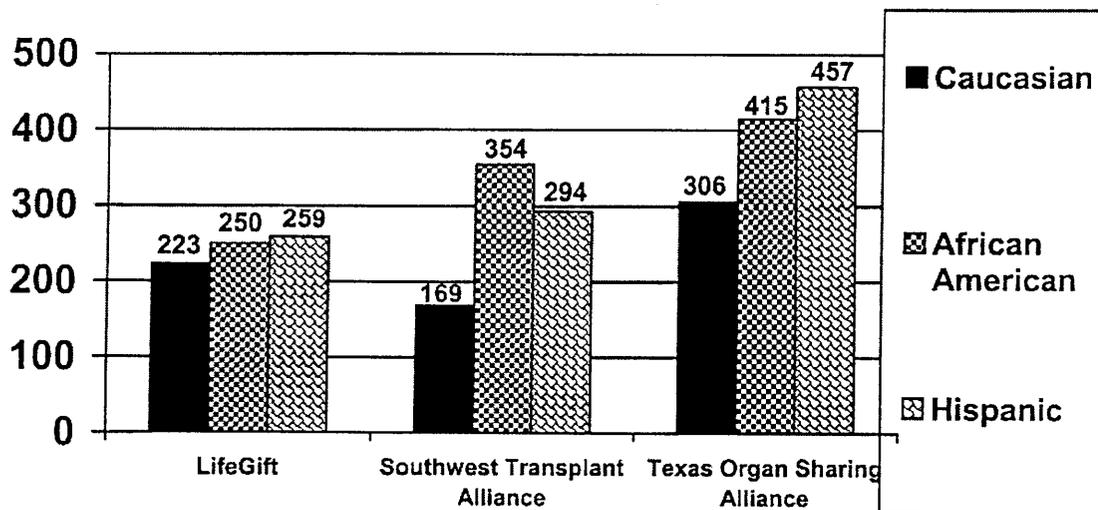
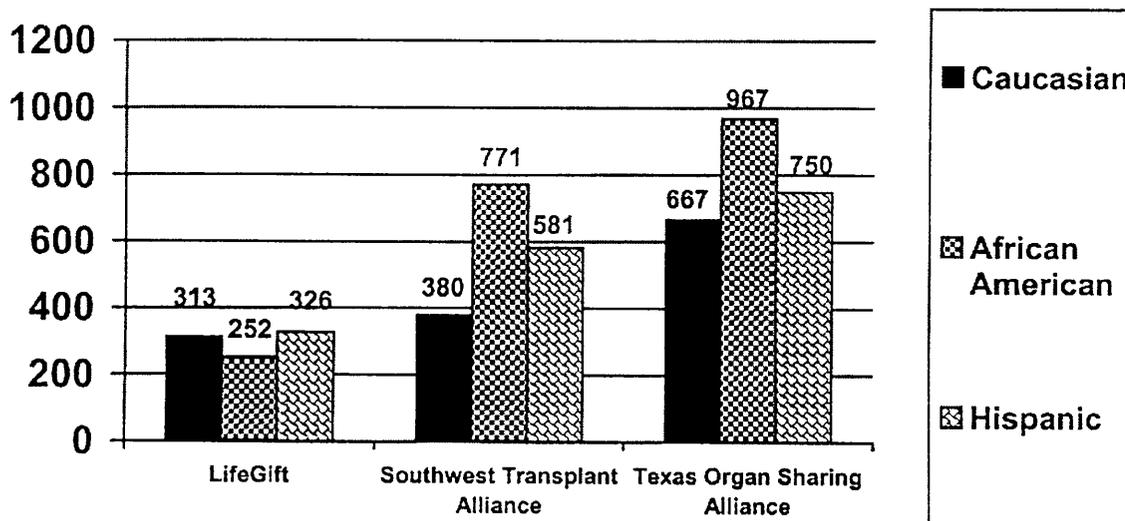


Figure 4: Median Waiting Time in Days, All Kidney Patient Registrations
Kaplain Meier Estimates, Texas OPOs: 1996*



*1996 only year that Kaplain Meier MWT available for all OPOs and all ethnic groups

b. How will the variance affect organ allocation and waiting times for highly sensitized transplant candidates?

This variance will not alter any current high PRA rules in place for kidney allocation.

c. How will HLA typing be utilized for determining organ allocation through the variance?

All donors are HLA typed. Recipients are ranked by waiting time only, as per the LifeGift variance, in Houston and Fort Worth, the Southeast and North Regions of LifeGift. This allocation method, this variance, will be extended to the West Region of LifeGift – the two transplant centers located in West Texas.

d. What is the anticipated effect on recipient and graft survival?

None. The renal transplant centers in Houston and Fort Worth have been using this system for a decade and have had not deleterious effects on graft survival. The graft survival at most of these centers is not statically different than the expected graft survival (See attachments, Table 10CL, ustransplant.org, Houston & Fort Worth Renal Transplant Centers).

e. How will the variance affect organ allocation and waiting times for transplant candidates who are pediatric, female, or represent racial minorities?

Racial Minorities. As proven by the decade long experience of the current LifeGift variance for elimination of HLA points for degree of match (with exception of 6 AG match / 0 Ag mismatch), racial and ethnic minorities will be advantaged by this policy. The is the entire reason for the variance in the first place was to ensure equity for minorities. The data presented earlier in this document shows that LifeGift's variance has resulted in equal waiting times between minorities and non-minorities.

Pediatric and female transplant candidates. This variance does not effect pediatric or female candidates. (Figures 7 - 10)

Figure 7: Kidney Waiting List

Percentage Tx Candidates by Gender

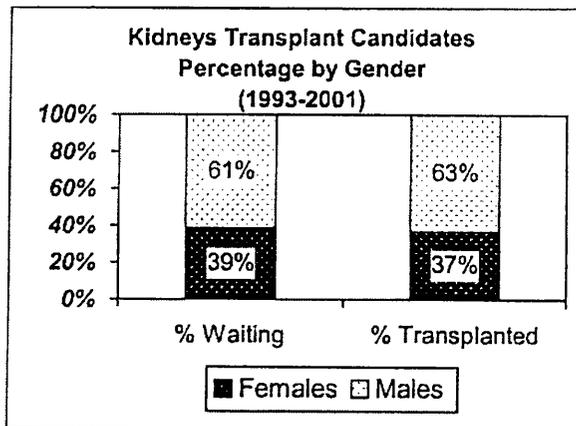
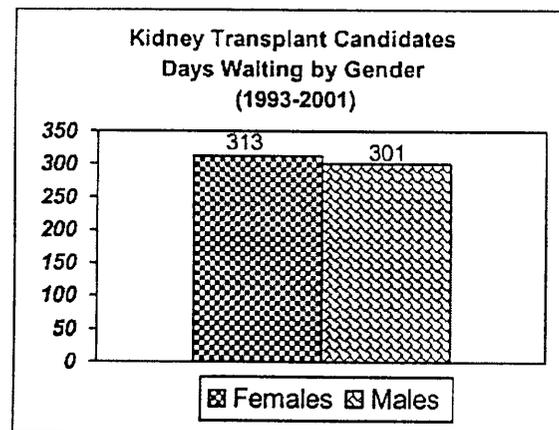


Figure 8: Kidney Waiting List

Days Waiting by Gender



This parity continues into the current period, 2001-2003. (Both sets of dates are used to demonstrate the new data since the most recent report by LifeGift to UNOS on this variance.)

Figure 7: Kidney Waiting List
Percentage Tx Candidates by Gender

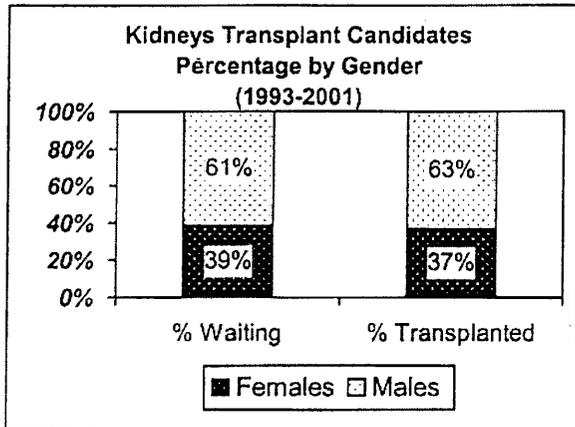
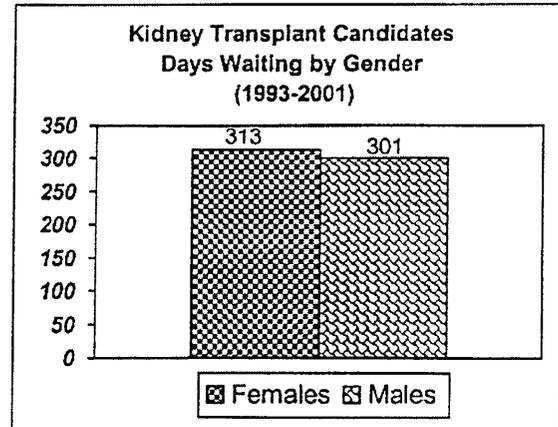


Figure 8: Kidney Waiting List
Days Waiting by Gender



f. How will the variance affect organ allocation and transplant candidate-waiting times among different blood types?

This allocation schematic will continue to be based on current UNOS blood group allocation. No change.

g. If the variance is proposed for heart, liver, intestinal organ or pancreas-islet allocation, how will it affect allocation and waiting times among the various categories of medical urgency?

Not applicable.

Table 10

Graft Survival by Donor Type by Age at Transplant and by Time since Transplant

For Patients Transplanted between 07/01/2000 and 12/31/2002 for the 1 Month and 1 Year Cohorts; between 07/01/1998 and 06/30/2000 for the 3 Year Cohort

Center: Harris Methodist Fort Worth (TXFW)

Organ: Ki: Kidney (Single-Organ Transplants Only)

Note: Deaths and retransplants are counted as graft failures

Graft Survival by Time since Transplant

Deceased Donor	This Center			United States		
	1 Month	1 Year	3 Years	1 Month	1 Year	3 Years
<u>Adult (Age 18+)</u>						
<u>Transplants (n=number) 1</u>	71	71	77	19662	19662	15183
<u>Graft Survival (%) 2</u>	97.2	90.6	84.4	95.8	88.7	77.6
<u>Expected Graft Survival (%) 3</u>	95.7	89.3	79.8	NA	NA	NA
<u>Ratio of Observed to Expected Failures</u>	0.7	0.7	0.8	NA	NA	NA
<u>95% Confidence Interval: Lower Bound 4</u>	0.1	0.2	0.4	NA	NA	NA
<u>Upper Bound 4</u>	2.4	1.6	1.4	NA	NA	NA
<u>P-value (2-sided) 5</u>	0.83	0.57	0.49	NA	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA	NA
<u>Follow-up days reported by center (%) 6</u>	100	100	100	100	100	100
<u>Maximum Days of Follow-up (n)</u>	30	365	1095	30	365	1095
<u>Pediatric (Age < 18)</u>						
<u>Transplants (n) 1</u>	-	-	-	728	728	633
<u>Graft Survival (%) 2</u>	-	-	-	95.6	91.6	76.8
<u>Expected Graft Survival (%) 3</u>	-	-	-	NA	NA	NA
<u>Ratio of Observed to Expected Failures</u>	-	-	-	NA	NA	NA
<u>95% Confidence Interval: Lower Bound 4</u>	-	-	-	NA	NA	NA
<u>Upper Bound 4</u>	-	-	-	NA	NA	NA
<u>P-value (2-sided) 5</u>	-	-	-	NA	NA	NA
How do the rates at this center compare to those in the nation?	-	-	-	NA	NA	NA
<u>Follow-up days reported by center (%) 6</u>	-	-	-	100	100	100
<u>Maximum Days of Follow-up (n)</u>	-	-	-	30	365	1095

Table 10

Graft Survival by Donor Type by Age at Transplant and by Time since Transplant
 for Patients Transplanted between 07/01/2000 and 12/31/2002 for the 1 Month and 1 Year Cohorts; between 07/01/1998 and 06/30/2000 for the
 3 Year Cohort

Center: Baylor All Saints Medical Center (TXAS)

Organ: KI: Kidney (Single-Organ Transplants Only)

Note: Deaths and retransplants are counted as graft failures

Graft Survival by Time since Transplant

	This Center			United States		
	1 Month	1 Year	3 Years	1 Month	1 Year	3 Years
<u>Transplants (n=number)</u> 1	20	-	20	19662	19662	15183
<u>Graft Survival (%)</u> 2	100.0	-	100.0	95.8	88.7	77.6
<u>Expected Graft Survival (%)</u> 3	96.8	-	91.5	NA	NA	NA
<u>Ratio of Observed to Expected Failures</u>	0.0	-	0.0	NA	NA	NA
<u>% Confidence Interval: Lower Bound</u> 4	0.0	-	0.0	NA	NA	NA
<u>Upper Bound</u> 4	4.6	-	2.4	NA	NA	NA
<u>P-value (2-sided)</u> 5	1.0	-	0.6	NA	NA	NA
<u>How do the rates at this center compare to those</u>	Not Significantly	Not Significantly	-	NA	NA	NA
<u>in the nation?</u>	Different (a)	Different (a)	-	NA	NA	NA
<u>How many days reported by center (%)</u> 6	100.0	-	100.0	100.0	100.0	100.0
<u>Minimum Days of Follow-up (n)</u>	30.0	-	183.0	30.0	365.0	1095.0
<u>Pediatric (Age < 18)</u>	-	-	-	728	728	633
<u>Transplants (n)</u> 1	-	-	-	95.6	91.6	76.8
<u>Graft Survival (%)</u> 2	-	-	-	NA	NA	NA
<u>Expected Graft Survival (%)</u> 3	-	-	-	NA	NA	NA
<u>Ratio of Observed to Expected Failures</u>	-	-	-	NA	NA	NA
<u>95% Confidence Interval: Lower Bound</u> 4	-	-	-	NA	NA	NA
<u>Upper Bound</u> 4	-	-	-	NA	NA	NA
<u>P-value (2-sided)</u> 5	-	-	-	NA	NA	NA
<u>How do the rates at this center compare to those</u>	-	-	-	NA	NA	NA
<u>in the nation?</u>	-	-	-	NA	NA	NA
<u>How many days reported by center (%)</u> 6	-	-	-	100	100	100
<u>Maximum Days of Follow-up (n)</u>	-	-	-	30	365	1095

Table 10

Graft Survival by Donor Type by Age at Transplant and by Time since Transplant

For Patients Transplanted between 07/01/2000 and 12/31/2002 for the 1 Month and 1 Year Cohorts; between 07/01/1998 and 06/30/2000 for the 3 Year Cohort

Center: The Methodist Hospital Baylor College of Medicine (TXMH)

Organ: Ki: Kidney (Single-Organ Transplants Only)

Note: Deaths and retransplants are counted as graft failures

Graft Survival by Time since Transplant

This Center	Graft Survival by Time since Transplant			United States		
	1 Month	1 Year	3 Years	1 Month	1 Year	3 Years
Transplants (n=number) 1	53	53	38	19662	19662	15183
Graft Survival (%) 2	98.1	92.5	86.8	95.8	88.7	77.6
Expected Graft Survival (%) 3	95.5	88.6	75.9	NA	NA	NA
Ratio of Observed to Expected Failures	0.41	0.76	0.50	NA	NA	NA
95% Confidence Interval: Lower Bound 4	0.01	0.21	0.16	NA	NA	NA
Upper Bound 4	2.26	1.95	1.18	NA	NA	NA
P-value (2-sided) 5	0.589	0.798	0.141	NA	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA	NA
Follow-up days reported by center (%) 6	100	100	100	100	100	100
Maximum Days of Follow-up (n)	30	365	1095	30	365	1095
Pediatric (Age < 18)	-	-	-	728	728	633
Transplants (n) 1	-	-	-	95.6	91.6	76.8
Graft Survival (%) 2	-	-	-	NA	NA	NA
Expected Graft Survival (%) 3	-	-	-	NA	NA	NA
Ratio of Observed to Expected Failures	-	-	-	NA	NA	NA
95% Confidence Interval: Lower Bound 4	-	-	-	NA	NA	NA
Upper Bound 4	-	-	-	NA	NA	NA
P-value (2-sided) 5	-	-	-	NA	NA	NA
How do the rates at this center compare to those in the nation?	-	-	-	NA	NA	NA
Follow-up days reported by center (%) 6	-	-	-	100	100	100
Maximum Days of Follow-up (n)	-	-	-	30	365	1095

Deceased Donor

Adult (Age 18+)

Transplants (n=number) 1

Graft Survival (%) 2

Expected Graft Survival (%) 3

Ratio of Observed to Expected Failures

95% Confidence Interval: Lower Bound 4

Upper Bound 4

P-value (2-sided) 5

How do the rates at this center compare to those in the nation?

Follow-up days reported by center (%) 6

Maximum Days of Follow-up (n)

Pediatric (Age < 18)

Transplants (n) 1

Graft Survival (%) 2

Expected Graft Survival (%) 3

Ratio of Observed to Expected Failures

95% Confidence Interval: Lower Bound 4

Upper Bound 4

P-value (2-sided) 5

How do the rates at this center compare to those in the nation?

Follow-up days reported by center (%) 6

Maximum Days of Follow-up (n)

Table 10

Graft Survival by Donor Type by Age at Transplant and by Time since Transplant

For Patients Transplanted between 07/01/2000 and 12/31/2002 for the 1 Month and 1 Year Cohorts; between 07/01/1998 and 06/30/2000 for the 3 Year Cohort

Center: St Lukes Episcopal Hospital (TXHI)

Organ: Kidney (Single-Organ Transplants Only)

Note: Deaths and retransplants are counted as graft failures

Graft Survival by Time since Transplant

	This Center			United States		
	1 Month	1 Year	3 Years	1 Month	1 Year	3 Years
Deceased Donor						
Adult (Age 18+)						
<u>Transplants (n=number)</u> 1	163	163	119	19662	19662	15183
<u>Graft Survival (%)</u> 2	98.2	90.4	73.9	95.8	88.7	77.6
<u>Expected Graft Survival (%)</u> 3	95.9	90.7	78.6	NA	NA	NA
<u>Ratio of Observed to Expected Failures</u>	0.4	1.1	1.3	NA	NA	NA
<u>95% Confidence Interval: Lower Bound</u> 4	0.1	0.6	0.9	NA	NA	NA
<u>Upper Bound</u> 4	1.3	1.7	1.8	NA	NA	NA
<u>P-value (2-sided)</u> 5	0.19	0.90	0.18	NA	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA	NA
<u>Follow-up days reported by center (%)</u> 6	100	100	100	100	100	100
<u>Maximum Days of Follow-up (n)</u>	30	365	1095	30	365	1095
Pediatric (Age < 18)						
<u>Transplants (n)</u> 1	-	-	2	728	728	633
<u>Graft Survival (%)</u> 2	-	-	50.0	95.6	91.6	76.8
<u>Expected Graft Survival (%)</u> 3	-	-	79.2	NA	NA	NA
<u>Ratio of Observed to Expected Failures</u>	-	-	3.9	NA	NA	NA
<u>95% Confidence Interval: Lower Bound</u> 4	-	-	0.1	NA	NA	NA
<u>Upper Bound</u> 4	-	-	21.9	NA	NA	NA
<u>P-value (2-sided)</u> 5	-	-	0.45	NA	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA	NA
<u>Follow-up days reported by center (%)</u> 6	-	-	100	100	100	100
<u>Maximum Days of Follow-up (n)</u>	-	-	1095	30	365	1095

Table 10

Graft Survival by Donor Type by Age at Transplant and by Time since Transplant
 For Patients Transplanted between 07/01/2000 and 12/31/2002 for the 1 Month and 1 Year Cohorts; between 07/01/1998 and 06/30/2000 for the 3
 Year Cohort

Center: Texas Childrens Hospital (TXTC)

Organ: Ki: Kidney (Single-Organ Transplants Only)

Note: Deaths and retransplants are counted as graft failures

Deceased Donor	Graft Survival by Time since Transplant			United States		
	1 Month	1 Year	3 Years	1 Month	1 Year	3 Years
Adult (Age 18+)						
Transplants (n=number) 1	5	5	5	19662	19662	15183
Graft Survival (%) 2	100	100	100	95.8	88.7	77.6
Expected Graft Survival (%) 3	95.9	92.6	92.6	NA	NA	NA
Ratio of Observed to Expected Failures	0	0	0	NA	NA	NA
4	0	0	0	NA	NA	NA
4	14.33	8.78	9.27	NA	NA	NA
P-value (2-sided) 5	0.999	0.999	0.904	NA	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA	NA
Follow-up days reported by center (%) 6	100	100	100	100	100	100
Maximum Days of Follow-up (n)	30	365	1095	30	365	1095
Pediatric (Age < 18)						
Transplants (n) 1	16	16	16	728	728	633
Graft Survival (%) 2	93.8	84.4	80.0	95.6	91.6	76.8
Expected Graft Survival (%) 3	92.3	90.6	73.0	NA	NA	NA
Ratio of Observed to Expected Failures	0.7	1.4	0.8	NA	NA	NA
4	0.0	0.2	0.2	NA	NA	NA
4	4.1	5.2	2.3	NA	NA	NA
P-value (2-sided) 5	1.0	0.8	1.0	NA	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA	NA
Follow-up days reported by center (%) 6	100	100	100	100	100	100
Maximum Days of Follow-up (n)	30	365	1095	30	365	1095

Table 10

Graft Survival by Donor Type by Age at Transplant and by Time since Transplant

For Patients Transplanted between 07/01/2000 and 12/31/2002 for the 1 Month and 1 Year Cohorts; between 07/01/1998 and 06/30/2000 for the 3 Year Cohort

Center: St Lukes Episcopal Hospital (TXHI)

Organ: KI: Kidney (Single-Organ Transplants Only)

Note: Deaths and retransplants are counted as graft failures

Graft Survival by Time since Transplant

	This Center			United States		
	1 Month	1 Year	3 Years	1 Month	1 Year	3 Years
Transplants (n=number) 1	163	163	119	19662	19662	15183
Graft Survival (%) 2	98.2	90.4	73.9	95.8	88.7	77.6
Expected Graft Survival (%) 3	95.9	90.7	78.6	NA	NA	NA
Ratio of Observed to Expected Failures	0.4	1.1	1.3	NA	NA	NA
95% Confidence Interval: Lower Bound 4	0.1	0.6	0.9	NA	NA	NA
Upper Bound 4	1.3	1.7	1.8	NA	NA	NA
P-value (2-sided) 5	0.19	0.90	0.18	NA	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA	NA
Follow-up days reported by center (%) 6	100	100	100	100	100	100
Maximum Days of Follow-up (n)	30	365	1095	30	365	1095
Pediatric (Age < 18)						
Transplants (n) 1	-	-	2	728	728	633
Graft Survival (%) 2	-	-	50.0	95.6	91.6	76.8
Expected Graft Survival (%) 3	-	-	79.2	NA	NA	NA
Ratio of Observed to Expected Failures	-	-	3.9	NA	NA	NA
95% Confidence Interval: Lower Bound 4	-	-	0.1	NA	NA	NA
Upper Bound 4	-	-	21.9	NA	NA	NA
P-value (2-sided) 5	-	-	0.45	NA	NA	NA
How do the rates at this center compare to those in the nation?	-	-	Not Significantly Different (a)	NA	NA	NA
Follow-up days reported by center (%) 6	-	-	100	100	100	100
Maximum Days of Follow-up (n)	-	-	1095	30	365	1095

Deceased Donor

Adult (Age 18+)

Transplants (n=number) 1

Graft Survival (%) 2

Expected Graft Survival (%) 3

Ratio of Observed to Expected Failures

95% Confidence Interval: Lower Bound 4

Upper Bound 4

P-value (2-sided) 5

How do the rates at this center compare to those in the nation?

Follow-up days reported by center (%) 6

Maximum Days of Follow-up (n)

Pediatric (Age < 18)

Transplants (n) 1

Graft Survival (%) 2

Expected Graft Survival (%) 3

Ratio of Observed to Expected Failures

95% Confidence Interval: Lower Bound 4

Upper Bound 4

P-value (2-sided) 5

How do the rates at this center compare to those in the nation?

Follow-up days reported by center (%) 6

Maximum Days of Follow-up (n)

Table 10

Graft Survival by Donor Type by Age at Transplant and by Time since Transplant
 For Patients Transplanted between 07/01/2000 and 12/31/2002 for the 1 Month and 1 Year Cohorts; between 07/01/1998 and 06/30/2000 for the 3 Year Cohort

Center: Texas Childrens Hospital (TXTC)

Organ: Kidney (Single-Organ Transplants Only)

Note: Deaths and retransplants are counted as graft failures

Deceased Donor	Graft Survival by Time since Transplant			P-value (2-sided) 5	How do the rates at this center compare to those in the nation?	Follow-up days reported by center (%) 6	Maximum Days of Follow-up (n)	Pediatric (Age < 18)	Transplants (n) 1	Graft Survival (%) 2	Expected Graft Survival (%) 3	Ratio of Observed to Expected Failures	P-value (2-sided) 5	How do the rates at this center compare to those in the nation?	Follow-up days reported by center (%) 6	Maximum Days of Follow-up (n)	United States			
	1 Month	1 Year	3 Years														1 Month	1 Year	3 Years	
Adult (Age 18+)																				
Transplants (n=number) 1	5	5	5				4		19662	19662	15183							19662	19662	15183
Graft Survival (%) 2	100	100	100				75		95.8	88.7	77.6							95.8	88.7	77.6
Expected Graft Survival (%) 3	95.9	92.6	92.6				85.1		NA	NA	NA							NA	NA	NA
Ratio of Observed to Expected Failures	0	0	0				1.66		NA	NA	NA							NA	NA	NA
	0	0	0				0.04		NA	NA	NA							NA	NA	NA
P-value (2-sided) 5	14.33	8.78	8.78				9.27		NA	NA	NA							NA	NA	NA
How do the rates at this center compare to those in the nation?	0.999	0.999	0.999				0.904		NA	NA	NA							NA	NA	NA
Follow-up days reported by center (%) 6	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)				Not Significantly Different (a)		NA	NA	NA							NA	NA	NA
Maximum Days of Follow-up (n)	100	100	100				100		100	100	100							100	100	100
Pediatric (Age < 18)									30	365	1095							30	365	1095
Transplants (n) 1	16	16	16				15		728	728	633							728	728	633
Graft Survival (%) 2	93.8	84.4	84.4				80.0		95.6	91.6	76.8							95.6	91.6	76.8
Expected Graft Survival (%) 3	92.3	90.6	90.6				73.0		NA	NA	NA							NA	NA	NA
Ratio of Observed to Expected Failures	0.7	1.4	1.4				0.8		NA	NA	NA							NA	NA	NA
	0.0	0.2	0.2				0.2		NA	NA	NA							NA	NA	NA
P-value (2-sided) 5	4.1	5.2	5.2				2.3		NA	NA	NA							NA	NA	NA
How do the rates at this center compare to those in the nation?	1.0	0.8	0.8				1.0		NA	NA	NA							NA	NA	NA
Follow-up days reported by center (%) 6	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)				Not Significantly Different (a)		NA	NA	NA							NA	NA	NA
Maximum Days of Follow-up (n)	100	100	100				100		100	100	100							100	100	100
	30	365	365				1095		30	365	1095							30	365	1095

Table 10

Graft Survival by Donor Type by Age at Transplant and by Time since Transplant

For Patients Transplanted between 07/01/2000 and 12/31/2002 for the 1 Month and 1 Year Cohorts; between 07/01/1998 and 06/30/2000 for the 3 Year Cohort

Center: Harris Methodist Fort Worth (TXFW)

Organ: KI: Kidney (Single-Organ Transplants Only)

Note: Deaths and retransplants are counted as graft failures

Deceased Donor	Graft Survival by Time since Transplant			United States		
	This Center 1 Month	1 Year	3 Years	1 Month	1 Year	3 Years
Adult (Age 18+)						
Transplants (n=number) 1	71	71	77	19662	19662	15183
Graft Survival (%) 2	97.2	90.6	84.4	95.8	88.7	77.6
Expected Graft Survival (%) 3	95.7	89.3	79.8	NA	NA	NA
Ratio of Observed to Expected Failures	0.7	0.7	0.8	NA	NA	NA
95% Confidence Interval: Lower Bound 4	0.1	0.2	0.4	NA	NA	NA
Upper Bound 4	2.4	1.6	1.4	NA	NA	NA
P-value (2-sided) 5	0.83	0.57	0.49	NA	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA	NA
Follow-up days reported by center (%) 6	100	100	100	100	100	100
Maximum Days of Follow-up (n)	30	365	1095	30	365	1095
Pediatric (Age < 18)						
Transplants (n) 1	-	-	-	728	728	633
Graft Survival (%) 2	-	-	-	95.6	91.6	76.8
Expected Graft Survival (%) 3	-	-	-	NA	NA	NA
Ratio of Observed to Expected Failures	-	-	-	NA	NA	NA
95% Confidence Interval: Lower Bound 4	-	-	-	NA	NA	NA
Upper Bound 4	-	-	-	NA	NA	NA
P-value (2-sided) 5	-	-	-	NA	NA	NA
How do the rates at this center compare to those in the nation?	-	-	-	NA	NA	NA
Follow-up days reported by center (%) 6	-	-	-	100	100	100
Maximum Days of Follow-up (n)	-	-	-	30	365	1095

Table 10

Graft Survival by Donor Type by Age at Transplant and by Time since Transplant

For Patients Transplanted between 07/01/2000 and 12/31/2002 for the 1 Month and 1 Year Cohorts; between 07/01/1998 and 06/30/2000 for the 3 Year Cohort

Center: Cook Children's Medical Center (TXCF)

Organ: KI: Kidney (Single-Organ Transplants Only)

Note: Deaths and retransplants are counted as graft failures
Graft Survival by Time since Transplant

Deceased Donor	This Center			United States		
	1 Month	1 Year	3 Years	1 Month	1 Year	3 Years
Adult (Age 18+)						
Transplants (n=number) 1	-	-	-	19662	19662	15183
Graft Survival (%) 2	-	-	-	95.8	88.7	77.6
Expected Graft Survival (%) 3	-	-	-	NA	NA	NA
Ratio of Observed to Expected Failures	-	-	-	NA	NA	NA
95% Confidence Interval: Lower Bound 4	-	-	-	NA	NA	NA
Upper Bound 4	-	-	-	NA	NA	NA
P-value (2-sided) 5	-	-	-	NA	NA	NA
How do the rates at this center compare to those in the nation?	-	-	-	NA	NA	NA
Follow-up days reported by center (%) 6	-	-	-	100	100	100
Maximum Days of Follow-up (n)	-	-	-	30	365	1095
Pediatric (Age < 18)						
Transplants (n) 1	1	1	5	728	728	633
Graft Survival (%) 2	100	100	80	95.6	91.6	76.8
Expected Graft Survival (%) 3	97.7	90.7	76.3	NA	NA	NA
Ratio of Observed to Expected Failures	0.0	0.0	0.7	NA	NA	NA
95% Confidence Interval: Lower Bound 4	0.0	0.0	0.0	NA	NA	NA
Upper Bound 4	126.7	30.6	3.9	NA	NA	NA
P-value (2-sided) 5	0.999	0.999	0.999	NA	NA	NA
How do the rates at this center compare to those in the nation?	Not Significantly Different (a)	Not Significantly Different (a)	Not Significantly Different (a)	NA	NA	NA
Follow-up days reported by center (%) 6	100	100	100	100	100	100
Maximum Days of Follow-up (n)	30	365	1095	30	365	1095

Excerpt from Executive Summary of the Minutes,
OPTN/UNOS Board of Directors Meeting, November 20-21, 2003

[**Bolded Text Below Indicates Issues Referred to Committee**]

The Board declined to approve modifications to Policies 3.2.2 (Multiple Listing Permitted), and 3.2.2.1 (Waiting Time Transferal) that would have restricted multiple listing such that transplant candidates who are multiple listed but do not meet certain defined conditions may remain multiple listed until they are transplanted or removed from the list. Since the Board declined to restrict multiple listing, a resolution supporting the current multiple listing policy was withdrawn.

The Board directed that every transplant program must inform every patient about the options of multiple listing, transferring primary waiting time, and the option to transfer his or her care to another transplant center without loss of accrued waiting time, during the evaluation process and maintain documentation that this was done and provide the patient written material on these options.

The Board directed that every transplant program that does not accept multiple listed patients and/or does not allow these patients to transfer their primary waiting time to that center if the patient so desires, must fully inform the patient during his or her evaluation or sooner.

The Board directed the development of a system within Unetsm that would inform centers that a patient is multiple listed, but not disclose the name of the other center(s) at which the patient is also listed.

The Board directed the development of a system within Unetsm that would notify transplant centers when a multiple listed patient has been transplanted at another center so that he or she can be removed from all other centers' waiting lists so as not to delay organ placement.

The Board directed the Kidney and Pancreas Transplantation Committee to study further and develop an allocation system to offer blood group A₂ (non-A₁) kidneys to blood group B candidates.

The Board directed all OPTN/UNOS committees to investigate further ways to assist biologically disadvantaged patients.

The Board directed the appropriate OPTN/UNOS committees to consider allocation policies that would award points for lower PRA values after a 6-antigen match allocation; encourage laboratories to identify all unacceptable HLA antigens for a sensitized patient; and apply a computer assisted matching algorithm that is based on CREGs to identify patients with the highest predicted probability of a negative crossmatch.

The Board declined to form a Task Force to review institutional multiple listing.

MOD M-2

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Exhibit N

Date: 12.9.2003 Organ Wait List: Kidney

Patient Name: _____

Patient Social Security Number or HIC Number (please specify which number is being provided): _____

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: 11.21.03

Listing Date Requested: 8.22.03

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation):

See attached

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: Yes, I have been instructed on the proper procedure activating patients on the Kidney wait list.
2. Send in the forms separately to tissue typing lab

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
 - Measured (actual urinary collection) creatinine clearance level or calculated GFR \leq 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please specify) _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

.....

facsimile transmittal

To: **Fax:** 804-782-4896

From: **Date:** 12/10/03

Re: Wait Time Modification request **Pages:** 12 including cover

CC:

- Urgent For Review Please Comment Please Reply Please Recycle
-

Hi

Here are the new request for wait time modification for 1

See you Monday.

Thanks.

CONFIDENTIAL PATIENT INFORMATION

The information contained in this facsimile transmission is confidential and is intended only for the use of the designated individual or department to which it is addressed. An unauthorized review, dissemination, distribution or duplicating of the information is prohibited. If you have received this fax in error, please notify the sender immediately and return the documents by mail to the above address. Thank you.

Signed by

ESA Unauthorized Conv

ID 09/08/2003 10:33

, MD

DD: 08/26/2003 DT: 08/28/2003 JOB: 000131259

cc:

other c

ESA Unauthorized Copy
SURGICAL DICTATION

NAME: _____	DATE: 08/26/2003
SURGEON: _____ ID _____	RECORD #: _____

DICTATED BY: _____ (448)

ANESTHESIOLOGIST: _____

ANESTHESIA: General anesthesia.

PREOPERATIVE DIAGNOSIS: Infarction of kidney transplant due to renal artery and vein thrombosis.

POSTOPERATIVE DIAGNOSIS: Infarction of kidney transplant due to renal artery and vein thrombosis.

DATE OF SURGERY: 8/26/03.

TITLE OF OPERATION: Transplant nephrectomy.

ASSISTANT: _____ M.D., fourth year medical student _____ and third year medical student _____ 1.

INDICATIONS: The patient received a living related kidney transplant 5 days ago. On the first postoperative day the renal scan showed no perfusion to the kidney. This was confirmed with a repeat renal scan as well as a renal artery duplex scan. Because there is no blood flow to the kidney, it was decided to remove the infarcted kidney transplant.

PROCEDURE: The patient was placed in the supine position and satisfactory general anesthesia was instituted. The patient was given 1 gram of ceftriaxone and 1 gram of ampicillin for antibiotic prophylaxis. The entire abdomen was prepped and draped in the usual manner. The skin staples were partially removed. The skin was reopened through the previous incision. The external oblique fascia was reopened by removing the stitches. The internal oblique muscle and transversalis fascia were opened by removing the stitches. The incision was measured to be 18 cm in length. The kidney was exposed and it was flabby and dusky color. There was no indication of the engorged, hemorrhagic kidney. The renal hilum was easily exposed. The ureter was thrombosed along the periureteral tissue. The ureter was easily exposed down to the bladder implantation. The ureter was transected flush with the bladder. The distal stump was ligated with 2-0 Vicryl ties. Two renal veins were exposed and there was a pulsation at the anastomotic site and the first few mm distal to the anastomosis. The right angle was applied on the renal artery just distal to the anastomosis and transected. There was dense organized blood clot extending to the kidney through both renal arteries. The renal vein was controlled with a Satinsky clamp which closed partially the axillary iliac vein. The renal vein was transected just distal to the venous anastomosis. There was loosely organized clot extending to the renal vein to the anastomotic site. There was no clot in the iliac vein. The iliac vein was controlled completely and the iliac vein was completely inspected. The venous clot extended up to the anastomosis and there was no further propagation. The renal vein stump was then closed with continuous 6-0 Prolene sutures. Venous circulation was promptly established. The renal artery was then further inspected and the proximal stump was closed with continuous 6-0 Prolene sutures. Complete hemostasis was confirmed. There was a small opening made on the peritoneum due to the retractor which was securely repaired using continuous 4-0 Vicryl sutures. Complete hemostasis was confirmed and the transversalis fascia and the internal oblique muscle were closed as a single layer using interrupted 0 PDS sutures. The external oblique fascia was then closed with interrupted 2-0 PDS sutures. Subcutaneous fatty tissue was irrigated with BAW solution and closed with interrupted 3-0 plain catgut sutures. The skin was reapproximated with the skin staples. The patient tolerated the procedure well and left for the recovery room in a satisfactory condition. At the completion of the procedure, the kidney was bisected and there was no hemorrhagic infarct and the findings compatible with ischemic infarct. The clot extended from the main renal vessel all the way to the renal hilum. Dr. _____ scrubbed in for the entire surgical procedure.

eScription document:1-1880535 Confirmation:131259 ME

GROSS DESCRIPTION

Eight (8) consult slides were received from
labeled "S03-12939".

; they are

SIGNED BY

.D. ON 09/17/03

By his/her signature above, the senior physician certifies that he/she personally conducted a microscopic examination ("gross only" exam if so stated) of the described specimen(s) and rendered or confirmed the diagnosis(es) related thereto.

- End of report -

Printed WED SEP 17, 2003 7:00 AM

A TEACHING AFFILIATE

DEPARTMENT OF PATHOLOGY

PATHOLOGY REPORT

PATIENT NAME	UNIT #	BIRTH DATE	SEX	ACCESSION NUMBER
	187-51-02-4	02/17/35	F	S03-31455
PROCEDURE DATE	RECEIVED	REPORT DATE	HOSPITAL LOCATION	
09/10/03	09/10/03	09/17/03		

PHYSICIAN(S)

PATHOLOGISTS
Resident: DR.
Staff: DR.

FINAL PATHOLOGIC DIAGNOSIS

CONSULT SLIDES RECEIVED FROM

RIGHT RENAL ALLOGRAFT, NEPHRECTOMY (S03-12939; 8/27/03):

RENAL INFARCTION (AT LEAST TWO DAYS OLD), EXTENSIVELY INVOLVING
CORTEX, MEDULLA, AND PELVIC STRUCTURES

THROMBOSIS OF RENAL ARTERY

NOTE:

All sections of kidney, as well as associated pelvic structures, are entirely infarcted. The potential role of the renal artery thrombus in this process or the potential for a hyperacute rejection cannot be determined from the submitted material.

CLINICAL DATA

History: 68-year-old woman with end stage renal disease, status post renal transplant five days prior to allograft nephrectomy. Documented no blood flow to allograft within 24 hours of transplant. ?Renal artery thrombosis or "vascular" rejection.

TISSUE SUBMITTED: Kidney biopsy

(continued on following page)

ESA Unauthorized Copy

oblique muscle were closed as a single layer using interrupted 0 PDS. The external oblique fascia was reapproximated using interrupted 2-0 PDS. The subcutaneous fatty tissue was reapproximated with 3-0 plain catgut sutures and the skin was reapproximated with skin staples. The patient tolerated the procedure well and left for the Recovery Room in a satisfactory condition. Dr. scrubbed in for the entire surgical procedure.

eScription document:1-1848027 Confirmation:131011 SE

Signed by

MD 08/22/2003 12:29

MD

DD: 08/20/2003 DT: 08/20/2003 JOB: 000131011

cc:

other :

ESA Unauthorized Copy
SURGICAL DICTATION

NAME:	DATE: 08/20/2003
SURGEON:	RECORD #: 2092995

LECTATED BY: j (448)

ANESTHESIOLOGIST:

ANESTHESIA: General anesthesia.

PREOPERATIVE DIAGNOSIS: Chronic renal failure and dialysis status.

POSTOPERATIVE DIAGNOSIS: Chronic renal failure and dialysis status.

DATE OF OPERATION: 8/20/2003

TITLE OF OPERATION: Living related kidney transplantation.

ASSISTANTS:

1. Dr. [redacted]
2. Dr. [redacted]
3. Third year medical student,

INDICATIONS: The patient has been on peritoneal dialysis for her chronic renal failure. She has a daughter who is ABO compatible and 1 haploid identical in tissue typing. Her donor work-up was acceptable for living related kidney donation. Therefore, a living unrelated kidney transplant procedure was scheduled.

PROCEDURE: The patient was placed in the supine position and satisfactory general anesthesia was instituted. The patient was given 1 gram of ceftriaxone and 1g of ampicillin for antibiotic prophylaxis. A #18 French Foley catheter was inserted into the urinary bladder and 120 cc of EAM solution were installed and the Foley drainage tubing was cross-clamped. The entire abdomen was prepped and draped in the usual manner. An oblique incision on the right iliac area, measuring 25 cm in length, was made. The underlying tissue was incised in the same direction. The external oblique fascia, internal oblique muscle, and transversalis fascia were incised with electrocautery. The deep epigastric artery and veins were divided between the clamps and tied with 3-0 silk ties. The right round ligament was divided between the clamps and tied with 2-0 silk ties. The retroperitoneum was entered and a self retaining Bookwalter retractor was applied. The lymphatics over the iliac vessel then were divided between the clamps and tied with 4-0 silk ties. The external iliac artery and vein were mobilized circumferentially. They were found to be of normal quality. The left kidney from the donor was removed using the techniques of a laparoscopic donor nephrectomy by the Donor team. The kidney contained 2 equal sized renal arteries as demonstrated on the CTA. However, during the surgery, there was a small polar artery measuring 1 mm in diameter supplying upper pole of the kidney. It supplied about 10 mm size of upper pole of renal parenchyma and looked superficial. The polar artery was too small to be repaired with a bench surgery for revascularization. Therefore, the small polar artery supplying the upper pole was ligated with 4-0 silk ties. The kidney was flushed well and it contained a single renal vein and a single ureter. The kidney was brought over to the Recipient Room for implantation. The recipient was anticoagulated with 3000 units of heparin. The external iliac artery was controlled with vascular clamps and 2 arteriotomies measuring, seven mm in length each, were made for the separate end-to-side anastomoses of the 2 renal arteries to the external iliac artery. This was accomplished using continuous 6-0 Prolene sutures. This was followed by an end-to-side renal vein to the iliac vein anastomosis using continuous 6-0 Prolene sutures. The venotomy was measured to be 20 mm in length. At the completion of the anastomoses, all of the vascular clamps were released and prompt perfusion was demonstrated, except in the area in the upper pole supplied by the polar artery. This area was measured to be 10 mm in size and felt firm. The vascular anastomosis time was 59 minutes. The patient was given 12.5 grams of mannitol and 40 mg of Lasix for diuresis. Complete hemostasis was confirmed and the bladder was easily exposed. The bladder was found to be of a normal quality and of a normal size. The detrusor muscle was then easily divided with the electrocautery and the bladder mucosa was exposed. An opening on the bladder mucosa, measuring 10 mm in length, was made. The donor ureter was transected and spatulated at the appropriate level and implanted on the bladder mucosa using continuous 6-0 PDS sutures. There was urine output from transplant ureter during the ureteral implantation. The detrusor muscle was then reapproximated over the transplant ureter using continuous 3-0 chromic catgut sutures. Complete hemostasis was confirmed and the wound was closed in layers. The transversalis fascia and the internal

Kidney Patient Activation Form

Your attention is drawn to the following rule adopted by the Board of Trustees on August 13, 1990: "Patients may be registered with the Tissue Typing Lab at any time. However, waiting time will not begin to accumulate until they are ready for transplant, i.e., until the required screening samples are present in the lab and the center has activated the patient. Sufficient clinical information will be furnished by the listing center to allow the Medical Affairs Committee to review the suitability of all activated patients." To fulfill the requirements of this rule, this form must be completed, signed by a physician, and submitted to the Tissue Typing Laboratory before any renal recipient will be added to the waiting list.

PATIENT NAME _____
LAST NAME
FIRST NAME
MIDDLE INITIAL

SOCIAL SECURITY# _____

DATE OF BIRTH _____

2
17
1935

 MONTH / DAY / YEAR

IS PATIENT CURRENTLY ON DIALYSIS? *

Yes No

IF YES, INITIAL DIALYSIS DATE: _____

10
14
2002

 MONTH / DAY / YEAR

IF NO, MEASURED CREATININE CLEARANCE (ML/MIN)
 DATE CLEARANCE BECAME <= 20ML/MIN _____

 MONTH / DAY / YEAR

OR

CALCULATED CREATININE CLEARANCE (ML/MIN)
 DATE CLEARANCE BECAME <= 20ML/MIN _____

 MONTH / DAY / YEAR

CENTER WILL ACCEPT HEPATITIS C POSITIVE KIDNEY FOR PATIENT? _____

Yes No

CENTER WILL ACCEPT HEPATITIS B CORE ANTIBODY POSITIVE KIDNEY FOR PATIENT?: _____

Yes No

CENTER WILL ACCEPT IMPORTED EXPANDED CRITERIA DONOR KIDNEY FOR PATIENT?: _____

Yes No

CENTER WILL ACCEPT LOCAL EXPANDED CRITERIA DONOR KIDNEY FOR PATIENT? _____

Yes No

CENTER WILL ACCEPT "TWO FOR ONE" (LOCAL) DONOR KIDNEYS FOR PATIENT?: _____

Yes No

I certify that this patient is ready for renal _____ and
 request that his/her name be put on the act _____ and

Physician's Signature: _____

Physician's name (Printed): _____

Transplant Center: _____

DATE FORM COMPLETED: _____

Aug
22
103

 MONTH / DAY / YEAR

(*): If dialysis status is not indicated on this form, it will be assumed that the patient is not on dialysis. Future initiation of dialysis must be submitted on a signed Status Change Form

(**): Calculated GFR = Cockcroft-Gault or other reliable formula

Status Change Form

Your attention is drawn to the following rule adopted by the Board of Trustees on August 13, 1990:

"All communications regarding a patient's status shall be made in writing and state the reason for the change. These communications will be available to the Medical Affairs Committee for review."

To fulfill the requirements of this rule, this form must be completed, signed by the designated transplant center representative(s), and submitted to the Tissue Typing Laboratory before the status of any renal recipient will be changed.

Patient name _____
Last Name First Name Middle Initial

Social Security# _____

Date of Birth 2 . 17 . 1935
M D Y

The above candidate should be changed to the following status:

- Dialysis start date: _____
- Available (AV)
- Temporarily Unavailable (TU)
- Patient Retired (PR)
If Patient expired, please indicate date of death
If patient received living donor transplant, please provide UNOS ID#, transplant date, left or right kidney
- Patient Transferred to Another Center (PR)

The reason for the change is 8-20-03 _____ received
the Left Kidney from _____ UNOS # _____

Signature: _____

Name (Printed): _____
Authorized Transplant Center Representative

Transplant Center: _____

Date: 8-22-03

Tissue Typing Laboratory FAX: _____

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____

(Please Print or Type)

Please Fax to: 804-697-4372

Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

December 10, 2003

After I received the November 2003 List of Unknown Patients, I discovered that Mrs. [redacted] was on the Delist. I notified the Tissue Typing Lab because she was activated on 8-22-03. Mrs. [redacted] received a living-related kidney on 8-20-03 from her daughter. On 8-21-03 she had a renal scan, which showed the renal artery had thrombosed. Dr [redacted] had me activate Mrs. [redacted] the cadaver kidney wait list. I sent the following forms a Status Change Form retiring Mrs. [redacted] and a Kidney Activation Form. I may have confused the staff at the Tissue Typing Lab by sending all the forms together. On 8-26-03 Mrs. [redacted] had a transplant nephrectomy. On 8-28-03 Dr [redacted] wanted to know her PRA so her serum was sent to the Tissue Typing Lab.

The only proof I have would be the forms I submitted on 8-22-03 and the surgical and pathology reports that back up my statement. Please show compassion and support for Mrs. [redacted] losing her daughter's kidney was devastating that I would prefer her not to lose any time. In actuality, Mrs. [redacted] should have been on the list since April of 03. It was an oversight on my part due to inexperience and lack of knowledge as a Transplant Coordinator. I had just started in this position the last week in March, and at the time I didn't know that a candidate who had a donor was placed on the kidney cadaver wait list. Thank you for all you help.

WAITING TIME MODIFICATION FORM (OPTN/UNOS Policy 3.2.1.8)

Date: 10/22/03 Organ Wait List: Kidney

Patient Name:

Patient Social Security Number or HIC Number (please specify which number is being provided):

Name of Transplant Center and UNOS Center Code:

Current Listing Date: 10/6/03

Listing Date Requested: 3/20/03

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): Pt. had activation form for kidney tx. submitted on 3/20/02. He was then removed from the list on 8/6/02 for medical reasons. He should have been made a status 1 rather than removed from the list at that time. Per Dr. the pt. then would have been ready to be reactivated as a status 1.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain:

Blank lines for corrective action explanation.

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
Measured (actual urinary collection) creatinine clearance level or calculated GFR <= 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation, Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
Organ Justification Form, if Applicable
Patient Listing Confirmation Letter
Other (Please specify)

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Handwritten notes: doesn't make sense, previously listed March 02, check to see if listed qualified candidate?, management reasons?, and back, review dates offered by act consistent to support doc assessing inform of regulation - type

CONTINUED NOTES

on the list on 9/3/03. We are requesting that the pt. receive his time back, if he had acquired any, between 3/20/02 and 8/6/02. We are also requesting that the pt. receive any time back from 9/3/03 to the present which was when the pt. should have changed from a Status 7 to a Status 1.

Status 1 time

5 mths	3/20/02	→	8/6/02	AND
4 mths	9/3/03	→	present.	

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____

Please Fax to:
Or Mail to:



Find Candidate Report

As of 01/08/2004 at 09:30:52

[← Back](#)

Listing Ctr	Candidate Name	SSN	Org	BG	Gender	TI	PA	Stat	Entry Date	Removal Date	Rem Code	Dono ID
			KI	O	F		0	1	11/12/2002			
			KI	A	M			1	02/28/1991	07/16/1991	4	
			KI	A	M			1	04/01/1998	01/09/1999	13	
			KI	A	M			Old 7	07/12/1996	04/08/1998	7	
			KI	B	M			1	01/02/1996	07/30/1999	8	
			KI	B	M			1	01/22/1990	05/11/1990	15	
			KI	A	F		0	1	08/08/2001			
			KI	A	M		0	1	12/03/2003			

[← Back](#)



Find Candidate Report

As of 01/08/2004 at 09:30:14

[← Back](#)

Listing Ctr	Candidate Name	SSN	Org	BG	Gender	TI	PA	Entry Stat	Entry Date	Removal Date	Rem Code	Donor ID
			KI	A	M	0		1	12/03/2003			

[← Back](#)

Copyright © 2003,

Public Burden/Privacy Act Statements

MOD M-3

Exhibit P

WAITING TIME MODIFICATION FORM (OPTN/UNOS Policy 3.2.1.8)

Date: 11/7/03 Organ Wait List: Kidney

Patient Name: _____

Patient Social Security Number or HIC Number (please specify which number is being provided):

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: 11/7/03

Listing Date Requested: 7/31/02

Explanation for Request (please continue on additional pages as necessary and attach any supporting documentation): Pt. had an activation form submitted on 7/24/02 with a calculated GFR of 20.6 ml/min. Her calculated GFR decreased to 17 ml/min. as of 7/31/03, but we did not notify UNOS of this change in GFR. We are requesting pt.'s waiting time back to 7/31/02.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: _____

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
- Measured (actual urinary collection) creatinine clearance level or calculated GFR \leq 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please specify) _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____

(Please Print or Type)

Please Fax to: 804-697-4372

Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Date: 6/20/03 Organ Wait List: kidney

Patient Name: _____

Patient Social Security Number or HIC Number (please specify which number is being provided):
SS#

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: 6/20/03

Listing Date Requested: 11/12/02

Explanation for Request (please continue on additional pages as necessary and attach any supporting documentation):

Pt. was originally scheduled for HLA typing on 5/22/02. He had several tubes of blood drawn that day, but by our error he was not given his lab slip for HLA typing. We sent an activation form to on 11/12/02. We overlooked for several months that this pt. did not

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: _____

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
 - Measured (actual urinary collection) creatinine clearance level or calculated GFR \leq 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please specify) _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

CONTINUED NOTES

have his HLA typing drawn. Pt. was re-schedule to have his HLA typing done on 6/3/03, but pt. was in the ER that day. We re-scheduled for 6/5/03 & requested a kit be sent to his dialysis center that day, but they never received the kit. He was again scheduled to have his typing done today 6/20/03. We are requesting that this pt. get his time back to 11/12/02 when his kidney activation form was submitted, as these ~~was~~ were our errors & not the patient's.

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____

Please Fax to: 804-697-4372

Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

Q-3

UNOS

Wait Time Modification Form

(UNOS Policy 3.2.1.8)

Date 8/12/03 Organ Wait List K

Patient Name _____

Patient Social Security Number or HIC Number (please specify which number is being provided) _____

Name of Transplant Center and UNOS Center Code _____

Current Listing Date 5/3/02

Listing Date Requested 1/9/03

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation)

Activation form sent, instead of status change form. Not discovered until today. [unclear] had not called me to correct incorrect form being used.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain

Will check to be sure correct form is used; if pt had previously been activated

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example.

Additionally, I: (must check one)

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please Specify) - Original activation form

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person _____

Phone _____ email _____

Physician/Surgeon Signature _____

Physician /Surgeon Name (please print or type) _____

Fax to: (804) 697-4372

Contact: Jim Creger (804) 782-4744

Or mail to: UNOS Organ Center, 700 North 4th Street, PO Box 2484, Richmond, Virginia, 23218

LP#

Kidney Patient Activation Form

Your attention is drawn to the following rule adopted by the Board of Trustees on August 13, 1990:

"Patients may be registered with the [redacted] at any time. However, waiting time will not begin to accumulate until they are ready for transplant, i.e., until the required screening samples are present in the lab and the center has activated the patient. Sufficient clinical information will be furnished by the listing center to allow the Medical Affairs Committee to review the suitability of all activated patients."

To fulfill the requirements of this rule, this form must be completed, signed by a physician, and submitted to the Tissue Typing Laboratory before any renal recipient will be added to the waiting list.

Patient name _____
Last name First Name Middle Initial

Social Security# _____

Date of Birth 7/21/1962
M D Y

Is the patient currently on dialysis*? Yes No

If yes, initial dialysis date 6/1/2001

If no, please provide either a measured creatinine clearance or GFR:

Measured creatinine clearance (ml/min)? 16
Date measured creatinine clearance became 20 or less 5/30/2001

Calculated GFR** (ml/min)? _____
Date GFR score became 20 or less _____

Center will accept HCV+ kidney for patient: Yes No

Center will accept Hepatitis B Core Antibody Positive kidney for patient Yes No

I certify that this patient is ready for renal transplantation, and request that his/her name be placed on the active list of the New England Organ Bank.

Physician's Signature: _____

Physician's name (Printed): _____

Transplant Center: _____

Date: 06/09/2003

1/9/03
already in comp
-Tru
TR# 70910

*Note: If dialysis status is not indicated on this form, it will be assumed that the patient is not on dialysis; under the current allocation system (September 3, 1996 implementation date), candidates not on dialysis do not accrue waiting time. Initiation of dialysis must be explicitly stated on a signed Status Change Form, when appropriate.

** Calculated GFR = Cockcroft-Gault or of R-2

UNOS

Wait Time Modification Form

(UNOS Policy 3.2.1.8)

Date 1/7/03 Organ Wait List Kidney

Patient Name _____

Patient Social Security Number or HIC Number (please specify which number is being provided)
SSN -

Name of Transplant Center and UNOS Center Code _____

Current Listing Date 1/7/03

Listing Date Requested ~~1/7/03~~ 8/20/01

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation) I faxed registration form activation form ABO + HLA. I got fax stamp confirmation that all 4 pages were faxed. Monthly summons have been sent so I was unaware of missing ABO. I did not know that a "?" under ABO meant - continued.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain I do now have the knowledge to prevent future occurrences. I will continue to use fax stamp + fax confirmation.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example.

Additionally, I: (must check one)

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please Specify) copies of original forms with stamp from fax machine.

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person _____

Phone _____ email _____

Physician/Surgeon Signature _____

Physician /Surgeon Name (please print or type) _____

Fax to: (804) 323-4326

Or mail to: UNOS Organ Center, 1100 Boulders Parkway, Suite 500, Richmond, Virginia, 23225

that ABO was missing. Nor did I know that missing ABO prevented the patient from gaining wait time.

additional supporting documentation:

note date ABO collected + date ABO report run.

note date HHA report.

These support original registration date.

Date of patient notification lags somewhat but still supports the original registration date.

Kidney Patient Activation Form

Your attention is drawn to the following rule adopted by the Board of Trustees on August 13, 1990:

"Patients may be registered with the Tissue Typing Lab at any time. However, waiting time will not begin to accumulate until they are ready for transplant, i.e., until the required screening samples are present in the lab and the center has activated the patient. Sufficient clinical information will be furnished by the listing center to allow the Medical Affairs Committee to review the suitability of all activated patients."

To fulfill the requirements of this rule, this form must be completed, signed by a physician, and submitted to the Tissue Typing Laboratory before any renal recipient will be added to the waiting list.

Patient name _____
Last name First Name Middle Initial

Social Security# _____

Date of Birth 05/14/56
M D Y

Is the patient currently on dialysis? Yes [] No

If yes, initial dialysis date 5/15/01

If no, please provide either a measured creatinine clearance or GFR:

Measured creatinine clearance (ml/min)? _____

Date measured creatinine clearance became 20 or less _____

Calculated GFR** (ml/min)? _____

Date GFR score became 20 or less _____

Center will accept HCV+ kidney for patient: [] Yes No

Center will accept Hepatitis B Core Antibody Positive kidney for patient:
 Yes [] No

I certify that this patient is ready for renal transplantation, and request that his/her name be placed on the active list of the _____.

Physician's Signature: _____

Physician's name (Printed): _____

Transplant Center: _____

Date: 6/22/01

*Note: If dialysis status is not indicated on this form, it will be assumed that the patient is not on dialysis; under the current allocation system (September 3, 1996 implementation date), candidates not on dialysis do not accrue waiting time. Initiation of dialysis must be explicitly stated on a signed Status Change Form, when appropriate.
** Calculated GFR = Cockcroft-Gault or other reliable formula

Laboratory Computer Registration Form

- PATIENT TYPE**
- Candidate for Cadaver Transplant
- Candidate for Living Transplant
- Living Donor

- ORGAN (S) AWAITED**
- Kidney
- Pancreas
- Heart
- Lung
- Liver
- Pancreas Islets

Transplant Center _____

Section I. Registrant Information

Last name	First name	MI	Previous Surname
Date of Birth	5/14/56		Gender: <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male
Social Security #:	State of Permanent Residence NH		
Citizenship: <input checked="" type="checkbox"/> U.S. Citizen <input type="checkbox"/> Resident Alien <input type="checkbox"/> Non-resident Alien If yes, home country		Ethnicity <input type="checkbox"/> Hispanic Origin <input checked="" type="checkbox"/> Not of Hispanic Origin	
Race: <input checked="" type="checkbox"/> White <input type="checkbox"/> Black <input type="checkbox"/> American Indian/Alaskan Native <input type="checkbox"/> Asian <input type="checkbox"/> Pacific Islander <input type="checkbox"/> Mid-East/Arabian <input type="checkbox"/> Indian Sub-Continent			
ABO Blood Group: O pos.			

Section II. Complete if Registrant is a Transplant Candidate

Primary Diagnosis (UNOS code or description)	3004		
Has the patient had a previous transplant?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	
If yes, give # of previous transplants for each organ type and latest transplant date:			
Organ:	Number	Month/Year	
Organ:	Number	Month/Year	

Section III. Complete if Registrant is a Living Donor

Name of Recipient:	Recipient's Date of Birth				
Relationship to Recipient: (circle one) Father Mother Sibling Half-sibling Aunt					
Uncle Cousin Spouse Friend Other _____					

Signature of Authorized Transplant Center Representative _____

Date 6/22/01

For TTL use only

Initials

Date entered

TTL#

11.98

RUN DATE: 06/08/01
RUN TIME: 1606

LAB **LIVE**
Specimen Inquiry
PCI User: RNO.CHAD Lab Database: LAB.NEC

PAGE 1

PATIENT: ACCI #: 1978731
AGE/SX: 45/M FROM: REC: 06/04/01
REQ DR: DOB: 05/14/56 HED: DIS:
SEARCH: REQ: RM: TLOC:

SPEC #: 0604:BB00107R COLL: 06/04/01-1445 STATUS: COMP REQ #: 00605694
RECD: 06/05/01-0935 SUBM DR:

ENTERED: 06/05/01-0937 OTHER DR:
ORD PRODS: (NO ORDERED PRODUCTS)
ORD TESTS: T&S - Adult

TEST RESULT
T&S - Adult
> T&S SUMMARY O POS
> ANTI-BODY SCREEN NEGATIVE
SSN -
DOB 5/14/56

** END OF REPORT **

(R)

July 9, 2001

ING

ry

un
MD

MR:

Dear Mr.

Thank you for coming to _____ for a transplant evaluation. The Transplant Committee has reviewed your case. We feel that you are an acceptable transplant candidate. No additional testing or information is required. You have been listed for a cadaveric transplant. Your dialysis unit should send a sample of your blood to the _____ monthly (see information in your evaluation booklet).

N
ator

We ask that you return once every six months to see Dr. _____. This allows us to review your medical situation and insure that transplantation remains appropriate. You can make that appointment by calling, _____. It was a pleasure to meet you. If you have any questions, please feel free to call me at _____.

-C
W

ator

Kidney Transplant Coordinator

Cc:

MOD M-9

Exhibit T

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Date: 10-14-03 Organ Wait List: Kidney

Patient Name: _____

Patient Social Security Number or IIC Number (please specify which number is being provided):

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: 10-14-03

Listing Date Requested: 10-1-01

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation):

See attached letter

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain:

See attached letter

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
- Measured (actual urinary collection) creatinine clearance level or calculated GFR \leq 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please specify) _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____

(Please Print or Type)

Please Fax to: 804-697-4372
Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

October 15, 2003

Transplant Services

RE:

UNOS
700 North Fourth Street
Richmond, VA 23219

F

To Whom It May Concern:

Mr. [redacted] completed his evaluation on June 16, 2001 and the team approved him for listing.

The patient, his dialysis unit and the team were under the assumption that he was listed, until it was discovered the patient was in fact never listed.

In retrospect, we believe this occurred at a time of staff transition in the kidney transplant department.

Because of our mistake, we have potentially disadvantaged this man and request he be re-instated back to his team approval date of June 16, 2001.

Sincerely,

Renal Transplant Coordinator

Medical Director

I, _____, MD, Kidney Program Director at _____ as a
member of UNOS and the _____ / do hereby give approval that
patient, _____, have kidney wait time adjustments
to include 553 days. Mr. _____ was not at fault for this list date discrepancy, and should
not be penalized.

Signature: _____

Date:

11/21/03

I, _____, MD, Chief of Surgery at _____, as a member of UNOS
 and the _____ do hereby give approval that _____ patient.
 _____ have kidney wait time adjustments to include 853 days.
 Mr. _____ was not at fault for this list date discrepancy, and should not be penalized.

Signature: _____

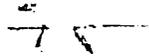
Date: _____

[Handwritten Signature]

 11/19/03

I, _____ MD, Chief Transplant Division at _____ as a member of _____
 UNOS and the _____ do hereby give approval that
 patient, _____ have kidney wait time adjustments to include 853
 days. Mr. _____ was not at fault for this list date discrepancy, and should not be
 penalized.

Signature:



Date:

10/23/03

RECEIVED OCT 20 2003

I, _____, MD, Medical Director Kidney Program at _____, as a member
of UNOS and the _____ do hereby give approval that
_____ a patient, V have kidney wait time adjustments to
include 853 days. Mr _____ was not at fault for this list date discrepancy, and should
not be penalized.

Signature:

Date:

10/20/03

MD, Chief and Director of Kidney and Pancreas Program at
 as a member of UNOS and the do hereby give
 approval that patient, have kidney wait time
 adjustments to include 853 days. Mr. was not at fault for this list date
 discrepancy, and should not be penalized.

Signature:

Date:

10/21/03

I, _____, MD, Director of Transplantation and Urology at
 as a member of UNOS and the _____ do hereby give approval
 that _____ patient, _____ have kidney wait time
 adjustments to include 853 days. Mr. _____ was not at fault for this list date
 discrepancy, and should not be penalized.

Signature:

Date:

10/21/03

I, _____ MD, Director Kidney Program at _____, as a member of
 UNOS and the _____ do hereby give approval that
 patient, _____ we kidney wait time adjustments to include 853
 days. Mr. _____ was not at fault for this list data discrepancy, and should not be
 penalized.

Signature: _____

Date:

Oct. 24 03

I feel that this patient should not be
 punished. But, the center should not
 be rewarded for their incompetence. The
 patient should be awarded the time
 and referred to another center. After
 all, does the patient have confidence
 in a center that made such a
 mistake?

FACSIMILE TRANSMITTAL SHEET

TO:

FROM:

Jim Cregar
COMPANY:

Sender's Phone Number

UNOS
FAX NUMBER:

12/8/2003
TOTAL NO. OF PAGES INCLUDING COVER:

004-697-4372
PHONE NUMBER:

11
RE: Time Modification

URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY PLEASE RECYCLE

NOTES/COMMENTS:

Please find attached wait time modification
for patient agreed to by all
surgeons.

If there are any questions, please call
me at Thank you!

This information has been disclosed to you from medical records whose confidentiality is protected under Federal Law. Federal regulations prohibit you from making disclosure of this material without written consent of the person to whom it pertains.

ANY DISCLOSURE OF MEDICAL INFORMATION BY THE RECIPIENT IS PROHIBITED!

IF YOU HAVE RECEIVED THIS FORM IN ERROR, IMMEDIATELY SHRED THE DOCUMENTS!

OCT-16-2003 17:51

P. 02/24

October 15, 2003

RE:

UNOS
700 North Fourth Street
Richmond, VA 23219

To Whom It May Concern:

Mr. [redacted] completed his evaluation on June 16, 2001 and the team approved him for listing.

The patient, his dialysis unit and the team were under the assumption that he was listed, until it was discovered the patient was in fact never listed.

In retrospect, we believe this occurred at a time of staff transition in the kidney transplant department.

Because of our mistake, we have potentially disadvantaged this man and request he be re-instated back to his team approval date of June 16, 2001.

Sincerely,

[Signature]
Renal Transplant Coordinator

[Signature]
Medical Director

November 28, 2003

To: OPTN/UNOS Kidney and Pancreas Transplantation Committee
United Network for Organ Sharing
700 North 4th Street
Richmond, Virginia 23218

The enclosed packet contains information relating to a request for wait time modification on one our kidney transplant patients. Should you have any questions pertaining to this patient or the information provided, you can contact me through one of the following numbers: (office), pager).

Sincerely,

Transplant Services

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Date: November 3, 2003 Organ Wait List: Kidney

Patient Name: _____

Patient Social Security Number or HIC Number (please specify which number is being provided):
SSN: _____

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: November 3, 2003

Listing Date Requested: July 18, 2003

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): _____ has a primary diagnosis of Medullary Cystic Disease. Prior to the start of his dialysis which was September 23, 2002, he was identified as renal transplant candidate. A potential living donor was identified, and on January 28, 2003, his uncle began the workup to be a living kidney donor. Because of this fact, The Transplant Team at _____ decided not to list _____ for a deceased donor kidney with UNOS. _____'s living donor transplant occurred on July 18, 2003. _____ began to experience problems shortly after transplant. His serum creatinine dropped by 25% in the first 12 hours but then began to rise. An emergent ultrasound showed abnormal venous flow. He underwent emergency surgery and an intrarenal thrombosis was found. The kidney was reflushed. Urine output improved and within 10 days creatinine level began to fall but never improved enough to discontinue dialysis. (Lowest creatinine on dialysis was 8.8) _____ started back on dialysis July 19, 2003. Post transplant ultrasounds were done on a regular basis. Flow to the kidney was noted to be improved. A biopsy was also done on August 6, 2003 which confirmed suspicion of Acute Tubular Necrosis. At this time _____ displayed 20% tissue infarction. There was also moderate medial thickening of the small arteries. Despite increased kidney flow per ultrasound on September 16, 2003, _____ had another biopsy at 2 months post transplant which showed complete infarction of the biopsy tissue. To this date he remains on dialysis.

At the time that renal transplant was indicated for _____, a living donor had already been identified. It was the perception by our center that if there is a potential living donor, listing with UNOS was not encouraged. Therefore, _____ has no accumulated wait time. Because he has had the unfortunate experience of graft failure from his living donor, we are requesting that his wait time be modified to start the date that his living donor transplant occurred. This would be July 18, 2003. Since _____ was not originally listed with UNOS when he was identified as a transplant candidate, he is not eligible for wait time reinstatement as the current policy now allows. However, the Transplant Team at _____ ask the OPTN/UNOS board to consider the request to modify _____'s wait time to make his chances equitable to other UNOS deceased donor kidney transplant candidates that are able to reinstate their wait time if they have documented graft failure 90 days post transplant.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: _____ When a living donor graft fails, it can be devastating to all who are involved. Until now, our center did not realize the need to list potential living donor recipients with

UNOS. This incident has made our team more aware of such and will influence how we manage our transplant program.

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
- Measured (actual urinary collection) creatinine clearance level or calculated GFR \leq 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
 - Organ Justification Form, if Applicable *N/A*
 - Patient Listing Confirmation Letter
 - Other (Please specify) Clinic notes, ESRD assessment and care plan
-

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____

(Please Print or Type)

Please Fax to: 804-697-4372

Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

U-3

SAMPLE

November 6, 2003

gy
hospital

Re: Wait time justification

This letter is in response to UNOS/OPTN policy 3.2.3.2: Waiting Time Reinstatement for Kidney Recipients. We currently have a patient that requires a wait time modification. The patient was a living donor transplant on July 18, 2003 and has experienced complete graft failure. (Please review the enclosed application form for further medical detail.) He was listed with UNOS on November 3, 2003.

As stated within UNOS/OPTN policy 3.2.1.8, "Wait time adjustments shall be approved by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the patient is listed, and then submitted to the OPTN/UNOS organ specific committees and Board of Directors for review. In compliance with this process, we are requesting the following:

1. Review the transplant candidate modification form.
2. Decide if you will approve of such a modification.
3. Sign the enclosed signature form indicating approval.
4. by faxing to
by 11/17/2003.
5. Mail original Signature page to:

Since this patient was never listed on the UNOS patient waiting list, we are requesting a modification of wait time dated the day of his living donor transplant which was: 7/18/03.

Your time and cooperation in this matter is greatly appreciated. Should you have any questions, please contact _____ RN, BSN, MA at phone number _____ or pager number _____

Sincerely,

MD
Director of Pediatric Nephrology

Signature page for approval of Modification to Waiting Time

MOCH Kidney Program Director/ UNOS Representative

Signature: _____

Print name here: _____

LOCAL TRANSPLANT CENTERS

Hospital -----
UNOS Representative(s): MD
MD

UNOS Representative(s): MD
MD

UNOS Representative: MD

Signature page for approval of Modification to Waiting Time

Kidney Program Director / TINOS Representative

Signature: _____

Print name here: _____

Signature page for approval of Modification to Waiting Time

Kidney Program Director/ UNOS Representative

Signature: _____

Print name here: _____

Signature page for approval of Modification to Waiting Time

Kidney Program Director UNOS Representative

Signature: _____

Print name here: _____

U-10

Signature page for approval of Modification to Waiting Time

Kidney Program Director/ UNOS Representative

Signature: _____

Print name here

103

Signature page for approval of Modification to Waiting Time

Kidney Program Director/INOS Representative

Signature: _____

Print name here: _____

INFORMATION IN THIS CIRCLE, CHECK, AND/OR COMPLETE ALL INFORMATION APPROPRIATELY.

Revised Plan _____
Annual Re-evaluation No. 1

Start Date: 9/24/02 Facility Name: _____ Provider #: _____

Transfer From: _____ Transfer Date: _____

PATIENT IDENTIFICATION:

Medicare#: _____ SS#: _____ Status: _____ Non-Medicare Medicare Per _____

Last Name: _____ First Name: _____ M.I.: K

Address: _____ City: _____ State: _____ ZIP: _____

Birthdate: 4/22/82 Sex: M F Marital Status: 1 2 3 4 5 Race: 1 2 3 4 5 6 7

Medical Data: Primary ESRD Diagnosis: Medullary cystic disease

Secondary Diagnosis: _____

Diabetes Mellitus: _____ Type I (Insulin) _____ Type II (non-insulin)

Peak Serum Creatinine or lowest GFR Before Initiation of Dialysis: Scr 27.3

CURRENT TREATMENT PLAN:

Date of Original Treatment Plan: 9/24/02 Re-evaluation Date: 9/03

A. Dialysis: Date of Initial Chronic Dialysis: 9/23

Number of Treatments per week: 3

Current Modality (check all that apply)

- | | |
|--|--|
| <input checked="" type="checkbox"/> 1. In-Center (In-Training) | <input type="checkbox"/> 2. Home Hemodialysis |
| <input type="checkbox"/> Staff Hemodialysis | <input type="checkbox"/> Home Hemodialysis |
| <input type="checkbox"/> Shortened Hemodialysis | <input type="checkbox"/> CCPD |
| <input type="checkbox"/> Self Hemodialysis | <input type="checkbox"/> CAPD (#Exchanges per day _____) |
| <input type="checkbox"/> CCPD | <input checked="" type="checkbox"/> CCPD <u>4/03</u> |
| <input type="checkbox"/> In-Center Hemodialysis | |

B. Home Hemodialysis: If NO, reason patient isn't on Home Hemo: 1 2 3 4 5 6 7

C. Home Peritoneal Dialysis: If NO, reason patient isn't on Home PD: 1 2 3 4 5 6 7 8

D. Transplantation: # of Previous transplants 0 Transplant code: 1 ^{7/03} 2 3 4 5 6

E. Vocational Rehabilitation: If NO, reason patient can't participate: 1 2 3 4 5 6 7

Annual Re-evaluation: 9/03 (1 transplant July)
12 mo 24 mo 36 mo 48 mo 60 mo mo

This Life Plan has been developed by members of the Professional Team whose signature appear below.

Attending Physician _____ Date 9/27/02 R.N. _____ Date 9/24/02

Dietician _____ Date 9-27-02 Social Worker _____ Date 9/27

Transplant Surgeon _____ Date _____

I have been informed of therapeutic options, risks, and complications, and I accept the treatment as indicated above.

Patient Signature: _____ Date: 9/24/02

SEE OTHER SIDE FOR INSTRUCTIONS

Initial Visit

Follow-up

Date

11/8/03

Primary Dr.

Primary renal diagnosis/reason for referral:

ESRD⁰ Metabolic Acute Disease S/P LRP Renal Transplant

History of Illness:

7/10/03 - Renal venous Thrombosis - still on PD,
15/7/12 male -

AP's 126 - 130 / 80 - 90 (pre)

130 / 90 - post-back later plates

Angiogram Home Choice
(47-51 min) TV - 18 liters (gt)
FV - 2 L
Total UF Time - 100
#bld - 8
All 1.5 E Dialyzed.

Review of systems (if positive, detail below if not in history)

General	Eyes & vision 1/0	ENT & hearing problem
CV chest pain	Resp & cough 1/0	GI & abd pain No diarrhea -
GU & dysuria, no DUP	Musculoskeletal & jt pain -	Integument
Neuro & headaches	Psych	Endocrine + state back to school
Heme & Head Sunits of PPSI - last 7/20/03	Allergic (w/alar)	Waste to bed about 1/2 hr a back to school - (10 grade)

Meds
Labetalol 200 mg po BID
Norvasc 5 mg po BID
Prednisone 15 mg po q day
Rapamune 6 mg q 2 pm

Family History:

(Unchanged/Changed) Cellcept 750 mg po q 12

Social History:

(Unchanged/Changed) Zoster 75 mg po q 12

Plavix 125 mg po q 80

Urine dipstick:

Septa SS 1/2 tab po q hrs

Fesly 325 mg po TID
Omeprazole 50 mg po day
Mycostad 6 ml q 12
Vit E 400 mg q day
Oxal III E meal TID
II E Snacks BID
Egogen 7000 u 50 (T/RTSU)

Leuko	Nitrite	Urobil	Prot	pH	Blood	SG	Ketone	Bili	Gluc
-	-	0.2	+	6.0	+	1005	-	-	-

(Student/Resident)

(Nephrologist)

Examination (5%)

Ht, cm: 158.0 cm	Wt, kg: 61 kg	Head Circ, cm:	Blood Pressure: 130/70 Cuff: 95% Tile: (127/41)
------------------	---------------	----------------	--

General appearance: 61.7 kg - different scale

Head: Asymptomatic
Eyes: Lids

Pupils P_{22} -
Lens SMI
Fundoscopic D_{12} sharp
Ears: Form
Internal T_{15} grey

Nose:
Mouth:

Mucosa no not
Teeth
Gums $clear$
Pharynx

Neck:

General $swollen$ -
Thyroid

Lungs:

Retractions &
Breath sounds $clear = BS$

CV:

Palpation R_{22}
Auscultation no (M)
Other vasculature

Abd: $soft$ - Tenderness $diff$ visible -
Liver Spleen

GU: BS - graft - BLA - not
Perineum $incision$ $infected$
Tanner $Tanner II$ Today

Lymph nodes:

Neck & Axillae &
Groin &

Musculoskeletal:

Gait
Extremities & edema.

Skin:

$(+)$ ACNE

Neuro:

CN
DTR
Orientation $x 3$
Mood
Other

$3.8 / 8.7 / 26.1 / 2.8$

$137 / 87 / 14$
 $97 / 25.4 / 14$

$Ca 8.4$
 $P 4.3$
 $A 3.8$
 $mg - 1.5$

Impression:

15 yo male - slip renal transplant but on PD due to
intra renal venous thrombosis - \rightarrow WBC today, Φ $lymph$
today

Diagnostic tests:

$flow$ to $stop$ $Rapamycin$ -
 $10^2 / 10^4$

Treatments(s):

1) Ac $Rapamycin$ 2) $Ribavirin$ $Tacrolimus$ @ $1.5mg$ po $3x$
3) DIC $misoprostol$ 4) \rightarrow $prednisone$ \rightarrow $12.5mg$ q day .

Patient/parent education:

Follow-up:

5) ~~back~~ on $Transplant$ $list$ - $open$ for $graft$ $rechecked$.
 $1st$ 2 $weeks$ of $December$

Resident's history reviewed, patient interviewed and examined. Briefly, history is

6) \checkmark Fe , $TIBC$, CMV , IgG , PCR , ESR - PCR not $done$ today

On exam, I find

7) $Return$ $next$ ~~$Monday$~~ @ 10 am .

Assessment & plan reviewed with resident.

8) Re \checkmark $Lipid$ $Panel$ in 1 $month$.

I confirm revise the differential diagnosis and care plan as follows:

(CIRCLE ONE)

9) $Calcitriol$ 0.5 mg po q day

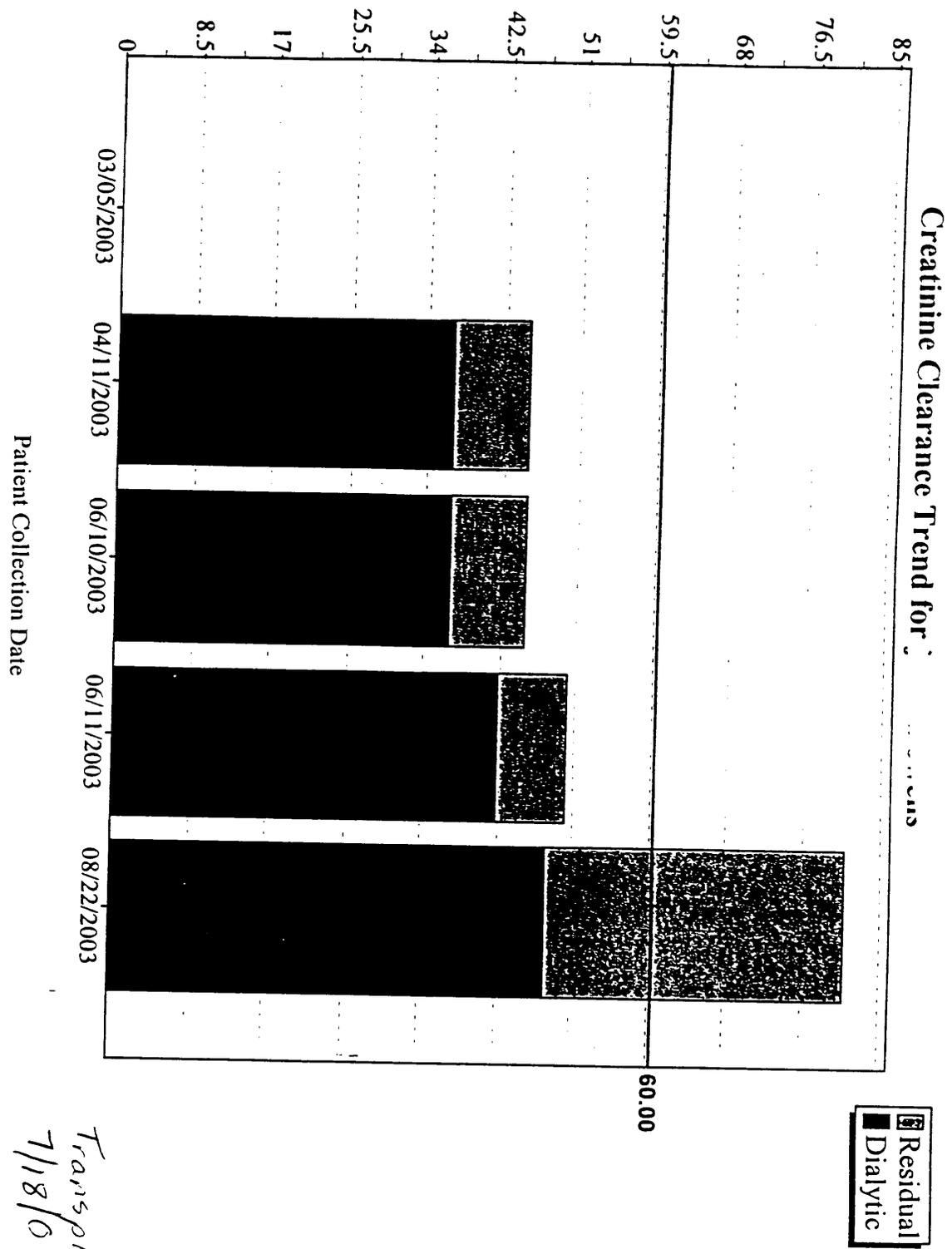
$Restriction$
 $protein$ is
 low fat
 $diet$ -

(Student/Resident)

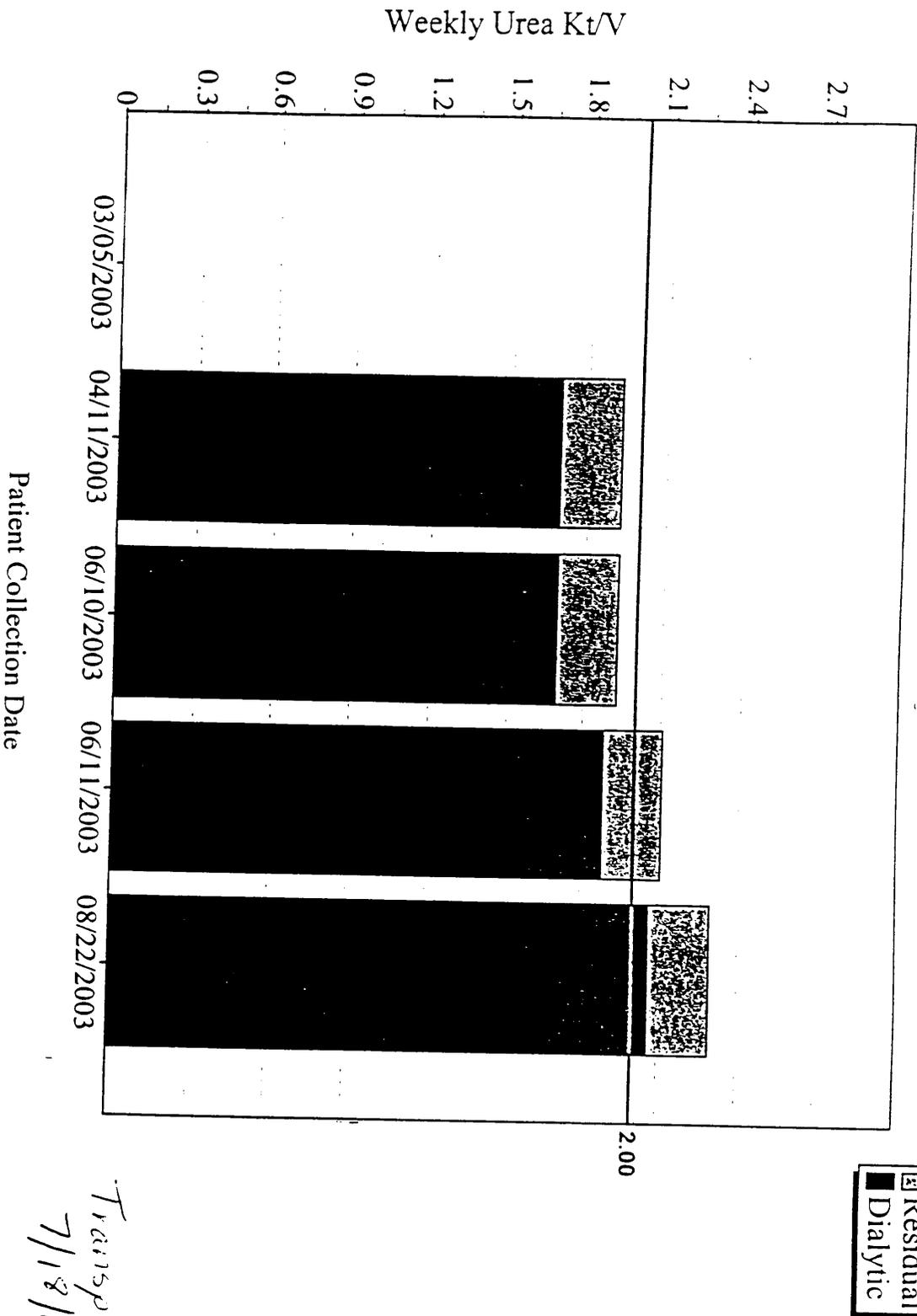
10) $Stool$ $Guaiacs$ (Nephrologist)

WHITE: MEDICAL RECORDS YELLOW: OFFICE COPY

Weekly Creatinine Clearance Trend (L/week/1.73m²)



Kt/V Trend for



*Transplant
7/18/03*

ESRD ASSESSMENT

ADDRESS:

PHONE:

BIRTHDATE 4/22/88		REC. # 1		SS #		EMERGENCY #/ADDRESS		PHONE	
DX		1st DIALYSIS TX		1st CHRONIC TX		DRY WT.		HbA	
HEALTH HISTORY		ALTERATIONS TO INITIAL HEALTH HISTORY		HOSPITALIZATIONS		HIV 9/20/02 induct		ALLERGIES	
ILLNESS		<p>Recorded @ 9/16 p̄ feeling sick for 4-5 days. Initially c/o feeling tired, vomited 1-2x daily starting on 9/12. Seen by MD on 9/16 in which bloodwork was drawn. He had 1 day of loose stools missed several days of school. Mom was called on 9/17 & admitted to abn lab results & BUN 227 Cr 27.3 & H/H 5.8/16 was transfused & supplec. 2 humed treatments done @ good somewhat then they transferred to further workup and management of renal failure.</p>		<p>@ age 3 for urinary to @ under finger</p>		<p>9/12/02</p>		<p>Vecibr</p>	
<p>Chronic disease p 1st humed next in 200 SE later that thick green → improvement / PSYCHIATRIC</p>		<p>ASVD</p>		<p>3.0 mg/l Kt bath</p>		<p>Ⓜ I J ask split cath 23cm</p>		<p>Vecibr</p>	
<p>After at summer - showed amount that actually built returned to normal</p>		<p>ATORY</p>		<p>3.0 mg/l Kt bath</p>		<p>Ⓜ I J ask split cath 23cm</p>		<p>Vecibr</p>	
<p>Loose stools of vomiting</p>		<p>INTESTINAL</p>		<p>3.0 mg/l Kt bath</p>		<p>Ⓜ I J ask split cath 23cm</p>		<p>Vecibr</p>	
<p>noticable in diet</p>		<p>URINARY</p>		<p>3.0 mg/l Kt bath</p>		<p>Ⓜ I J ask split cath 23cm</p>		<p>Vecibr</p>	
<p>LOSKELETAL</p>		<p>DIET/FORMULA/FLUID RESTRICTION</p>		<p>3.0 mg/l Kt bath</p>		<p>Ⓜ I J ask split cath 23cm</p>		<p>Vecibr</p>	
<p>ing school & playing sports. Mom and stepfather</p>		<p>DIET/FORMULA/FLUID RESTRICTION</p>		<p>3.0 mg/l Kt bath</p>		<p>Ⓜ I J ask split cath 23cm</p>		<p>Vecibr</p>	
<p>9/20/02</p>		<p>DIET/FORMULA/FLUID RESTRICTION</p>		<p>3.0 mg/l Kt bath</p>		<p>Ⓜ I J ask split cath 23cm</p>		<p>Vecibr</p>	
<p>D</p>		<p>DIET/FORMULA/FLUID RESTRICTION</p>		<p>3.0 mg/l Kt bath</p>		<p>Ⓜ I J ask split cath 23cm</p>		<p>Vecibr</p>	

ESRD CARE PLAN

REC. #

B.D. 9/22/88

DATE 9/24/02

UPDATED

IT/FAMILY PROBLEM
Why due to
wldg deficit

INTERVENTION/PLAN

- 1) Explain all procedures prior to performing them
- 2) Allow them to visit the HD unit & forming dialogues
- 3) Encourage them to talk 2 other families who have children & kidney disease.
- 4) Provide reading material for families
- 5) Encourage to ask questions
- 6) Involve parental care if family interested
- 7) Involve child life for role playing
- 8) Include patient on treatment plan and decision making

for anemia
to worsening
functions

- 1) Monitor H/H weekly as ordered
- 2) Emphasizing the importance of med compliance & Fe.
- 3) Administer Erygen as ordered
- 4) Monitor von studies as ordered
- 5) Monitor vs that might be affected due to anemia:
 - a) tracing cardiac, v/bio
 - b) monitor achinhy level
 - c) monitor skin color
- 6) Monitor circuit for + blood loss: blood leaks, clots in dialyzer, + bldg from access
- 7) Monitor pt. for blood loss in other systems i.e. dark stools
- 8) Monitor circuit for hemolysis: churning red blood.
- 9) Monitor for infection: +T, site warm/red

HOME HEALTH CARE

N/A

DISCUSSED CCPD 9/21	(date/initials) HEMO 9/18/02	TRANSPLANT N/A	DATE & TYPE PERMANENT ACCESS Bakdash cath 9/8/02
	R.O.		
	TX 1/1/1		DATE DIALYSIS STARTED 9/20/02

VERBALIZES UNDERSTANDING	DEMONSTRATES KNOWLEDGE	NEEDS REINFORCEMENT
9/24/02 - spent a lot of time regarding chronic illness 10/02, 11/02, 12/02, 1/03, 2/03, 3/03, 4/03, 5/03 Returned to school 10/03	large time & from and step	pen

H/H upon admission to Rehabilit. in 10/02, 11/02, 12/02, 1/03, 2/03, 3/03, 4/03, 5/03. Erygen held due to + H/H

SHORT TERM GOALS/EXPECTED PT. OUTCOMES
H/H will be in range, hct > 34
w/ dialysis

LONG TERM GOALS/EXPECTED PT. OUTCOMES
Med compliance due to + knowledge about disease
emphasize will improve & + knowledge

ESRD CARE PLAN

REC. # _____ B.D. 4/22/88 DATE 9/24/02

UPDATED _____

T/FAMILY PROBLEM	INTERVENTION/PLAN	VERBALIZES UNDERSTANDING	DEMONSTRATES KNOWLEDGE	NEEDS REINFORCEMENT
<p>rate of electrolyte levels due to rising kidney function</p> <p>8 bleeding due to irregular</p>	<ol style="list-style-type: none"> 1) Monitor labo as ordered 2) Assess Kt levels & Δ both accordingly 3) Assess P₂ levels & assess compliance by meds emphasize the importance of phosphorus binders 4) Assess pre/post BUN and URE - If < 65% inform physician so appropriate dialysis Δ's can be made. 5) Monitor dialysis SD conductivity, pH & temp are acceptable 6) Monitor vs during treatment: ureg HE, Wt/BP, T₁HR, ↓VT ↓URE 7) Monitor equipment so delivery remains in range (age) 8) Inform the pt to tell nurse if any occur: Nausea, h/a, restlessness, dry case thirst 9) monitor for hemolysis - chry red blood (venous) have pt notify if SOB, chest pain, hiccups, generalized pain occurs 10) Administered anticoagulant medicine as ordered 11) Monitor ACT's during treatment (adjust accordingly) 12) Assess pt. for any bleeding that might occur @ site 13) Assess pt for bleeding that might occur in other areas of body ie: stomach, nose bleeds, bruising 14) Obtain NH and clothing things as ordered 15) Teach patient reasoning behind antineoplastic 16) Inform patient to notify physician of complications of bleeding, bleeding @ site, electrical cap from perm cath 17) Provide pt. with upon dep cath to hold perm cath 18) Kill pt to avoid physical contact sports 	<p>✓</p> <p>BUN 220's on adm, Cr 2.73 Kt @ 3.5 - using 3.0 H bath act 4 S.D. Dialyzed 2 daily since adm to 4th venor</p> <p>10/2 - visit with mom is unable to return to work as out patient ID F health care from home 3/03 003, 1/03, 11/03</p>	<p>✓</p> <p>dialyzed @ 4th venor until break tumor to Cr 4 F having 263 - Δ to PD + during well on PD 4/03, 5/03</p>	<p>POW</p> <p>surgery - Cath - HD home 1/15 plan to Δ to PD + transcribing PD 4/03, 5/03</p>
<p>UTOR</p>	<p>HOME HEALTH CARE</p> <p>N/A</p>			<p>SHORT TERM GOALS/EXPECTED PT. OUTCOMES</p> <p>Further complications from abnormal labo will not occur change will be thru in to normal level</p>
<p>5 9/21</p> <p>DISCUSSED 9/61 (date/initials)</p> <p>CCPD</p>	<p>HEMO 9/10</p> <p>TRANSPLANT N/A</p>	<p>DATE & TYPE PERMANENT ACCESS</p> <p>28 CALASH CATH - 9/18/02</p>	<p>DATE DIALYSIS STARTED</p> <p>9/20/02</p>	<p>LONG TERM GOALS/EXPECTED PT. OUTCOMES</p> <p>transplant, labo will be in normal range, no complications will occur due to electrolyte</p>

ESRD CARE PLAN

REC. #

B.D. 4/aa/88

DATE 9/24/82

UPDATED

FAMILY PROBLEM

re for fluid level due to rising kidney

INTERVENTION/PLAN

- 1) Review the importance of fluid compliance a/nm & mother & effects on body.
 - a) F.B.P, b) CHF, c) pulmonary edema, d) H/H
- 2) Have pt demonstrate measuring fluids
- 3) Inform pt of fluid restriction: 1000ml/day
- 4) Monitor pt weight - wt gains ~ 1.0 kg between treatments, 1.2 kg on uremia.
- 5) Monitor neck vein distention, HR, RR
- 6) Monitor for anemia
- 7) Monitor dietary restrictions: Na+ → 4g/m
- 8) Assess degree of residual function
- 9) Monitor for dehydration: W/D eyes sunken, haring, J.B.P dry mucous membranes
- 10) Inform of foods that may be liquid status: rice, cere, etc
- 11) Follow treatment for wt gain: 3 OK
- 12) Encourage hard candy, gum if fluid status remains out of control.
- 13) ✓ B.P @ home as ordered.
- 14) Dietary consult
- 15) Encourage foods other than meat/meat/during run
- 16) Attempt to find supplements to which pb delays
- 17) Monitor lab as ordered: Bun, Cr, Pns, Na, H/H MS by alb: keep ^{weight gain} ^{weight gain} ^{weight gain}
- 18) Monitor for any Pica episodes
- 19) Assess weight: determine between fluid & actual wt. gain
- 20) Monitor for any N/V especially if vomit
- 21) Monitor for lunch modeling
- 22) Encourage more than one meal/day
- 23) Dietary change if wt. loss occurring
- 24) Monitor activity level

HOME HEALTH CARE

N/A

DISCUSSED 9/21

CCPD 9/21

HEMO 9/18

TRANSPLANT

AD 7.8

TX

DATE & TYPE PERMANENT ACCESS

Rebutal adreach 9/18/82

DATE DIALYSIS STARTED

9/20/82

VERBALIZES UNDERSTANDING

DEMONSTRATES KNOWLEDGE

NEEDS REINFORCEMENT

Currently is not on fluid restriction.
 10/2, 11/02, 12/02, 1/83, 2/03, 3/03, 4/03, 5/03, 6/03

9/02, 10/02 - rd/m for vomiting/diarrhea,
 febrile
 11/02, 12/02, 1/03, 2/03, 3/03, 4/03, 5/03, 6/03, 7/03 - appetite
 good. 11/03 - appetite increased & steroids.
 weight maintained during short and period
 of hospitalization kidney placement

SHORT TERM GOALS/EXPECTED PT. OUTCOMES

fluid status will be optimum
 a) Peritite will improve.

LONG TERM GOALS/EXPECTED PT. OUTCOMES

Ability to transport → long term
 heart problems will be alleviated.
 Hearing will not be delayed due to
 poor nutritional status.

ESRD CARE PLAN

REC. # _____ B.D. 4/22/82 DATE _____

UPDATED _____

FAMILY PROBLEM	INTERVENTION/PLAN	VERBALIZES UNDERSTANDING	DEMONSTRATES KNOWLEDGE	NEEDS REINFORCEMENT
<p>1) for diarrhea 2-11(15/82)</p>	<p>1) Monitor I/O 2) Daily weights 3) Lab-test of stools as ordered: (+) for c/d/y 4) Monitor vs COP Temp & BP 5) continue to support E-hand 6) monitor CxR as ordered - chest wht'd out & bidat 2/18/82</p> <p>Obtain as ordered: <input type="checkbox"/> CMV "1/83 <input checked="" type="checkbox"/> EBV (+) "1/83 <input checked="" type="checkbox"/> Hepa "1/83 <input checked="" type="checkbox"/> Hep C "1/83 <input checked="" type="checkbox"/> Hep B/AB "1/83 <input checked="" type="checkbox"/> HIV "1/83</p> <p>Varicella (+) VULV 9/22/82 - om</p>	<p>Decided to be transferred to stool output of watery diarrhea and blood and clumping times unmanageable, 2-Dinner out of average pus stria dice <u>Resolved</u></p>	<p>transplanted 7/1/83 - developed poor renal vein blood flow to transplant - returned to E in 30% of explant - had large clot in renal vein to transplant - never regained enough function to cont. on PD</p>	<p>pill due to unmanageable pus stria dice</p>
<p>7/17-8/3/83) transplant > 120</p>	<p>1) Obtain as ordered 2) Review complications & family 3) Start to review meds & family 4) Start to explain procedure, happenings of transplant</p> <p>1) convert to field 2) Review complications that could occur 3) Review visiting policies, activities in lines 4) Talk about different needs used supply done 8/6/83</p>	<p>emergent surgery 7/19 due to poor blood flow urine output low functional (compressed) - urine output + -> RTN -> back on PD 8/15/83 - continued on PD. urine output large - continued on urined spacer</p>	<p>pen</p>	<p>pen</p>
<p>1) TOR homebound red due to not all 7 treatments</p>	<p>OT/PT N/A HOME HEALTH CARE N/A</p>	<p>SHORT TERM GOALS/EXPECTED PT. OUTCOMES Become injection free, absence of pleural effusions</p>	<p>LONG TERM GOALS/EXPECTED PT. OUTCOMES Transplant</p>	<p>pen</p>
<p>1) DISCUSSED CCPD 9/21/82</p>	<p>HEMO 9/18/82 TRANSPLANT N/A</p>	<p>DATE & TYPE PERMANENT ACCESS 28 cm cath 9/18/82</p>	<p>DATE DIALYSIS STARTED 9/20/82</p>	<p>pen</p>

ESRD
MARCH 17, 2003

MEMBERS PRESENT:

OTHERS PRESENT:

[
f
:

PATIENT

COMMENTS

O. C.	Next clinic visit will start transition to Adult Nephrology.
H. F.	Will need prolonged dialysis after recurrence of Wilm's Tumor. Will plan a PET scan prior to transplant in about 15 months if no evidence of recurrence prior to that time.
E. C.	Having pain over kidney and low grade temp last week, on PD. She was scheduled for a transplant nephrectomy, however pain and temperature disappeared overnight so nephrectomy was cancelled for now. Off Tacrolimus, blood pressure better.
F. G.	Dr. [] saw last week, making some progress. Last immunization's were completed on 3/11/03. Weight 9.8 kg, Slowly gaining weight. Middle of May earliest time for transplant. His father is being evaluated for LRD transplant.
J. J.	Hospitalized March 3-5, will need to start hemo dialysis soon. He will be having blood work done every 1-2 weeks.
C. M.	Remains in PICU – condition is progressively worsening.
J. N.	PET test over spring break to help with dialysis prescription. Weight 25 kilos. Mom has begun evaluation for transplant. Hope to do LRD transplant over the summer.
J. M.	Creatinine 2.3, Mom does not want him to start on growth hormones. Missed appointment, rescheduled next week.
J. W.	Stable on hemo dialysis. Meeting with family to discuss compliance issues (major noncompliance with fluid restriction, doing better with taking medications). Psych appointment next week and to see psychologist on a regular basis. Plan to list for cadaver transplant if compliance improves.

ESRD
PAGE 2

PATIENT

E. W.

COMMENTS

PET test last week to help with dialysis management on PD. Just started Valproic acid for seizures. Continues to have extensive physical therapy, OT, and speech therapy.

J. O.

PET test a week ago to help with dialysis management, back in school on CCPD. Uncle having work up done for transplant. Hope to transplant during the summer.

J. J.

Transferred to adult nephrology.

B. R.

Did not keep appointment last week.

W. R.

Creatinine clearance 18. Mom's friend wants to be evaluated as a potential donor. If BP stable and coagulation status is normal, potential candidate for preemptive transplant.

Approved:

Director, Division of Pediatric Nephrology

/mrj

CC.

ESRD
APRIL 14, 2003

MEMBERS PRESENT:

OTHERS PRESENT:

<u>PATIENT</u>	<u>COMMENTS</u>
H. F.	Hospitalized for enterococcal sepsis, also had rotavirus. Dad has brain tumor, will go to SLU for surgery early to mid May.
E. C.	Urine out put worsening, creatinine is rising, have increased PD prescription. BP medicines increased to lower BP.
F. G.	VCUG normal for pre transplant evaluation. Coming later this week for an ultra sound of IVC to make sure of patient IVC pre transplant.. Weight 9.8 kg.
J. J.	Here two weeks ago doing better. BP 140/90
J. N.	met with Mom – she needs to lose about 23 more lbs. Hoping to have most of the weight off by early June to be able to transplant this summer.
J. M.	Having trouble with textured foods, coming for Barium swallow test April 22, 2003.
J. W.	Multiple issues regarding compliance before listing for transplant. Needs to see psychology on a regular basis. will contact
E. W.	Walking with less help, and more alert. Valporic acid dose has been increased by Neurology trying to improve seizure control. Continues on PD. Home health terminated. Mom started antidepressants and seems to be doing better.

ESRD
PAGE 2

PATIENT

U. -


COMMENTS

Stable on PD. Learning to do epogen shots himself. KT/V 1.9. Possible transplant this summer.

Creatinine ~ 5, has not been seen since October, 2002. Has another appointment scheduled soon.

Transplant – meeting with family this week.

) Approved:

Professor of Nephrology
Director, Division of Pediatric Nephrology

/mrj

cc:

MEMBERS PRESENT:

OTHERS PRESENT:

on.

PATIENT

COMMENT

Hemo catheter exchanged for new line due to recurrent enterococcal infection. Infusaport removed. Dad will have appointment at SLU with neurosurgery in a couple of weeks concerning possible brain tumor.

Hospitalized 2 weeks for shoulder and arm pain complicated by peritonitis and pseudotumor cerebri. Has appointment next week with Dr. Mom and Dad having problems and refusing marital and family counseling.

Scheduled for LRD transplant on 5/14/03. Final cross match drawn this am. Right internal jugular vein not patent, general surgery to place central venous access in OR prior to transplant. Dr. met with mother and to meet with father today reviewing procedures and risks associated with transplant and immunosuppression.

Started dialysis April 21, 2003. Problems with non-compliance and to see psychiatry. PPD done today due to exposure at babysitting. Patient not self-cathing, family aware that this necessary prior to and after transplant.

Follow up this week. Mom has lost some weigh, with plan to hopefully be donor. Discussion held regarding removal of native kidneys prior to transplant due to reflux, hydronephrosis.

Next appointment will have Barrium Swallow. Will also talk with Mom about growth hormone. Seen by Dr in endocrinology.

Gaining excess weight between dialysis treatments. BP elevated. Echocardiogram good. Family conference held in March concerning non-compliance. Made a "Make a Wish" trip to Florida.

PATIENT

COMMENT

Was here 2 weeks ago. More anemic since valproate dosage increased to help with seizures. Iron studies good. Epogen dosage adjusted. Weight up to 18.8 kg. PD setting adjusted to lengthen dwell time to try to improve urea clearance.

Doing well on home PD and in school. Uncle to be donor for transplant tentatively scheduled for 6/24/03. Coming next week for complete work up.

Appointment this month. Last lab work in Jan 2003. Missed last appointment. Holding off on A/V graft until closer to starting hemodialysis.

To complete 24 hour urine to reassess creatinine clearance and proteinuria. Needs serologic tests and VCUG to complete workup. Mom has lost insurance.

Approved:

Associate Professor of Pediatrics
Division of Pediatric Nephrology

Cc:

ESRD
JUNE 9, 2003

MEMBERS PRESENT:

OTHERS PRESENT:

1.
ms.

PATIENT

COMMENTS

Transplant delayed due to development of enterococcal peritonitis. Treated with 14 days intraperitoneal antibiotics. Culture from PD exit site growing yeast on day four in one of the tube, identification in progress. Repeat culture pending. Climbed out of crib and pulled Tenckoff apart – mom put it back together. Placed on Ancef in PD fluid. Returning this week to check PD site and repeat culture. Needs ultrasound of right subclavian with sedation to assess patency prior to transplant. Mom and Dad are back together. LRD transplant scheduled July 9, 2003.

Seeing a psychiatrist today at hospital. On hemodialysis M-W-F, has a perm cath in place. Cholesterol and weight up; will talk to Mom about giving diet drinks only.

Developed Staph Epidermidis peritonitis the day before leaving for camp after he contaminated his catheter and no one called until the next morning. The last night of camp had abdominal pain – did a PD cell count upon return – 338 white cells, 60% eosinophils. Remain on intraperitoneal vancomycin: coming to clinic tomorrow. Mother still interested in being donor, but weight loss moving slow. Will need nephrectomies before transplant. To discuss proceeding with this and placing on cadaveric list while Mother continues to work on weight loss with her at clinic appointment.

Non compliant with fluid restriction - went to two weeks ago for excessive weight gain. Not gaining excessive weight at but may have to leave sooner than planned. -- will try to get extension based on behavior issues. Needs to have fistula restudied pulling off a lot of clots during hemo. Tested last week by , mom saw in Psychology.

Will be in clinic tomorrow – asked to bring effluent for urea clearance. Needs a final cross match on 6/20/03. Transplant 6/25/03.

PATIENT

COMMENT

Last creatinine 4.7, creatinine clearance 26.4 ml/min/1.73 m2. 24 hour protein excretion 4.29 grams, and serum albumin 4.6. Will need to schedule coagulation studies with Dr. prior to proceeding with transplant due to proteinuria to exclude hypercoagulable state.

Went to renal camp. Continues to have some elevated BP. Should be able to stop oral gancyclovir. Patient refuses to see a counselor.

Has moved out of a crib to the regular hemodialysis chair. Came in hypertensive about ten days ago. Eating 200-300 calories on her own. Dad had MRI to evaluate possible brain tumor, surgery date not yet set.

Non complaint – admitted to when serum creatinine 6.4, serum calcium 6.3. Last week had ultra sound of left subclavian showing patency. May be ready for A/V grafdt soon..

No change, will stay on growth hormone

Valproate acid dose lowered due to worsening anemia, so far no increase in seizure frequency. Needs dental work. Walking now just holding her hands. Labs will be done end of this week.

Congenital cystic kidney problems. Steady rise in creatinine since December. In hospital last week for IV fluids – no change in creatinine. Getting a PEG today at Needs Varicella and DPT. Dad has hypertension.

EBV positive. Developed acute renal failure – will have biopsy this week. Developed hypertension, wants to do PD.

First transplant August, 1992 - has chronic allograft nephropathy. Hospitalized about 1 month ago for hypertension (168/112) went home on Labetalol and Norvasc. Labs last night with a BUN of 62 and creatinine of 4.0, cyclosporine level at 124.

ics
JY

Cc:

November 05, 2003

Re:

Dear and Family,

I am writing this letter on behalf of the Pediatric Transplant Team at to inform you that was listed for kidney transplant with the United Network of Organ Sharing (UNOS) on Monday November 03, 2003.

If you would have any questions regarding his listing please feel free to contact me at

Sincerely,

Transplant Coordinator
Transplant Services

cc:

December 2, 2003

United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218

RE: – Wait Time Adjustment Request

Dear Dr. Leichtman:

Per the Kidney/Pancreas Transplantation Committee request, I have enclosed the documentation supporting intent to list Mr. f as of June 26, 2000. Mr. completed his final diagnostic test on 6/26/00 and was medically cleared to be listed for a kidney transplant.

Please contact me at f you have any questions.

Sincerely,

cc: Transplant File

October 15, 2003

Dear Dr.

This letter is in reference to your request for a waiting time adjustment under OPTN/UNOS Policy 3.2.1.8 for social security number _____.

This policy provides a mechanism to request an adjustment to a patient's kidney or pancreas waiting time on the UNOS Computer. The policy allows time to be reinstated in several specific cases without review by the appropriate OPTN/UNOS committee or Board of Directors. In all other cases (not otherwise addressed in OPTN/UNOS policy), the request, at the time your application was submitted, had to be:

- Approved by unanimous agreement among the kidney or pancreas (as applicable) transplant hospitals within the local area in which the patient is listed and submitted to UNOS for consideration with appropriate supporting documentation, or, if such agreement cannot be obtained despite efforts to do so, submitted to UNOS for consideration along with reasons provided by the dissenting party(ies) for any disagreement and other appropriate supporting documentation;
- Reviewed by the OPTN/UNOS Kidney and Pancreas Transplantation Committee; and
- Approved by the OPTN/UNOS Board of Directors, or Executive Committee subject to ratification by the full Board (this criterion has now been modified to allow the Committee's decision to be implemented upon completion of computer programming, with retrospective reporting to the Board).

Policies 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients) and 3.8.7 (Waiting Time Reinstatement for Pancreas Recipients) provide separate mechanisms for requesting adjustment to a patient's kidney or pancreas waiting time in the event the patient has received a transplant and experienced immediate and permanent non-function of the graft.

The Kidney/Pancreas Transplantation Committee has reviewed your request for a waiting time adjustment under Policy 3.2.1.8 for Mr. _____. The application includes signatures indicating approval from the appropriate kidney transplant programs. However, the application does not indicate whether the patient met waiting time criteria (*i.e.*, either on dialysis or creatinine clearance level or GFR less than or equal to 20 ml/min) as of the listing date requested. The application also includes no documentation supporting intent to list the patient as of June 26, 2000. The Committee, therefore, recommended approval of the

President
Russell H. Wiesner, M.D.

Vice President
Robert A. Metzger, M.D.

Vice President
Patient & Donor Affairs
Paul B. Oldam, B.S.S.

Secretary
Marc J. Lorber, M.D.

Treasurer
Dean F. Kappel, M.S.W.

Immediate Past President
Clyde F. Barker, M.D.

Regional Councilors
George S. Lipkowitz, M.D. (1)
Andrew S. Klein, M.D. (2)
Shirley D. Schlessinger, M.D., FACP (3)
Kristene K. Gugliuzza, M.D. (4)
John P. McVicar, M.D. (5)
Douglas E. Wood, M.D. (6)

Christopher P. Johnson, M.D. (7)
Cass Franklin, M.D., FACS (8)
Frank S. Szmalc, M.D. (9)
Mark D. Pescovitz, M.D. (16)
P. R. Rajagopalan, M.D. (11)

At Large Board Members
Margo L. Auerman, M.S.
The Hon. Antonio Bened.
Ronald W. Busutil, M.D., Ph.D.
Anthony M. D'Alessandro, M.D.
John Davis
Richard J. DeSanto, M.D.

Melissa J. Doniger, I.D.
Barry S. Friedman, RN, BSN, MBA, CFTC
Rose Marie Gray-Finnell, ARRT (R)
Jackie L. Johnson, MSW, LICSW
Lloyd H. Jordan, Jr., CPA
Bertram L. Kassis, M.D.
Sharon C. Kiehl, M.D., MPH
Helen W. Leslie, RN, CFTC
Donna L. Luebke, RN, MSN, CNP
Stephen M. Oelrich
Esther Padilla, M.S.W.
W. Steves Ring, M.D.
Charles Bruce Robinson, Ph.D.

Margaret J. Schaeffer, RN, CPTC
Nancy L. Sensi, RN, BSN, CPTC
Charles F. Shield, M.D.
Juán J. Tisdale, Ph.D.
Adriana Zeest, Ph.D.

Past Presidents
G. Melville Williams, M.D. 1984-85
Oscar Salatierra, Jr., M.D. 1985-86
John C. McDonald, M.D. 1986-88
H. Keith Johnson, M.D. 1988-89
Robert J. Corr, M.D. 1989-90
James S. Wolf, M.D. 1990-91

Robert Mender, M.D. 1991-92
R. Randal Bollinger, M.D., Ph.D. 1992-94
Douglas J. Norman, M.D. 1995-94
Margaret D. Allen, M.D. 1994-95
Bruce A. Lucas, M.D. 1995-96
James F. Burdick, M.D. 1996-97
Lawrence C. Hunsicker, M.D. 1997-98
William W. Pfaff, M.D. 1998-99
William D. Payne, M.D. 1999-2000
Patricia L. Adams, M.D. 2000-2001
Jeremiah G. Turcotte, M.D. 2001-2002

Executive Director Emeritus
Gene A. Pierce

adjustment of the waiting time pending receipt of documentation verifying that the patient met waiting time criteria as of June 26, 2000 and receipt of documentation supporting intent to list the patient as of June 26, 2000. This recommendation was approved by the Board of Directors on June 26-27, 2003.

If you have any questions regarding this matter, please do not hesitate to contact Cindy Sommers, UNOS Director of Allocation Policy, by telephone at (804) 782-4867 or by electronic mail at sommercm@unos.org.

Sincerely,

A handwritten signature in cursive script that reads "Alan B. Leichtman" followed by a stylized flourish.

Alan B. Leichtman, M.D., Chair
OPTN/UNOS Kidney and Pancreas Transplantation Committee

RENAL TRANSPLANT CLINIC
NEW PATIENT EVALUATION

DATE: 03/08/00

NAME:

SUBJECTIVE:

Mr. is a 59 y/o African-American male with end-stage renal disease, secondary to diabetic nephropathy, who presented to the Renal Transplant Clinic for his initial evaluation as a potential renal transplant recipient.

KIDNEY HISTORY:

The patient stated that he was first told that he had kidney problems in 1998. He was started on dialysis on March 1, 1998. He is currently undergoing hemodialysis three times a week on Tuesdays, Thursdays, and Saturdays at Hospital. He is under the care of Dr. . His target weight is 77 kg. He stated that he makes about less than one cup of urine each day.

INFECTION HISTORY:

The patient had a skin test for tuberculosis in October of 1996 and this was reportedly negative. He denies any history of tuberculosis. There is no history of infection in the bladder or kidneys that required hospitalization. The patient stated that he has never been tested positive for HIV, hepatitis C, or hepatitis B.

CARDIOVASCULAR HISTORY:

There is a history of hypertension for about a year and patient currently takes medication for his blood pressure. Patient denies prior history of heart attacks, stroke, pericarditis, problems with heart valves, and there has been no open-heart surgery.

GASTROINTESTINAL HISTORY:

The patient was told that he had two stomach ulcers about six months ago after an EGD; he reports being treated for these.

CANCER HISTORY:

There is no personal history of cancer in the patient.

DIABETIC HISTORY:--

Patient was diagnosed with non-insulin-dependent diabetes mellitus when he was 36 years-of-age. He states that there is a family history of diabetes in his brother and maybe his sister. He denies episodes of DKA. Patient admits to retinopathy and stated he had laser treatments to both of his eyes. Patient stated that he is legally blind in one eye.

RENAL TRANSPLANT CLINIC
NEW PATIENT EVALUATION

DATE: 03/08/00

Page: 2

NAME: ,

DIABETIC HISTORY: continued

He also admits to diabetic neuropathy, but denied gastropathy or problems with nonhealing foot ulcers. Patient has never been on insulin and he was maintained on oral diabetic medications. He states that he has a glucometer at home and checks his blood sugars once daily; blood sugars have been 110-130 at home.

NEUROPSYCHIATRIC HISTORY:

There is no history of prior hospitalization for psychiatric problems. The patient stated that he was never under the care of psychiatrist and does not take medication for psychiatric problems. Patient also denied any previous history of seizure disorder.

SURGICAL HISTORY:

Patient had surgery to his eyes in August of 1998 for glaucoma at Hospital. He had right upper extremity AV graft placement in February of 1999 at the same hospital.

CURRENT MEDICATIONS:

1. Renagel and Os-Cal: with meals
2. Nephrocaps: 1 q.d.
3. Glyburide: 7.5 mg q.a.m. and 5 mg q.p.m.
4. Lansoprazole: 15 mg b.i.d.
5. Minoxidil: 2.5 mg b.i.d.
6. Fosinopril: 40 mg q.d.
7. Cisapride: 10 mg b.i.d.
8. Clonidine: 0.1 mg t.i.d.

ALLERGIES:

He has no known drug allergies.

TRANSFUSION HISTORY:

Patient stated that he thinks he might have been transfused last year with about one pint of blood.

TRANSPLANT HISTORY:

There is no previous history of transplantation in the patient.

FUNCTIONAL STATUS:

The patient states he has no activity limitation.

SOCIAL HISTORY:

The patient has been separated for about ten years.

RENAL TRANSPLANT CLINIC
NEW PATIENT EVALUATION

DATE: 03/08/00

Page: 3

NAME:

SOCIAL HISTORY: continued

He lives with his son. He has three children; a son 24 years-old, a daughter 23 years-old, and a son 10 years-old. He is retired; he use to work as a food service manager in the City of New York Board of Education. He completed three years of college. Patient stated that he quit drinking alcohol in 1976, after about ten years of drinking about half-a-pint per day. The patient stated that he never smoked and never used illegal drugs.

FAMILY HISTORY:

The patient has a 24 y/o son, who is alive and well, and a 23 y/o daughter, who is also alive and well. The patient has a 57 y/o brother with diabetes mellitus on insulin and a 56 y/o sister who is alive and well and currently living in Alexandria, Virginia.

PHYSICAL EXAMINATION:

General: this was a 59 y/o African-American male, alert and oriented times three, in no acute distress.

Vital Signs: blood pressure 120/60 mmHg, heart rate of 72, height 5'10", weight 78.9 kg.

HEENT: was unremarkable.

Neck: was supple, no jugular venous distention, no carotid bruits, no lymphadenopathy.

Lungs: chest was clear to auscultation bilaterally.

Cardiovascular: heart was regular rate and rhythm, a II/VI systolic ejection murmur at left sternal border was audible, no rub.

Abdomen: was soft, nontender, nondistended, with positive bowel sounds, no organomegaly could be appreciated.

Extremities: with no edema and rather distal peripheral pulses.

Neurological: was intact.

IMPRESSION:

1. Mr. _____ appears to be an acceptable medical candidate for activation on the renal transplantation waiting list.

PLAN:

1. As start of his prerenal transplant evaluation, Mr. _____ will have to undergo cardiac catheterization, ultrasound of his right upper quadrant, a colonoscopy (patient reported that he had recent colonoscopy at _____ in February of 2000; we will try to obtain the records), chest x-ray, EKG, VCUG, dental examination, PPD with control, and PSA examination; will also check laboratory data, including serologies, today.

RENAL TRANSPLANT CLINIC
NEW PATIENT EVALUATION

DATE: 03/08/00

Page: 4

NAME:

PLAN: continued

2. Return to our clinic as instructed.
3. Patient was instructed to talk to his family members in order to determine if there would be any family member that could be considered as a potential living-related or unrelated donor for his kidney transplant.

M.D.

Renal Fellow

, M.D.

Associate Professor of Medicine and Surgery
Division of Nephrology

PATIENT INFORMATION (Stamp Patient Plate-Front and Back) Page _____ of _____ Pages

DATE	TIME	NOTES
	02/26/00	FAS-A Cardiology attending: Dr. _____ See Hx of 4/10/00. ✓ Additional hx. - Although no hx C.A.D. H - does give hx chest pressure at discomfort nocturnally resolves w/ sitting up & 1 hour. He attributes to "gas" No C.P. & activity. UGI - 1 wk. ago, results unknown - PMN: additional to recorded. Hx CVA - 2 yrs. ago, permanent blindness O.S. Told he had "blockage on left." Med. - - NO longer taking Prevacid & cissap - Cessit tabs. Nephrocaps T qd. glyburide 5g BID Minoxidil 8.5g BID Bactrim T qd (x4 days for U Fosinopril 40g qd. Clonidine .2g BID = 1g @ noon. PE: afelaxie HEENT - coracids + 3 @ bil. limit. L - clear CV - RRR 5.5g - WNL, gi. 1/2 sys. (u) loudest' 2nd L ICS. Abd - benign ExtR - femorals + 2, & limit.

MEDICAL RECORDS COPY

PATIENT INFORMATION (Stamp Patient Plate-Front and Back) Page _____ of _____ Pages

DATE	TIME	NOTES
6/26/00	1340	Post-Cath Note
		Procedure: (R) + (L) Int. cath. LV
		Operators: J. P. Suh
		Complications: None
		Access: (R) fem. art.
		Results: Full report to follow.
		Cath F/U
		Cath shows CAD involving 2 marginal branches of Lcx - ~ 70-75% narrowing in 1 st marginal - mid size distal vessel + ~ 60% narrow in 2 nd marginal - mid size distal vessel.
		LAD has mild irregularity + RCA has no signif narrowing.
		LV angiogram mild gen hypokinesis - EF ~ 40-45%.
		No clear evid of ischemia, although has some atypical dwarfed at night or which may be of GI origin.
		Plan: Stress nuclear study to eval for ischemia.
		Angioplasty of marginal branches feasible if evid of signif ischemia. If no major ischemia, then should be OK for kidney transplant.
		Also add ASA (qd) + TNE PRN.
		Discharge later today (out pt care)
		Dialysis tomorrow at usual center.
		Followup - Dr. _____

MEDICAL RECORDS COPY

MATRIX #18269 HOSP# 1 11/28/01 03:31 PM
DYNAMIC MATRIX
p176Y

11/28/01 03:31 PM PAGE 001 LAB RESULT RETRIEVAL (Q2E
AGE: 060 SEX: M MR#:
LABORATORY RESULTS FROM 11/28/99 12:00 MN THROUGH 11/28/01 11:59

=====

p512Y TYPE (ABORH)
SPEC'M 03/08/00 09:35 AM

p608Y PT ABORH 0 POS !

p800Y ANTIBODY SCREEN
SPEC'M 03/08/00 09:35 AM

p896Y ANTIBODY SCREEN . NEG !

*p992Y

RETURN	NEXT	MASTER	REVIEW
ERR	TYPE	RETRIEVE	TIME-SCHED

p1424Y
--*

M 062 6

HM PH: 2 SERV:CLIN TRANS - RENAL REG: 06/04/02 CLINIC: CLTR
ATTENDING MD: L. REFERRING PHYS: ,DR.
===== REPORT PERIOD: 06/07/02 01:10 AM - 06/10/02 01:10 AM =====
PRIMARY CARE PHYSICIAN:

HEP B SRF AB QN
SPEC'M 06/04 11:40 AM

HEP B SAB QUANT . NEGATIVE MIU/ML ! UNDEFINED
HEP B SURFACE ANTIBODY
REFERENCE RANGE EQUALS
NEGATIVE
FOR VACCINATED INDIVIDUALS A
VALUE OF >10 MIU-ML INDICATES
A PROTECTIVE ANTIBODY RESPONSE.

HEP B CORE AB
SPEC'M 06/04 11:40 AM

HBCAB TOTAL NEGATIVE ! (NEG)

-*- END OF LAB REPORT -*-

ORDERS NOT YET RESULTED THAT HAVE BEEN RECEIVED BY THE LAB OR THAT
WERE ORDERED SPECIMEN COLLECTED, OR THAT HAVE BEEN MARKED IN
PROCESS BY AN ANCILLARY DEPARTMENT:

06/04/02 QUANT HCV BY PCR (VIRAL LOAD), PERIPHERAL BLOOD....
DESTINATION 35, SST TUBE. CENTRIFUGE TUBE WITHIN 1/2 HOUR.
NO HEMOLYSIS. FREEZE SERUM AT -20 DEGREES CELSIUS WITHIN 4
HOURS., TODAY, (06/04/02)

LAST PAGE

-*-

=====
OUTPT TEST RESULTS
=====

M 062

HM PH: SERV:CLIN TRANS - RENAL REG: 06/04/02 CLINIC: CLTRN
ATTENDING MD: L. REFERRING PHYS: Y,DR.
=====
REPORT PERIOD: 06/05/02 01:10 AM - 06/06/02 01:10 AM
PRIMARY CARE PHYSICIAN: GENINA, VERA Y.
=====

PROSTATE SPE AG
SPEC'M 06/04 11:40 AM

PSA (DPC) 1.1 NG/ML ! (0-4.0)

=====
HIV ABY PROFILE
SPEC'M 06/04 11:40 AM

HIV PROFILE NEGATIVE FOR HIV 1 AND 2
ANTIBODIES. !

REFERENCE RANGE: NEGATIVE

=====
RPR TEST
SPEC'M 06/04 11:40 AM

RPR QUAL NONREACTIVE ! (NORMAL-NONRE

=====
HEP B SURFACE A
SPEC'M 06/04 11:40 AM

HEP B SURF AG ... NEGATIVE ! (NEG)

=====
-* - END OF LAB REPORT - * -

CONTINUED

M 062

SERV:CLIN TRANS - RENAL REG: 06/04/02 CLINIC: CLTF

ATTENDING MD: REFERRING PHYS: Y,DR.

=====
REPORT PERIOD: 06/04/02 01:10 AM - 06/05/02 01:10 AM
=====

PRIMARY CARE PHYSICIAN:

HEMOGLOBIN GLYC
SPEC'M 06/04 11:40 AM

HB A1C 7.3 % 1*(4.0-6.0)

=====
-* - END OF LAB REPORT - * -
=====

ORDERS NOT YET RESULTED THAT HAVE BEEN RECEIVED BY THE LAB OR THAT WERE ORDERED SPECIMEN COLLECTED, OR THAT HAVE BEEN MARKED IN PROCESS BY AN ANCILLARY DEPARTMENT:

- # 06/04/02 PSA
- # 06/04/02 HIV ANTIBODY PROFILE (CONSENT REQUIRED), TODAY, (06/04/02)
- # 06/04/02 RPR
- # 06/04/02 HEPATITIS CONVALESCENT BATTERY, TODAY, (06/04/02)
- # 06/04/02 X-RAY: PA&LAT CHEST, TRANSPORT: AMBULATORY, PRE-TXP, R/O D/Z, SCHEDULE ROUTINE

=====
CURRENT ORDERS NOT MARKED AS RECEIVED BY THE LAB OR IN PROCESS BY AN ANCILLARY:

- 06/04/02 QUANT HCV BY PCR (VIRAL LOAD), PERIPHERAL BLOOD...
DESTINATION 35, SST TUBE. CENTRIFUGE TUBE WITHIN 1/2 HOUR.
NO HEMOLYSIS. FREEZE SERUM AT -20 DEGREES CELSIUS WITHIN 4 HOURS., TODAY, (06/04/02)
- 06/04/02 ROUTINE EKG, INDICATIONS: HYPERTENSION, ESSENTIAL, UNSPEC.
401.9, SCHEDULE: SEND PT TO MAIN 1 ADMITTING

LAST PAGE

- * -

PATIENT LOCATION: CLOSD 999 A.M.
 REFERRING PHYSICIAN: V I
 ADMITTING PHYSICIAN:
 ATTENDING PHYSICIAN:
 ORDERING PHYSICIAN:
 BIRTHDATE/SEX/RACE: 04/21/1940 Male Black
 ADMIT DATE/TIME: 03/08/2000 08:21:00
 PATIENT PHONE #:

COMMON SERUM/PLASMA CHEMISTRY PROCEDURES

Date: 03/08/2000
 Time: 09:35AM

Procedure:	Ref Range:	Units:	
PSA, Total	[0.00-4.00]	ng/mL	0.99
Hemoglobin A1c	[4.0-6.0]	%	6.5 H

IMMUNOLOGY PROCEDURES

Date: 03/08/2000
 Time: 09:35:00

Procedure:	Ref Range:	Units:	
CMV Ab - IgG	[Negative]		Positive
CMV Ab - IgM	[Negative]		Negative
EBV Nuclear Ag, IgG	[Negative]		Positive
EBV Capsid Ag, IgG	[Negative]		Positive
EBV Capsid Ag, IgM	[Negative]		Negative
Hep B Surface Ab Quantitation I		mIU/mL	9
Hep B cAb ELA Result	[Negative]		Negative
Hep B sAg	[Negative]		Negative
HIV Final Report I			See Below
RPR Qualitative	[Nonreactive]		Nonreactive
VZV Antibody - IgG I	[Negative]		Positive

03/08/2000 09:35:00 HIV Final Report
 Negative for HIV 1 and 2 antibodies.

LEGEND: A - abnormal; C - critical; H - high; I - interpretation/comment; L - low; X - corrected result; Date = collected date
 PATHOLOGY/printed: 11/01/01 10:29 AM Page: 10

PATIENT LOCATION: CLOSD 999 A
REFERRING PHYSICIAN:
ADMITTING PHYSICIAN:
ATTENDING PHYSICIAN:
ORDERING PHYSICIAN:
BIRTHDATE/SEX/RACE: 04/21/1940 Male Black
ADMIT DATE/TIME: 03/08/2000 08:21:00
PATIENT PHONE #:

IMMUNOLOGY PROCEDURES

03/08/2000 09:35:00 Hep B Surface Ab Quantitation:

PATIENT POPULATION REFERENCE RANGE AND INTERPRETATION:

All Individuals: < 3 mIU/ml – Indicates no antibody detected.
Non-Immunized Individuals: > 3 mIU/ml – Indicates past infection.
Immunized Individuals: > 10 mIU/ml – Indicates vaccine response.
Passively-Immunized Individuals: Titer to be interpreted by physician.

03/08/2000 09:35:00 HIV Final Report:

Reference Range: Negative

03/08/2000 09:35:00 VZV Antibody - IgG:

A negative result indicates absence of protective antibody. A positive result is consistent with immunity, except when active infection is suspected. Repeat testing is suggested when result is equivocal.

03/08/2000 09:35:00 CMV IgG:

PRINT REQ

03/08/2000 09:35:00 CMV IgM:

PRINT REQ

03/08/2000 09:35:00 EBNA - IgG:

PRINT REQ

03/08/2000 09:35:00 EBVCA-IgG:

PRINT REQ

03/08/2000 09:35:00 EBVCA-IgM:

PRINT REQ

03/08/2000 09:35:00 HBsAb-Quant:

PRINT REQ

03/08/2000 09:35:00 Hep B Core Ab:

PRINT REQ

03/08/2000 09:35:00 HBsAg:

PRINT REQ

03/08/2000 09:35:00 HIV Final Report:

PRINT REQ

LEGEND: A – abnormal; C – critical; H – high; I – interpretation/comment; L – low; X – corrected result; Date = collected date
PATHOLOGY/printed: 11/01/01 10:29 AM Page: 2 of

PATIENT LOCATION: CLOSD 999 A M
REFERRING PHYSICIAN:
ADMITTING PHYSICIAN:
ATTENDING PHYSICIAN:
ORDERING PHYSICIAN:
BIRTHDATE/SEX/RACE: 04/21/1940 Male Black
ADMIT DATE/TIME: 03/08/2000 08:21:00
PATIENT PHONE #:



Date: 03/08/2000
Time: 09:35:00

Procedure:	Ref Range:	Units:	
Pt ABORH			O POS
Antibody Screen			NEG

03/08/2000 09:35:00 Type ABORh:
PRINT REQ
03/08/2000 09:35:00 ABSC:
PRINT REQ

LEGEND: A - abnormal; C - critical; H - high; I - interpretation/comment; L - low; X - corrected result; Date = collected date
PATHOLOGY/printed: 11/01/01 10:29 AM Page: 3 c

MATRIX #18269 HOSP# 1 11/28/01 03:31 PM
DYNAMIC MATRIX
p176Y

11/28/01 03:31 PM PAGE 002 LAB RESULT RETRIEVAL (Q2E
AGE: 060 SEX: M MR#:
LABORATORY RESULTS FROM 11/28/99 12:00 MN THROUGH 11/28/01 11:59
=====

VARICELA-ZOST AB
SPEC'M 03/08/00 09:35 AM

p512Y

VARICELA-ZOS AB . POSITIVE !
A NEGATIVE RESULT INDICATES
ABSENCE OF PROTECTIVE
ANTIBODY. A POSITIVE RESULT
IS CONSISTENT WITH IMMUNITY,
EXCEPT WHEN ACTIVE INFECTION
IS SUSPECTED. REPEAT TESTING
IS SUGGESTED WHEN RESULT IS
EQUIVOCAL.

*p992Y

RETURN BACK NEXT MASTER REVIEW
ERR TYPE RETRIEVE TIME-SCHED

p1424Y

-*-

MATRIX #18269 HOSP# 1 11/28/01 03:32 PM
DYNAMIC MATRIX
p176Y

11/28/01 03:31 PM PAGE 003 LAB RESULT RETRIEVAL (02F

AGE: 050 SEX: M MR#:

LABORATORY RESULTS FROM 11/28/99 12:00 MN THROUGH 11/28/01 11:59

=====

RPR TEST
SPEC'M 03/08/00 09:35 AM

p560Y RPR QUAL NONREACTIVE ! (NO
p656Y

EBV NA
SPEC'M 03/08/00 09:35 AM

p848Y EBV NA POSITIVE ! (NEC
p944Y

p1040Y

RETURN BACK NEXT MASTER REVIEW
ERR TYPE RETRIEVE TIME-SCHED

p1424Y
--*

11/28/01 03:31 PM PAGE 004 LAB RESULT RETRIEVAL (02E
AGE: 060 SEX: M MR#:
LABORATORY RESULTS FROM 11/28/99 12:00 MN THROUGH 11/28/01 11:59
=====

EBV IGG,
SPEC'M 03/08/00 09:35 AM
p512Y
EBV IGG POSITIVE ! (NEC
p608Y

EBV IGM
SPEC'M 03/08/00 09:35 AM
p800Y
EBV IGM NEGATIVE ! (NEC
p896Y

*p992Y

RETURN BACK NEXT MASTER REVIEW
ERR TYPE RETRIEVE TIME-SCHED

p1424Y

--*

11/28/01 03:31 PM PAGE 005 LAB RESULT RETRIEVAL (025
AGE: 030 SEX: M MR#:
LABORATORY RESULTS FROM 11/28/99 12:00 MN THROUGH 11/28/01 11:59
=====

CMV ABDY IGG
SPEC'M 03/08/00 09:35 AM
p512Y
CMV IGG POSITIVE ! (NEG

CMV ABDY IGM
SPEC'M 03/08/00 09:35 AM
p800Y
CMV IGM NEGATIVE ! (NEG

*p992Y

RETURN BACK NEXT MASTER REVIEW
ERR TYPE RETRIEVE TIME-SCHED

p1424Y
-*-

MATRIX #18269 HOSP# 1 11/28/01 03:32 PM
DYNAMIC MATRIX
p176Y

11/28/01 03:31 PM PAGE 006 LAB RESULT RETRIEVAL (Q27
AGE: 060 SEX: M MR#:
LABORATORY RESULTS FROM 11/28/99 12:00 MN THROUGH 11/28/01 11:59
=====

HEP B SRF AB QNT
SPEC'M 03/08/00 09:35 AM

p512Y

HEP B SAB QUANT . 9 MIU/ML !

PATIENT POPULATION
REFERENCE RANGE AND
INTERPRETATION:

p752Y

ALL INDIVIDUALS:
< 3 MIU-ML -- INDICATES NO
ANTIBODY DETECTED.
NON-IMMUNIZED INDIVIDUALS:
> 3 MIU-ML -- INDICATES

p1040Y

RETURN BACK NEXT MASTER REVIEW
ERR TYPE RETRIEVE TIME-SCHED

p1424Y

--*

MATRIX #18269 HOSP# 1 11/28/01 03:32 PM
DYNAMIC MATRIX
p176Y

11/28/01 03:31 PM PAGE 008 LAB RESULT RETRIEVAL (02)

AGE: 030 SEX: M MR#: _____

LABORATORY RESULTS FROM 11/28/99 12:00 MN THROUGH 11/28/01 11:59

=====

HEP B CORE AB
SPEC'M 03/08/00 09:35 AM

p512Y

HBCAB TOTAL NEGATIVE ! (NE

p608Y

HEP B SURFACE AG
SPEC'M 03/08/00 09:35 AM

p800Y

HEP B SURF AG ... NEGATIVE ! (NE

p896Y

*p992Y

RETURN BACK NEXT MASTER REVIEW
ERR TYPE RETRIEVE TIME-SCHED

p1424Y

-*-

MATRIX #18269 HOSP# 1 11/28/01 03:32 PM
DYNAMIC MATRIX
p176Y

11/28/01 03:31 PM PAGE 009 LAB RESULT RETRIEVAL (Q2E)
AGE: 060 SEX: M MR#:
LABORATORY RESULTS FROM 11/28/99 12:00 MN THROUGH 11/28/01 11:59

=====

HEMOGLOBIN GLYCO
SPEC'M 03/08/00 09:35 AM

p512Y
HB A1C 6.5 % !*(4.0-6.0)
p608Y

HIV ABY PROFILE
SPEC'M 03/08/00 09:35 AM

p800Y
HIV PROFILE NEGATIVE FOR HIV 1 AND 2 !
ANTIBODIES.
REFERENCE RANGE: NEGATIVE

*p992Y

RETURN	BACK	NEXT	MASTER	REVIEW
ERR	TYPE	RETRIEVE	TIME-SCHED	

p1424Y
--*

MATRIX #18269 HOSP# 1 11/28/01 03:32 PM
DYNAMIC MATRIX
p176Y

11/28/01 03:31 PM PAGE 010 LAB RESULT RETRIEVAL (Q2)
AGE: 630 SEX: M MR#:
LABORATORY RESULTS FROM 11/28/99 12:00 MN THROUGH 11/28/01 11:59

=====

PROSTATE SPE AG
SPEC'M 03/08/00 09:35 AM

p560Y PROSTATE SPE AG . 0.99 NG/ML ! (0-

p656Y

p752Y

p848Y

-- END OF REPORT --

RETURN	BACK	MASTER	REVIEW
ERR	TYPE	RETRIEVE	TIME-SCHED

p1424Y

-*-

PATIENT NAME:
 PATIENT NUMBER:
 HOSPITAL:
 PATIENT LOCATION: CLTRN
 PATIENT BIRTHDATE: 4/21/40
 SEX: M RACE: B AGE: 62

CASE NO:
 DATE COLLECTED: 6/4/02
 TIME COLLECTED: 11:40 hr
 DATE RECEIVED: 6/5/02
 TIME RECEIVED: 07:47 hr
 ORDERING PHYSICIAN:
 ATTENDING PHYSICIAN:

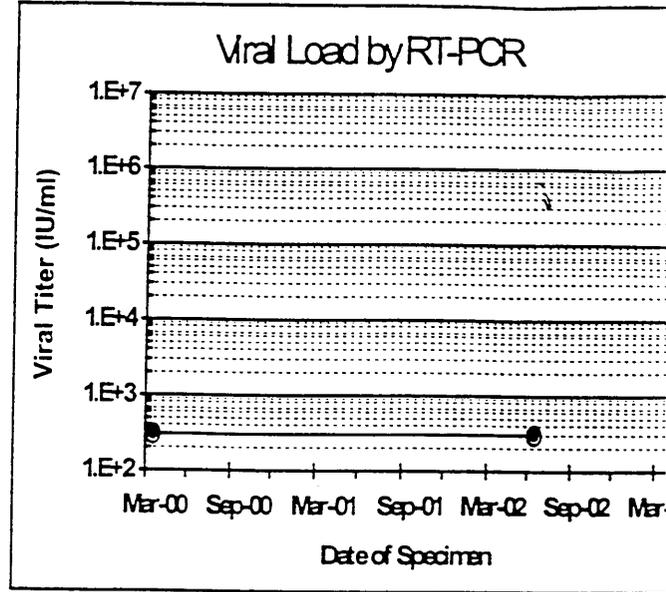
Seney

Specimen: Serum

Clinical Diagnosis:

STUDY:

RNA was extracted from 100 microliters of the patient's Serum with guanidine thiocyanate and recovered by isopropanol precipitation. Quantitative RT-PCR was performed to detect the 5'-non coding region of the HCV genome as well as an internal control standard (IQS) using rTth polymerase in the presence of Mn⁺⁺. Amplified product was detected using a colorimetric assay. The specimen is judged to be negative if the viral load is less than 650 IU/ml.



CONCLUSION: HCV RNA was NOT detected in the specimen (viral load zero to <650 IU/ml)**

Note: The reagents used in the preceding test have not been FDA approved and therefore the results should be used in conjunction with other laboratory findings.

4:00 PM - 6/13/02

Date - Time

4:00 PM - 6/13/02

Date - Time

MEDICAL RECORDS COPY

Date	03/08/00	06/04/02
HCV Titer	<1000	<650IU
Genotype	--	--

** Note: This test result is reported in International units per milliliter (IU/mL). Studies performed by the manufacturer and the Department have shown that differences between the units of copies/mL and IU/mL fall within the precision of the assay and are not expected to be of clinical significance. For the graphical presentation of the data in this report, the historical values originally reported in copies/mL, have been converted to IU/mL.

Patient Name:	MRN:		Date of Birth:	04/21/1940
Procedure:	Chest: PA+lateral	Date:	03/08/2000	Order #:	000036452506-
Physician(s):			Procedure ID:	12
	Unknown Clinician				00172258
Indication for Study:	KIDNEY TRANSPLANT^KIDNEY EVAL				

PA AND LATERAL CHEST 3/8/2000 (12:09 P.M.)

INDICATIONS: ESRD, pre-op evaluation for kidney transplantation.

There are no old chest radiographs available for comparison. The examination is suboptimum in quality since the patient did not effect a deep inspiratory effort. The heart is mildly enlarged with a left ventricular configuration and the aorta is slightly tortuous. There are signs consistent with chronic bronchitis in the lung bases but there is no acute process. The bony thorax is intact except for evidence of degenerative disc disease at several levels in the lower thoracic spine area and slight wedging of T10, T11, and to a lesser extent T12.

CONCLUSION:

1. Mild cardiomegaly with a left ventricular configuration and slight tortuosity of the aorta consistent with systemic hypertension.
2. Chronic bronchitis and no acute process.
3. Degenerative disc disease in the mid and lower thoracic spine with slight wedging of T10, T11, and ? T12 due to old trauma.

Verified: 03/09/2000

1
1
1

Patient Name:	_____	MRN:	_____	Date of Birth:	04/21/1940
Procedure:	ABD US. RUO	Date:	04/24/2000	Order #:	00C037144680-15
Physician(s):	Unknown Clinician	Procedure ID:	00202494		
Indication for Study:	E.S.R.D. ^PRE OP EVAL/ BOX				

ABDOMINAL ULTRASOUND – RIGHT UPPER QUADRANT: 4/24/00

INDICATIONS: End-stage renal disease. Preop evaluation.

FINDINGS: Multiple survey images of the right upper quadrant of the abdomen were performed using a curved transducer. The left upper abdomen was also examined. The liver and spleen are normal sonographically without evidence of focal lesions. There is no evidence of biliary ductal dilatation. The size of the common bile duct is normal and measures 4.7mm in diameter. The gallbladder is visualized with out evidence of gallstones or other abnormalities. Sonographic pictures of the right and left kidneys are within normal limits. However, the patient is under dialysis for two years. There is no evidence of hydronephrosis seen. The right kidney measures 9.8cm in length, and the left kidney is 10.5cm. There is no evidence of ascitic fluid seen. The pancreas is visualized and unremarkable.

IMPRESSION: The findings of the abdominal ultrasound are unremarkable. Please see above.

Verified: 04/24/2000

**** Report Electronically Signed ****

Dictated By:

Interpreted By:

Approved By: _____

Transcribed By:

Js
y

Patient Name:		MRN:		Date of Birth:	04/11/1940
Procedure:	VOIDING CYSTOURETHROGRAM	Date:	04/24/2000	Order #:	16
Physician(s):	Unknown Clinician			Procedure ID:	00222580
Indication for Study:	ESRD, PRE-OP BOX				

VOIDING CYSTOURETHROGRAM: 4/24/00

INDICATIONS: End stage renal disease-assess.

The preliminary abdominal radiographs shows diffuse density of the right ileum and ischium and a portion of the inferior and superior pubic rami. The remainder of the bony pelvis has a normal appearance as does the lumbosacral spine aside from mild degenerative changes. The bowel gas pattern was normal. There were minimal vascular calcifications of the pelvis.

Water soluble contrast material (Hypaque 30) was infused into the bladder via a Foley catheter. The bladder capacity was small (150 cc) and there were diffuse trabeculations along the superior and lateral as well as posterior margins of the bladder. No ureteral leaflets was noted. There were no filling defects. The urethral was normal and no significant post void residual was noted.

CONCLUSION:

1. Decreased bladder capacity with trabeculation of bladder as described above-no ureteral reflux.
2. Dense bone right pelvis as described-differential diagnosis includes Padgett's disease versus blastic metastases from primary such as prostatic cancer-further evaluation suggested. If patient has had previous abdominal or pelvic radiographs, this would be helpful in confirming a diagnosis of Padgett's disease.

Verified: 06/08/2000

** Report Electronically Signed **

Diagnostic Catheterization Report

Patient Name:
Address:
City, State Zip:

CINE: 51549

Date: June 26, 2000

MCV Patient #
 Referring Doctor:
 Primary Doctor:

Procedure: Left Heart Cath, Coronary Angio, LV Gram

Hemodynamics:

	RA	RV	PA	W	AA	LV	LVEDP
Pressure Data (mm Hg)					160/65	174/12	30
Oxygen Saturation (%)	Low Mid High	Inflow Mid Outflow	Left Main Right		97		

Coronary Angiography

LEFT MAIN: The left main coronary artery is large in caliber and essentially normal. It bifurcates into the circumflex and left anterior descending arteries.

LEFT ANTERIOR DESCENDING: The left anterior descending is medium in caliber and gives rise to 1 diagonal branch that is essentially normal.

FIRST DIAGONAL: The first diagonal is medium in caliber and essentially normal.

LEFT CIRCUMFLEX: The circumflex is medium in caliber and gives rise to 2 obtuse marginal branches that are essentially normal.

FIRST MARGINAL: The first marginal is medium in caliber. There is a 60% lesion in the proximal portion of the vessel.

SECOND MARGINAL: The second marginal is medium in caliber. There is a 75% lesion in the proximal portion of the vessel.

RIGHT CORONARY: The right coronary artery is medium in caliber and essentially normal. It is a dominant vessel.

POSTERIOR DESCENDING: The posterior descending is medium in caliber and essentially normal.

POSTEROLATERAL BRANCH: The posterolateral branch is medium in caliber and essentially normal.

LEFT VENTRICULOGRAM: The LV is normal with an estimated ejection fraction of 40-45%. There is no mitral regurgitation.

Patient Name:

n

CINE: 51549

Date: June 26, 2000

MCV Patient #:

Typist initials: CA

Conclusions

- 1) Normal resting hemodynamics.
 - 2) Significant 1 vessel coronary artery disease.
 - 3) Depressed global LV systolic function.
-

11. B

UNOS

Wait Time Modification Form

MOD N-4

(UNOS Policy 3.2.1.8)

Date 3/16/04 Organ Wait List Kidney

Patient Name _____

Patient Social Security Number or HIC Number (please specify which number is being provided) _____

Name of Transplant Center and UNOS Center Code _____

Current Listing Date 3/4/04

Listing Date Requested 2-8-00

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation)

pt was not listed in UNOS as old internal documentation had down.
It should have been listed 2-8-00.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain

currently we are comparing our UNOS list to our internal patient lists to verify pts are truly listed.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example.

Additionally, I: (must check one)

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter

Other (Please Specify) operative chart of pt, UNOS listing letter

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person _____

Phone _____ email _____

Physician/Surgeon Signature _____

Physician /Surgeon Name (please print or type) _____

Fax to: (804) :

Or mail to: UNOS Organ Center, 1100 Boulders Parkway, Suite 500, Richmond, Virginia, 23225

Revised 9/7/01

March 4, 2004

To Whom It May concern,

In reviewing our patient lists it was noted that a patient we originally saw at our transplant center in 1999 was never placed on the UNOS list. Our internal documentation from 1999-2000 reflects that initially we were awaiting DR/DNA confirmation and once that was received (2/8/00) it was documented that she was indeed listed with UNOS, see attached. The UNOS listing form we complete internally was also in the chart.

Unfortunately the patient was somehow not truly listed with UNOS. The employees who originally handled the patient's case are no longer employed here. Our tracking system reflected that she was listed and until recently, the error was not discovered.

We sincerely regret the error and respectfully request the patients waiting time be reinstated to the aforementioned date of 2/8/00.

In accordance with UNOS policy it is our duty to inform and ask the local centers to acknowledge and agree for reinstatement of the patients waiting time. As surgical directors your signature below is graciously requested. I appreciate your time and attention to this matter.

Sincerely,

Name:	Nephro: ,	ABO	1851
Tel:	Age / Sex / Race	Tel:	HI PRA: 0 oi
Date: 3/4/04	List	Loc:	MD/CO:
HLA: A1[2] A2[11] B1[38] B2[75]			0 ft 1 in. 1 lbs

PROGRESS NOTES

9/1/00 6:15:21 PM

By: :

11/18/99 - SCHED FOR EVAL ON 11/24/99. PACKET SENT, CHART TO _____
 11/23/99 Rescheduled patients appt for 11-30-99. Her family is not available for appt tomorrow as well as
 Sent revised itinerary.
 11/29/99 Pt was admitted to _____ for _____ apt to be placed. Will need to reschedule appointment tomorrow.
 12/20/99 Spoke to _____ and requested that she interpret for us 01/06/2000. Pager# _____ Sent pt letter to
 confirm appt with _____ 01/06/00, TI
 1-6-00 Met with patient for renal transplant evaluation. Discussed the following topics in detail:
 1) transplantation as a treatment option, not a cure for end-stage renal disease
 2) advantages/disadvantages & patient responsibilities with regard to transplantation
 3) types of kidney transplants & definitions of each; living-related, living non-related and
 cadaveric
 4) statistical outcomes at 1 year for LRD vs. CAD
 5) selection criteria for potential donors: (a) ABO compatibility (b) tissue typing (c) crossmatches
 and (d) antibody levels
 6) components of cadaveric waiting list and what determines recipient selection: (a) availability
 of organs (b) antigen matching (c) length of time on list and (d) presence of antibodies
 7) pre-operative preparation, operative procedure and associated risks, inpatient stay, post-
 operative care, including follow-up in transplant clinic, frequency of visits and lab draws
 8) concepts and definition of organ rejection and immunosuppression
 9) immunosuppressive medications and their potential side effects
 10) expectations for potential living donors, including pre-operative work-up and post-operative
 lifestyle.

Patient questions addressed and patient verbalizes understanding of material.

01/11/2000 Faxed ur _____ to _____ at _____
 01/17/2000 _____ in called from _____ and requested phone # for SS worker at
 Dialysis to follow up on patient status. JML
 01/21/2000 Colleen called from Aetna and said that the transplant is being approved through Aetna and Medical group.
 Auth will be sent to us. Concern with patients family support system and financial ability. She suggested pt be seen by
 clinical counselor. Referred chart to _____ s.
 2-4-99 PT. MET WITH _____ SOCIAL WORKER FOR TRANSPLANT EVAL.T.K.
 2-8-00 NOT ABLE TO LIST PT IN UNOS UNTIL DNA/PCR DONE. MUST HAVE A LEAST ONE DR TO LIST. LETTER
 MAILED TO PT AND _____ H&P AND LETTER FAXED TO _____ CHART TO _____
 2-8-00 PER _____ AT HLA PTS DR. #4 CRART TO _____ TO LIST.
 02-8-00 Pt listed in Unos. Form faxed to HLA LAB along w/H&P.
 04/19/2000 - Rec'd pts new insurance info. Pt now has Medi-Medi. Info verf thru AEVS. See insurance notes for #. Pt also
 has Medicare part A&B. Pt no longer has _____
 04/25/2000 - Pt sched for pap smear with _____ 4 @ 2:30 pm. Letter mailed to pt
 and faxed to dx unit.lj
 12/15/00 DATA CONFIRMED
 7/3/01 Rcvd SS from dx unit, chart given to KH for review.-ec
 7/6/01-Chart reviewed need to recheck VZV status. Pt was VZV neg and was supposed to be vaccinated. Not sure is she
 ever received. Request faxed to lab to re-draw VZV while pt on dialysis kh
 8/2/01 _____ ALERTED TO PT PPD STATUS, SHE REPORTS BEING VACINNATED AT EARLIER AGE.
 STILL NO VZV RESULT CALL TO LAB KH
 8/10/01-VZV RE-DRAW WAS NEGATIVE. WILL SK KRISTIN HOW TO OBTAIN VZV IMMUNIZATION FOR PT.KH
 9/27/01-Pt has seen _____ he plans on starting her on INH therapy and starting VZV vaccine (mid-Sept.) kh
 11/8/01 Scheduled pt for revl on 11/20/01. -ec
 11/20/01-Pt seen in re-eval has not yet started her INH although she was give a prescription. Explained she needs to
 take it for transplant, is preventative for TB post-op. Also call to _____ s office as she hsa not yet had VZV vaccine.
 Adrian reports she has not received it yet because they were out and had it on order, but they have not forgottne her and
 will call her when they receive it. kh
 11/28/01-Follow up call to dialysis unit. Spoke with _____ she was unaware pt was not taking INH. She will f/u and if pt
 not taking will f/u with rounding MD to put her on soemthing else. kh
 12/3/01-Spoke with _____ he plans on trying to have pt try INH again. Alerted that original prescribing MD was _____
 and he advised checking liver enzymes to R/O hepatitis and that if pt can't tolerate INH he may prescribe an

Name:		Nephro:		ABO: _
Te	Age / Sex / Race	Tel#:		HI PRA: 0 on 10/01/2003
Date: 3/4/04	List 1/31/01	Loc:	MD/CO:	
HLA: /				0 ft 1 in. 1 lbs

alternative.
4/16/02-Pt here seeing ~~still~~ has not had VZV immunization yet. Call to ' office-they will call pt and me with f/u info.
7/1/03-Pt has received one immunization at this point. kh

March 4, 2004

To Whom It May concern,

In reviewing our patient lists it was noted that a patient we originally saw at our transplant center in 1999 was never placed on the UNOS list. Our internal documentation from 1999-2000 reflects that initially we were awaiting DR/DNA confirmation and once that was received (2/8/00) it was documented that she was indeed listed with UNOS, see attached. The UNOS listing form we complete internally was also in the chart.

Unfortunately the patient was somehow not truly listed with UNOS. The employees who originally handled the patient's case are no longer employed here. Our tracking system reflected that she was listed and until recently, the error was not discovered.

We sincerely regret the error and respectfully request the patient's waiting time be reinstated to the aforementioned date of 2/8/00.

In accordance with UNOS policy it is our duty to inform and ask the local centers to acknowledge and agree for reinstatement of the patient's waiting time. As surgical directors your signature below is graciously requested. I appreciate your time and attention to this matter.

Sincerely,

STATUS CODE	KIDNEY	1	8	9
ACCEPT CODE	0			
RECIPIENT NAME	LAST	FIRST		
NIC NUMBER				
CENTER CODE	CASH			
AGE/DOB				
SEX				
RACE				
PRA	O/h			
TX# PATIENT IS AWAITING	1			
BLOOD GROUP	A	B	O	AB
A1				
A2				
B1				
B2				
DR1				
DR2				
UNACCEPTABLES	NO			
WILL ACCEPT HCV +	YES			
DIALYSIS CENTER	NONE			
CARDIAC INDICATORS	<input checked="" type="radio"/> NO	<input type="radio"/> YES		
DIABETES	<input checked="" type="radio"/> NO	<input type="radio"/> YES		
MILITARY CONNECTION	<input checked="" type="radio"/> NO	<input type="radio"/> YES		
DATE LISTED IN UNOS			REG. ID#	
ADDED TO WAITING LIST	Nif list 2-8-00 WT list 2-8-00		UNOS TCR	
LIST-8 PENDING				
ADDED TO MAILING LIST	done 2/8/00			
ADDED TO CALL BOOKS				
PINK PACKET MADE				
WHITE PACKET MADE				
FAX TO BRUCE *LISTING FORM *PT INFO & CLINICAL HX	2-8-00 w/ H&P.			

To: UNOS

From: _____



FAXED

MAR 18 2004

Fax: 804-697-4372

Date: 3-18

Page(s): 1

Comments: Urgent - Please call me @
to verify that
you have received these papers.
Thanks

CONFIDENTIALITY STATEMENT

This message is intended for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or is not the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please contact us immediately by telephone for instructions regarding return or destruction of this communication. Thank you.

MODE = MEMORY TRANSMISSION

START-OCT-02 11:18

END-OCT-02

FILE NO.=474

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	<07>	UNOS	002/002	00:00:47

MOD N-6

WAITING TIME MODIFICATION FORM (OPTN/UNOS Policy 3.2.1.8)

Date: 10/2/03 Organ Wait List Kidney

Patient Name: _____

Patient Social Security Number or HIC Number (please specify which number is being provided): _____

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: 10/2/03

Listing Date Requested: 9/4/03

Explanation for Request (please continue on additional pages as necessary and attach any supporting documentation):

pt was made active 9/4/03 - forms faxed to the UNOS (with copies to verify) in stating the fax was not received & fax busy -

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain:

I will follow up with a phone call after faxing Activation forms -

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

Patient on dialysis, or

Measured (actual urinary collection) creatinine clearance level or calculated GFR ≥ 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please specify) Forms originally faxed to the UNOS -

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval

Attn:

Re:

SSN:

Fax:

October 3, 2003

Dear:

I am unable to make this change to the UNOS wait list or forward the request to the appropriate UNOS Committee because the request to backdate the wait time for _____ does not meet the minimum requirements specified in UNOS policy 3.2.1.8, and the Wait Time Modification form, which require the signatures of the other local transplant centers with programs of the applicable organ, along with the appropriate supporting documentation.

Thanks, Jim Creger
Manager Organ Center Quality Group

Cregerjh@unos.org

CONFIDENTIALITY NOTICE

This electronic message transmission contains information from the United Network for Organ Sharing, and this information is confidential. If you are not the intended recipient, be aware that disclosure, copying, distribution or use of all or any portion of the content of this information is prohibited, except by authority of the sender. If you received this transmission in error, please notify us as soon as possible by e-mail and delete the original message.

Chairman
Board of Trustees

September 04, 2003

Dear

We are pleased to inform you that on September 04, 2003 we notified _____ I to
have you placed onto the Active Kidney Transplant List at _____

While you are waiting for your kidney transplant, it is important that you contact our office if you have any changes in your health status, dialysis modality, center or time of treatment. If you are not yet on dialysis, it is important that you notify us when you have your first treatment. If any changes occur in your life, such as a new home address, new telephone numbers or any new insurance information, please call us with that information. It is also important to provide our office with the location and contact numbers if you are planning to go out of town.

Please find enclosed a copy of our protocol regarding monthly tissue typing specimens. The instructions must be followed carefully. Missing or mislabeled specimens will seriously jeopardize your chances of receiving a transplant. Be certain that each sample has your name, social security number and the date it was drawn. Mislabeled specimens are discarded by the tissue typing lab.

If there are persons who are interested in finding out about being a living donor for you, they may now call _____ at _____

Your nephrologist will be informed of your status on our Active Kidney Transplant List, as well as the nurses in your dialysis unit, if applicable. If you have any questions, please feel free to contact me at _____ . You may also call us toll-free at _____ /, or fax us at _____

Sincerely,

Transplant Coordinator

CC:

UNOS Modification Form

TO: The Sharing Network Tissue Typing Lab

Date: 9/4/03

Name: _____

Make changes to this list:

SS#: _____

Kidney

DOB: 7/17/45 ABO: O

Simultaneous Kidney-Pancreas (SPK)

Sex: female / male Race: B

Pancreas after kidney (PAK)

Make Active (Status 1)

Delete from Waiting List because

Make Active (Zero mm only)

Transplanted Date: _____

Make FULLY Active (was listed for 0mm only)

En bloc kidneys

Right kidney

SPK

Left kidney

PAK

Reactivate (from Status 7)

Cadaveric

Donor ID: _____

Previously transplanted? Yes / No

Live Donor: LRD LURD

Dialysis-dependent? Yes / No

Name: _____

If Yes... Start date: 5/23/03

Txp Elsewhere: _____

If No.....Cr Cl: _____ ml/mn calculated measured

Expired ...Date _____

Date of CrCl: _____

Transferred to another center

Is patient Hepatitis C positive? Yes / No

Not medically suitable

Make Inactive (Status 7)

Patient choice

Reason: _____

Lost to follow-up (cannot locate)

This individual DOES NOT wish to be considered for an organ from an Expanded Criteria Donor

This individual had previously indicated that s/he did not wish to be considered for an organ from an expanded donor. They have reconsidered, and now wish to be listed on the full list and considered for an organ from any donor.

This individual was listed for a Zero mm organ but should now be made fully active and begin accruing points because the Creatinine Clearance is now 20 ml/mn or less.

Authorized Signature: _____

(has) completed form to _____

Date: 9/4/03

Director/Supervisor Approval: _____

Date: _____

Client Service Representative: _____

Date: _____

FILE NO.=225

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	400	2		000/002	00:00:36

UNOS Modification Form

TO: The Sharing Network Tissue Typing Lab

Date: 9/4/03

Name: _____

Make changes to this list:

SS#: 4

Kidney

DOB: 7/17/45 ABO: O

Simultaneous Kidney-Pancreas (SPK)

Sex: female / male Race: B

Pancreas after kidney (PAK)

Make Active (Status 1)

Delete from Waiting List because

Make Active (Zero mm only)

Transplanted Date: _____

Make FULLY Active (was listed for 0mm only)

En bloc kidneys

Reactivate (from Status 7)

Right kidney SPK

Previously transplanted? Yes / No

Left kidney PAK

Dialysis-dependent? Yes / No

Cadaveric

If Yes... Start date: 5/23/03

Donor ID: _____

If No... Cr Cl: _____ ml/min calculated measured

Live Donor: LRD LURD

Name: _____

Date of CrCl: _____

Txp Elsewhere: _____

Is patient Hepatitis C positive? Yes / No

Expired ...Date _____

Make Inactive (Status 7)

Transferred to another center

Reason: _____

Not medically suitable

Patient choice

Lost to follow-up (cannot locate)

This individual DOES NOT wish to be considered for an organ from an Expanded Criteria Donor

This individual had previously indicated that s/he did not wish to be considered for an organ from an expanded donor. They have reconsidered, and now wish to be listed on the full list and considered for an organ from any donor.

This individual was listed for a Zero mm organ but should now be made fully active and begin accruing points because the Creatinine Clearance is now 20 ml/min or less.

Authorized Signature: _____

(fax completed form to _____)

Date: 9/4/03

Director/Supervisor Approval: _____

Date: _____

Client Service Representative: _____

Date: _____

UNOS KIDNEY-KIDNEY/PANCREAS WAITING TIME QUALIFICATION FORM

Date of Status Change: 9/4/03 Patient Name: _____

Patient's SS#: _____ Candidate Registration ID: _____

Transplant Center Code: _____ UNOS Center Code: _____

Patient's Date of Birth: 7/17/45

Except for candidates who are less than 18 years old, the "time of waiting" begins when a patient listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information is recorded on the UNOS Computer. A completed kidney-kidney/pancreas Waiting Time Qualification Form documenting satisfaction of the criteria must be received by UNOS within 24 hours of entry of the information on the computer.

Check all that apply:

- Measured (actual urinary collection) creatinine clearance level less than or equal to 20 ml/mn.

Specify actual value: _____

- Calculated GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/mn.

Specify formula used: _____

- Initiation of dialysis.

Specify date: 5/23/03

This form must be signed and dated by the candidate's physician or surgeon and forwarded to UNOS within 24 hours of entry of the patient information on the UNOS Computer.

Physician/Surgeon Signature: _____

Physician/Surgeon Name (printed): _____

Date: 9/4/03

FAX TO UNOS: (804) 782-4817

FILE NO. =226

STN NO.	COMM.	RETR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	<87>	UNOS	002/002	00:00:44

UNOS KIDNEY-KIDNEY/PANCREAS WAITING TIME QUALIFICATION FORM

Date of Status Change: 9/4/03 Patient Name: _____

Patient's SS#: _____ Candidate Registration ID: _____

Transplant Center Code _____ UNOS Center Code: _____

Patient's Date of Birth: 7/17/45

Except for candidates who are less than 18 years old, the "time of waiting" begins when a patient listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information is recorded on the UNOS Computer. A completed kidney-kidney/pancreas Waiting Time Qualification Form documenting satisfaction of the criteria must be received by UNOS within 24 hours of entry of the information on the computer.

Check all that apply:

Measured (actual urinary collection) creatinine clearance level less than or equal to 20 ml/min.

Specify actual value: _____

Calculated GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min.

Specify formula used: _____

Initiation of dialysis.

Specify date: 5/23/03

This form must be signed and dated by the candidate's physician or surgeon and forwarded to UNOS within 24 hours of entry of the patient information on the UNOS Computer.

Physician/Surgeon Signature: _____

Physician/Surgeon Name (printed)

Date: 9/4/03

FAX TO UNOS: (804) 782-4817

CHAIRMAN
Board of Trustees

Re:

Dear Dr

In pursuant of UNOS policy 3.2.1.8 (Waiting Time Modification), a request will be made to UNOS to backdate the wait time for SSN . We made a request for the patient to be listed for kidney on 9/04/03. This request was made via fax. The fax request did not go through; hence the patient was never put on the deceased donor waitlist. This occurrence was discovered 28 days later, in which the request was re-sent, and the patient was eventually listed.

Before requesting to backdate the wait time for , UNOS policy calls for initial approval by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the patient is listed. (Policy 3.2.1.8, pg.3-2).

If you are in agreement with this request, please sign and print below, and fax this letter to
Pre Transplant Coordinator

Fax.

Thank you for your time.

Transplant Coordinator

I have reviewed the request being made by
; request to UNOS.
Surgeon's Signature

and I approve

Date

1/12/04

Chairman
Board of Trustees

Re:

Dear Dr.

In pursuant of UNOS policy 3.2.1.8 (Waiting Time Modification), a request will be made to UNOS to backdate the wait time for _____ SSN _____. We made a request for the patient to be listed for kidney on 9/04/03. This request was made via fax. The fax request did not go through; hence the patient was never put on the deceased donor waitlist. This occurrence was discovered 28 days later, in which the request was re-sent, and the patient was eventually listed.

Before requesting to backdate the wait time for _____, UNOS policy calls for initial approval by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the patient is listed. (Policy 3.2.1.8, pg.3-2).

If you are in agreement with this request, please sign and print below, and fax this letter to _____
Pre Transplant Coordinator

Fax.

Thank you for your time.

Transplant Coordinator

I have reviewed the request being made by _____
request to UNOS.
Surgeon's Signature

_____ and I approve

Date

1/12/04

Chairman
Board of Trustees

Re:

Dear Dr

In pursuant of UNOS policy 3.2.1.8 (Waiting Time Modification), a request will be made to UNOS to backdate the wait time for SSN We made a request for the patient to be listed for kidney on 9/04/03. This request was made via fax. The fax request did not go through; hence the patient was never put on the deceased donor waitlist. This occurrence was discovered 28 days later, in which the request was re-sent, and the patient was eventually listed.

Before requesting to backdate the wait time for UNOS policy calls for initial approval by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the patient is listed. (Policy 3.2.1.8, pg.3-2).

If you are in agreement with this request, please sign and print below, and fax this letter to
Pre Transplant Coordinator

Fax.

Thank you for your time.

Transplant Coordinator

I have reviewed the request being made by
request to UNOS.
Signature

and I approve

Date

1/8/04

Chairman
Board of Trustees

Re:

Dear Dr

In pursuant of UNOS policy 3.2.1.8 (Waiting Time Modification), a request will be made to UNOS to backdate the wait time for SSN We made a request for the patient to be listed for kidney on 9/04/03. This request was made via fax. The fax request did not go through; hence the patient was never put on the deceased donor waitlist. This occurrence was discovered 28 days later, in which the request was re-sent, and the patient was eventually listed.

Before requesting to backdate the wait time for ; UNOS policy calls for initial approval by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the patient is listed. (Policy 3.2.1.8, pg.3-2).

If you are in agreement with this request, please sign and print below, and fax this letter to Pre Transplant Coordinator

Fax.

Thank you for your time.

Transplant Coordinator

I have reviewed the request being made by request to UNOS.
Surgeon's Signature

and I approve

Date

1/8/04

Chairman
Board of Trustees

Re:

Dear Dr.

In pursuant of UNOS policy 3.2.1.8 (Waiting Time Modification), a request will be made to UNOS to backdate the wait time for SSN . We made a request for the patient to be listed for kidney on 9/04/03. This request was made via fax. The fax request did not go through; hence the patient was never put on the deceased donor waitlist. This occurrence was discovered 28 days later, in which the request was re-sent, and the patient was eventually listed.

Before requesting to backdate the wait time for UNOS policy calls for initial approval by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the patient is listed. (Policy 3.2.1.8, pg.3-2).

If you are in agreement with this request, please sign and print below, and fax this letter to
Pre Transplant Coordinator

Fax.

Thank you for your time.

Transplant Coordinator

I have reviewed the request being made by
request to UNOS.
Surgeon's Signature

and I approve

Date

1/8/04

January 22, 2004

Fax:

Re:

Hi This is your requested verification that I received the Wait Time Modification request from you on January 13th. The next scheduled meeting will be in May 2004. thanks, jim

Cregerjh@unos.org

CONFIDENTIALITY NOTICE

This electronic message transmission contains information from the United Network for Organ Sharing, and this information is confidential. If you are not the intended recipient, be aware that disclosure, copying, distribution or use of all or any portion of the content of this information is prohibited, except by authority of the sender. If you received this transmission in error, please notify us as soon as possible by e-mail and delete the original message.

Transplant Department

Phone # _____

Fax # _____

Fax Transmittal

TO: Jim Cregor

Fax #: 804 6974372

From: _____

Date: 1/13/04

Number of pages including cover sheet: _____

Comments: Jim - I hope this is sufficient to adjust the wait time on I followed directions. Thank for your help. Pls send me written verification that you read this packet & let me know when it will go to committee for review. Thanks

The information in this fax message and any attachments thereto, may be confidential and may not be disclosed without our expressed permission. If you are not the intended recipient or an employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that you have received this message in error. Any review, distribution or copying of this message, or any attachment thereto, in whole or in part, is strictly prohibited. If you have received this message in error please immediately notify us by telephone, fax or e-mail and delete the message and all of its attachments.

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Exhibit Y

Date: 3/16/04 Organ Wait List: kidney

Patient Name: _____

Patient Social Security Number or HIC _____ or (please specify which number is being provided): _____

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: 3/16/04

Listing Date Requested: 10/14/99 to 1/16/00, 4/23-01 to 7/18/01 Active dates

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): was determined to have not understood instructions

(verbal) for pre-transplant cancer screenings. Verbal interest in reevaluation completion in 2003, and met requirements in 2004.

Had admission with diagnosis of possible depression, anxiety, and/or melancholia which may have impacted patient's ability to attend to verbal instructions.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: The transplant program at

revised correspondence in 2003 to include more specific, written instructions and tools to assist patients in receiving and obtaining necessary health screenings.

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
- Measured (actual urinary collection) creatinine clearance level or calculated GFR \leq 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please specify) note and physician consult notes

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____
(Please Print or Type)

Please Fax to: 804-697-4372
Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

Y-2

RM#:

ACCT#:

MR#:

LOC:

DOB:

AGE:

SEX:

ADMIT:

DISCHARGE:

ATTENDING:

CONSULTATION

DATE OF CONSULTATION

December 9, 2002

CONSULTING PHYSICIAN

IDENTIFICATION

This is a 51-year-old white woman admitted voluntarily for multiple medical concerns.

CHIEF COMPLAINT

"I'm sad."

HISTORY OF PRESENT ILLNESS

Patient used to be very energetic. Stated she was fun, outgoing, self-reliant, held 2 jobs. In December 2001 she contracted pneumonia. She did get over this and got back to work. However, in January 2002 she developed pneumonia and 3 days after being admitted to the hospital she had left renal failure and nearly died. However, she did pull through.

In March 2002, husband, who worked in Wisconsin last 12 years, decided to quit work. He would normally work for 2-3 months and then would be home for 3-4 days. Patient meanwhile tried to stay busy at home. She could not work any more, but when spring came around she worked in the garden. She was also into fitness a couple of hours every morning. By the end of summer, around September 2002, her husband did retire. Went home because he could not walk.

They subsequently went to Florida for a few weeks. Patient suddenly became disoriented, lost 3 days of memory at the hospital and also could not find the cause despite lots of tests. They did come home and 1 week after that she was hospitalized with same symptoms for a week and a half. She did get better and got home. However, then she started developing jerking and twitching of legs and arms, describing asterixis.

She went to the hospital last Thursday again. It was presumed that she was on Dilantin, overdose. She has been on this every since twitching began. However, labs coming back here on December 7, 2002, showed normal Dilantin levels. She had an MRI 1 month ago. She had an EEG in Florida in October 2001.

Patient does state that life with her husband home has been quite hard. He has been very verbally abusive and controlling. He is yelling, he is unsupportive. Basically with his hip pain, he gets very annoyed whenever there is activity around him. She states that he was never compassionate, never affectionate. She cries when she states this. Wishes that some time in life she had some compassion and affection.

CONSULTATION REPORT

Y-4

CONSULTATION

DOB: AGE: SEX:
ADMIT: DISCHARGE:
ATTENDING: :

She does state that occasionally she has trouble focusing. She has trouble with her eyes. Her concentration is significantly declined with memory, and she is occasionally experiencing some double vision. Very hard in making decisions in general.

She is on chronic renal peritoneal dialysis. After admit she has also had an abdominal wound culture for Pseudomonas.

Her labs currently show anemia with increased ferritin, increased iron, decreased iron-binding capacity, increased phosphates. BUN is 39, creatinine is 12.9. Protein is declined, ammonia is up.

PAST MEDICAL HISTORY

Nothing psychiatric. Nonpsychiatric, of course she has renal failure, the Guillain-Barre syndrome as mentioned earlier. She has also had renal stones and peritoneal dialysis for 2-1/2 years, 10 hours every night. Has had numerous pneumonias. She had a seizure in the hospital in February 2002, verified, which was when she got on Dilantin. She has had a right nephrectomy. She had a tonsillectomy. She has had hypertension and arthritis. She has had significant weight loss. They are currently trying Boost for her. She is postmenopausal, had 2 births.

ALLERGIES

No drug allergies.

CURRENT MEDICATIONS

1. Since February she has been on Zoloft 50 daily. This was discontinued Thursday, December 5, 2002.
2. She has also Sinemet CR 50/200 b.i.d.
3. She is on Compazine 10 t.i.d.
4. Diatex (uncertain what this is).
5. She is on Celebrex 200 daily.
6. Neurontin 300 daily.
7. Synthroid 0.1 daily.
8. Coreg 1.25 b.i.d.
9. Digoxin 0.125 every other day.
10. PhosLo 667 t.i.d.

SUBSTANCE ABUSE

Patient admits to smoking.

MENTAL STATUS EXAMINATION

Patient is an older woman, appropriately groomed. She has fair eye contact. Voice is quiet, slow, normal rhythm and tone. She does exhibit some tremors that increase in muscle straining; when she relaxes her arm, tremors is decreased. She is quite melancholic. She relates well to interviewer. She is

CONSULTATION REPORT

Y-5

Run:

Page 2 of 4

RM#

ACCT#:

MR#:

DOB:

AGE:

SEX:

LOC:

ADMIT: 12/05/02 DISCHARGE:

ATTEND:

CONSULTATION

cooperative throughout the interview. Affect is very flat. Mood is very depressed, melancholic, quite labile. Thought production is quite slow. Thought content is free of pathology; however, significant expression of hopelessness. Sensorium is clear. She is oriented to person, place and time. Memory is fair, intermediate and recent. She recalls 1 of 3 words after 5 minutes. Remote memory is intact. Intelligence estimated as average. Abstractive ability shows very concrete thinking pattern. Attention is good to interview. Concentration is fair. She has some difficulty counting serial 7's and some difficulty spelling world backwards. Insight is good. Judgment is fair per giving in to verbally abusive husband.

SUMMARY AND FORMULATION

This is a 51-year-old white woman admitted with significant renal problem and other medical problems. Has developed some tremulous behavior since her husband retired in September 2002. Apparently husband is quite abusive verbally at home, very bossy, very controlling. She also laments lack of intimacy and affection at home. Muscle twitching does seem like it may have some component of reflexive stretching; however, uncertain without any tests. Patient certainly has melancholic depression and anxiety. It is unknown whether this is all related to the husband retiring or whether underlying major depressive disorder is predominant feature here.

DSM-IV DIAGNOSES

- Axis I. Major depressive disorder with anxiety and melancholia versus adjustment disorder with melancholic depressed features and anxiety.
- Axis II. Deferred.
- Axis III. Multiple per chart. Note epileptic seizures versus nonepileptic seizure workup at the moment.
- Axis IV. Psychosocial stressors: Severe: Marital relationship.
- Axis V. Global Assessment of Functioning: Currently 30; past year best is 70.

TREATMENT RECOMMENDATIONS

1. Trazodone 25 mg for sleep. Psychiatry will monitor for effect. Trazodone is known for no significant interaction or side effects and can be increased p.r.n. dosing to maximum dose of around 400 mg and is safe in dialysis.
2. Lexapro 10 mg q.a.m. of depression. Psychiatry can monitor for side effects. Possibility for increase to 20 mg in 3-4 days to normal effective dose range. This is safe in dialysis. Lexapro is a pure derivative of Celexa which is the SSRI with the fewest side effects and interactions, certainly less than Zoloft, and managed similar to SSRIs. The alternative is Remeron 15 mg q.h.s. This medication is presumed to be better for melancholic depression and has effect a little bit faster. It

CONSULTATION REPORT

Y-6

Run:

CONSULTATION

RM#:					
ACCT#:					
MR#:					
LOC:					
DOB:	1	AGE:		SEX:	
ADMIT:	/02	DISCHARGE:			
ATTENDING:					

also improves sleep, possibly negating the need for trazodone. Thus the patient can be on 1 medication instead of 2. This can later be increased to 30 mg p.o., giving better antidepressant effective when sleep is back to normal.

3. EEG while experiencing the tremors to confirm or rule out epileptic seizures versus nonepileptic seizures. Patient has reported EEG in the past; however, states when this was done she did not have any of the tremors.
4. Discharge meds and followup must be per _____; per patient being fearful that husband will find out that she is seeing a psychiatrist. She is not willing to admit to husband that she has seen psychiatrist, afraid he will be full of rage at this, and thus we will need to coordinate with _____ for outpatient followup of these medications. Psychiatry will be available for consultation with _____. Pager number is on bottom of progress note, and we will follow while patient in the hospital and observe _____ notes.

Thank you for the consult.

Dictated by _____

sg/ced/950482,

3

D: 12/09/02

T: 12/10/02

acs: Y roi: U

Family Phy:

Referring Phy: UNKNOWN

THIS COPY TO:

CC:

CONSULTATION REPORT

Y-7

Run:

Page 4 of 4

Confidential Facsimile Cover Sheet

Date: 4/13/04

Time: 8:15 a.m. p.m.

Number of pages (including cover sheet): 8

TO: UNOS Organ Ctr
(authorized receiver's name and/or department)

(authorized receiver's facility name)

(authorized receiver's facility address)

Telephone: _____
(authorized receiver's number)

FAX: 804-697-4372
(authorized receiver's fax number)

FROM: _____
(sender's name and department)

Telephone: _____
(sender's number)

FAX: _____
(sender's fax number)

REMARKS: RE: - waiting time

CONFIDENTIALITY NOTICE: This fax transmission, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender at the above telephone number and destroy all faxed information.

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Exhibit Z

Date: 2-26-04 Organ Wait List: Kidney

Patient Name: _____

Patient Social Security Number or HIC Number (please specify which number is being provided): _____

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: 6/27/00

Listing Date Requested: _____

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): this patient was inadvertently changed to Status 7 in July 2003. He has since been reactivated to status 1, and we are requesting reinstatement of activity days he would have accrued while on "7"

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: yes, patient was reactivated to Status 1. He was notified of error. We will regularly review our Status 7 pts @ a designated renal conference with HRA and renal coordinators present.

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
- Measured (actual urinary collection) creatinine clearance level or calculated GFR \leq 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please specify) _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____

(Please Print or Type)

Please Fax to: 804-697-4372

Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23298

eMailed
(CY)

Office # for

FAX #: ---

E-mail: ---

To: Whom it May Concern

Date: January 26, 2004 (revised February 17, 2004)

From: ---

Re: Waiting Time Reinstatement Request for

This patient was incorrectly changed from Status 1 to Status 7 in July, 2003, by a technologist in our laboratory.

A memo had been sent from the coordinator, ---, to the laboratory requesting a change from Status 7 to Status 1 (attachment #1). However, the patient had actually not previously been listed as Status 7 and the technologist erroneously, therefore, made the change in the wrong direction, from Status 1 to Status 7 (attachment #2).

The problem was unfortunately called to my attention when the patient became very upset at the excessive delay in his being called for transplant and actually asked to be taken off the list altogether. He was taken off the UNOS list before we discovered that error. Realizing, now, that he would have been eligible for a transplant shortly after the incorrect change, last July, we urgently request that his re-activation not only be accompanied by a reinstatement of his original waiting time points but also by the inclusion of waiting time points for the 5+ months he would have accrued had he not been incorrectly changed to status 7.

Your prompt approval of this request would be greatly appreciated.

y

eMailed
(CM)

Office # fo

E-mail:

To: Whom it May Concern

Date: January 26, 2004 (revised February 17, 2004)

From:

Re: Waiting Time Reinstatement Request for

This patient was incorrectly changed from Status 1 to Status 7 in July, 2003, by a technologist in our laboratory.

A memo had been sent from the coordinator, to the laboratory requesting a change from Status 7 to Status 1 (attachment #1). However, the patient had actually not previously been listed as Status 7 and the technologist erroneously, therefore, made the change in the wrong direction, from Status 1 to Status 7 (attachment #2).

The problem was unfortunately called to my attention when the patient became very upset at the excessive delay in his being called for transplant and actually asked to be taken off the list altogether. He was taken off the UNOS list before we discovered that error. Realizing, now, that he would have been eligible for a transplant shortly after the incorrect change, last July, we urgently request that his re-activation not only be accompanied by a reinstatement of his original waiting time points but also by the inclusion of waiting time points for the 5- months he would have accrued had he not been incorrectly changed to status 7.

Your prompt approval of this request would be greatly appreciated.

Fax

To: _____ From: _____
Fax: _____ Pages: _____
Date: 2/25/2004
Re: Wait Time Modification Request CC: _____
 Urgent For Review Please Comment Please Reply Please Recycle

I am attaching a Wait Time Modification Request from _____ As you are aware, a patient's wait time may only be modified if all renal transplant programs unanimously agree to the circumstances surrounding the case.

In summary, this 72 y/o BM was wait listed on 12 December, 2000 by _____ He remained active on the waitlist until July 2003 when he was inadvertently placed on an inactive status. As a result of this listing error, he has lost approximately 5 months of wait time.

This candidate has been removed from his inactive status _____ is requesting your consideration in qualifying this patient to receive approximately 150 days of listed priority time on UNOS. Per UNOS policy the organ specific program director must be the approving signature. I am affixing a signature block on this fax memo cover sheet. Please fax back to my attention at 214-756-2729.

Supporting documentation is attached for your review. Please call me if you should have any questions regarding this matter.

Thank you.

Approved

Disapproved

Comments:

Name (print)

Name (signature)

Title

Date

Fax

To: _____ From: _____
Fax: _____ Pages: Multiple
Date: 2/25/2004
Re: Wait Time Modification Request
 Urgent For Review Please Comment Please Reply Please Notify

I am attaching a Wait Time Modification Request from _____ (2004) As you are aware, a renal candidate's wait time may only be modified if all renal transplant programs unconditionally agree with the circumstances surrounding the case.

In summary, this 77 y/o BM was wait listed on 12 December, 2000 by UNOS and he has remained active on the waitlist until July 2003 when he was inadvertently placed on an inactive status. As a result of this listing error, he has lost approximately 2 months of wait time.

This candidate has been removed from his inactive status. _____ is requesting your consideration in qualifying this patient to receive approximately 150 days of missed priority time on UNOS. Per UNOS policy the organ specific program director must be the approving signature. I am affixing a signature block on this fax memo cover sheet. Please fax back to my attention at telephone 2129.

Supporting documentation is attached for your review. Please call me if you should have any questions regarding this matter.

Thank you.

Approved Disapproved Comments

Name (print) _____ Name (signature) _____ Title _____



You have expected Waitlist Data
Kidney Candidate
Successfully updated registration fo

1000001 page: 5

- List
- Print History
- Edit
- Remove
- Change to KP

Provider Information

Transplant Center:
24 Hour Contact Phone Number:

Demographic Information for SSN:

Name: ID: DO:

Center's Patient ID: Gender: Male

State of Permanent Residence:
Permanent Zip Code:

Race:
Ethnicity:

Black or African American
Non-Hispanic/Non-Latino
U.S. CITIZEN

Charles Soto
7-15-07

Clinical Information

BO: .eight: A
Weight: A
HLA: A: 2 DR: 15 A: 30 DR: B: 13 DR51: B: 57 DR52: A

Peak PRA: Choose PRA for allocation scoring:
Current PRA: Is candidate currently on dialysis?
Initial Dialysis Date: Measured Creatinine Clearance:
Date Creatinine Clearance became 20

Peak PRA: 4
Current PRA: 0
Initial Dialysis Date: Peak
Measured Creatinine Clearance: Yes
Date Creatinine Clearance became 20

of less:
Calculated GFR Score:
Date GFR became 20 or less:

kidney Organ Information

Candidate Medical Urgency Status: **Temporarily inactive (7)**
 Total UNOS Waiting Time: **1107 days 0 hrs 11 mins 54 secs**
 Activation Date: **06/27/2000 14:35:49**
 Maximum Acceptable Number of HLA Mismatches: **ABDR:6**
 Number of previous Kidney Transplants: **0**
 Will receive Donation Status points: **No**
 Will accept local expanded criteria donor kidney(s): **Yes**
 Maximum Acceptable Number of HLA Mismatches for local expanded criteria donor kidney(s): **ABDR:6**
 Will accept imported expanded criteria donor kidney(s): **Yes**
 Maximum Acceptable Number of HLA Mismatches for imported expanded criteria donor kidney(s): **ABDR:6**

Additional Organs

*This is for informational use only and does not affect the match. You must register the patient on the waitlist for each additional organ checked.

None Found

Key Minimum Donor Acceptance Criteria

Minimum acceptable Donor Age: **3 Years**
 Maximum acceptable Donor Age: **70 Years**
 Accept an HCV Antibody Positive donor? **No**
 Accept a Hepatitis B Core Antibody Positive donor? **No**
 Maximum acceptable Warm Ischemic time: **60 minutes**
 Maximum acceptable Cold Ischemic time upon arrival: **60 hours**
 Maximum acceptable percent glomerular sclerosis with less than 20 glomeruli observed: **30 %**
 Maximum acceptable percent glomerular sclerosis with 10 or more glomeruli observed: **30 %**
 Maximum acceptable donor Serum Creatinine - Peak: **4 mg/dl**

Maximum acceptable donor Serum Creatinine - Final

2 mg/dl

Acceptable Antigens

- List
- State History
- Edit
- Remove
- Change to KP

Copyright © 2003, United Network for Organ Sharing. All rights reserved.

Public Burden/Privacy Act Statements

02/17/2004 16:28
Feb 17 04 05:51 P



You have exported Waitlist Data

Candidate Status History



Status History for Candidate:

SSN: _____ Organ: Kidney HFSR _____ Name: _____ ABC _____

Status	Change Date & Time	Change User	Action	Rem Code
1	11/05/2003 07:43:25	Convert to new inactive codes (U)	Mod	
1	07/09/2003 14:47:42		Mod	
1	09/30/2002 12:14:30	Legal-	Mod	
1	08/20/2002 13:30:33		Mod	
1	08/19/2002 14:24:41		Mod	
1	08/19/2002 14:24:19		Mod	
1	05/09/2001 08:04:17	Convert w/req_kipa_mismatch_acpt_cd valu (U)	Mod	
1	02/28/2001 14:58:59		Mod	
1	01/17/2001 15:31:56		Mod	
1	12/01/2000 16:29:19		Mod	

Page 1 of 2

Copyright © 2003, United Network for Organ Sharing all rights reserved

[Legend]
Public Burden/Privacy Act Statements

From:
 Sent: Wednesday, July 9, 2003 12:55
 To:
 Subject:



ATT4230210.txt

Listed kidney pt - please re-activate to status 1- he decided he wants to continue on the list. Thanks- Car.

...and id=137690&wl OFE-K16311 08*

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Mon N-3

Exhibit AA

Date: March 19, 2004 Organ Wait List: Kidney/Pancreas

Patient Name: _____

Patient Social Security Number or HIC Number (please specify which number is being provided):
SS# _____

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: 3/18/04

Listing Date Requested: 6/1/03

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): Miscommunication with insurance company and patient resulted in him not being listed in June, 2003.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: Process for listing and communication with insurance companies regarding listing is being reviewed.

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
- Measured (actual urinary collection) creatinine clearance level or calculated GFR \leq 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please specify) _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____

(Please Print or Type)

Please Fax to: 804-697-4372

Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

MINUTES OF ESRD MEETING

Date: 2/26/03

Patient: _____

Kidney

Kidney/Pancreas

Pancreas

Presented by: _____, M.D.

Discussion: _____

LR/LUR Donor Recipient: _____

Relationship to Patient: _____

Plan: Accepted

Follow Up: _____, M.D.

Rejected _____

Tx Coordinator

Medical Hold x _____ months.

U/L KDP Tx Coordinator

Psychosocial Hold x _____ months.

List Any Negative Cross Match Pending

/ Represent Pending

/ Proceed With LDKT

1. Insurance & Drug Coverage Approval

2. Current & q month PRA's

3. CARDIOLITE EVERY YEAR

4. OKAY TO LIST FOR A KIDNEY PANCREAS

5. _____

6. _____

7. _____

8. _____

9. _____

10. _____

11. _____

12. _____

Attachment
UNOS Time Modification Form

Other Local Transplant Center:

_____ r approve
_____ 's request to modify the waiting time of Robert Jones as outlined in the UNOS
Wait Time Modification Forms attached.

3/19/04
Date

TOTAL P.02

AA-4

TOTAL P.05

FAXED

Kidney-Liver-Pancreas
Fax Cover Sheet

To: UNOS Phone: _____
Attn: Jim Kreger Fax: 804-697-4372

From: _____ Phone: _____
Dept: Kidney-Liver-Pancreas Transplant Center Fax: _____

Date: 3/19/04 3/23/04 Time Sent: 2:20 p

The documents accompanying this transmission contain confidential information. This information is intended only for the use of the individual or entity named above. The authorized recipient of this information is prohibited from disclosing this information to any other party unless required to do so by law or regulation. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken based on the contents of these documents is strictly prohibited by law. If you have received this facsimile message in error, please notify the _____ or at _____ (or digital pager _____) and arrange for the return or destruction of these documents.

Thank you.

RE: Please consider adjusting waiting
time.

Thank you.

Urgent: Yes No

Total Pages: 5

MOD N-5

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Date: 1-29-04 Organ Wait List: Kidney

Patient Name: _____

Patient Social Security Number or HIC Number (please specify which number is being provided): _____

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: 1-29-2004

Listing Date Requested: 10-17-2002

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): This patient was discussed at the Kidney Selection meeting on October 3, 2002. It was decided that the patient could be listed once a Repeat Urinalysis & Urine Culture were received. They were received and noted to be WNL for a patient

(Please see additional page attached)
If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: The pretransplant coordinator who had been working on this case no longer holds the position. We have also been working diligently for the past several weeks to do a complete review of our patient files.

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
- Measured (actual urinary collection) creatinine clearance level or calculated GFR \leq 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please specify) insurance predetermination

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Revised form 02/7/03 Page 1 of 2

At this time, 2 regions - do something about these centers that are not showing up in the list. Please check listing status with each center. If you are unable to check listing status with a center, please contact the UNOS representative for that center. If you are unable to check listing status with a center, please contact the UNOS representative for that center. If you are unable to check listing status with a center, please contact the UNOS representative for that center.

Decision assistance - Myra... no 2 offer - over last 3yrs... blood histogram centers & open... error in # of registrations... ID habitual errors

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____

(Please Print or Type)

Please Fax to: 804-697-4372

Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

with E⁺. (The UA+ urine culture was dated 10/11/02).
 Predetermination for kidney transplant was received
 by _____ on October 8, 2002. At that point an
 error was made and the patient's chart was placed
 with the listed patient files without the listing
 actually taking place. The patient believed he had
 been on the waiting list since that time. When
 the error was discovered we immediately contacted
 the patient and had him come for a blood sample, and
 we placed him on the active waiting list.

1/29/04

Mr. Jim Creger
UNOS
Organ Center Quality Manager

Dear Mr. Creger:

Local Transplantation Centers for Kidney Transplantation currently (other than

UNOS representative = _____ administrator

Administrator, Cleveland Clinic Foundation

2-5-04

Date

FAX COVER SHEET

SEND TO: UNOS ORGAN CENTER
ATTENTION: Jim Cresser
OFFICE LOCATION:
FAX NUMBER: 804-697-4372

Urgent Reply ASAP Please Comment Please Review For Your Information

Total pages, including cover 5

COMMENTS:

IF YOU DO NOT RECEIVE ALL PAGES, PLEASE TELEPHONE US IMMEDIATELY.

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

MOD N-1

Date: 11/10/03 Organ Wait List: Kidney
First Name Last Name

Patient Name: _____

Patient Social Security Number or HIC Number (please specify which number is being provided):
SS #

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: 8/25/03

Listing Date Requested: 11/22/99

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): We received a call from this patient's dialysis unit 2/01 stating that the patient was transplanted at _____ in _____ on 12/99. He was removed from UNOS. The unit did not send any more ^{blood} samples monthly. Patient's ^{son} called in August 2003 to request testing with wife as possible donor. Never transplanted at _____; verified with center.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: Have changed our procedure. Will verify patient's SS# with the staff member who is calling. Verify date of transplant with patient him/herself. Will call transplant center as well. Document conversation with date, time, and names in Progress Notes.

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
- Measured (actual urinary collection) creatinine clearance level or calculated GFR \leq 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please specify) _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____
(Please Print or Type)

Please Fax to: 804-697-4372
Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

CC-2

Transplantation Division

Re: Reinstatement of Waiting Time for

UNOS Representative: Please sign, date, and fax to

_____) ✓
_____) ✓
_____) ✓
_____) ✓
_____) ✓
_____) ✓
_____) ✓
_____) ✓
_____) ✓
_____) ✓

CC-3

Affiliated with

Phone

• Fax

Transplantation Division

Re: Reinstatement of Waiting Time for

UNOS Representative: Please sign, date, and fax to _____, RN.

CC-4

Transplantation Division

Re: Reinstatement of Waiting Time for

UNOS Representative: Please sign, date, and fax to _____ RN.

CC-5

Transplantation Division

Re: Reinstatement of Waiting Time for

UNOS Representative: Please sign, date, and fax to

, RN,

Transplantation Division

Re: Reinstatement of Waiting Time for

UNOS Representative; Please sign, date, and fax to

RN,

Transplantation Division

Re: Reinstatement of Waiting Time for

UNOS Representative: Please sign, date, and fax to

, RN,

CC-8

Transplantation Division

Re: Reinstatement of Waiting Time for

UNOS Representative: Please sign, date, and fax to

RN,

CC-9

Transplantation Division

Re: Reinstatement of Waiting Time for

UNOS Representative: Please sign, date, and fax to _____, RN,

) _____

Transplantation Division

Re: Reinstatement of Waiting Time for

UNOS Representative: Please sign, date, and fax to _____, RN,

CC-11

Transplantation Division

FAX TRANSMITTAL FORM



DATE: 1/22/04

TO: UNOS

FAX No. 804-697-4372

of pages (including cover sheet) 12

FROM: _____

RE: Wait Time Modification Request

COMMENTS:

Confidentiality Notice: Protected Health Information Enclosed

Private and sensitive information, or Protected Health Information (PHI) is related to a person's health care and is being faxed after appropriate authorization from the patient or under conditions that do not require patient authorization. The recipient(s) is (are) required to maintain it secure, safe, and confidential. It is Prohibited to: further disclose this information without additional patient consent or as permitted by law; copy, disclose, use, or distribute this information to somebody else than the intended recipient, employee, or representative responsible to deliver it to the intended recipient. Federal and state laws enforce penalties for any breach of confidentiality or unauthorized re-disclosure of PHI. If you have received this message by error, please notify us/the sender immediately regarding these documents' destruction or return.

WARNING: This message is intended for the use of the person or entity to which it is addressed and may contain private and confidential information; its disclosure is ruled by appropriate law. Please call _____ if you have any problems receiving this message.

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

MOD N-8

Date: 12/10/03 Organ Wait List: Kidney

Patient Name: _____

Patient Social Security Number or HIC Number (please specify which number is being provided):
SSN

Name of Transplant Center and UNOS Center Code: _____

Current Listing Date: 4-2-01

Listing Date Requested: 4-2-01

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation):

- was made a Status when transplant program became inactive. At that time, she sought to transfer to . After several months went by, did not feel her case was being handled efficiently as her time had yet to be

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain:

transferred. She was placed on our list as of 11-13-03, and the waiting time she had previously accrued was transferred.

is requesting that the time she lost while held from 4-1-03 to 11-13-03 be reinstated.

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- Patient on dialysis, or
- Measured (actual urinary collection) creatinine clearance level or calculated GFR \leq 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- Patient Selection Minutes
- Organ Justification Form, if Applicable
- Patient Listing Confirmation Letter
- Other (Please specify) _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____
(Please Print or Type)

Please Fax to: 804-697-4372

Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

DD-2

12/22/03

Mr. Jim Creger
UNOS
Organ Center Quality Manager

Dear Mr. Creger:

Local Transplant Centers for Kidney Transplantation currently (other than

UNOS representative =

I approve of the wait time modification for

12-23-03
Date

Attn:

Re:

SSN:

Fax:

December 19, 2003

Dear:

I am unable to make this change to the UNOS wait list or forward the request to the appropriate UNOS Committee because the request to backdate the wait time for does not meet the minimum requirements specified in UNOS policy 3.2.1.8, and the Wait Time Modification form, which require the signatures of the other local transplant centers with programs of the applicable organ, along with the appropriate supporting documentation.

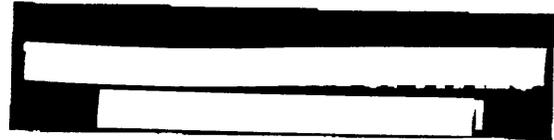
Thanks, Jim Creger
Organ Center Quality Manager

Cregerjh@unos.org

CONFIDENTIALITY NOTICE

This electronic message transmission contains information from the United Network for Organ Sharing, and this information is confidential. If you are not the intended recipient, be aware that disclosure, copying, distribution or use of all or any portion of the content of this information is prohibited, except by authority of the sender. If you received this transmission in error, please notify us as soon as possible by e-mail and delete the original message.

DisplayText cannot span more than one line!



Fax

To:	Jim Creger	From:	
Fax:	804 697-4372	Pages:	5
Phone:		Date:	2/19/04
Re:		CC:	

Urgent
 For Review
 Please Comment
 Please Reply
 Please Recycle

Please let me know if you need further documentation.

Thanks you,

If the information transmitted by this fax contains protected health information, the following statement applies:

The information accompanying this transmission is **STRICTLY CONFIDENTIAL** and is intended for the use of the addressee only. /

/ disclaims any responsibility for the unauthorized disclosure of this information to individuals or parties other than the addressee. This information has been disclosed to you from records whose confidentiality is protected by Federal and /, including HIPAA, Federal Regulation (42 CFR Part 2) and which prohibit you from making any further disclosure of it without the specific written consent of the person to whom it pertains, or as otherwise permitted by such laws. A general authorization for the release of medical or other information, including HIV/AIDS-related information, is NOT sufficient for this purpose.

If you received this information in error, please notify the sender immediately by e-mail, fax or telephone, or call Information Services at to arrange for return of the original documents as soon as possible. In addition, if you are not the intended recipient, any dissemination, distribution or duplication of this transmission is strictly prohibited.

CC: JASON BYRD
CINDY SOMMER
~~FRANK BISS~~
FOR KIPPA COM
MTG. . .



Texas Organ Sharing Alliance

December 19, 2003

Doug Heiney
Director of Membership Services
and Policy Development
United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218

RECEIVED DEC 19 2003

Dear Mr. Heiney:

On behalf of the Texas Organ Sharing Alliance (TOSA) and the renal transplant programs in TOSA's service area, the attached sharing proposal, entitled "Alternative Points Assignment (Variance) and Texas Inter-OPO Sharing Agreement" is respectfully submitted for consideration. The purpose for submitting this proposal at this time is to comply with Texas Senate Bill 1226 (see attached bill and letter), requiring organ procurement organizations (OPOs) that have a defined service area that includes all or part of the state and that are members of the Organ Procurement Transplant Network (OPTN), and transplant centers in the state that are members of the OPTN to submit a kidney sharing agreement by December 20, 2003 (180 days after the effective date of the Act).

The focus of the new law is to provide for a statewide sharing arrangement which will assist in alleviating waiting times for patients waiting the longest for a kidney. Key components of the law and proposal call for the creation of a pool of medically eligible patients comprising the top 20% of all patients waiting and the sharing of 20% of kidneys from deceased donors in the state to be provided for those patients in the pool. It is through this primary sharing feature that the proposal is expected to reduce the waiting times for the patients waiting the longest.

Relevant details of the sharing arrangement are contained in the attached agreement proposal and serve as a viable foundation for the development of responses to be included in a formal UNOS application document. Due to the high level of complexity of this type of sharing arrangement and the multiple parties and issues reflecting the statewide nature of the proposal, it is anticipated that as the formal UNOS application is completed, additional aspects of the agreement will be incorporated.

TOSA and the renal transplant programs in TOSA's service area have provided a significant good faith effort to develop a plan which would reflect the widest consensus and which would be in the best interests of the transplant patients waiting the longest for a kidney from a deceased donor. We will continue those efforts to achieve a satisfactory level of consensus as we develop the formal application.

Sincerely,

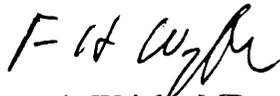
Patrick J. Giordano, MHA, CHE
Chief Executive Officer

Enclosures

42

EE-1

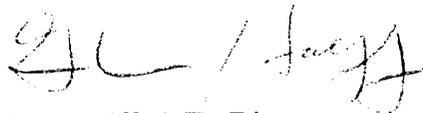
**Texas Organ Sharing Alliance Submission to United Network for Organ Sharing in
Compliance with Texas Senate Bill 1226
December 19, 2003**



Francis Wright, MD
Director, Organ Transplant
Texas Transplant Institute
Methodist Specialty and Transplant Hospital



Ernest Hodge, MD
Program Director
Renal Transplantation
North Austin Medical Center



Glenn Halff, MD, Director
Division of Transplantation
University of Texas Health Science Center

Surgical Director
CHRISTUS Transplant Institute
San Antonio



Ken Washburn, MD
Medical Director
Texas Organ Sharing Alliance

Copies to:

Senator Jane Nelson

Karen Hilton
Legislative Assistant

Walter Graham
Executive Director
United Network for Organ Sharing

Fred Geiger
Regional Administrator
United Network for Organ Sharing

Dr. Steve Katz
President
Texas Transplantation Society

Laurie Reece
Texas Transplantation Society

Jim Cutler, Executive Director
Southwest Transplant Alliance

Sam Holtzman, Executive Director
LifeGift Organ Donation Center

Glenn Halff, MD
Ernest Hodge, MD
Charles Moritz, MD
Michael Schultz, MD
Vince Speeg, MD
Ken Washburn, MD
Francis Wright, MD

Joe Nespral, Director
Clinical Services
Texas Organ Sharing Alliance

Ann Roberson, Manager
Quality Systems
Texas Organ Sharing Alliance

[] = Deleted Language
< > = New Language

Bill Number: TX78RSB 1226
ENROLLED

Date: 05-27-2003

1- 1 AN ACT
1- 2 relating to the allocation of kidneys available for transplant in
1- 3 this state.
1- 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
1- 5 SECTION 1. Chapter 161, Health and Safety Code, is amended
1- 6 by adding Subchapter R to read as follows:
1- 7 <SUBCHAPTER R. ALLOCATION OF KIDNEYS AVAILABLE FOR TRANSPLANT>
1- 8 <Sec. 161.451. DEFINITION. In this subchapter, "organ"
1- 9 <procurement organization" means an organization that is a qualified>
1-10 <organ procurement organization under 42 U.S.C. Section 273 that is>
1-11 <currently certified or recertified in accordance with that federal>
1-12 <law.>
1-13 <Sec. 161.452. FORMATION OF KIDNEY SHARING POOL AND>
1-14 <DISTRIBUTION TO LONGEST WAITING PATIENTS. (a) Under the system>
1-15 <for allocating kidneys available for transplant in this state, to>
1-16 <the extent allowed by federal law, a statewide pool of 20 percent of>
1-17 <the kidneys from deceased donors of each blood type recovered by>
1-18 <each organ procurement organization that has a defined service area>
1-19 <that includes all or part of this state is provided to a special>
1-20 <pool for redistribution to patients who have been waiting the>
1-21 <longest for transplantation in this state.>
1-22 <(b) Medically eligible patients with low panel reactive>
1-23 <antibodies of less than 10 percent who, in terms of accumulated>
1-24 <waiting time, comprise the top 20 percent of all patients waiting>
2- 1 <will be put in a pool. As one of those patients receives a>
2- 2 <transplant, the patient will be replaced in the pool, in turn, by>
2- 3 <the next longest waiting patient. Only accumulated waiting time>
2- 4 <will be used to establish priority access to the pool.>
2- 5 <(c) With the exception of assigning points for a six antigen>
2- 6 <match with zero antigen mismatch, assigning points for human>
2- 7 <leukocyte antigen (HLA) match will be eliminated by organ>
2- 8 <procurement organizations that are participating in the pool>
2- 9 <established under Subsection (a).>
2-10 <(d) After a patient has qualified for entry into the pool>
2-11 <established under Subsection (b), the order of distribution is>
2-12 <based solely on the length of time each patient has waited.>
2-13 <(e) Use of the pools will be managed by the federal Organ>
2-14 <Procurement and Transplantation Network.>
2-15 <(f) A panel of appropriate physician specialists of Texas'>
2-16 <Organ Procurement and Transplantation Network members will monitor>
2-17 <the listing of patients and the appropriate use of the pools.>
2-18 SECTION 2. Organ procurement organizations that have a
2-19 defined service area that includes all or part of this state and
2-20 that are members of the Organ Procurement and Transplantation
2-21 Network, and transplant centers in this state that are members of
2-22 the Organ Procurement and Transplantation Network, shall submit to
2-23 the Organ Procurement and Transplantation Network a kidney sharing
2-24 agreement not later than the 180th day after the effective date of
2-25 this Act.
2-26 SECTION 3. This Act takes effect immediately if it receives
2-27 a vote of two-thirds of all the members elected to each house, as
3- 1 provided by Section 39, Article III, Texas Constitution. If this
3- 2 Act does not receive the vote necessary for immediate effect, this
3- 3 Act takes effect September 1, 2003.
3- 4
3- 5 _____
3- 5 President of the Senate Speaker of the House
3- 6 I hereby certify that S.B. No. 1226 passed the Senate on
3- 7 May 6, 2003, by the following vote: Yeas 31, Nays 0.
3- 8
3- 9 _____
3- 9 Secretary of the Senate
3-10 I hereby certify that S.B. No. 1226 passed the House on
3-11 May 25, 2003, by the following vote: Yeas 117, Nays 0, two
3-12 present not voting.
3-13
3-14 _____
3-14 Chief Clerk of the House



THE SENATE OF TEXAS
COMMITTEE ON HEALTH AND HUMAN SERVICES

SAM HOUSTON BLDG.
ROOM 420
P.O. BOX 12068
AUSTIN, TEXAS 78711
(512) 463-0360
FAX: (512) 463-9889
DIAL 711 FOR RELAY CALLS
E-MAIL: jane.nelson@senate.state.tx.us

SENATOR JANE NELSON
Chair
SENATOR KYLE JANEK
Vice Chair
SENATOR JOHN CARONA
SENATOR BOB DEUELL
SENATOR MARIO GALLEGOS
SENATOR JON LINDSAY
SENATOR BILL RATLIFF
SENATOR ROYCE WEST
SENATOR JUDITH ZAFFIRINI

September 28, 2003

Stephen M. Katz, MD
Texas Transplantation Society
401 W. 15th St.
Austin, TX 78701

Dear Dr. Katz,

Thank you for your letter regarding the Texas Transplantation Society's efforts to bring the transplant community together to formulate a plan for sharing kidneys as required in Senate Bill 1226, 78(R).

It appears that the proposed plan outlined in your August 19, 2003 correspondence would require each Organ Procurement Organization (OPO) to develop its own plan for sharing kidneys with the longest-waiting patients within that OPO. While this would provide incremental change and benefit some patients, SB 1226 requires a unified statewide sharing system rather than an intra-OPO system. However, there is nothing in SB 1226 that precludes the submission of your plan for review by the OPTN, in addition to a statewide plan as called for in the bill.

Since SB 1226 was passed unanimously, the deadline for presenting a plan to the Organ Procurement Transplantation Network (OPTN) is December 20, 2003. If a viable statewide plan is not submitted by the deadline, the issue may need to be revisited by the 79th Legislature. While realizing that, ultimately, organ allocation is governed at the federal level, I am convinced that there are measures we can take in Texas to alleviate some of the inequities of geography, and am confident that the transplant centers and OPOs can come together to draft a statewide plan that meets the statutory requirements.

I encourage you to continue your hard work to develop a consensus solution, to this critical issue. I also hope that you will plan another Transplant Day for 2005. We need to make every effort to educate legislators, as well as the public, of the critical shortage of donors. I remain committed to working with you on both fronts.

Sincerely,

A handwritten signature in cursive script that reads "Jane Nelson".

Senator Jane Nelson

Alternate Points Assignment (Variance) and Texas Inter-OPO Sharing Agreement

A Task Force created by Senate Bill 862 during 1999 and 2000 deliberated to address ways to improve organ donation and allocation in the state of Texas. One of the outcomes of the Task Force was a recommendation to create a kidney "pool" concept organ sharing arrangement to assist patients waiting the longest for kidney transplantation.

Senate 1226 (SB1226) will effectively operationalize the pool concept for those waiting the longest for a kidney transplant. SB1226 mandates that each OPO and transplant center in the state (ostensibly through the OPOs) submit a plan to the United Network for Organ Sharing (UNOS) which effectively creates statewide sharing and expedited kidney allocation to a pool of patients waiting the longest for a donated kidney.

Supporting information used in the Task Force deliberations on wait time disparities included studies of the kidney wait time disparity among Renal Transplant Centers (RTC's) within the three OPOs, identification of patient populations potentially disadvantaged, and impact on ABO blood groups. Minorities and highly sensitized patients were found to comprise the greatest sectors of renal transplant candidates who had waited greater than three years for transplantation *or* who are currently wait listed with greater than three years of accrued activity time.

Texas Senate Bill 1226 (SB1226), state legislation enacted into law in May 2003, specifically addressed the wait time disparity among Texas RTC candidates who had current Panel Reactive Antibodies (PRA) ≤ 10 percent and who have been waiting on the renal candidate wait list ≥ 3 years. The following requirements are mandated within the law (excerpted from Bill Number TX78RSB 1226 An Act):

- Under the system for allocating kidneys available for transplant in this state, to the extent allowed by federal law, a statewide pool of 20 percent of the kidneys from deceased donors of each blood type recovered by each OPO that has a defined service area that includes all or part of this state is provided to a special pool for redistribution to patients who have been waiting the longest for transplantation in this state.
- Medically eligible patients with low panel reactive antibodies of less than ten percent who comprise the top 20 percent of all patients waiting will be put into a pool. As one of those patients receives a transplant, the patient will be replaced in the pool, in turn, by the next longest waiting patient. Only accumulated wait time will be used to establish priority access to the pool.
- With the exception of assigning points for a zero antigen mismatch, assigning points for human leucocyte antigen (HLA) match will be eliminated by organ procurement organizations are participating in the pool.
- After the patient has qualified for entry into the pool the order of distribution is based solely on the length of time each patient has waited.

- Use of the pool will be managed by the Organ Procurement and Transplantation Network (OPTN).
- A panel of appropriate physician specialists of Texas' OPTN members will monitor the listing of patients and the appropriate use of the pools.

On two separate occasions, August 19th and November 11, 2003, Texas renal transplantation physicians, the leadership of the three Texas OPOs, and other donation and transplantation professionals met in Austin TX to discuss and deliberate on possible proposals that would comply with the intent of the law while applying sound practices utilizing medical justice and utility in the allocation of deceased donor kidneys.

The following is the proposed plan developed and submitted by the Texas Organ Sharing Alliance, that addresses not only the demonstrated wait time disparity for renal transplantation in Texas, but, will also adhere to the intent of SB1226.

SB1226 Proposed Plan

1) As required by SB1226, medically eligible patients waiting on a Texas Transplant Center list with PRA <10% who comprise the top 20% of patients waiting (in terms of accumulated waiting times) will be put into a pool. Eligibility for placement into this pool will include:

- Patients who have a PRA used for allocation of less than or equal to ten percent.
- Patients who have a PRA less than or equal to ten percent on three consecutive PRA tests within the most recent nine months.
- Re-transplant candidates who meet the above criteria would be included ONLY if the method(s) used for measuring their PRA is the same as the method(s) that would be used for any final cross-match.
- To be maintained in the pool, the patient must not have turned down two previous organ offers (unless appealed to and supported by their transplant surgeon).
- An oversight committee (see paragraph four) would determine listing criteria for patients to be included in the pool.
- Wait time activity will begin when the patient is placed on the UNOS renal transplant list.

EE-7

48

2) Also as required by SB1226, each of the state's OPOs will contribute 20 percent of the kidneys from deceased donors of each blood type to the pool. Every fifth kidney, by ABO blood group, will be distributed to patients in the low PRA candidate pool.

- Donor Kidney Criteria
 - All non ECD donor kidneys

The decision matrix below is excerpted from UNOS Policy 3.5.1

Donor Condition	Donor Age Categories				
	< 10	10 - 39	40 - 49	50 - 59	≥ 60
CVA + HTN + Creat > 1.5				X	X
CVA + HTN				X	X
CVA + Creat > 1.5				X	X
HTN + Creat > 1.5				X	X
CVA					X
HTN					X
Creatinine > 1.5					X
None of the above					X

- Zero antigen mismatch imported kidneys with local back-up should be allocated to the local low PRA pool when imported and not used for designated recipient.
- With the exception of mandatory shared kidneys, every effort will be made to transplant the paired kidneys locally, enabling later comparisons on outcomes between local vs. shared kidneys.

3) The following guidelines will apply to patient access to the pool and allocation of kidneys within the pool:

- Only accumulated waiting time, regardless of HLA matching, will be used to establish priority access to the pool. The patient with the longest waiting time, no matter where the patient is located in the state, will be at the head of the waiting list. Local patients that are one of the first five candidates of a donor pool allocation match run will be awarded additional points.
- As one of the patients receives a transplant, that patient will be replaced in the pool, in turn, by the next longest waiting patient.

- The necessary computer programming to establish the pool will be performed by the OPTN and updated in real time.
- Distribution of kidneys to patients in the pool is based solely on the length of time each patient has waited, in order. Thus, HLA matching will not be used to allocate pool kidneys. The only exception would be 0 mismatched kidneys. If a patient in the pool receives a 0 mismatched kidney from any of the State's 3 OPOs, including the patient's "local" OPO, the kidney will count as a contribution from that OPO to the pool.
- Additional points will be awarded to "local" candidates who fall within the top five candidates on the donor kidney match run.
- The UNOS organ center will be given four hours to place pool kidneys.
- If a potential kidney is offered to the pool and turned down, but subsequently gets transplanted in Texas, it counts as a one-in-five share for the host OPO toward the pool.
- Discarded kidneys do not count toward the pool.
- If an OPO accepts and imports a kidney for a designated pool patient and the kidney is not transplanted into that designated patient, it is offered back to the low pool PRA recipient list. If the kidney subsequently remains with the accepting OPO and is transplanted into a non-pool patient, the recipient OPO then owes the next kidney procured of the same ABO blood group to the statewide pool. The host OPO will continue to count the kidney export as a one-in-five share. In this case, any transplant center declining this offer will not be penalized for declining pursuant to paragraph (1). These cases will be continuously monitored by the oversight committee.

4) All Texas RTC programs participating in this plan also agree to eliminate HLA matching in the allocation of additional points for the equitable distribution of all donor kidneys.

- The exception remains that zero antigen mismatch kidneys will continue to be mandatory shares, nationally and regionally.

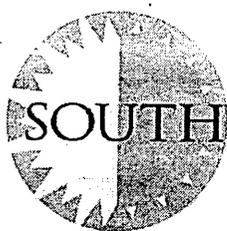
5) A panel of appropriate physician specialists of Texas' Organ Procurement and Transplantation Network members will monitor the listing of patients and the appropriate use of the pools. Oversight of the pool will include, but not be limited to, the following:

- The OPTN and/or the oversight committee will monitor the number of offers to a given patient without the patient being transplanted.

- There may be extenuating circumstances in which the allocation of an organ to a local patient on the pool waiting list (but who is not at the top of the list) may be justified. Any such circumstance would require consent of any transplant center preceding that local patient's transplant center on the waiting list. Also, any such circumstance will be reviewed by the oversight committee.
- The frequency of negative virtual cross-matches but final positive cross-matches at the intended transplant center will be assessed by the oversight committee.
- The status of the pool and its impact upon statewide waiting list trends as well as outcomes and costs will be reviewed on an annual basis by the oversight committee. If the oversight committee determines a transplant center is abusing the system, the committee will notify that transplant center in writing of its concerns. The transplant center then would have 30 days to respond in writing to the committee. If afterward the committee still believes abuses are occurring, the committee will send a letter to the UNOS Membership and Professional Standards Committee, and ask the committee to review, pursuant to its usual and customary procedures.
- The oversight committee will include four physicians as members, plus one alternate member, from each OPO with appropriate geographical, academic vs. private and large vs. small transplant center representation. Additionally, the CEO of each of Texas' OPO (or their designee) shall be represented on the oversight committee. Data collection and analysis will be ongoing
- Six months following implementation of the plan and annually thereafter, the oversight committee will assess graft outcomes, and resources expended as a result of the implementation of SB1226.

CC: JASON BYRD
1-5-03 CINDY SOAMENS

Exhibit FF



SOUTHWEST TRANSPLANT ALLIANCE

A NONPROFIT CORPORATION

3710 Rawlins Suite 1100 Dallas, Texas 75219 214-522-0255 TEL 214-522-0430 FAX

December 19, 2003

Doug Heiney
Director of Membership Services
and Policy Development
United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218

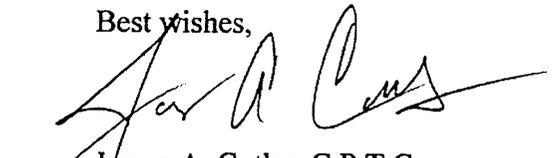
RECEIVED JAN 5 2004

Dear Mr. Heiney:

In Texas, Senate Bill 1226 requires that the transplant centers in Texas and the three Organ Procurement Organizations (OPOs) create a proposal to improve kidney allocation in Texas. The Texas Transplantation Society attempted to create a consensus proposal, but was unable to reach a consensus before the Bill's deadline.

The Texas Organ Sharing Alliance (TOSA) recently submitted a proposal in compliance with the law. Southwest Transplant Alliance and its member transplant centers stand ready to work with TOSA and UNOS in the consideration of this proposal for the benefit of patients, and to consider other proposals that may be brought forward through the UNOS process to benefit waiting patients in Texas.

Best wishes,


James A. Cutler, C.P.T.C.
President and Chief Executive Officer

cc: Senator Jane Nelson
Karen Hilton
Laurie Reece
Pat Giordano
Sam Holtzman

FF-1

Heiney.lt1 admin unos coor 2003

52

Visit us on the web at www.organ.org



RECEIVED DEC 22, 2003

CC: JASON BYRD
CINDY SOMERS

December 19, 2003

Doug Heiney
Director of Membership Services
and Policy Development
United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218

TO GO W/ THE TOSA
VARIANCE SUBMITTED ON
12/19/03

Dear Mr. Heiney:

The Texas Organ Sharing Alliance (TOSA) and its affiliated renal transplant programs recently submitted a proposed kidney sharing arrangement entitled "Alternative Points Assignment (Variance) and Texas Inter-OPO Sharing Agreement" to UNOS.

The LifeGift Organ Donation Center supports this proposed kidney sharing arrangement as submitted. Due to time limitations I am not able to provide you with the signatures of program directors from the renal transplant programs in the LifeGift service area who support this proposal at this time. However, based upon prior discussions I believe that eight of the nine programs served by LifeGift will support this proposal.

This proposal creates a special pool of medically eligible patients with a PRA \leq 10 who have been waiting the longest for a kidney transplant. The proposal also requires that each participating OPO contribute 20% of the kidneys it recovers to a separate pool of organs to be used by these patients who have been waiting the longest no matter where they might be listed for transplant in the state of Texas.

The proposal also requires that participating OPOs discontinue using the HLA point system in the distribution of cadaver kidneys. This would apply to all patients, not just those in the 20% pool. Zero antigen mismatch kidneys will continue to be mandatory shares, nationally and regionally.

LifeGift will continue to work with all parties to develop a plan with the broadest consensus possible and which would be in the best interests of the transplant patients waiting the longest for a kidney transplant. LifeGift would be fully supportive of a variance request that reflected the basic elements of the kidney sharing arrangement submitted by TOSA.

Sincerely,

Samuel M Holtzman
President and Chief Executive Officer

FF-2

53

December 19, 2003

Page 2

Copies to:

Senator Jane Nelson

Karen Hilton
Legislative Assistant

Walter Graham
Executive Director
United Network for Organ Sharing

Dr. Steve Katz
President
Texas Transplantation Society

Laurie Reece
Texas Transplantation Society

Jim Cutler
Executive Director
Southwest Transplant Alliance

Glenn Halff, MD
Ernest Hodge, MD
Charles Van Buren, MD

LifeGift Board of Directors

FF-3

54

Alternate Points Assignment (Variance) and Texas Inter-OPO Sharing Agreement

A Task Force created by Senate Bill 862 during 1999 and 2000 deliberated to address ways to improve organ donation and allocation in the state of Texas. One of the outcomes of the Task Force was a recommendation to create a kidney "pool" concept organ sharing arrangement to assist patients waiting the longest for kidney transplantation.

Senate 1226 (SB1226) will effectively operationalize the pool concept for those waiting the longest for a kidney transplant. SB1226 mandates that each OPO and transplant center in the state (ostensibly through the OPOs) submit a plan to the United Network for Organ Sharing (UNOS) which effectively creates statewide sharing and expedited kidney allocation to a pool of patients waiting the longest for a donated kidney.

Supporting information used in the Task Force deliberations on wait time disparities included studies of the kidney wait time disparity among Renal Transplant Centers (RTC's) within the three OPOs, identification of patient populations potentially disadvantaged, and impact on ABO blood groups. Minorities and highly sensitized patients were found to comprise the greatest sectors of renal transplant candidates who had waited greater than three years for transplantation or who are currently wait listed with greater than three years of accrued activity time.

Texas Senate Bill 1226 (SB1226), state legislation enacted into law in May 2003, specifically addressed the wait time disparity among Texas RTC candidates who had current Panel Reactive Antibodies (PRA) ≤ 10 percent and who have been waiting on the renal candidate wait list ≥ 3 years. The following requirements are mandated within the law (excerpted from Bill Number TX78RSB 1226 An Act):

- Under the system for allocating kidneys available for transplant in this state, to the extent allowed by federal law, a statewide pool of 20 percent of the kidneys from deceased donors of each blood type recovered by each OPO that has a defined service area that includes all or part of this state is provided to a special pool for redistribution to patients who have been waiting the longest for transplantation in this state.
- Medically eligible patients with low panel reactive antibodies of less than ten percent who comprise the top 20 percent of all patients waiting will be put into a pool. As one of those patients receives a transplant, the patient will be replaced in the pool, in turn, by the next longest waiting patient. Only accumulated wait time will be used to establish priority access to the pool.
- With the exception of assigning points for a zero antigen mismatch, assigning points for human leucocyte antigen (HLA) match will be eliminated by organ procurement organizations are participating in the pool.
- After the patient has qualified for entry into the pool the order of distribution is based solely on the length of time each patient has waited.

- Use of the pool will be managed by the Organ Procurement and Transplantation Network (OPTN).
- A panel of appropriate physician specialists of Texas' OPTN members will monitor the listing of patients and the appropriate use of the pools.

On two separate occasions, August 19th and November 11, 2003, Texas renal transplantation physicians, the leadership of the three Texas OPOs, and other donation and transplantation professionals met in Austin TX to discuss and deliberate on possible proposals that would comply with the intent of the law while applying sound practices utilizing medical justice and utility in the allocation of deceased donor kidneys.

The following is the proposed plan developed and submitted by the Texas Organ Sharing Alliance, that addresses not only the demonstrated wait time disparity for renal transplantation in Texas, but, will also adhere to the intent of SB1226.

SB1226 Proposed Plan

1) As required by SB1226, medically eligible patients waiting on a Texas Transplant Center list with PRA <10% who comprise the top 20% of patients waiting (in terms of accumulated waiting times) will be put into a pool. Eligibility for placement into this pool will include:

- Patients who have a PRA used for allocation of less than or equal to ten percent.
- Patients who have a PRA less than or equal to ten percent on three consecutive PRA tests within the most recent nine months.
- Re-transplant candidates who meet the above criteria would be included ONLY if the method(s) used for measuring their PRA is the same as the method(s) that would be used for any final cross-match.
- To be maintained in the pool, the patient must not have turned down two previous organ offers (unless appealed to and supported by their transplant surgeon).
- An oversight committee (see paragraph four) would determine listing criteria for patients to be included in the pool.
- Wait time activity will begin when the patient is placed on the UNOS renal transplant list.

2) Also as required by SB1226, each of the state's OPOs will contribute 20 percent of the kidneys from deceased donors of each blood type to the pool. Every fifth kidney, by ABO blood group, will be distributed to patients in the low PRA candidate pool.

- Donor Kidney Criteria

- All non ECD donor kidneys

The decision matrix below is excerpted from UNOS Policy 3.5.1

Donor Condition	Donor Age Categories				
	< 10	10 - 39	40 - 49	50 - 59	≥ 60
CVA + HTN + Creat > 1.5				X	X
CVA + HTN				X	X
CVA + Creat > 1.5				X	X
HTN + Creat > 1.5				X	X
CVA					X
HTN					X
Creatinine > 1.5					X
None of the above					X

- Zero antigen mismatch imported kidneys with local back-up should be allocated to the local low PRA pool when imported and not used for designated recipient.
- With the exception of mandatory shared kidneys, every effort will be made to transplant the paired kidneys locally, enabling later comparisons on outcomes between local vs. shared kidneys.

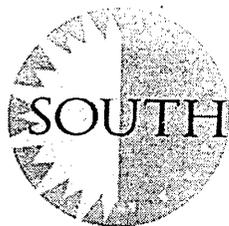
3) The following guidelines will apply to patient access to the pool and allocation of kidneys within the pool:

- Only accumulated waiting time, regardless of HLA matching, will be used to establish priority access to the pool. The patient with the longest waiting time, no matter where the patient is located in the state, will be at the head of the waiting list. Local patients that are one of the first five candidates of a donor pool allocation match run will be awarded additional points.
- As one of the patients receives a transplant, that patient will be replaced in the pool, in turn, by the next longest waiting patient.

- The necessary computer programming to establish the pool will be performed by the OPTN and updated in real time.
 - Distribution of kidneys to patients in the pool is based solely on the length of time each patient has waited, in order. Thus, HLA matching will not be used to allocate pool kidneys. The only exception would be 0 mismatched kidneys. If a patient in the pool receives a 0 mismatched kidney from any of the State's 3 OPOs, including the patient's "local" OPO, the kidney will count as a contribution from that OPO to the pool.
 - Additional points will be awarded to "local" candidates who fall within the top five candidates on the donor kidney match run.
 - The UNOS organ center will be given four hours to place pool kidneys.
 - If a potential kidney is offered to the pool and turned down, but subsequently gets transplanted in Texas, it counts as a one-in-five share for the host OPO toward the pool.
 - Discarded kidneys do not count toward the pool.
 - If an OPO accepts and imports a kidney for a designated pool patient and the kidney is not transplanted into that designated patient, it is offered back to the low pool PRA recipient list. If the kidney subsequently remains with the accepting OPO and is transplanted into a non-pool patient, the recipient OPO then owes the next kidney procured of the same ABO blood group to the statewide pool. The host OPO will continue to count the kidney export as a one-in-five share. In this case, any transplant center declining this offer will not be penalized for declining pursuant to paragraph (1). These cases will be continuously monitored by the oversight committee.
- 4) All Texas RTC programs participating in this plan also agree to eliminate HLA matching in the allocation of additional points for the equitable distribution of all donor kidneys.
- The exception remains that zero antigen mismatch kidneys will continue to be mandatory shares, nationally and regionally.
- 5) A panel of appropriate physician specialists of Texas' Organ Procurement and Transplantation Network members will monitor the listing of patients and the appropriate use of the pools. Oversight of the pool will include, but not be limited to, the following:
- The OPTN and/or the oversight committee will monitor the number of offers to a given patient without the patient being transplanted.

- There may be extenuating circumstances in which the allocation of an organ to a local patient on the pool waiting list (but who is not at the top of the list) may be justified. Any such circumstance would require consent of any transplant center preceding that local patient's transplant center on the waiting list. Also, any such circumstance will be reviewed by the oversight committee.
- The frequency of negative virtual cross-matches but final positive cross-matches at the intended transplant center will be assessed by the oversight committee.
- The status of the pool and its impact upon statewide waiting list trends as well as outcomes and costs will be reviewed on an annual basis by the oversight committee. If the oversight committee determines a transplant center is abusing the system, the committee will notify that transplant center in writing of its concerns. The transplant center then would have 30 days to respond in writing to the committee. If afterward the committee still believes abuses are occurring, the committee will send a letter to the UNOS Membership and Professional Standards Committee, and ask the committee to review, pursuant to its usual and customary procedures.
- The oversight committee will include four physicians as members, plus one alternate member, from each OPO with appropriate geographical, academic vs. private and large vs. small transplant center representation. Additionally, the CEO of each of Texas' OPO (or their designee) shall be represented on the oversight committee. Data collection and analysis will be ongoing
- Six months following implementation of the plan and annually thereafter, the oversight committee will assess graft outcomes, and resources expended as a result of the implementation of SB1226.

RECEIVED APR 19 2004



SOUTHWEST TRANSPLANT ALLIANCE

A NONPROFIT CORPORATION

3710 Rawlins Suite 1100 Dallas, Texas 75219 214-522-0255 TEL 214-522-0430 FAX

April 13, 2004

Alan B. Leichtman, M.D.
 Chair, OPTN/UNOS Kidney & Pancreas Transplantation Committee
 UNOS
 700 North 4th Street
 Richmond, VA 25218

RE: Proposal for kidney sharing in Texas:

Dear Dr. Leichtman:

I am in receipt of your letter dated April 2, 2004 regarding the Southwest Transplant Alliance (STA) proposal for an inter-state variance and sharing agreement for kidney allocation between the three Organ Procurement Organizations (OPOs) in Texas.

The proposal by STA and its member transplant centers was submitted by STA and was not endorsed by either the LifeGift Organ Donation Center or by the Texas Organ Sharing Alliance. By way of a different correspondence from UNOS, STA was notified that the UNOS Kidney/Pancreas Committee could not review any proposal until 75% of the involved members had agreed to the proposal.

Based on that correspondence, the UNOS members of Region IV met on April 2nd, and determined to form a committee containing equal representation from each of the three OPOs to try and reconcile the two proposals into one. If that could be accomplished, a Regional vote could be taken at its next meeting (October 2004), so that a single proposal could be forwarded to UNOS for its review.

In the meantime, please table the proposal from STA, contingent upon the tabling of the TOSA proposal, until the attempt to create a single regional proposal has been resolved.

Best wishes,

James A. Cutler, CPTC
 President and Chief Executive Officer

cc: Walter K. Graham
 Patrick J. Giordano, CHE
 Samuel M. Holtzman, BA
 Fred Geiger

Leichtman.lt3 admin unos 2004

73

GG-1

Visit us on the web at www.organ.org



April 14, 2004

Fred Geiger, Regional Administrator
United Network for Organ Sharing
P. O. Box 2484
Richmond, Virginia 23218

Mr. Fred Geiger,

On December 19, 2003 the LifeGift Organ Donation Center sent a letter of support for an "Alternative Points Assignment (Variance) and Texas Inter-OPO Sharing Agreement" which had been proposed by the Texas Organ Sharing Alliance. This agreement was intended to allow all three OPOs and all kidney transplant programs in Texas into compliance with Texas Senate Bill 1226.

At the April 2, 2004 Region 4 meeting in Dallas all affected parties in attendance agreed to form a working group to try to arrive at a regional consensus on how to comply with Texas Senate Bill 1226 and submit a variance request to UNOS, if necessary, that all parties could sign off on. In light of this development LifeGift would like to rescind its December 19th request that the TOSA proposed agreement be considered by UNOS.

The hope is that the OPOs and kidney programs in Texas will be able to forge an agreement by the time of the next Region 4 meeting in September, 2004 that can be submitted to UNOS on a consensus basis. If you have any questions please contact me.

Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Samuel M. Holtzman".

Samuel M Holtzman
President and Chief Executive Officer

74

GG-2

CORPORATE OFFICE

5615 KIRBY DRIVE, SUITE 900 HOUSTON, TEXAS 77005 PHONE (713) 523-GIFT (4438) FAX (713) 737-8100

www.lifegift.org

Jason Byrd

From: Doug Heiney
Sent: Tuesday, April 27, 2004 10:59 AM
To: 'PatTXSA2@aol.com'
Cc: Fred Geiger; Cindy Sommers; Jason Byrd
Subject: RE: recent TOSA submission

Thanks Pat! I'll let the committee liaisons to the Kidney/Pancreas Committee know.

Doug Heiney
Director Membership Services and Policy Development
Phone: 804-782-4810
E-Mail: heineyde@unos.org

-----Original Message-----

From: PatTXSA2@aol.com [mailto:PatTXSA2@aol.com]
Sent: Tuesday, April 27, 2004 10:04 AM
To: Doug Heiney
Cc: Fred Geiger; jnespral@txorgansharing.org; aroberson@txorgansharing.org; Laurie.Reece@texmed.org
Subject: recent TOSA submission

Hi Doug:

Fred Geiger advised us to notify you in order to withdraw our proposal for changes in kidney allocation pursuant to Texas Senate Bill 1226 for consideration at the upcoming UNOS meetings in May 2004. The reason behind this notification, and as was discussed at the most recent UNOS region 4 meeting, is that there are plans to meet on a statewide basis over the next few months to try to achieve consensus about a final proposal which may have better chances for implementation.

If you have any questions please contact me at your convenience.

Sincerely,

Patrick J. Giordano, MHA, CHE
CEO
Texas Organ Sharing Alliance
8122 Datapoint Dr.
Suite 200
San Antonio, TX
78229
(210) 614 7030

GG-3

75



September 16, 2003

Mr. Cliff McClenney
Administrator, UNOS region 7
UNOS
700 North 4th Street
Richmond, VA 23219

Re: Combining the K/P and Pancreas alone candidates to one list for local pancreas allocation

Dear Cliff,

This letter covers 2 issues:

- A request for reprogramming the Illinois local list for K/P and Pancreas alone candidates
- Follow up on the GOH Application for Variance from July, 2002.

As per our recent communications and my communication with the Development staff at UNOS, we hereby request for UNOS to program our K/P candidates and our Pancreas alone candidates into one list, as per modifications to UNOS policies 3.8.1.1, 3.8.1.2 and 3.8.1.3 approved in June 2002.

In the Gift of Hope Application for Local Variance submitted in July 2002 we requested the combined list to print out in the following priority order:

- I. **For local allocation, the SPK/PAK list will be comprised of those patients where the initial intention is or was to treat with a Simultaneous Pancreas-Kidney (SPK) transplant. It includes:**
 - a. Patients waiting for SPK transplant.
 - b. Patient waiting for PAK (Pancreas after Kidney) transplant who were initially listed on the simultaneous Pancreas-Kidney transplant waiting list who then received either a living donor kidney or cadaver kidney only transplant (while on the SPK list)
 - c. Patient who underwent SPK transplant who the suffered immediate lost of pancreas function as defined by UNOS policy 3.8.7. The previously accumulated SPK list waiting time for the PAK patient will be maintained.

- II. **All other patients awaiting pancreas transplant** will be assigned to the second tier that includes active candidates for **PTA** (pancreas transplant alone), **PAK** (patients not included above), and **PAKP** (pancreas after kidney pancreas not included above).

I would appreciate if you could make the above happen without further delays. Please let me know if there are any problems with this request.

Relative to our original application for variance submitted on July 22, 2002:

This application was "shelved" pending Modifications to Policies 3.8.1, 3.8.1.4 and 3.8.1.5. These modifications are now out for public comment. I would like to take this opportunity to put UNOS on notice that the Illinois Pancreas Transplant Centers' response to the proposed modifications relative to Pancreas for Islet transplant allocation is that Illinois continues to prefer that **all pancreata be considered for local islet transplantation prior to Regional Sharing for whole organ**. This is currently the approved variance for some centers in our region. There certainly can be no equitable regional sharing unless all OPO's in the region abide by the same distribution policies.

We need to receive a response to this comment from the UNOS Kidney and Pancreas committee promptly since our variance request, along with other similar requests in the Region have now been on hold for over a year.

Thank you for your prompt attention to the first request and for getting us a response to the second issue as well.

Sincerely

Martin F. Mozes M.D., FACS
Medical Director, Gift of Hope organ and Tissue Network

cc: Illinois Pancreas Transplant Center Directors
Dr. Alan Leichtman, Chair UNOS Kidney and Pancreas Committee.
Sue Dziewior, GOH
Jerry Anderson, CEO, GOH

**Gift of Hope- Allocation of Pancreata for Transplantation
Proposal for a local variance**

**DR. Kaufman's Revision of July, 2002 version – for input
December 19, 2003**

The Proposed allocation policy system is based for the most part on the recently modified and approved UNOS policies 3.8.1.1 , 3.8.1.2 and 3.8.1.3

For local allocation, the **SPK/PAK** list will be comprised of those patients where the initial intention is or was to treat with a Simultaneous Pancreas-Kidney (SPK) transplant. It includes:

- 1) Patients waiting for SPK transplant.
- 2) Patients waiting for PAK (Pancreas after Kidney) transplant who were initially listed on the simultaneous Pancreas-Kidney transplant waiting list who then received either a living donor kidney or cadaver kidney only transplant (while on the SPK list)
- 3) Patients who underwent SPK transplant who then suffered immediate loss of pancreas function as defined by UNOS policy 3.8.7 (see below *)

The previously accumulated SPK list waiting time for the PAK patients will be maintained.

All other patients awaiting pancreas transplant will be assigned to the second tier that includes active candidates for **PTA** (pancreas transplant alone), **PAK** (patients not included above), and **PAKP** (pancreas after kidney pancreas not included above).

Proposed Policy (this reflects the most recent changes in UNOS pancreas allocation):

A cadaver donor pancreas shall be offered to potential recipients in the following order. Within each group the wait list will be ranked by time waiting.

1. As a simultaneous pancreas-kidney to any zero-mismatch SPK recipient that is highly sensitized ($PRA \geq 80\%$)
Local, pediatric (age ≤ 18 yrs), then
Local, adult, then
Regional, then National, based on time waiting
2. To a local SPK or Pancreas alone recipient with $PRA \geq 80\%$ who has negative preliminary crossmatch
Pediatric (age ≤ 18 yrs), then
Adult
3. To a zero-mismatch SPK or Pancreas alone recipient ($PRA < 80\%$)
Local, pediatric (age ≤ 18 yrs), then
Local, adult, then
Regional, then National, based on time waiting

4. **To a local blood type identical recipient on the SPK/PAK list based on waiting time-(If the GOH kidney debt in that blood group exceeds the UNOS limit, then one kidney may needed to be first offered out as paybacks).**
Local, pediatric (age \leq 18 yrs), then
Local, adult, then
5. **To a local blood type compatible recipient on the PTA/PAKP list.**
Local, pediatric (age \leq 18 yrs), then
Local, adult, then
6. **To a local islet alone, islet after solid organ, or simultaneous islet-solid organ recipient (blood type identical for kidney-islet, blood type compatible for others).**
7. **Regional Whole Pancreas allocation (based on time waiting):**
To isolated pancreas candidates and to combined kidney-pancreas candidates, if kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in UNOS policy 3.5.1 and the kidney must be paid back s specified in policy 3.5.7
8. **National whole Pancreas recipients-with same hierarchy as # 7**
9. **To Pancreas alone patients at centers who have recorded their desire to participate in the UNOS system for facilitated pancreas allocation (as per policy 3.8.1.3)**
10. **Islet alone recipients [regional>national]**
11. **Pancreas or islets for research**

***UNOS Policy 3.8.7 Waiting Time Reinstatement for Pancreas Recipients.** In those instances where there is immediate and permanent non-function of a transplanted cadaveric or living donor pancreas, the patient may be reinstated to the waiting list and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non-function shall be defined as pancreas graft failure resulting in removal of the organ within the first two weeks of transplant. Waiting time will be reinstated upon receipt by the Organ Center of a completed Pancreas Waiting Time Reinstatement Form and documentation, including but not limited to, the patient operative report. UNOS will notify the OPO serving the recipient transplant center of the relisting and forward a copy of the relisting form to that OPO.

Signatures of Local Program directors:

Enrico Benedetti M.D.
Dir. Pancreas Transplantation
University of Illinois at Chicago (ILUI)

Beverly Ketel M. D.
Dir. Pancreas Transplantation
St. Francis Hospital, Peoria (ILSF)

Robert Harland M.D.
Dir. Pancreas Transplantation
University of Chicago Hospital (ILUC)

Deepak Mital M.D.
Dir. Pancreas Transplantation
Rush Presbyterian St. Luke's (ILPO)

David Holt M.D.
Dir. Pancreas Transplantation
Loyola University Medical Center (ILLU)

Timothy O'Connor M.D.
Dir. Pancreas Transplantation
Southern Illinois Medical Ctr. (ILMM)

Dixon Kaufman M.D.
Dir Pancreas Transplantation
Northwestern Memorial Hospital (ILNM)

Jarold Anderson
CEO
Gift of Hope Organ and Tissue Network



January 5, 2004

Dr. Alan Leichtman
Chairman, UNOS Kidney and Pancreas Committee
UNOS
700 North 4th Street
Richmond, VA 23219

Ms Cindy Sommers
UNOS Staff Liaison
UNOS Kidney and Pancreas Committee

Re: Resubmission of Gift of Hope's (GOH) application for a variance in allocation of
Pancreata for Transplantation

Dear Colleagues,

As per recent communications, GOH is hereby resubmitting its revised application to the UNOS K/P Committee for the January 20-21, 2004 meeting.

The original application was submitted in August 2002 but UNOS K/P committee's recommendations have been delayed until the committee formulated the proposed modifications to OPTN/UNOS Policies 3.8.1.4 and 3.8.1.5 in November 2003. We are resubmitting our application following review of these recommendations.

As per communication with Ms. Sommers, this cover letter comes in lieu of a full justification document, which was previously submitted with the original application. The revision concerns giving an advantage to pediatric (\leq age 18) recipients in each category. The different categories of whole organ pancreas recipients pertain to LOCAL allocation only and have no bearing on any Regional or National sharing.

65

HH-6

As to the issue of allocating pancreata for islet transplantation locally before regional sharing for whole organ, the Illinois pancreas transplant centers request that this be considered for ALL donors, rather than only for the donors as per the committee's recommendations from November 2003. In 2003 Illinois shared only 7 solitary pancreata with the Region and one of these was a mandatory share of a Zero ABDR MM pancreas alone*. Thus the impact of the above request would be minimal. At current level of sharing, suggesting a numerical cap for the variance requested will likely be irrelevant. What appears to be increasingly relevant is that, with increasing local interest in islet transplantation (in Illinois, 2 centers with FDA approved programs and an additional center seeking approval), having a variance for local islets first at one Region 7 OPO and not at the other 2 OPO's creates an inequitable sharing environment.

Thank you for putting this request before the UNOS K/P committee for consideration.

Sincerely,



Martin F. Mozes M.D, FACS
Medical Director,
Gift of Hope Organ & Tissue Donor Network

Is the Regional/National sharing of Zero ABDR MM, <80% PRA Pancreas alone continue to be mandated?

Attachment: Revised GOH Variance Proposal

cc Mr. Cliff McClenney, UNOS Region 7 Administrator
GOH Pancreas Subcommittee members

Gift of Hope- Allocation of Pancreata for Transplantation
Proposal for a local variance
(Revised)
December, 2003

The Proposed allocation policy system is based for the most part on UNOS policies 3.8.1.1 , 3.8.1.2 and 3.8.1.3

For local allocation, the **SPK/PAK** list will be comprised of those patients where the initial intention is or was to treat with a Simultaneous Pancreas-Kidney (SPK) transplant. It includes:

- 1) Patients waiting for SPK transplant.
- 2) Patients waiting for PAK (Pancreas after Kidney) transplant who were initially listed on the simultaneous Pancreas-Kidney transplant waiting list who then received either a living donor kidney or cadaver kidney only transplant (while on the SPK list)
- 3) Patients who underwent SPK transplant who then suffered immediate loss of pancreas function as defined by UNOS policy 3.8.7 (see below *)

The previously accumulated SPK list waiting time for the PAK patients will be maintained.

All other patients awaiting pancreas transplant will be assigned to the second tier that includes active candidates for **PTA** (pancreas transplant alone), **PAK** (patients not included above), and **PAKP** (pancreas after kidney pancreas not included above).

Proposed Policy (this reflects the most recent changes in UNOS pancreas allocation):

A cadaver donor pancreas shall be offered to potential recipients in the following order. Within each group the wait list will be ranked by time waiting.

1. As a simultaneous pancreas-kidney to any zero-mismatch SPK recipient that is highly sensitized ($PRA \geq 80\%$)
Local, pediatric (age ≤ 18 yrs), then
Local, adult, then
Regional, then National, based on time waiting
2. To a local SPK or Pancreas alone recipient with $PRA \geq 80\%$ who has negative preliminary crossmatch
Pediatric (age ≤ 18 yrs), then
Adult
3. To a zero-mismatch Pancreas alone recipient ($PRA < 80\%$)
Local, pediatric (age ≤ 18 yrs), then
Local, adult, then
Regional, then National, based on time waiting

4. To a local blood type identical recipient on the SPK/PAK list based on waiting time-(If the GOH kidney debt in that blood group exceeds the UNOS limit, then one kidney may needed to be first offered out as paybacks).
Local, pediatric (age ≤18 yrs), then
Local, adult, then
5. To a local blood type compatible recipient on the PTA/PAKP list.
Local, pediatric (age ≤18 yrs), then
Local, adult, then
6. To a local islet alone, islet after solid organ, or simultaneous islet-solid organ recipient (blood type identical for kidney-islet, blood type compatible for others).
7. Regional Whole Pancreas allocation (based on time waiting):
To isolated pancreas candidates and to combined kidney-pancreas candidates, if kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in UNOS policy 3.5.1 and the kidney must be paid back s specified in policy 3.5.7
8. National whole Pancreas recipients-with same hierarchy as # 7
9. To Pancreas alone patients at centers who have recorded their desire to participate in the UNOS system for facilitated pancreas allocation (as per policy 3.8.1.3)
10. Islet alone recipients [regional>national]
11. Pancreas or islets for research

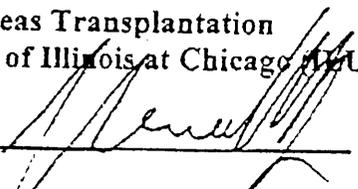
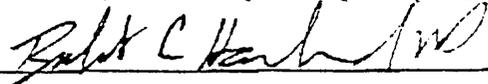
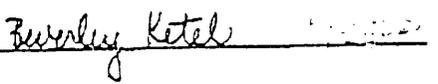
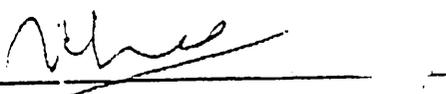
Signatures of Local Program directors:

Enrico Benedetti M.D.
Dir. Pancreas Transplantation
University of Illinois at Chicago (ILUI)

Robert Harland M.D.
Dir. Pancreas Transplantation
University of Chicago Hospital (ILUC)

Beverly Ketel M. D.
Dir. Pancreas Transplantation
St. Francis Hospital, Peoria (ILSF)

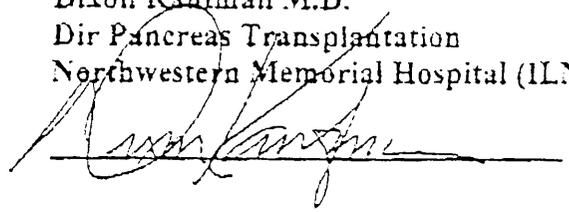
Deepak Mital M.D.
Dir. Pancreas Transplantation
Rush Presbyterian St. Luke's (ILPL)

Timothy O'Connor M.D.
Dir. Pancreas Transplantation
Southern Illinois Medical Ctr. (ILMM)



Dixon Kaufman M.D.
Dir Pancreas Transplantation
Northwestern Memorial Hospital (ILNM)



Jarold Anderson
CEO
Gift of Hope Organ and Tissue Network





10/31/03
cc: Jason B.
Kubina
Deanna
Hilke

Ms. Sommers,

Dr. Mozes would like the Application for New Local
Variance for Kidney – OPT/UNOS Policy 3.5.11.2
(enclosed) presented at the next OPTN/UNOS Kidney
& Pancreas Transplantation Committee Meeting.

RECEIVED OCT 30 2003



October 27, 2003

Ms Cindy Sommers
Director of Allocation Policy, OPTN/UNOS
Alan B. Leichtman M.D., Chair
OPTN/UNOS Kidney & Pancreas Transplantation Committee
UNOS
700 N. 4th Street
Box 2484
Richmond, VA 23218
Tel 804 782 4800
email: sommercm@unos.org

Re: Application for New Local Variance for Kidney Allocation – OPTN/UNOS Policy 3.5.11.2

Dear Ms. Sommers and Dr. Leichtman:

Pursuant to Dr. Leichtman’s letter dated March 21, 2003 and our response dated April 15, 2003 regarding a local exemption from Policy 3.5.11.2, we have reviewed our local outcome data under our previous allocation variance. That variance included the assignation of 7 points for 0-CREG,0-DR and 6 points for 0-A,B mismatches. SRTR derived data did not show any advantages in 1 and 3 year graft survival associated with these match grades or with HLA matching in general, in either African American or Non-African American recipients, sensitized or non-sensitized (Attachments 2-11). Furthermore, our own data did not indicate a significant benefit of lesser sensitization following a failed graft when CREG and DR matching were used (Attachment 12).

We therefore would like to apply for a new variance (Attachment 1), which is more in line with the current OPTN/UNOS policy 3.5.11.2, but which retains our previous priority given to children and adolescents and emphasizes priority for patients who have previously donated an organ for transplantation. The current proposal represents no deviation from existing national policy in the priority assigned to 0-A,B,DR mismatch, in the points assigned for waiting time and for PRA \geq 80 %). In the spirit of the national policy it eliminates points for HLA. With no local evidence for advantages in outcome or sensitization, points for DR matching have also been eliminated thus increasing equity in allocation.

II-2

The GOALS of our new alternative allocation schema can be summarized as follows:

1. To maximize equitable access to available kidneys for all ethnic groups.
2. To increase the advantage for highly sensitized patients (PRA \geq 80%) so as to increase their chances to receive a cross match negative kidney.
3. To prioritize children and adolescents so as to shorten their waiting time.
4. To further advantage prior organ donors.
5. To make kidney allocation more predictable so as to optimize management of wait list.
and, as stated,
6. To minimally deviate from the national OPTN/UNOS policy 3.5.11.2.

The methods by which the Gift of Hope allocation system proposes to achieve these goals will be outlined in responses to the following UNOS standard variance application format questions

a) *Advantages of proposed variance over current UNOS policy. Explain how equitable organ allocation would be facilitated:*

This question will be answered in two parts, both pertaining to the equity issue:

1. It is well established that any system that assigns points to HLA in the allocation of kidneys tends to disadvantage the African American patients on the waiting list and creates a waiting time disparity in favor of the Non-African American waiting patients. Conversely, as has been repeatedly demonstrated by protocols that eliminated points for HLA matching, this wait time disparity was diminished.

In our local area we are unable to show graft survival advantages with any degree of HLA matching, including CREG and DR (Attachments 1-4). We believe that the overall excellent results achieved in our area are due to the sensitive cross match techniques used in our local distribution of kidneys. These include the routine use of T- and B-cell flow cytometric cross matches.

Thus we propose a system where no points are given for HLA matching. We propose to maintain the top priority for the 0-A,B,DR mismatch grade because this match level offers a needed advantage to at least some highly sensitized patients.

Furthermore, we propose to emphasize waiting time by adopting the UNOS point system rather than maintain our previous cap of 3 points.

2. To further advantage prior organ donors:
We feel that patients who had previously donated an organ for transplantation, either to a designated recipient or to the pool of recipients, deserve a high priority in receiving an organ transplant when they need one. It is the least the system can do to reward these potentially unfortunate good Samaritans and having this as a contract up front is certainly reassuring to persons when considering live donation. The number of these potential recipients is predictably small and will not effect the overall kidney allocation to any significant measure.

b) *Effect of variance on waiting times for highly sensitized transplant candidates:*

With the goal to increase the advantage for highly sensitized patients so as to increase their chances to receive a cross-match negative kidney we propose to increase the number of points assigned to highly sensitized patients from our current 3 point variance to 4 points, in line with the UNOS policy.

c) *What is the anticipated effect on recipient and graft survival?*

As previously stated under (a), in our local area we are unable to show graft survival advantages with any degree of HLA matching, including CREG and DR (Attachments 2-5).

With no points being allocated for HLA matching, with the exception of the 0-A,B,DR mismatched kidney, the pediatric recipient and the occasional highly sensitized patient further down the wait list, all kidneys will be allocated based on waiting time. Such is already the case with Expanded Criteria donor kidneys per UNOS policy. This means that transplant centers will be able to better predict who the next likely recipient will be on the deceased kidney waiting list in any given ABO blood group. Thus, patients most likely to receive a kidney can be medically optimized for their transplant. Cardiac evaluation and any necessary diagnostic and therapeutic measures can be performed and updated in a more elective fashion. **This will likely result in lowering post transplant patient mortality, currently a major cause of graft loss in the early period following transplantation.**

An additional benefit of above scenario is the ability of the tissue typing laboratory to decrease the number of initial (screening) cross matches to only the top of the wait list plus a few previously defined patients (pediatric and PRA \geq 80%). Also, the distribution system will gain efficiency and shorten CIT by making offers only to actually active and ready patients.

d) *Effect on organ allocation in Pediatric, female or racial minority groups:*

We have examined the waiting time of children and adolescent patients in our area and have found that our previous point system that gave an advantage to these patients actually resulted in significantly shorter waiting times locally when compared to waiting times for children nationally (Attachment 13). We would like to continue a system that advantages children and therefore propose to give them priority in allocation at all times.

The question of improving equitable allocation to minority groups has already been addressed. There is no anticipated effect on allocation based on recipient gender.

e) *Effect of waiting times in different blood groups:*

This allocation variance does not affect the UNOS ABO blood group related allocation.

f) *How does the variance affect allocation and waiting times among various categories of medical urgency ?*

Medical urgency is not a routine consideration in the allocation of kidneys, locally or nationally, and is not addressed in this variance.

g) *Consideration of proposal by Region:*

This allocation variance relates to local allocation only. The national policy of sharing at the Zero ABDR mismatch level is not affected by this variance. On the advice of Dr. Leichtman, regional review of this proposal is not required. Signatures of all Illinois Kidney transplant directors are attached (attachment 8).

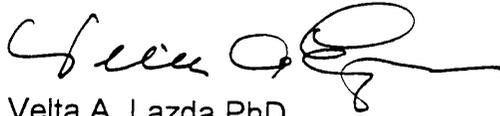
As per my previous communication with Dr. Leichtman, we would like for this application to be reviewed by the UNOS Kidney and Pancreas committee at its very next meeting with hopefully a positive recommendation to the upcoming UNOS Board of Directors.

Thank you for your assistance. If you have any inquiries regarding this application please do not hesitate to contact either of us at GOH, at 630 758 2660.

Sincerely



Martin F. Mozes M.D
Medical Director, Gift of Hope Organ and Tissue Network.



Velta A. Lazda PhD
Director, Histocompatibility laboratory

Encl. Attachments 1-12

Signatures of GOH Kidney Program
Directors

Richard Cohn, M.D.
Children's Memorial Hospital

Richard A. Cohn MD
Date: 10/29/03

Robert Harland, M.D.
University of Chicago Hospitals

Robert C. Harland
Date: 10/27/03

David Holt, M.D.
Loyola University Medical Center

David Holt
Date: 10/28/03

Enrico Benedetti
University of Illinois at Chicago

Enrico Benedetti
Date: 10/28/03

S. Forrest Dodson
Rush Presbyterian St. Luke's Med Ctr

S. Forrest Dodson
Date: 10/29/03

Dr. Frank Darras, M.D.
University of Illinois at Peoria

Frank Darras MD
Date: _____

Frank Stuart, M.D.
Northwestern Memorial Hospital

Frank Stuart MD
Date: Oct 28, 2003

Timothy O'Connor, M.D. -IL-MM
SIU School of Medicine

Timothy P. O'Connor MD
Date: 10-27-03

Frederick Merkel, M.D.
Rush Presbyterian St. Luke's Med Ctr

Frederick Merkel
Date: 10/29/03

GOH Local Kidney Allocation Variance Proposal
October 27, 2003

GIFT OF HOPE ORGAN & TISSUE DONOR NETWORK
CADAVER KIDNEY DISTRIBUTION POLICY

PRIORITY 1: Zero (0) A,B,DR Mismatch Locally and/or Nationally in the Following Order:

- A. ABO-Identical
- B. ABO- Compatible (for blood group O donors, to B before A or AB)

Within priorities 1A and 1B the distribution is as follows:

- a. Local Recipients
 - i. Pediatric (<13 years old)
 - ii. Pediatric, ≥ 13 to < 18 years old
 - iii. Others
- b. National Recipients

PRIORITY 2: PEDIATRIC: ABO identical, >zero (0) A,B,DR Mismatch - Local

- A. Pediatric, <13 years old
- B. Pediatric, ≥ 13 to < 18 years old

PRIORITY 3: Others, ABO-Identical >Zero (0) A, B, DR Mismatch -Local
 For blood group A, compatible after ABO identical

- a. Patients who previously donated organ or organ segment
- b. Others

PRIORITY 4: Double Kidney Allocation- Local

- a. Local Recipients
- b. Regional Recipients
- c. National Recipients

PRIORITY 5: Others, ABO-Identical >Zero (0) A, B, DR Mismatch -National

Distribution to local recipients within each priority is by the UNOS Point System as follows:

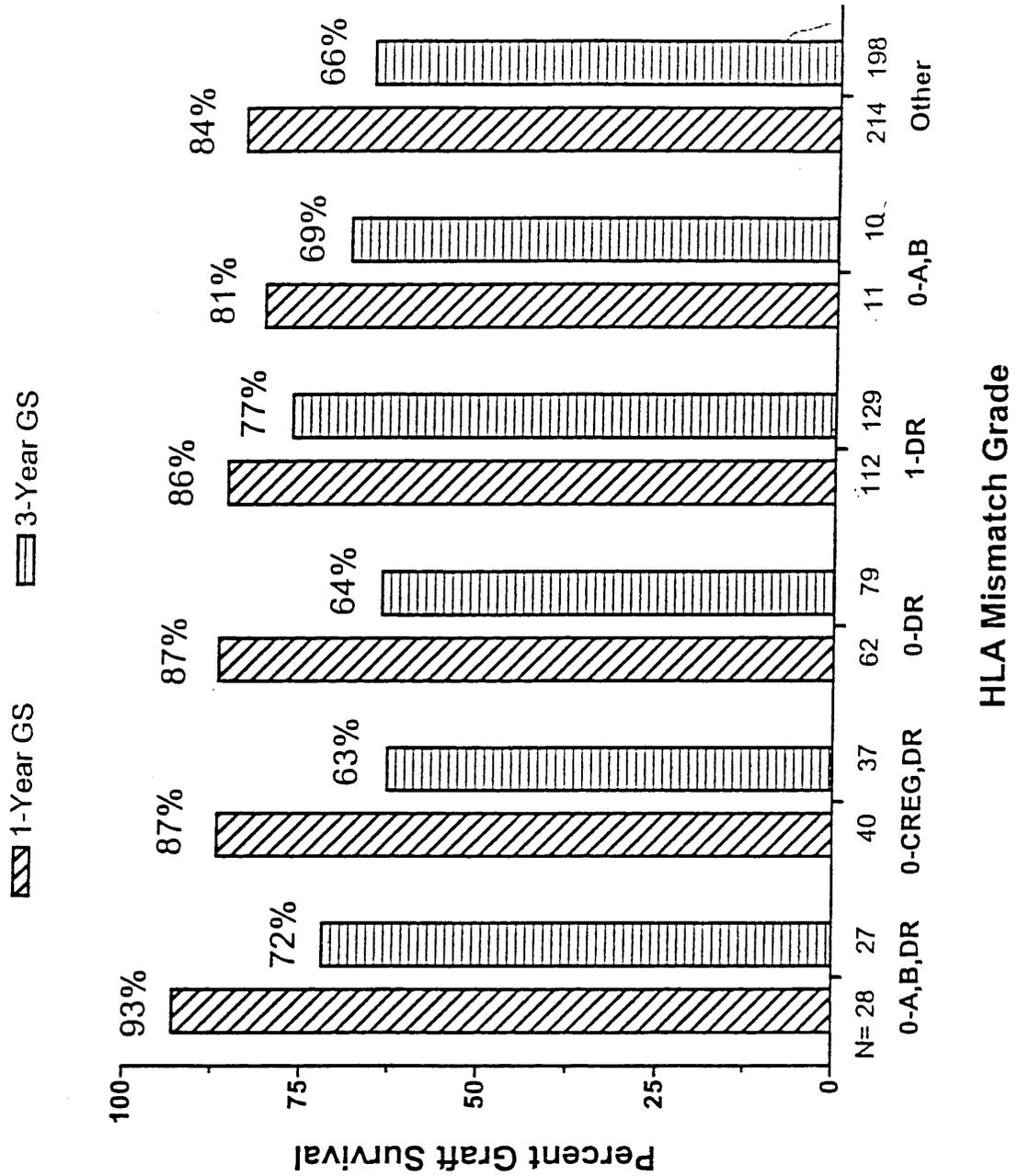
<u>Points</u>	<u>Category</u>
(per UNOS wait time points)	waiting time
4	PRA ≥80% (in last 3 months)

In case of ties, priority will be determined based on the following (in order of priority):

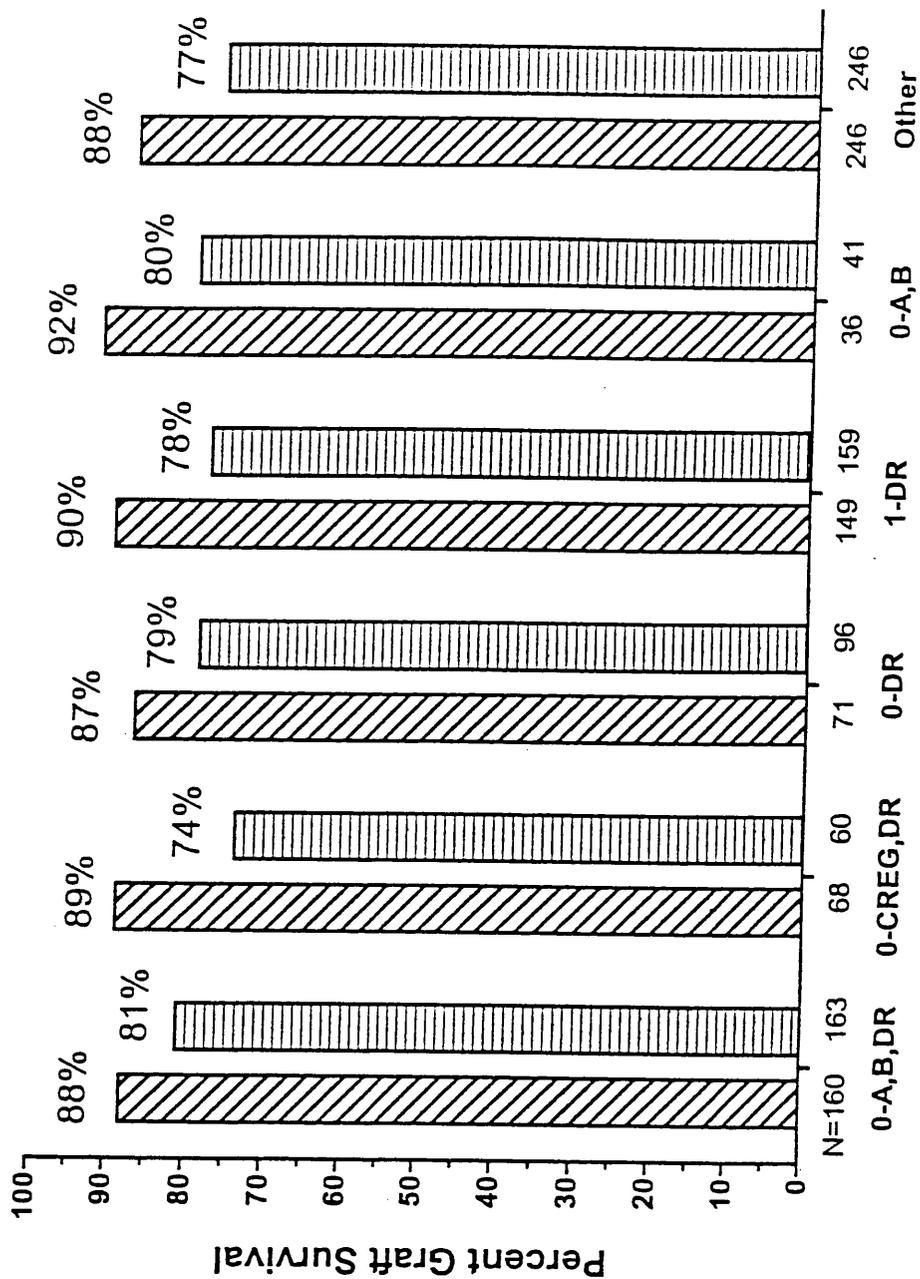
1. Longest time on the list
2. Fewest DR mismatches
3. Alphabetical Order

Pediatric kidney transplant candidates who are <18 years old at date of listing, will remain in the same priority they were in until transplanted.

Effect of HLA Matching on One and Three Year Graft Survival in Blacks



Effect of HLA Matching on One and Three Year Graft Survival in Non-Blacks



HLA Mismatch Grade

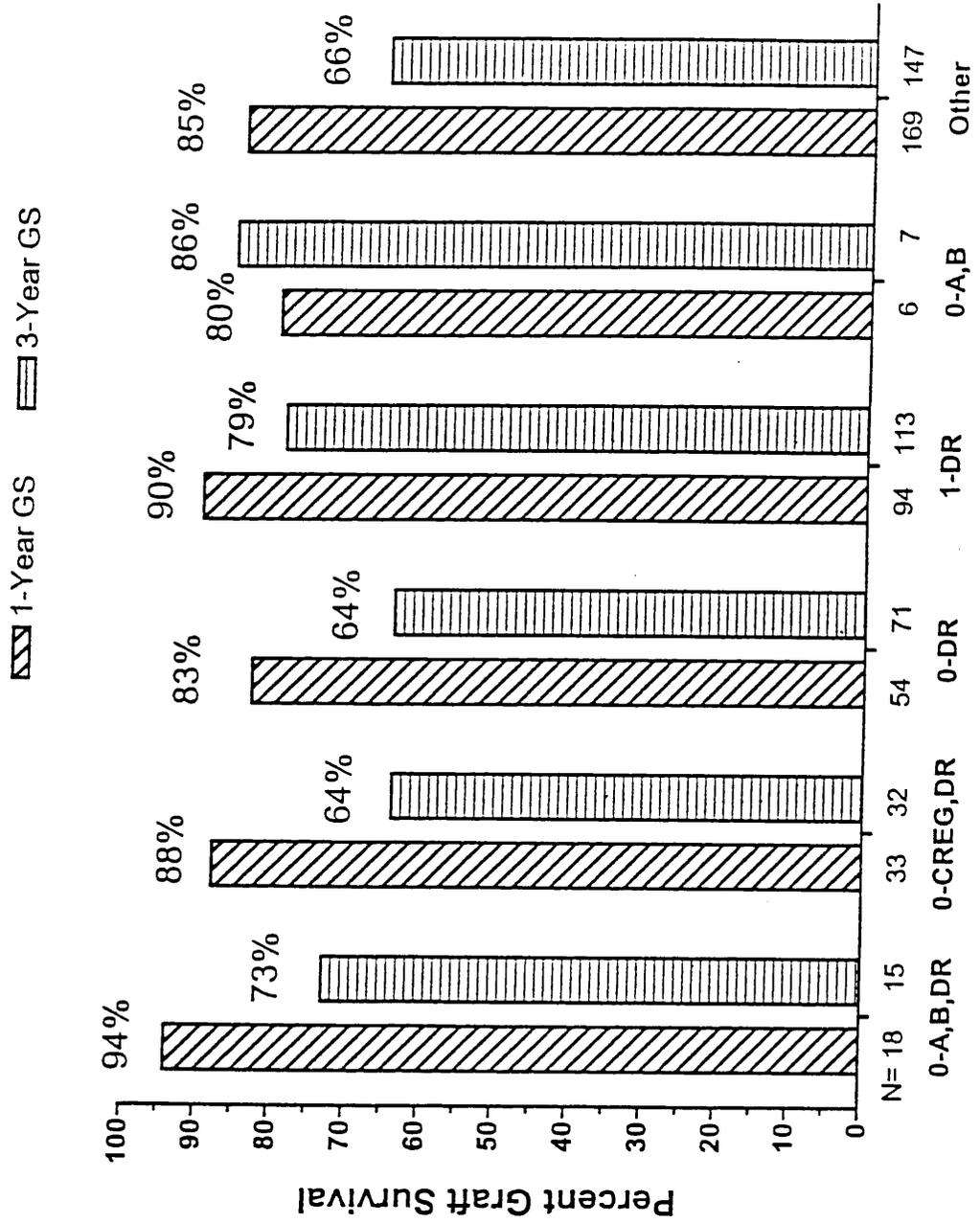
**Estimated One Year Graft Survival at Illinois Transplant Centers
1997-2000 Deceased Donor Kidney Transplants**

Race	Mismatch Group	Number of Transplants	Estimated Survival	Lower 95% CI	Upper 95% CI
African American	0-A,B,DR	28	92.86%	83.32%	100.0%
African American	0-CREG,0-DR	40	87.29%	76.86%	97.71%
African American	>0-CREG,0-DR	62	87.04%	78.66%	95.42%
African American	>0-CREG,1-DR	112	86.47%	80.10%	92.84%
African American	0-A,B,>0-DR	11	80.81%	56.80%	100.0%
African American	All others	214	84.42%	79.54%	89.31%
Non-African American	0-A,B,DR	160	88.09%	83.06%	93.11%
Non-African American	0-CREG,0-DR	68	89.39%	81.97%	96.82%
Non-African American	>0-CREG,0-DR	71	87.01%	79.08%	94.93%
Non-African American	>0-CREG,1-DR	149	90.48%	85.74%	95.23%
Non-African American	0-A,B,>0-DR	36	91.67%	82.64%	100.0%
Non-African American	All others	246	87.69%	83.56%	91.81%

**Estimated Three Year Graft Survival at Illinois Transplant Centers
1995-1998 Deceased Donor Kidney Transplants**

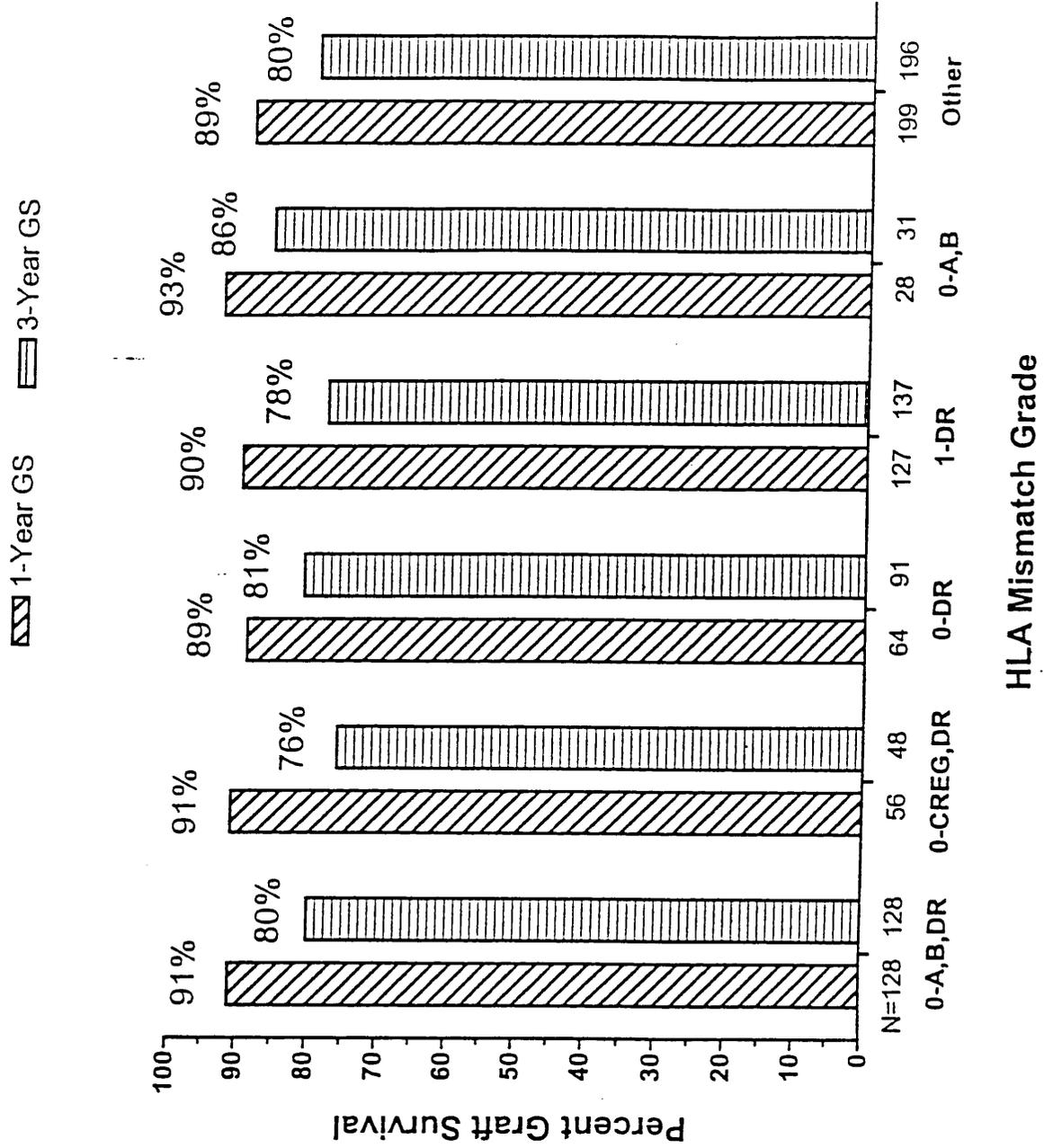
Race	Mismatch Group	Number of Transplants	Estimated Survival	Lower 95% CI	Upper 95% CI
African American	0-A,B,DR	27	71.58%	53.47%	89.70%
African American	0-CREG,0-DR	37	63.43%	47.54%	79.32%
African American	>0-CREG,0-DR	79	63.93%	52.98%	74.88%
African American	>0-CREG,1-DR	129	76.76%	69.18%	84.34%
African American	0-A,B,>0-DR	10	68.57%	38.88%	98.26%
African American	All others	198	65.71%	58.92%	72.51%
Non-African American	0-A,B,DR	163	81.49%	75.39%	87.59%
Non-African American	0-CREG,0-DR	60	73.75%	62.28%	85.22%
Non-African American	>0-CREG,0-DR	96	79.10%	70.70%	87.49%
Non-African American	>0-CREG,1-DR	159	78.31%	71.74%	84.88%
Non-African American	0-A,B,>0-DR	41	79.81%	67.29%	92.33%
Non-African American	All others	246	77.02%	71.61%	82.42%

Effect of HLA Matching on One and Three Year Graft Survival in Non-Sensitized Blacks

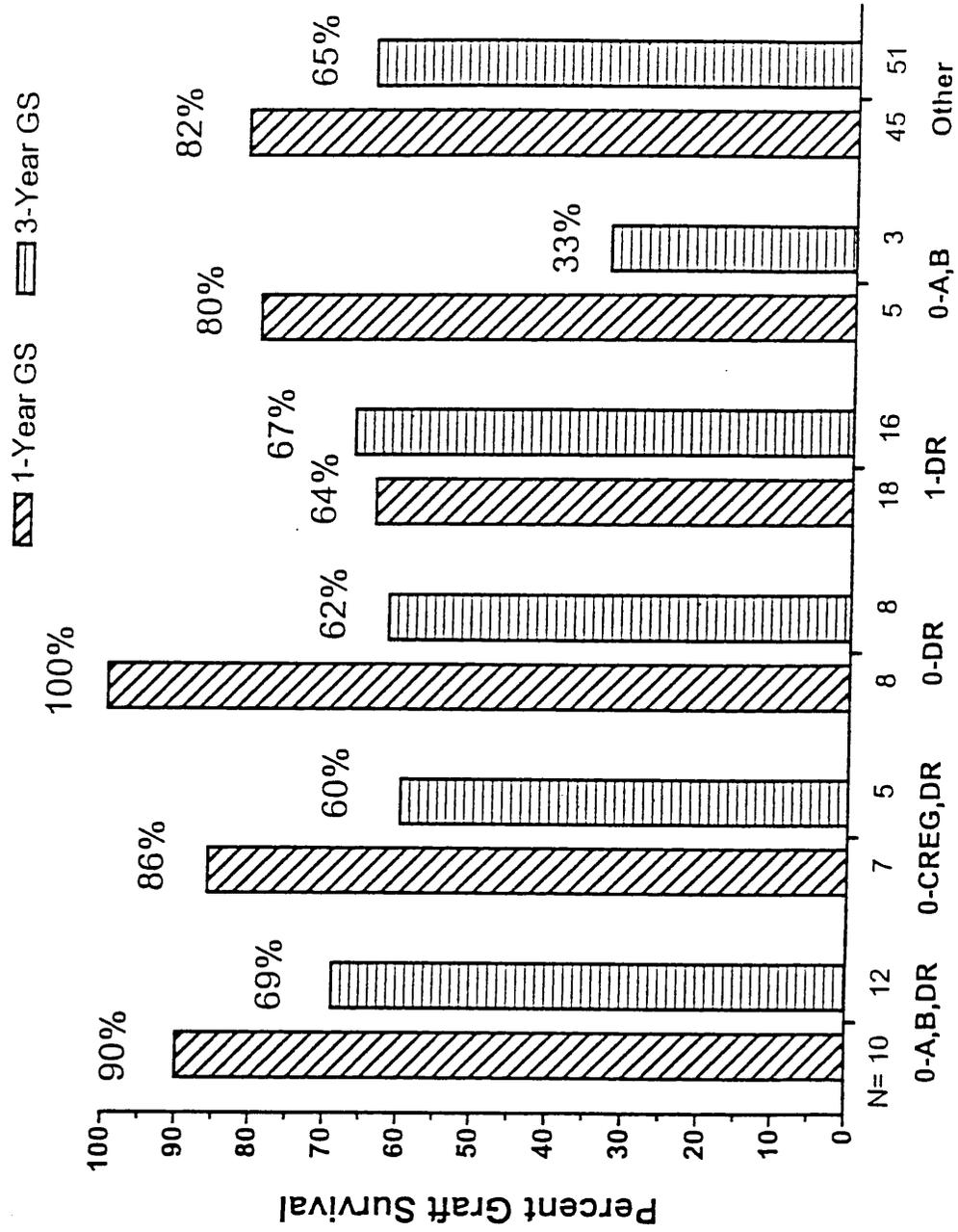


HLA Mismatch Grade

Effect of HLA Matching on One and Three Year Graft Survival in Non-Sensitized Non-Blacks

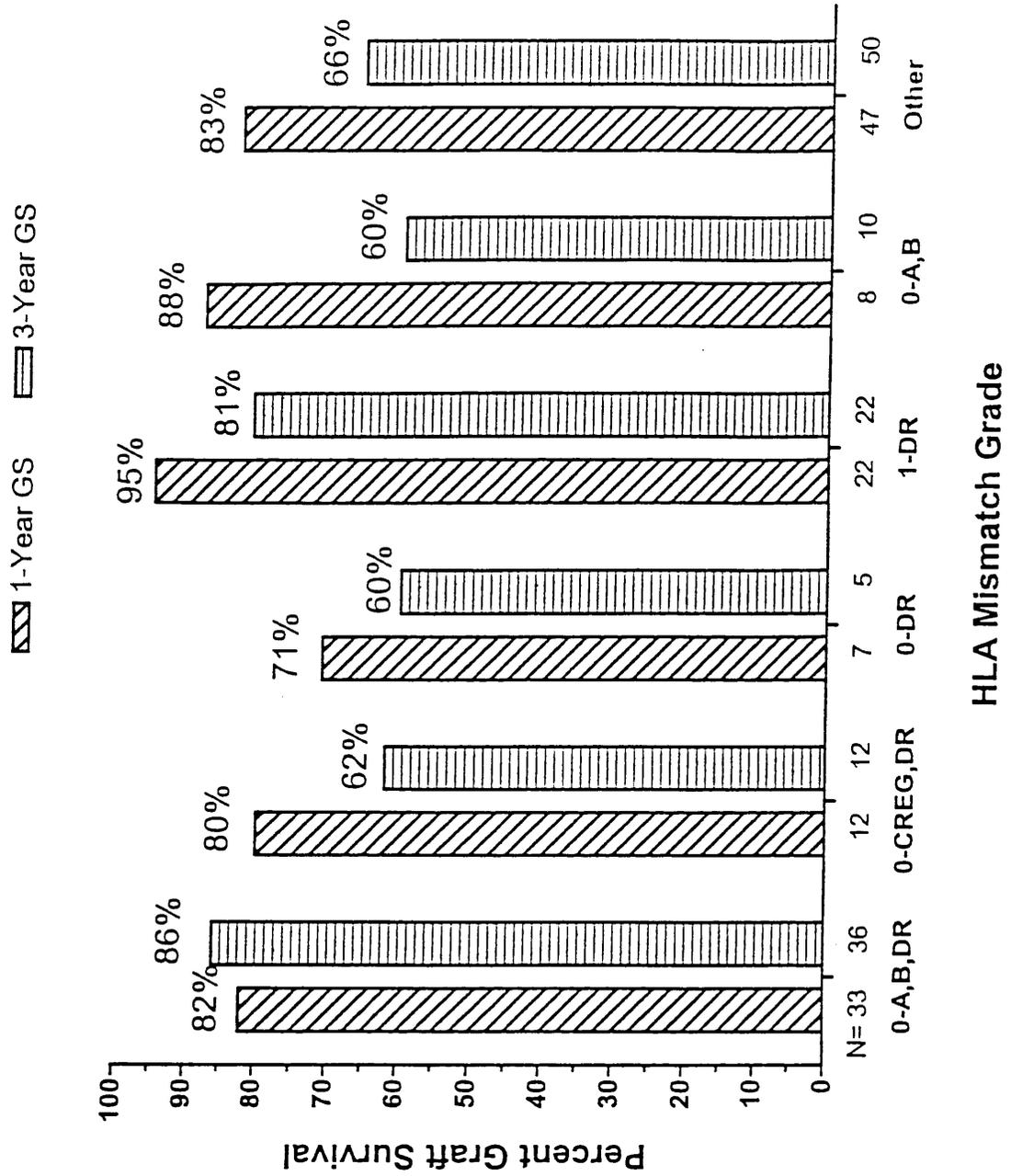


Effect of HLA Matching on One and Three Year Graft Survival in Sensitized Blacks



HLA Mismatch Grade

Effect of HLA Matching on One and Three Year Graft Survival in Sensitized Non-Blacks



Estimated One Year Graft Survival at Illinois Transplant Centers
1997-2000 Deceased Donor Kidney Transplants

Race	Mismatch Group	PRA Group	Number of Transplants	Estimated Survival	Lower 95% CI	Upper 95% CI
African American	0-A,B,DR	PRA<=10%	18	94.44%	83.86%	100.00%
African American	0-A,B,DR	PRA>10%	10	90.00%	71.41%	100.00%
African American	0-CREG,0-DR	PRA<=10%	33	87.66%	76.33%	99.00%
African American	0-CREG,0-DR	PRA>10%	7	85.71%	59.79%	100.00%
African American	>0-CREG,0-DR	PRA<=10%	54	83.22%	73.21%	93.22%
African American	>0-CREG,0-DR	PRA>10%	8	100.00%	100.00%	100.00%
African American	>0-CREG,1-DR	PRA<=10%	94	90.43%	84.48%	96.37%
African American	>0-CREG,1-DR	PRA>10%	18	64.17%	41.12%	87.23%
African American	0-A,B,>0-DR	PRA<=10%	6	80.00%	44.94%	100.00%
African American	0-A,B,>0-DR	PRA>10%	5	80.00%	44.94%	100.00%
African American	All others	PRA<=10%	169	85.04%	79.63%	90.45%
African American	All others	PRA>10%	45	82.22%	71.05%	93.39%
Non-African American	0-A,B,DR	PRA<=10%	128	90.62%	85.57%	95.67%
Non-African American	0-A,B,DR	PRA>10%	33	81.82%	68.66%	94.98%
Non-African American	0-CREG,0-DR	PRA<=10%	56	91.07%	83.60%	98.54%
Non-African American	0-CREG,0-DR	PRA>10%	12	80.00%	55.21%	100.00%
Non-African American	>0-CREG,0-DR	PRA<=10%	64	88.83%	81.03%	96.63%
Non-African American	>0-CREG,0-DR	PRA>10%	7	71.43%	37.96%	100.00%
Non-African American	>0-CREG,1-DR	PRA<=10%	127	89.67%	84.35%	94.99%
Non-African American	>0-CREG,1-DR	PRA>10%	22	95.24%	86.13%	100.00%
Non-African American	0-A,B,>0-DR	PRA<=10%	28	92.86%	83.32%	100.00%
Non-African American	0-A,B,>0-DR	PRA>10%	8	87.50%	64.58%	100.00%
Non-African American	All others	PRA<=10%	199	88.89%	84.51%	93.27%
Non-African American	All others	PRA>10%	47	82.82%	71.98%	93.66%

**Estimated Three Year Graft Survival at Illinois Transplant Centers
1995-1998 Deceased Donor Kidney Transplants**

Race	Mismatch Group	PRA Group	Number of Transplants	Estimated Survival	Lower 95% CI	Upper 95% CI
African American	0-A,B,DR	PRA<=10%	15	72.73%	49.85%	95.60%
African American	0-A,B,DR	PRA>10%	12	69.44%	39.01%	99.88%
African American	0-CREG,0-DR	PRA<=10%	32	63.96%	46.85%	81.06%
African American	0-CREG,0-DR	PRA>10%	5	60.00%	17.06%	100.00%
African American	>0-CREG,0-DR	PRA<=10%	71	64.05%	52.46%	75.65%
African American	>0-CREG,0-DR	PRA>10%	8	62.50%	28.95%	96.05%
African American	>0-CREG,1-DR	PRA<=10%	113	79.01%	71.19%	86.84%
African American	>0-CREG,1-DR	PRA>10%	16	67.03%	43.13%	90.94%
African American	0-A,B,>0-DR	PRA<=10%	7	85.71%	59.79%	100.00%
African American	0-A,B,>0-DR	PRA>10%	3	33.33%	0.00%	86.68%
African American	All others	PRA<=10%	147	65.73%	57.82%	73.65%
African American	All others	PRA>10%	51	65.47%	52.12%	78.81%
Non-African American	0-A,B,DR	PRA<=10%	128	80.46%	73.43%	87.50%
Non-African American	0-A,B,DR	PRA>10%	36	85.65%	73.98%	97.32%
Non-African American	0-CREG,0-DR	PRA<=10%	48	76.41%	64.17%	88.64%
Non-African American	0-CREG,0-DR	PRA>10%	12	62.34%	32.94%	91.74%
Non-African American	>0-CREG,0-DR	PRA<=10%	91	80.55%	72.23%	88.87%
Non-African American	>0-CREG,0-DR	PRA>10%	5	60.00%	17.06%	100.00%
Non-African American	>0-CREG,1-DR	PRA<=10%	137	77.95%	70.84%	85.06%
Non-African American	>0-CREG,1-DR	PRA>10%	22	80.95%	64.16%	97.75%
Non-African American	0-A,B,>0-DR	PRA<=10%	31	86.41%	74.01%	98.81%
Non-African American	0-A,B,>0-DR	PRA>10%	10	60.00%	29.64%	90.36%
Non-African American	All others	PRA<=10%	196	79.82%	74.07%	85.58%
Non-African American	All others	PRA>10%	50	66.14%	52.54%	79.74%

II-18

87

DRID 1510

SENSITIZATION RATE FOLLOWING GRAFT LOSS *

HLA MISMATCH GRADE	N	SENSITIZED AFTER GRAFT LOSS	
		N	%
0-A, B, DR	16	1	6%
0-A, B	8	4	50%
0-CREG, 0-DR	9	3	33%
0-CREG, >0-DR	11	8	73%
OTHER	126	85	67%
ALL	170	101	59%

*Cadaver renal transplants for the period 1-1-96 through 12-31-02 (recipients nonsensitized at time of transplant).

MEDIAN TIME TO TRANSPLANT (DAYS) FOR PEDIATRIC PATIENTS

AGE AT LISTING	YEAR OF LISTING					
	1999		2000		2001	
	GOH	NATIONAL	GOH	NATIONAL	GOH	NATIONAL
<13 Years	189 (N=6)		219 (N=4)		156 (N=14)	
<11 Years		274 - 383 (N=137)		315 - 373 (N=157)		205 - 386 (N=190)
13- <18 Years	245 (N=14)		224 (N=12)		270 (N=21)	
11 - 17 Years		344 (N=317)		370 (N=295)		422 (N=348)

COPY

VIA FACSIMILE & REGULAR MAIL

March 21, 2003

Martin F. Mozes, M.D., Medical Director
Velta A. Lazda, Ph.D., Director, Histocompatibility Laboratory
Jarold A. Anderson, CEO
Gift of Hope Organ & Tissue Donor Network
660 N. Industrial Drive
Elmhurst, IL 60126

Dear Drs. Mozes and Lazda and Mr. Anderson:

As you know, at its November 14-15, 2002 meeting, the OPTN/UNOS Board of Directors approved modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) to (a) eliminate from the national system of standard criteria donor kidney allocation points assigned for human leukocyte antigen (HLA) similarity between potential donor and recipient pairs at the B locus, and (b) revise points assigned for HLA similarity between potential donor and recipient pairs at the HLA DR locus to 2 points for a 0 DR mismatch and 1 point for a 1 DR mismatch. The changes are intended to increase access to kidney transplantation for minority patients with minimal impact upon transplant outcomes for patients overall.

The Board also approved the recommendation of the OPTN/UNOS Kidney & Pancreas Transplantation Committee to apply these policy modifications to both the national system of kidney allocation and to OPOs operating with previously approved alternative systems for allocating kidneys, except in the case of OPOs with previously approved alternative systems that request exemptions from application of the modifications to their alternative systems. The Committee and Board acknowledged that certain OPOs may believe, for example, that they have addressed through their alternative systems the issues of waiting time disparity underlying the policy modifications and wish to maintain these systems within their areas without change. OPOs operating with approved alternative systems were provided a deadline of January 8, 2003, to evaluate their systems in light of the policy modifications and request an exemption if they did not want the modifications applied to their system.

Gift of Hope Organ & Tissue Donor Network (Gift of Hope) was among the OPOs that requested such an exemption. Your request was reviewed by the Kidney and Pancreas Transplantation Committee at its meeting on January 21, 2003. The Committee acknowledges the data you provided with your proposal, but determined that it did not have sufficient information to make a decision regarding Gift of Hope's request. The Committee further determined that upon initial

II-21

96

Martin F. Mozes, M.D., Medical Director
Velta A. Lazda, Ph.D., Director, Histocompatibility Laboratory
Jarold A. Anderson, CEO
March 21, 2003
Page 2

COPY

implementation, the modifications to Policy 3.5.11.2 would **not** be applied to Gift of Hope. Instead, the Committee would inform Gift of Hope of the information needed to make a determination and reconsider the request for exemption at the Committee's May 2003 meeting together with this new information. It is expected that the Committee would make a final decision at that time regarding application of the policy changes to your OPO.

The Committee was particularly concerned with OPOs that operate with alternative systems that assign greater priority to HLA matching in allocating kidneys than the new modified standard policy. These allocation policy changes are based upon studies confirming a general increase in relative graft failure rates with increasing numbers of mismatches at each of the A, B, and DR loci. The differences are not significant, however, except at the DR locus or in the case of a 0 antigen mismatch between donor and recipient. Allocation models have demonstrated that assigning points for HLA-B similarity disadvantaged patients with HLA antigens that are uncommon in the pool of available donors, and may have inhibited opportunities to optimize HLA-DR matching across the OPTN system.. The new system (assigning 2 points for a zero HLA-DR mismatch, and one point for a one HLA-DR mismatch) is intended to increase allocation of HLA-DR matched kidneys and reduce disparities in access to transplantation among patient groups, resulting in improved equity while maintaining or improving system utility.

Enclosed with this letter is a summary description of your alternative system for allocating kidneys. With respect to HLA matching priority specifically, Gift of Hope assigns the following points:

- 7 points – 0 CREG, DR mismatch;
- 6 points – 0 A, B mismatch.

The Committee requests the following information regarding your system:

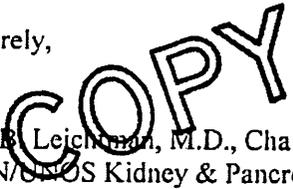
1. Based upon your responses to the questions included in (2), (3), and (4) below, do you continue to request an exemption from application of the modifications to Policy 3.5.11.2 to your alternative system?
2. Please define the goals of your alternative system for kidney allocation/distribution and, using objective data, demonstrate how Gift of Hope is meeting these goals through this alternative system.
3. Please describe the consequences of your alternative system on access to kidney transplantation for minority patients and on transplant outcomes for patients overall. If you believe that these objectives are achieved, please describe how they are achieved. Please provide supporting data for your responses to these questions.
4. Have you considered requesting a modification to your alternative system to retain any aspects that you continue to believe are justified, while bringing the system closer to the new standard system, thereby potentially achieving goals of both systems? For example, have you considered retaining assignment of some points for a 0 CREG, DR mismatch, while eliminating points for a 0 A, B mismatch and assigning points for a 0 or 1 DR mismatch

Martin F. Mozes, M.D., Medical Director
Velta A. Lazda, Ph.D., Director, Histocompatibility Laboratory
Jarold A. Anderson, CEO
March 21, 2003
Page 3

consistent with the changes to Policy 3.5.11.2? Application of the changes to Policy 3.5.11.2 to your system would not impact the elements of your system that address factors other than HLA matching unless you specifically request such modifications.

We request responses to these inquiries on or before April 30, 2003. You are welcome to provide any other information you deem useful. Please submit the information to my attention in care of Cindy Sommers, Director of Allocation Policy, United Network for Organ Sharing (UNOS). Please note UNOS' new address as shown on the first page of this letter. If you have questions regarding this matter, please do not hesitate to contact Cindy or me. We appreciate your timely response to this inquiry.

Sincerely,


Alan B. Leichman, M.D., Chair
OPTN/UNOS Kidney & Pancreas Transplantation Committee

Enclosure

cc: Richard Cohn, M.D.
Frederick K. Merkel, M.D.
David Holt, M.D.
Frank P. Stuart, Jr., M.D.
S. Forrest Dodson, M.D.
Frank Darras, M.D.
Timothy O'Connor, M.D.
Robert Harland, M.D.
Enrico Benedetti, M.D.

COPY

Title: Regional Organ Bank of Illinois (ILIP) Alternative System for Kidneys - Region 7

Summary

Description: Regional Organ Bank of Illinois uses the standard distribution and allocation system with the following exceptions. For allocation of standard criteria donor kidneys, the OPO:

- Assigns 7 points for a 0 CREG,DR mismatch and 6 points for a 0 A,B mismatch;
- Assigns a maximum of 3 points for waiting time;
- Assigns 3 points for PRA > 80%;
- Assigns 5 points to potential recipients between 13-17 years of age. These points are awarded upon waiting list registration and retained until the patient is transplanted or reaches 18 years of age. Candidates under 13 years of age at time of listing who are ABO-identical with a kidney donor receive priority over all other patients except for 0 antigen mismatched patients and standard system paybacks.
- Patients continue to accrue waiting time after 30 days of inactive status.

Rationale: To improve transplant outcomes and the likelihood of sensitized patients to receive a transplant. In addition, the alternative system reduces the likelihood of a patient becoming sensitized if the transplant is unsuccessful and provides greater access to well matched transplants for minority candidates.

cc: Jason Byrd
Cindy Sommers

December 30, 2002

Mr. Douglas A. Heiney
Director, UNOS Department of Membership Services
& Policy Development
United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23219

**Re: Changes to OPTN/UNOS Policy 3.5.11.2 - Modification to Points for
HLA Similarity between Potential Donor and Recipient Pairs**

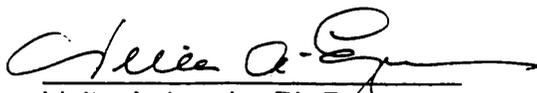
Dear Mr. Heiney:

This is to request exemption from application of the above-referenced modification to points for HLA to our Approved Alternative System for Kidney Allocation/Distribution (see attached copy). This request is based on data showing that the issues of waiting time disparity underlying the UNOS policy modifications have already been addressed by our alternate allocation system (see attached abstract).

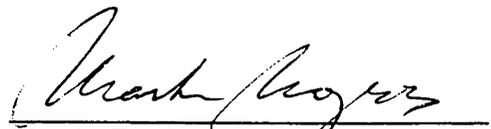
This request for exemption has been unanimously approved by all nine of the kidney transplant centers in Gift of Hope's local service areas (see attached signed agreements).

We thank UNOS for considering this request and would expect early approval.

Sincerely,



Velta A. Lazda, Ph.D.
Director, Histocompatibility Laboratory



Martin F. Mozes, M.D.
Medical Director

cc: Jarold Anderson, CEO

- Attachments: 1. Gift of Hope Kidney Distribution Policy
2. Abstract
3. Signed Agreements (9)

660 N. Industrial Drive • Elmhurst, IL 60126 • Tel 630/758-2600 • Fax 630/758-2601
Offices: Elmhurst • Champaign • Normal • Peoria • Rockford • Springfield
www.giftofhope.org • Donor Hotline 800/545-GIFT

GIFT OF HOPE ORGAN & TISSUE DONOR NETWORK CADAVER KIDNEY DISTRIBUTION POLICY

PRIORITY 1: Zero (0) A,B,DR Mismatch Locally and/or Nationally in the Following Order:

- A. ABO-Identical
- B. ABO-Compatible

Within priorities 1A and 1B the distribution is as follows:

- a. Local Recipients, HLA-A,B,DR Phenotype Identical
 - i. Pediatric (<13 years old)
 - ii. Others
- b. National Recipients, HLA-A,B,DR Phenotype Identical
- c. Local Recipients, 0-A,B,DR Mismatch
 - i. Pediatric (<13 years old)
 - ii. Others
- d. National Recipients, 0-A,B,DR Mismatch

PRIORITY 2: Pediatric (<13 years old) > Zero (0) A,B,DR Mismatch

PRIORITY 3: Others > Zero (0) A,B,DR Mismatch - locally

- a. ABO-Identical
- b. ABO-Compatible

PRIORITY 4: Double Kidney Allocation

- a. Local Recipients
- b. Regional Recipients
- c. National Recipients

PRIORITY 5: Others > Zero (0) A,B,DR, Mismatch - UNOS

Distribution to local recipients within each priority is by the GOH Point System as follows:

<u>Points</u>	<u>Category</u>
10	zero (0) A,B,DR mismatch
7	zero (0) CREG,DR
6	zero (0) A,B mismatch
5	pediatric, ≥ 13 to < 18 years old
4	donated organ or organ segment
3	waiting time (max.)
3	PRA $\geq 80\%$ in last 3 months

In case of ties, priority will be determined based on the following (in order of priority):

1. Longest time on list
2. Highest PRA
 - a. Current PRA
 - b. Peak PRA
3. Fewest B,DR mismatches
4. Fewest A mismatches
5. Alphabetical Order

Pediatric kidney transplant candidates who are <18 years old at date of listing, will remain in the same priority they were in until transplanted, i.e., Priority 2 for <13 year olds and receive 5 extra points if between the ages of 13 - <18 years.

PAYBACK: The payback must occur within the next ABO identical donor, as monitored by UNOS.

IMPACT OF HLA CROSS-REACTIVE GROUP (CREG) MATCHING ON RENAL ALLOCATION IN A HETEROGENEOUS RACIAL POPULATION

V.A. Lazda, Regional Organ Bank of Illinois, Chicago, IL USA

Matching of cadaver kidney recipients and donors for HLA cross-reactive antigen groups (CREGs) is expected to increase the frequency of HLA matched transplants for ethnic minorities. We report an analysis of cadaver kidney distribution for a 2-year period (Sept 20, 1999 to Sept 20, 2001) following implementation of a CREG-based allocation scheme and compare it to that for the prior two years. The CREG-based allocation algorithm differed from that used previously as follows: 7 points were awarded for 0-CREG,0-DR mismatches in place of 0-B,DR mismatches, 3 points were eliminated for 1-B,DR mismatches and 3 points were awarded for panel-reactive antibodies (PRA) >80%, instead of PRA >50%. Points for 0-A,B,DR mismatches (10), 0-A,B mismatches (6), waiting time (3), age 13 - <18 (5) and pediatric (age <13) priority were retained. The potential and actual allocation of kidneys was compared for 351(26% blacks) and 411 (25% blacks) local donors in the pre and post CREG periods respectively. We found that over 55% of 411 donors in the post CREG period had 1 or more (range 1-62) 0-CREG,0-DR mismatched potential recipients, with the top-ranked potential recipient being a black patient 38% of the time. As seen in the Table, actual transplants with a 0-CREG,0-DR mismatched donor were achieved for a higher percentage of transplants in the post CREG, compared to pre CREG period, 17% (N=430) vs. 6% (N=316), $p<0.0001$, which also was a significantly higher percentage than that for 0-A,B,DR and 0-A,B mismatched transplants combined (6%, N=430), $p<0.0001$; 34% of 0-CREG,0-DR mismatched transplants in the post CREG period were into black recipients, compared to 24% for 0-A,B,DR and 0-A,B mismatched transplants combined.

Period	Number (%) of Transplants:			
	All	0-A,B,DR	0-A,B	0-CREG,0-DR
Pre CREG	316	11 (3%)	5 (2%)	20 (6%)
Post CREG	430	17 (4%)	8 (2%)	74 (17%)

Overall the proportion of transplants into black recipients remained the same in the pre CREG (46%, N=316) and post CREG periods (46%, N=430), comparable to their numbers on the waiting list, i.e., 47.8% (N=2,088) and 45.7% (N=2,532), $p=NS$, respectively. In conclusion, the incorporation of points for 0-CREG,0-DR mismatches in kidney allocation has improved the access to HLA matched transplants for all racial groups and may have also improved the rate of transplantation of black recipients.



MEMORANDUM

DATE: December 9, 2002

TO: **GOH Kidney Transplant Program Directors:** Richard Cohn, M.D., Frederick K. Merkel, M.D., David Holt, M.D., Frank P. Stuart, M.D., Stephen C. Jensik, M.D., Frank Darras, M.D., Timothy O'Connor, M.D., Robert Harland, M.D. and Enrico Benedetti, M.D.

FROM: Martin F. Mozes, M.D. (MAC Chairman) and Velta A. Lazda, Ph.D. (Chairperson, Histocompatibility Subcommittee)

RE: Vote for Exemption from Application of UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) to our Local Variance for Kidney Allocation

The OPTN/UNOS Board of Directors has approved the implementation of Policy 3.5.11.2 (Quality of HLA Mismatch Points) that will remove all points for similarity between potential donors and recipients at the B locus and assign 2 and 1 points for 0 and 1 mismatches at the DR locus, respectively. **These policy modifications will also apply to OPO's operating with previously approved alternative systems for allocating kidneys, unless the OPO requests for an exemption by January 8, 2003.**

The Kidney OP& D Subcommittee and MAC unanimously approved to request for an exemption, since our variance for allocating kidneys that is based on CREG matching has already addressed the issues of waiting time disparity that underlie the UNOS policy modifications.

Please vote on this issue and return this memo by FAX: 630-758-2602 as soon as possible. Thank you.

NAME	YES/NO/ABSTAIN	SIGNATURE
<u>Richard Cohn, M.D.</u>	<u>YES</u>	<u>(see attached)</u>
<u>Frederick K. Merkel, M.D.</u>	<u>YES</u>	<u>"</u>
<u>David Holt, M.D.</u>	<u>YES</u>	<u>"</u>
<u>Frank P. Stuart, M.D.</u>	<u>YES</u>	<u>"</u>
<u>S. Forrest Dodson, M.D.</u> Stephen C. Jensik, M.D.	<u>YES</u>	<u>"</u>
<u>Frank Darras, M.D.</u>	<u>YES</u>	<u>Frank Darras MD</u>
<u>Timothy O'Connor, M.D.</u>	<u>YES</u>	<u>(see attached)</u>
<u>Robert Harland, M.D.</u>	<u>Yes</u>	<u>Robert Harland</u>
<u>Enrico Benedetti, M.D.</u>	<u>yes</u>	<u>Enrico Benedetti</u>

MEMORANDUM

DATE: December 9, 2002

TO: GOH Kidney Transplant Program Directors: Richard Cohn, M.D., Frederick K. Merkel, M.D., David Holt, M.D., Frank P. Stuart, M.D., Stephen C. Jensik, M.D., Frank Darras, M.D., Timothy O'Connor, M.D., Robert Harland, M.D. and Enrico Benedetti, M.D.

FROM: Martin F. Mozes, M.D. (MAC Chairman) and Velta A. Lazda, Ph.D. (Chairperson, Histocompatibility Subcommittee)

RE: Vote for Exemption from Application of UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) to our Local Variance for Kidney Allocation

The OPTN/UNOS Board of Directors has approved the implementation of Policy 3.5.11.2 (Quality of HLA Mismatch Points) that will remove all points for similarity between potential donors and recipients at the B locus and assign 2 and 1 points for 0 and 1 mismatches at the DR locus, respectively. These policy modifications will also apply to OPO's operating with previously approved alternative systems for allocating kidneys, unless the OPO requests for an exemption by January 8, 2003.

The Kidney OP&D Subcommittee and MAC unanimously approved to request for an exemption, since our variance for allocating kidneys that is based on CREG matching has already addressed the issues of waiting time disparity that underlie the UNOS policy modifications.

Please vote on this issue and return this memo by FAX: 630-758-2602 as soon as possible. Thank you.

NAME	YES/NO/ABSTAIN	SIGNATURE
<u>Richard Cohn, M.D.</u>	<u>yes</u>	<u><i>Richard A. Cohn</i></u>
<u>Frederick K. Merkel, M.D.</u>	_____	_____
<u>David Holt, M.D.</u>	_____	_____
<u>Frank P. Stuart, M.D.</u>	_____	_____
<u>Stephen C. Jensik, M.D.</u>	_____	_____
<u>Frank Darras, M.D.</u>	_____	_____
<u>Timothy O'Connor, M.D.</u>	_____	_____
<u>Robert Harland, M.D.</u>	_____	_____
<u>Enrico Benedetti, M.D.</u>	_____	_____



MEMORANDUM

DATE: December 9, 2002
TO: GOH Kidney Transplant Program Directors: Richard Cohn, M.D., Frederick K. Merkel, M.D., David Holt, M.D., Frank P. Stuart, M.D., Stephen C. Jensik, M.D., Frank Darras, M.D., Timothy O'Connor, M.D., Robert Harland, M.D. and Enrico Benedetti, M.D.
FROM: Martin F. Mozes, M.D. (MAC Chairman) and Velta A. Lazda, Ph.D. (Chairperson, Histocompatibility Subcommittee)
RE: Vote for Exemption from Application of UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) to our Local Variance for Kidney Allocation

The OPTN/UNOS Board of Directors has approved the implementation of Policy 3.5.11.2 (Quality of HLA Mismatch Points) that will remove all points for similarity between potential donors and recipients at the B locus and assign 2 and 1 points for 0 and 1 mismatches at the DR locus, respectively. These policy modifications will also apply to OPO's operating with previously approved alternative systems for allocating kidneys, unless the OPO requests for an exemption by January 8, 2003.

The Kidney OP&D Subcommittee and MAC unanimously approved to request for an exemption, since our variance for allocating kidneys that is based on CREG matching has already addressed the issues of waiting time disparity that underlie the UNOS policy modifications.

Please vote on this issue and return this memo by FAX: 630-758-2602 as soon as possible. Thank you.

Table with 3 columns: NAME, YES/NO/ABSTAIN, SIGNATURE. Includes names like Richard Cohn, M.D., Frederick K. Merkel, M.D., David Holt, M.D., Frank P. Stuart, M.D., Stephen C. Jensik, M.D., Frank Darras, M.D., Timothy O'Connor, M.D., Robert Harland, M.D., Enrico Benedetti, M.D. and a handwritten signature.

MEMORANDUM

DATE: December 9, 2002

TO: GOH Kidney Transplant Program Directors: Richard Cohn, M.D., Frederick K. Merkel, M.D., David Holt, M.D., Frank P. Stuart, M.D., Stephen C. Jensik, M.D., Frank Darras, M.D., Timothy O'Connor, M.D., Robert Harland, M.D. and Enrico Benedetti, M.D.

FROM: Martin F. Mozes, M.D. (MAC Chairman) and Velta A. Lazda, Ph.D. (Chairperson, Histocompatibility Subcommittee)

RE: Vote for Exemption from Application of UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) to our Local Variance for Kidney Allocation

The OPTN/UNOS Board of Directors has approved the implementation of Policy 3.5.11.2 (Quality of HLA Mismatch Points) that will remove all points for similarity between potential donors and recipients at the B locus and assign 2 and 1 points for 0 and 1 mismatches at the DR locus, respectively. These policy modifications will also apply to OPO's operating with previously approved alternative systems for allocating kidneys, unless the OPO requests for an exemption by January 8, 2003.

The Kidney OP& D Subcommittee and MAC unanimously approved to request for an exemption, since our variance for allocating kidneys that is based on CREG matching has already addressed the issues of waiting time disparity that underlie the UNOS policy modifications.

Please vote on this issue and return this memo by FAX: 630-758-2602 as soon as possible. Thank you.

NAME	YES/NO/ABSTAIN	SIGNATURE
<u>Richard Cohn, M.D.</u>	_____	_____
<u>Frederick K. Merkel, M.D.</u>	_____	_____
<u>David Holt, M.D.</u>	yes for exemption	<i>David K. Holt</i>
<u>Frank P. Stuart, M.D.</u>	_____	_____
<u>Stephen C. Jensik, M.D.</u>	_____	_____
<u>Frank Darras, M.D.</u>	_____	_____
<u>Timothy O'Connor, M.D.</u>	_____	_____
<u>Robert Harland, M.D.</u>	_____	_____
<u>Enrico Benedetti, M.D.</u>	_____	_____



MEMORANDUM

DATE: December 9, 2002

TO: GOH Kidney Transplant Program Directors: Richard Cohn, M.D., Frederick K. Merkel, M.D., David Holt, M.D., Frank P. Stuart, M.D., Stephen C. Jensik, M.D., Frank Darras, M.D., Timothy O'Connor, M.D., Robert Harland, M.D. and Enrico Benedetti, M.D.

FROM: Martin F. Mozes, M.D. (MAC Chairman) and Velta A. Lazda, Ph.D. (Chairperson, Histocompatibility Subcommittee)

RE: Vote for Exemption from Application of UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) to our Local Variance for Kidney Allocation

The OPTN/UNOS Board of Directors has approved the implementation of Policy 3.5.11.2 (Quality of HLA Mismatch Points) that will remove all points for similarity between potential donors and recipients at the B locus and assign 2 and 1 points for 0 and 1 mismatches at the DR locus, respectively. **These policy modifications will also apply to OPO's operating with previously approved alternative systems for allocating kidneys, unless the OPO requests for an exemption by January 8, 2003.**

The Kidney OP& D Subcommittee and MAC unanimously approved to request for an exemption, since our variance for allocating kidneys that is based on CREG matching has already addressed the issues of waiting time disparity that underlie the UNOS policy modifications.

Please vote on this issue and return this memo by FAX: 630-758-2602 as soon as possible. Thank you.

NAME	YES/NO/ABSTAIN	SIGNATURE
<u>Richard Cohn, M.D.</u>	_____	_____
<u>Frederick K. Merkel, M.D.</u>	_____	_____
<u>David Holt, M.D.</u>	_____	_____
<u>Frank P. Stuart, M.D.</u>	YES for Exemption to 3.5.11.2	Frank Stuart
<u>Stephen C. Jensik, M.D.</u>	_____	_____
<u>Frank Darras, M.D.</u>	_____	_____
<u>Timothy O'Connor, M.D.</u>	_____	_____
<u>Robert Harland, M.D.</u>	_____	_____
<u>Enrico Benedetti, M.D.</u>	_____	_____

MEMORANDUM

DATE: December 9, 2002

TO: GOH Kidney Transplant Program Directors: Richard Cohn, M.D., Frederick K. Merkel, M.D., David Holt, M.D., Frank P. Stuart, M.D., Stephen C. Jensik, M.D., Frank Darras, M.D., Timothy O'Connor, M.D., Robert Harland, M.D. and Enrico Benedetti, M.D.

FROM: Martin F. Mozes, M.D. (MAC Chairman) and Velta A. Lazda, Ph.D. (Chairperson, Histocompatibility Subcommittee)

RE: Vote for Exemption from Application of UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) to our Local Variance for Kidney Allocation

The OPTN/UNOS Board of Directors has approved the implementation of Policy 3.5.11.2 (Quality of HLA Mismatch Points) that will remove all points for similarity between potential donors and recipients at the B locus and assign 2 and 1 points for 0 and 1 mismatches at the DR locus, respectively. These policy modifications will also apply to OPO's operating with previously approved alternative systems for allocating kidneys, unless the OPO requests for an exemption by January 8, 2003.

The Kidney OP&D Subcommittee and MAC unanimously approved to request for an exemption, since our variance for allocating kidneys that is based on CREG matching has already addressed the issues of waiting time disparity that underlie the UNOS policy modifications.

Please vote on this issue and return this memo by FAX: 630-758-2602 as soon as possible. Thank you.

YES NO ABSTAIN

NAME: S F Dodson DATE: 12/19/02

SIGNATURE: [Signature]

102

II-33

DATE: December 9, 2002

TO: GOH Kidney Transplant Program Directors: Richard Cohn, M.D., Frederick K. Merkel, M.D., David Holt, M.D., Frank P. Stuart, M.D., Stephen C. Jensik, M.D., Frank Darras, M.D., Timothy O'Connor, M.D., Robert Harland, M.D. and Enrico Benedetti, M.D.

FROM: Martin F. Mozes, M.D. (MAC Chairman) and Velta A. Lazda, Ph.D. (Chairperson, Histocompatibility Subcommittee)

RE: Vote for Exemption from Application of UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) to our Local Variance for Kidney Allocation

The OPTN/UNOS Board of Directors has approved the implementation of Policy 3.5.11.2 (Quality of HLA Mismatch Points) that will remove all points for similarity between potential donors and recipients at the B locus and assign 2 and 1 points for 0 and 1 mismatches at the DR locus, respectively. **These policy modifications will also apply to OPO's operating with previously approved alternative systems for allocating kidneys, unless the OPO requests for an exemption by January 8, 2003.**

The Kidney OP&D Subcommittee and MAC unanimously approved to request for an exemption, since our variance for allocating kidneys that is based on CREG matching has already addressed the issues of waiting time disparity that underlie the UNOS policy modifications.

Please vote on this issue and return this memo by FAX: 630-758-2602 as soon as possible. Thank you.

NAME	YES/NO/ABSTAIN	SIGNATURE
<u>Richard Cohn, M.D.</u>	_____	_____
<u>Frederick K. Merkel, M.D.</u>	_____	_____
<u>David Holt, M.D.</u>	_____	_____
<u>Frank P. Stuart, M.D.</u>	_____	_____
<u>Stephen C. Jensik, M.D.</u>	_____	_____
<u>Frank Darras, M.D.</u>	_____	_____
<u>Timothy O'Connor, M.D.</u>	Yes (for exemption)	
<u>Robert Harland, M.D.</u>	_____	_____
<u>Enrico Benedetti, M.D.</u>	_____	_____

Jason Byrd

From: Betsy Gans
Sent: Monday, December 08, 2003 2:51 PM
To: Jason Byrd
Subject: FW: K/P Committee Report

Follow Up Flag: Follow up
Due By: Monday, January 05, 2004 5:00 PM
Flag Status: Flagged

Hi Jason:

I provided feedback to Charlie Alexander at MDPC about their request to eliminate their AB KI debt. Following is his response.

Betsy

-----Original Message-----

From: Charlie Alexander [mailto:calexander@mdtransplant.org]
Sent: Monday, December 08, 2003 2:23 PM
To: Betsy Gans
Subject: Re: K/P Committee Report

Thank you Betsy. Unfortunate the decision by the Board does not address the issue. In four years we've been unable to make a dent in the ABO AB group, and we will be lucky to make any progress in the next two years. Informally, many OPO's are starting to be very selective about incurring any AB debt into their short term tally because they know they'll likely not be able to pay them back for a very long time (if ever) and therefore limit their remaining pool of short term debts to work with. This needs to be addressed.

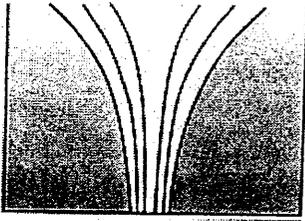
CA

Charlie Alexander RN, MSN, MBA, CPTC
Director, Clinical & Hospital Services
Transplant Resource Center of Maryland
1540 Caton Center Drive, Ste. R
Baltimore, Maryland 21227

(o) 410-242-7000 x3015
(f) 443-568-0126
(p) 877-318-5849 (toll free)

JJ-1

January 14, 2003



Transplant Resource Center of Maryland

Betsy Gans
United Network for Organ Sharing
Region II Administrator
Post Office Box 2484
Richmond, Virginia 23218

Dear Ms Gans:

I am writing this letter to request a review of the Transplant Resource Center of Maryland long term kidney debt status. Specifically, I am requesting a review of the long term blood group AB debt. Since early March, 1999 the Transplant Resource Center of Maryland has successfully decreased its kidney debt position from a peak of 72 to a current long term debt of eight (8). We are pleased to have made this progress and are poised to satisfy the remainder of the debt in the coming months.

My concern and subsequent request for review is that four of the remaining long term debt kidneys reside in the AB blood group. This is the same total of AB debt that we had in March of 1999 when our overall (all blood groups) debt was 72. Despite our best efforts to satisfy the debt in its entirety, it seems unlikely that we will be able to eliminate these four kidneys from our long term tally. I am requesting that the four kidneys be removed from our long term total. This would allow us to operate within the short term debt parameters set forth by UNOS after the remaining four long term debt kidneys are repaid (3-ABO – O and 1-ABO – B).

I appreciate your consideration in this manner and trust that it is evident that my program has operated in good faith in eliminating our kidney debt and remain committed to operating within established UNOS policies.

Cordially,

A handwritten signature in cursive script, appearing to read 'Charlie Alexander'.

Charlie Alexander RN, MSN, MBA, CPTC
Director, Program Development & Donor Services Center

490

OPO	Short-Term Debts as of 1/09/04					Long-Term Debts as of 1/09/04				
	A	AB	B	O	TOTAL	A	AB	B	O	TOTAL
1	5	1	4	0	10	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0
3	0	0	1	0	1	0	1	0	0	1
4	1	1	0	0	2	0	0	0	0	0
5	0	0	0	1	1	0	0	0	0	0
6	0	0	1	5	6	0	0	0	0	0
7	2	0	0	3	5	0	0	0	0	0
8	1	2	0	0	3	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0
10	0	0	1	0	1	0	0	0	0	0
11	0	0	2	2	4	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0
13	0	0	1	0	1	0	0	0	0	0
14	0	0	1	0	1	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0
16	0	0	1	0	1	0	0	0	0	0
17	0	0	1	0	1	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0
20	2	2	1	2	7	0	1	0	0	1
21	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0
23	0	0	1	1	2	0	0	0	0	0
24	1	0	1	0	2	0	0	0	0	0
25	3	0	1	3	7	0	3	0	0	3
26	0	0	0	0	0	0	0	0	0	0
27	0	1	1	0	2	0	0	0	0	0
28	1	0	0	0	1	0	0	0	0	0
29	0	0	0	0	0	0	1	0	0	1
30	0	1	0	1	2	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0
32	0	0	2	1	3	0	0	0	0	0
33	1	0	1	0	2	0	0	0	0	0
34	2	1	1	16	20	0	0	0	0	0
35	2	0	0	2	4	0	0	0	0	0
36	0	0	1	0	1	0	1	0	0	1
37	0	0	0	0	0	0	0	0	0	0
38	0	0	1	2	3	0	0	0	0	0
39	2	0	1	4	7	0	1	0	0	1
40	0	0	0	0	0	0	0	0	0	0
41	1	0	2	7	10	0	1	0	0	1
42	0	0	0	0	0	0	0	0	0	0
43	1	0	0	0	1	0	0	0	0	0
44	1	0	0	1	2	0	1	1	0	2
45	1	0	0	0	1	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0
47	1	0	0	1	2	0	0	0	0	0
48	0	0	1	0	1	0	0	0	0	0

OPO	Short-Term Debts as of 1/09/04					Long-Term Debts as of 1/09/04				
	A	AB	B	O	TOTAL	A	AB	B	O	TOTAL
49	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0
51	0	0	1	0	1	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0
53	0	1	0	0	1	0	0	0	0	0
54	1	1	2	4	8	0	0	0	0	0
55	0	0	0	1	1	0	1	0	0	1
56	0	0	0	0	0	0	0	0	0	0
57	3	1	1	4	9	0	4	0	0	4
58	0	0	1	0	1	0	0	0	0	0
59	0	1	0	1	2	0	0	0	0	0
60	0	0	0	4	4	0	0	0	0	0
61	0	0	0	0	0	0	0	0	0	0
62	0	0	0	0	0	0	0	0	0	0
63	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0
TOTAL	32	13	33	66	144	0	15	1	0	16

Re: OPTN Policy Development, Final Rule, and OPTN Long Range Planning

RESOLVED THAT when making policy recommendations to the Board of Directors regarding organ allocation, committees shall include recommendations specifically addressing the performance goals set forth in the OPTN Final Rule, including performance indicators to measure the achievement of performance goals and transplant center performance. Such performance indicators shall include baseline data evaluating how the policy being addressed is meeting the performance goals, the estimated or desired amount of improvement to be achieved by implementation of the policy as proposed, and the assessment required by the OPTN Final Rule. Committees shall make recommendations to the Board of Directors at its next regularly scheduled meeting regarding such performance goals, performance indicators, and assessments for existing policies regarding organ allocation. In doing so, committees shall take into consideration the deliberations of the strategic planning process of the OPTN.

OPTN Final Rule

Policy Development Framework

MM-1



OPTN Policies

- **OPTN Board responsible for developing policies**
 - **Equitable allocation of cadaveric organs**
 - **Donor testing to prevent spread of infectious diseases**
 - **Reduce socio-economic inequities**
 - **MD requirements for designated programs**
 - **As Secretary directs**



Policy Development

- Board must seek public comment
- Secretary must approve enforceable policies
 - Must publish significant policies and refer to ACOT; may refer others
 - May direct OPTN to change policies inconsistent with NOTA
 - May take action as necessary
- Interested party may appeal to the Secretary

Allocation Policy Criteria

- Sound medical judgment
- Best use of organs
- Give programs the right to refuse
- Organ-specific
- Avoid wastage and futile transplants
- Promote patient access
- Promote efficient organ placement
- Not based on candidate's location unless...



Performance Goals

- Standardized objective listing/removal criteria
- Prioritized by objective measurable medical criteria
- Ranking by urgency
 - Taking into account the policy criteria and alternative approaches
- Distribution over as large an area as feasible in order of decreasing urgency
- Performance indicators
- Reduce inter-program variance as reasonable



Allocation Performance Indicators

- Each allocation policy shall include performance indicators to measure –
 - achievement of performance goals
 - transplant center performance

Indicators To Be Included

- **Baseline data evaluating how the current policy meets the goals**
- **Amount of improvement to be achieved by the new policy in meeting the performance goals**
- **Proposed by Board & approved by HHS**
- **Others required by HHS**

Assessment

- **For each organ specific policy provide data to assess -**
 - **organ procurement and allocation**
 - **access to transplantation**
 - **effects on programs by volume**
 - **OPO and OPTN contractor performance**

Required Assessment Data

- **By organ and patient status**
- **Program and OPO – specific data**
- **By Program size**
- **By OPO, Regionally, and Nationally**
- **Other geographic areas required by HHS**

Inter-program Variation Data

- Risk-adjusted total life years
 - Pre-transplant
 - Post-transplant
- Risk-adjusted patient & graft survival
- Risk-adjusted waiting time & transplant rates

DRAFT: FOR DISCUSSION PURPOSES ONLYDraft Response to OPTN/UNOS Board Resolution from the OPTN/UNOS Kidney and Pancreas Transplantation Committee**Introduction to OPTN/UNOS Kidney Allocation/Distribution Policy.**

Objectives Statement. The objectives of OPTN/UNOS policy for allocating and distributing deceased donor kidneys are to provide candidates with a donor kidney best suited to the candidate as quickly as possible while (i) balancing other medical considerations that contribute to organ, transplant, and overall system utility, as well as medical factors unique to particular patient populations, (ii) increasing the availability of organs, and (iii) preserving the public's trust in the national organ allocation system.

Listing. A candidate can be listed for a kidney or combined kidney/pancreas transplant based upon his/her physician's medical judgment regarding suitability for transplantation. Once added to the waiting list, adult candidates begin accruing waiting time when they meet minimum, objective measures of renal function. Pediatric candidates (< 18 years old) begin accruing waiting time upon listing. The intent is to better standardize initiation of waiting time as well as comparisons of waiting time across the country without delaying opportunities for children to be transplanted.

Allocation. The allocation algorithm addresses two categories of donor kidneys: standard donor (the majority of deceased donor kidneys) and expanded criteria donor kidneys (defined by relative risk of graft failure using donor age, creatinine, cerebral vascular accident, and hypertension). **HLA Matching for Zero Mismatch.** Human leukocyte antigen (HLA) matching has been a factor in kidney allocation from initiation of the OPTN/UNOS organ allocation systems. This is because differences in HLA or tissue type between kidney donor and recipient stimulate the recipient's immune system to reject the donor kidney. Pharmacologic immunosuppression is required in order to impede the immune responses and, hopefully, prevent rejection and enable long-term acceptance of the donor kidney. Transplants between recipients and donors well matched for HLA generally function longer and with less immunosuppression, thereby maximizing utility of the donors' organs. Significant improvement in outcomes due to HLA matching presently is demonstrated currently only with a zero antigen mismatch (the highest level of match based upon degree of HLA identity between donor and candidate) and matches at the HLA DR locus. HLA match also provides greatest opportunity for transplanting patients who have developed anti-HLA antibodies directed against a relatively substantial proportion of the donor pool, as further discussed

below. Therefore, for both standard and expanded criteria donor kidneys, priority is given nationally to zero antigen mismatched candidates, due to the documented graft survival benefit experienced by recipients of such kidneys and enhanced access to transplantation for sensitized patients. These zero antigen mismatched candidates are stratified based on a number of factors including, blood type, panel reactive antibody, payback status, age and location. **Blood Group Compatibility.** The systems for allocating standard and expanded criteria donor kidneys are similar also in ensuring compatibility between donor and candidate ABO blood group, which is necessary for success of the transplant procedure, while directing that organs are allocated based upon blood group identity or to particular compatible blood groups to avoid disadvantaging these patients based upon blood type. **Waiting Time.** Waiting time is an additional factor used in the allocation of standard as well as expanded criteria donor kidneys. Patients with end-stage kidney failure can be sustained on dialysis over a period of time with good results, with exceptions noted below for children. Dialysis therapy has adverse quality of life implications, however. Additionally, studies now show improved long-term patient survival for recipients of kidney transplantation versus individuals waiting for kidney transplantation on dialysis. Differences in survival may be impacted by patient medical condition such as diabetes, glomerulonephritis, or other causes of end-stage renal disease. The potential patient survival advantage attributable to kidney transplantation and its role in the allocation system is being explored. At the present time, however, relative patient waiting time plays a unique role in kidney allocation in defining system fairness.

Standard Kidney Allocation. Within the standard donor allocation system additional allocation priority is awarded as follows. **HLA Matching.** Points are awarded for less than the optimal (zero antigen mismatch) degree of HLA identity between donor and candidate based upon significantly improved transplant outcomes with matching at the HLA DR locus. **Anti-HLA Sensitization.** Kidney transplant candidates who have been exposed to the HLA antigens of another individual as a consequence of pregnancy, blood transfusions, or previous transplantation are at risk for developing antibodies against foreign HLA antigens. Anti-HLA antibodies prevent candidates from receiving transplants from donors with HLA antigens to which the antibodies are directed. Candidates who have developed high levels of these antibodies generally need donors with a very good HLA match to avoid rejection. Due to the documented difficulty such candidates experience in obtaining a donor kidney with a negative crossmatch, they are assigned extra points. **Prior Living Donors.** Candidates who need a kidney and who previously donated a living donor organ for transplantation are awarded additional allocation priority

with the intent of encouraging organ availability through living donation and acknowledging these candidates' sacrifice and exposure to medical risk. *Age for Pediatric Patients.* Young children and adolescents experience unique problems associated with dialysis, including disruption of expected growth and development processes due to renal failure. Early reversal of uremia through transplantation can avoid the special problems of dialysis and ameliorate many of the adverse effects of end stage renal disease which confront these patients. Rapid treatment provides the best opportunity for reversing the growth and development deficits and preventing lifelong adverse consequences. Threshold times to transplant these candidates are, therefore, established in policy with additional priority assigned when children reach these thresholds without being transplanted. The intent is to expedite access for these patients to donor kidneys considered medically suitable for use in pediatric transplant candidates.

Expanded Criteria Donor Kidney Allocation. The allocation algorithm for expanded criteria donor kidneys allocates kidneys to candidates who have agreed to accept them based only on accrued waiting time and blood type considerations after the zero antigen mismatched level of priority. The intent is to maximize procurement and use of these kidneys, providing a mechanism for more rapid placement of the organs while minimizing cold ischemic time. The policy recognizes the additional risk expected with expanded criteria donor kidney transplantation and establishes a protocol for offering them under conditions intended to improve acceptance and enhance outcomes. Pediatric candidates waiting for a kidney transplant generally are not considered good candidates for expanded criteria donor kidneys due to long-term graft survival concerns and possibility of sensitization. It is anticipated that ongoing review of outcome data will help in better defining the most appropriate candidates for such kidneys.

Evaluation. Policies for kidney allocation are based on objective, measurable criteria and then reviewed on a periodic basis to ensure policy objectives are being achieved. For instance, the point system for HLA matching has been modified over time as data have demonstrated diminished impact of matching on graft survival. Such revisions have unique consequences for minority patients due to differences in HLA and blood group biology among the various ethnic groups and between donor and candidate populations. Assigning less emphasis to HLA matching in kidney allocation is expected to increase opportunities for transplantation for minority patients and reduce present disparities in waiting times to transplant. This is especially true since variability in DR antigens among ethnic groups is less pronounced than at the other HLA loci. Disparities in access to kidney transplantation among patient populations continue to be an area of study for further policy refinement intended to address these disparities. This includes, for

example, an OPTN/UNOS Board of Directors approved study to permit kidney waiting time accrual to commence from the initiation of chronic maintenance dialysis to address differences in patient waiting time not explained by differences in renal function. Additionally, the policies are being assessed to further define the best outcome — be it graft survival rates, years of life gained, quality of life measures or net benefit — hoped to be achieved through the kidney allocation system.

Medical Judgment. Sound medical judgment and right of organ refusal are maintained by the kidney allocation system. The ultimate determination of whether a particular kidney offer should be accepted and transplanted into a particular candidate resides with the responsible transplant surgeon or physician. The surgeon or physician can base the decision on a number of factors including, but not limited to, candidate medical status and donor history. The intent is to promote best use of kidneys.

Payback System. The kidney payback system stipulates that OPOs receiving kidneys for transplantation under certain situations will incur a debt to the national system, requiring that the shared kidney must be paid back to the system through the UNOS Organ Center. A payback debt is created when a kidney is shared pursuant to (i) the zero antigen mismatch sharing policy, or (ii) voluntary arrangements for sharing donor kidneys with an organ other than a kidney for transplantation into the same recipient, or for sensitized patients. The intent of the payback system is to compensate for disparities in the distribution of the optimally matched (zero antigen mismatched) deceased donors and recipients. This objective can be accomplished only if the kidneys used to satisfy payback debts function relatively well. Studies have shown that requiring a payback for shared zero antigen mismatched kidneys does not appear to jeopardize graft survival of these payback kidneys.

Distribution. With exceptions for the optimally matched (zero antigen mismatched) kidneys and kidneys shared in satisfaction of payback obligations, organs are offered initially to patients on the local list (generally defined as patients listed for transplantation at transplant centers within the organ procurement organization (OPO) designated service area), then regionally (other non-local patients listed for transplantation at transplant centers with the OPTN region), and then nationally (other patients listed for transplantation at transplant centers in all other OPTN regions). The rank order of patients on the local, regional, or national lists is determined by the allocation system described above. The organ distribution system is intended to enhance placement efficiency and minimize cold ischemia time, thereby resulting in increased organ usage and outcomes.

Importantly, both the systems for sharing optimally matched kidneys, as well as the system for allocating payback kidneys to the pool of available kidneys, contribute to disassociating candidate place of listing (residence) with distribution/allocation. In each case, organs are allocated to patients who meet specified criteria and who are listed for transplantation anywhere in the country before they are offered for other patients locally. In the case of zero antigen mismatched organs, patient eligibility is defined by factors such as HLA match, blood group, and sensitization. In the case of payback kidneys, patient eligibility is defined by factors such as blood group and time debt has been owed. There is, therefore, no direct reciprocity between transplant centers or even OPOs in the allocation of payback kidneys. Each of the systems expands the geographic area over which organs are distributed.

Further expansion of the geographic area within which it is reasonable to distribute kidneys is impacted by practical limitations upon the ability to share patient sera to determine if a candidate has antibodies against a particular donor. A positive reaction indicates the likelihood of hyperacute rejection if a kidney from that donor is used to transplant the original intended candidate. Renal transplants are rarely donor prior to testing (crossmatching) patient serum against the donor's cells or if the test is positive.

Policy Performance Measures. Whether kidney allocation policies are approaching their goals will be assessed on an ongoing basis using modeling and other approaches that incorporate a number of metrics including but not restricted to the following:

- Pre- and post-transplant graft and patient survival;
- Listing, transplant, death and removal rates for various patient groups (*e.g.*, diagnostic groups, allocation point ranges, demographic (*e.g.*, blood type, ethnicity, age), and geographic groups);
- Indicators of morbidity and quality of life (functional status), as measured by available data and current methodologies;
- Time on dialysis;
- Profile of recipient characteristics that are factors in kidney allocation (*e.g.*, HLA mismatch level, PRA level, age)
- Risk of progression of disease;
- Organ discard rates;
- Impact upon organ availability.

Policy Compliance Measures. Compliance with OPTN/UNOS policy for allocating/distributing kidneys is assessed using processes and protocols developed by the OPTN Contractor in accordance with the contract with the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) to operate the Organ Procurement and Transplantation Network (OPTN).

Draft Response to OPTN/UNOS Board Resolution from the OPTN/UNOS Kidney and Pancreas Transplantation Committee

Introduction to OPTN/UNOS Pancreas and Pancreatic Islet Cell Allocation/Distribution Policy.

Objectives Statement. The objectives of OPTN/UNOS policy for allocating and distributing deceased donor pancreata are to provide candidates with a donor pancreas best suited to the candidate as quickly as possible while (i) balancing other medical considerations that contribute to organ, transplant, and overall system utility, as well as medical factors unique to particular patient populations, (ii) increasing the availability of organs, and (iii) and preserving the public's trust in the national organ allocation system.

Allocation. The allocation algorithm addresses two categories of donor pancreata, pancreata used primarily for whole organ transplantation and pancreata used for islet cell transplantation after certain priorities for whole organ transplantation are exhausted. ***HLA Matching for Zero Mismatch.*** Human leukocyte antigen (HLA) matching has been a factor in pancreas allocation from relatively early in development of the OPTN/UNOS organ allocation systems. This is because differences in the HLA or tissue type between pancreas donor and recipient stimulate the recipient's immune system to reject the donor pancreas. Pharmacologic immunosuppression is required in order to impede the immune responses and, hopefully, prevent rejection and enable long-term acceptance of the donor pancreas. Data no longer show improved transplant outcomes based upon HLA match between recipients of kidney/pancreas combinations and donors, even at the highest level of match based upon degree of HLA identity between donor and candidate (zero antigen mismatch). For isolated pancreas transplantation there is a trend toward improved outcomes, although the results do not demonstrate statistical significance. HLA match does, however, provide greatest opportunity for transplanting patients who are sensitized against a relatively substantial proportion of the donor pool. Optimally (zero antigen mismatched) matched organs provide the best chance for avoiding rejection for these candidates and a large donor pool provides greater options for locating such matches. Therefore, for all donor pancreata, priority is given nationally to zero antigen mismatched combined kidney/pancreas sensitized candidates, first, and then to zero antigen mismatched isolated pancreas sensitized candidates (with exceptions for mismatched sensitized candidates at the local level of organ distribution), due to enhanced access to transplantation for these patients and, in the case of isolated pancreas transplants, demonstration of at least a trend toward

improved graft survival benefit experienced by recipients of such kidneys. These zero antigen mismatched candidates are stratified based on waiting time.

Donor Characteristics. After zero antigen mismatched candidates, allocation of pancreata is dependent upon characteristics of the donor. The distinction is based on analyses of organ discard rates and pancreas islet cell yields. The intent is to balance transplant opportunities for whole organ candidates with opportunities to test the efficacy of islet transplantation by providing first priority for local use of pancreata to patients in need of whole organ transplantation, and then allocating those pancreata most suitable for islet transplantation for patients in need of islets, first, locally, then regionally, and then nationally. Pancreata procured from donors aged less than or equal to 50 years and with body mass indexes (BMI) less than or equal to 30 kg/m² are allocated locally for isolated pancreas candidates, combined kidney/pancreas candidates, or combined solid organ/islet candidates based on waiting time. The rationale for local donor service area emphasis is to minimize cold ischemia time and maximize graft survival. Such pancreata would then be allocated regionally and nationally for whole organ transplantation or combined kidney/pancreas transplantation based on waiting time and then for islet cell transplantation.

Pancreata procured from donors aged greater than 50 years or with BMIs greater than 30 kg/m² are allocated locally to isolated pancreas candidates, combined kidney/pancreas candidates, or combined solid organ/islet candidates and then to clinical islet candidates based on medical need and transplant candidate length of waiting time. The intent is to determine whether islet cell transplantation is a viable alternative for diabetics on insulin, ensure the application of medical judgment, and minimize the wastage of pancreata and islet cells.

Facilitated Placement. The pancreas allocation system provides a further mechanism to minimize organ wastage and maximize organ utilization. The facilitated pancreas allocation system is available after five hours of placement effort or if organ retrieval is imminent. Transplant centers must notify the UNOS Organ Center of their intent to participate in the facilitated pancreas system and an expedited placement is managed based on candidate waiting time.

Policy Performance Measures. Whether pancreas allocation policies are approaching their goals will be assessed on an ongoing basis using modeling and other data that reflect a number of metrics including but not restricted to the following:

- Pre- and post-transplant graft and patient survival;
- Listing, transplant, death and removal rates for various patient groups (*e.g.*, diagnostic groups, allocation point ranges, demographic (including, for example, PRA level, blood type, ethnicity, age), and geographic groups);
- Indicators of morbidity and quality of life (functional status), as measured by available data and current methodologies;
- Risk of progression of disease;
- Organ discard rates;
- Impact upon organ availability.

Policy Compliance Measures. Compliance with OPTN/UNOS policy for allocating/distributing pancreata is assessed using processes and protocols developed by the OPTN Contractor in accordance with the contract with the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) to operate the Organ Procurement and Transplantation Network (OPTN).

KPSAM (Kidney-Pancreas Simulated Allocation Model) Update

SRTT

Kidney-Pancreas Simulated Allocation Model (KPSAM)

- **Final draft will be delivered to HRSA on March 31, 2004**
- **Current version 0.3.6**
- **After HRSA review, model will be available for public use**

Simulated Allocation Models

Designed to simulate a virtual transplant system

Family of models for allocation processes

- Liver (LSAM, version 1.3.1),
- Thoracic organs (TSAM version 1.2.1), and
- Kidney and pancreas (KPSAM version 0.3.6)

Inputs to models yield projected transplant outcomes

- waiting list and donor organ characteristics
- allocation policies
- post-match run event probability functions (e.g. organ placement)

Provides a means to predict relative outcomes under alternative allocation policies prior to implementation

SRTM

KPSAM Has Features Not In TSAM or LSAM

- **Payback**
- **Mismatch score**
- **Point system, including time limits**
- **Models of graft failure**
- **Relisting after graft failure**

Simulated Allocation Model (KPSAM)

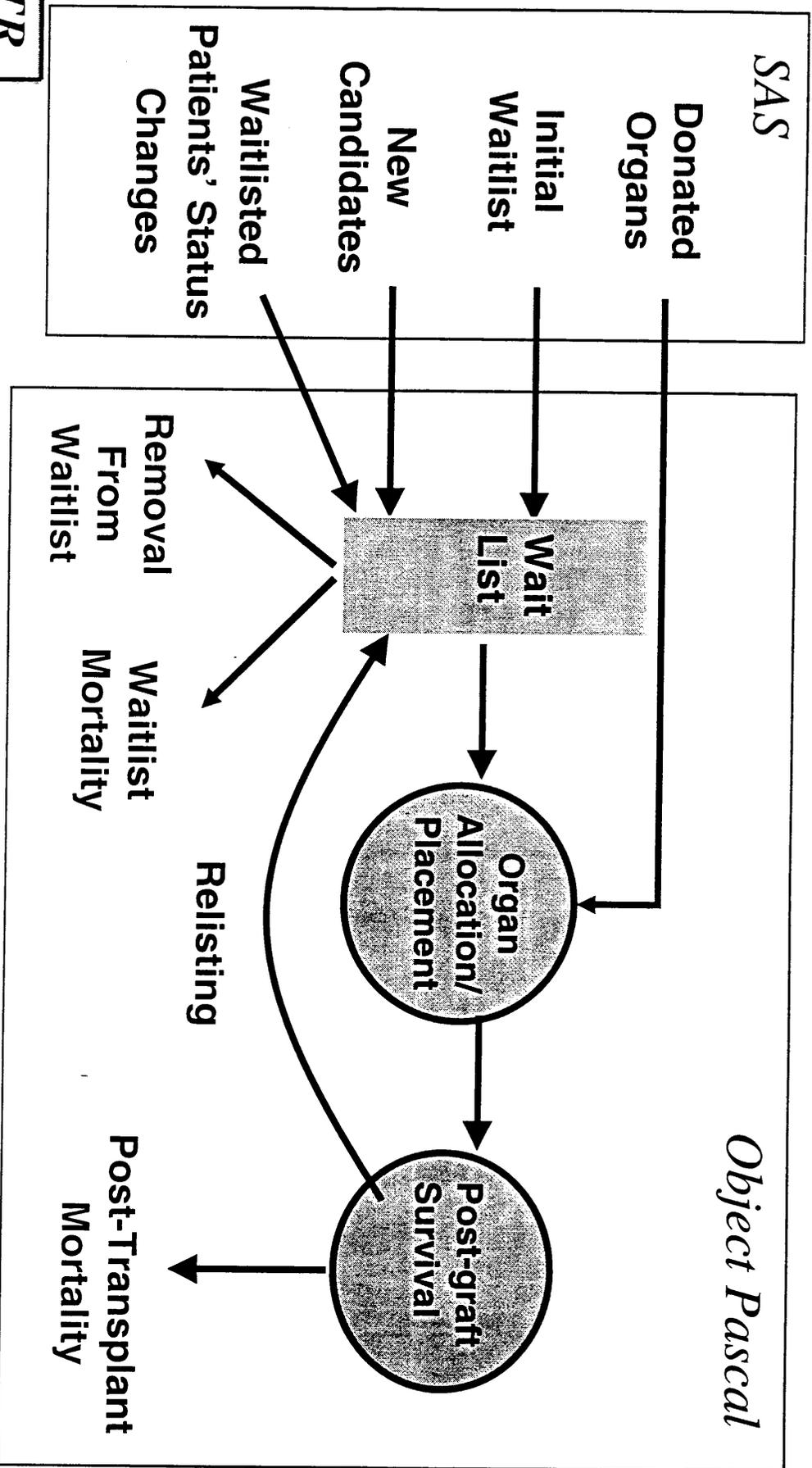
- **Simulation incorporates both deterministic and random factors**
- **Events occur sequentially through time**
- **Simulation allows user provided inputs and promotes flexibility**
 - **candidate and organ input data from the SRTR database**
 - **probability functions for events after the match run are built into the model engine**

SRTR

SAM Uses Event-Sequenced Monte Carlo Simulation

- **All steps within the simulation are determined by data and allocation rules.**
- **Events after the match run are probabilistic:**
 - **Organ placement**
 - **Time from transplant to death**
 - **Re-listing events and re-listing history**

SAM Event-Sequenced Modeling Processes Events in Time Order



SRTTR

KPSAM Predicts Counts of Transplants, Graft Failures, and Deaths Resulting from Proposed Changes in National Allocation Policies

KPSAM can change the order of categories of patients, combine categories, and create new categories based on:

- DSA boundaries**
- PRA**
- Age groups**
- etc.**

KPSAM can rank within ordered categories based on:

- Points**
- Years of survival**
- Waiting time**
- Lab values**
- etc.**

Top Category Rankings Under 2001 Allocation Order

Organ	ABO	OMM	PRA>80	OPO debt	OPO owed	Geo.
KP	Ident	Y				Loc
KP	Ident	Y	Y			Reg
KP	Ident	Y	Y			Nat
KP	Compat	Y				Loc
KP	Compat	Y	Y			Reg
KP	Compat	Y	Y			Nat
KI,KP	Ident	Y				Loc
KI,KP	Ident	Y	Y		N	Reg,Nat
KI,KP	Ident	Y	Y		N	Reg
⋮	⋮	⋮	⋮	⋮	⋮	⋮

Kidneys within each category allocated according to points.

SRTTR

Points Under 2001 Allocation System

- 0 BDR mismatch: 7 points
- 1 BDR mismatch: 5 points
- 2 BDR mismatch: 2 points
- Adolescent (11-18) at listing: 3 points
- Child (<11) at listing: 4 points
- Sensitized (PRA > 80): 4 points
- Every whole year listed: 1 point
- Rank according to time listed within OPO: 0-1 point
- Candidate is organ donor: 4 points

SRTT

Other KPSAM Features

OPO debt and payback

Child and adolescent allocation time goals

KPSAM will be able to predict consequences of:

- **Changes in allocation policies**
- **Allocation according to transplant benefit (expected lifetimes with vs. without transplant)**
- **Changes in DSA boundaries**
- **Expanded criteria donor policy**

SRTR

Initial KPSAM Implementation

KPSAM is provided with actual waitlist arrivals, status changes, and removal information for candidates on the waitlist during recent year

A completed history of waitlist status changes and mortality is appended for patients who received a transplant in real life. The appended history allows comparisons between alternative systems which might result in different individuals receiving transplants.

SRTT

Patients Transplanted in Real Life Need a Status History Until the Time at Which They Would Have Died Without a Transplant

Patient	Time →		
A	Listed	Active	Tx
		[Redacted]	
		Death	
B	Listed	Active	Inactive
		Active	
C	Listed	Active	Tx
		[Redacted]	
D	Listed	Active	Inactive
		Active	Death

Wait-list status history not available in real life

Status history from patient B, C, or D used to fill in the status history for patient A needed after their real-life transplant.

SRTTR

Waitlist Status Histories

Patient Matching

Patients were only considered for matching status histories if they:

- Were listed for the same organ (KI, KP, PA),**
- Had been on the waitlist for a similar length of time,**
- Had the same active/inactive status,**
- Were in the same age category (0-11, 12-17, 18-34, 35-49, 50-64, >64),**
- Had the same diabetes status (yes/no), and**
- Had the closest risk of mortality based on the waitlist survival models**

SRTR

Predictors of Waitlist Mortality Used to Match Patient Histories

Kidney

Gender, age, race, ethnicity, diagnosis, log height and weight, previous transplant, albumin, patient hospitalized or on life support at listing, diabetes, peripheral vascular disease, time on dialysis by modality (PD v. HD), NYHA functional status, PRA, angina, hypertension, COPD, creatinine, cerebral vascular disease, creatinine clearance, and state-level gen. pop. mortality rate.

Kidney-Pancreas

Gender, age, race, log height and weight, time on dialysis, albumin, peripheral vascular disease, NYHA functional status, PRA, calendar year of listing, and state-level gen. pop. mortality rate.

Pancreas

Gender, age, race, patient hospitalized or on life support at listing, creatinine clearance and state-level gen. pop. mortality rate.

SPTT

Models based on prevalent sample of 1999-2003 KI waitlist patients
Time on waitlist prior to 1999 accounted for in each model

Placement Models

- **Allocation models determine the order in which patients are offered organs**
- **Placement models cover the steps leading from offer to transplant**
- **Placement models only deal with organs recovered for transplant**
- **Positive crossmatches are part of the placement model**

SRT^R

Predictors of Organ Placement

- **KI to KI patient**
 - Recipient: age, ethnicity, PRA
 - Donor: age, gender, cause of death
 - Recipient/donor: local/regional/national and interactions with shared, number of mismatches
- **KI to KP patient**
 - Recipient: PRA
 - Donor: age, gender
 - Recipient/donor: local/regional/national, number of mismatches
- **KP to KP patient**
 - Recipient: ethnicity, PRA
 - Donor: cause of death
 - Recipient/donor: local/regional/national and interactions with shared, ABO, number of mismatches
- **PA to KP**
 - Not currently allowed in KPSAM
- **PA to PA patient**
 - Recipient: PRA
 - Donor: cause of death
 - Recipient/donor: local/regional/national, ABO, number of mismatches

SRTT

Predictors of Post-Transplant Graft Failure (To Be Implemented in Final KPSAM)

kidney

Recipient:

- Age, gender, ethnicity, race, diagnosis, PRA, previous Tx, time on dialysis and modality, BMI, peripheral vasc. dis., albumin, angina, previous transfusion, hospitalized or life support, HTN, previous malignancy, peptic ulcer

Donor:

- Age, gender, ethnicity, race, HTN, creatinine, CoD, ECD, diabetes

Recipient/Donor:

- ABO, 0-2 MM for A, B, and DR separately, weight ratio

Pancreas

• Recipient:

- Age, gender, race, BMI, NYHA functional status

• Donor:

- Age, gender, race

• Recipient/Donor:

- 0-2 MM for B.

SKTR

All recipient factors at patient listing, not transplant

Predictors of Post-Transplant Mortality

- **Recipient:**
 - Age, gender, ethnicity, race, PRA*, BMI, previous transplant, and albumin*
- **Donor:**
 - Age, gender, ethnicity, race, BMI, and cause of death
- **Recipient/Donor:**
 - ABO compatible v. identical, and 0-6 MM for A, B, and DR combined
- **Final post transplant model will take graft failure into account**

SKTR

*Not used in Pancreas model

Validation

SPTP

Kidneys and Pancreata in KPSAM Follow National Patterns in 2001

Kidneys	Actual	KPSAM
Discards	1601	1490
Transplants	8101	8522
Pediatric	287	244
ABO identical	7761	8042
0 ABDR Mismatch	1235	1155
0 BDR Mismatch	1339	1238
0 DR Mismatch	2670	2745
1 DR Mismatch	3267	3585
2 DR Mismatch	2164	2192

Kidney-Pancreas	Actual	KPSAM
Discards	50	24
Transplants	893	885
Pediatric	1	2
ABO identical	844	853

Pancreas	Actual	KPSAM
Discards	365	395
Transplants	407	432
Pediatric	19	10
ABO identical	350	421

SRTT

SPTP

00-22

**OPTN/UNOS Kidney and Pancreas Transplantation Subcommittee on
Kidney Allocation and KPSAM
Ann Arbor, Michigan
February 11, 2004**

Exhibit PP

Summary Discussion Points

A meeting of a subgroup of the OPTN/UNOS Kidney and Pancreas Transplantation Committee and the respective Chairs of the OPTN/UNOS Pediatric Transplantation, Minority Affairs and Histocompatibility Committees was held at the offices of URREA in Ann Arbor, Michigan. The intent of the meeting was to review and discuss the structure and functions of the Kidney and Pancreas Simulated Allocation Model (KPSAM) being developed by the SRTR, as well as future directions for allocation policy. A copy of the agenda for the meeting is attached. Due to time constraints, a number of topics were deferred for discussion at a full Kidney/Pancreas Committee meeting at a later time.

Overview of KPSAM

- Scheduled for delivery to HRSA on March 31, 2004.
- Features unique to KPSAM (vs. simulation models for other organs), include: payback, HLA matching, waiting time calculations, models of graft failure for combinations of kidney and pancreas, and re-listing after graft failure.
- Uses data from 2001 for inputs to model. 2001 selected as the most recent year for which completed patient histories are available. Inputs include, for example, waiting list and donor organ characteristics as well as allocation algorithm. Events after the match run are probabilistic.
- Uses an event-sequenced Monte Carlo Simulation to allow multiple runs and an average of results obtained.
- Predicts the magnitude and direction of a change in the allocation system. For example, changes in allocation points or priorities, allocation according to transplant benefit (expected lifetimes with vs. without transplant), changes in DSA boundaries, changes in ECD kidney policy.

Waitlist Mortality-Possible Approaches for Study

- Assess factors affecting rate of death on the kidney waitlist using comorbidity data collected at time of listing. Includes the following comorbid conditions: diabetes (RR=1.57; p-value < .0001), diabetes with insulin, peptic ulcer disease, angina/coronary artery disease, hypertension (RR=0.93; p-value=0.0015), cerebrovascular disease, peripheral vascular disease, COPD, pulmonary embolism, and cancer.
- Association of comorbid conditions and mortality in hemodialysis patients. DOPPS analysis included the following variables: age, male (vs. female), Black (vs. other), coronary artery disease, congestive heart failure (RR=1.22; p-value<0.0001, other cardiac disease, left ventricular hypertrophy, cardiomegaly by x-ray, hypertension (RR=0.74; p-value<0.0001), cerebrovascular disease, peripheral vascular disease, diabetes mellitus (RR=1.27; p-value<0.0001), lung disease (RR=1.29; p-value<0.0001), dyspnea, smoking, cancer, HIV/AIDS (RR=2.96; p-value<0.0001), gastrointestinal bleed (RR=1.25; p-value<0.0001), peptic ulcer disease, hepatitis B, hepatitis C, neurological disorder (RR=1.39; p-value<0.0001), psychiatric disease (RR=1.30; p-value<0.0001), recurrent cellulitis or gangrene (RR=1.48; p-value<0.0001), and vision problems.

- Index of Co-Existent Disease (ICED) to predict functional status at one year. Uses scales for individual disease severity and indices of physical impairment.
- Medicare Comorbidity Index, measured at start of dialysis. Includes congestive heart failure (.25), ischemic heart disease (.16), myocardial infarction, cardiac arrest, cardiac dysrhythmia (.15), pericarditis, cerebrovascular disease (.16), peripheral vascular disease, hypertension, diabetes (.12), diabetes with insulin, COPD (.18), smoker, cancer (.37), alcohol dependence (.13), drug dependence (.31), HIV, AIDS, inability to ambulate (.39), and inability to transfer (.26).
- **Discussion:**
 - Applicability of medical urgency (*e.g.*, mortality risk without a transplant) in kidney allocation, versus, for example, liver allocation: how does the option of dialysis fit in the paradigm?
 - Objective(s) of kidney transplantation; what is the expected benefit from receipt of a kidney transplant?
 - Objective(s) of kidney allocation system; what degree of improvement can be expected from a change in policy?
 - Applicability of “transplant benefit”/“net benefit” concepts in kidney allocation (*e.g.*, balance of expected waitlist survival with survival following transplantation).
 - Applicability of other outcome measures in kidney allocation, including, for example, hospitalization, quality of life, burden of disease, and cost.
 - Considerations for pediatric, minority, sensitized patients, facing unique health care needs and challenges with respect to access to kidney transplantation.
 - Data needed to evaluate mortality risk in kidney transplantation: does this include data not presently collected/available?

KPSAM Validation

- KPSAM results (based upon single run) compared against actual experience for first six months of 2001.
- Some discrepancies with actual data expected due to: physician medical judgment/permitted OPO discretion, approved local alternative allocation/distribution systems, en bloc transplants, and medical urgency.
- Validation results, as of time of meeting, shown in attached slides. Graft failure models were being updated, which, once incorporated, would be expected to reduce disparities between actual and KPSAM results.
- Recommendations to further improve predictability of KPSAM:
 - In assessing patient matching status histories for model inputs, include sensitization status (*e.g.*, whether patient is highly sensitized).
 - For probability of positive crossmatch with potential donors, HLA mismatches with donor as well as patient PRA level should be considered.

OPTN Final Rule-Policy Development

- Establish and articulate policy objectives, *i.e.*, what is to be accomplished by the (proposed) policy
 - Allocation policy criteria – preamble to Final Rule provides, “that there may well be different approaches to kidney allocation policy than those for other types of organs,

perhaps along the lines of the current policies, which take into account such factors as immunologic compatibility between the donor and patient, whether the patient's immune system is highly sensitized, and other medical factors.”

- Performance goals
- Establish and articulate measures to assess policy performance
 - Unit of measure
 - Measures themselves
- Evaluate policies using policy performance measures

Defining and Reducing Disparity in Access to Kidney and Pancreas Transplantation

- Possible remedies outlined (see attached slides)
 - Geographic disparity-waitlisting
 - Ethnic disparity-waitlisting
 - Geographic disparity-transplantation
 - Ethnic disparity-transplantation
 - Disparity by insurance-waitlisting
 - Disparity by insurance-transplantation

Special Pediatric Issues

- Recommendation outlined for modeling changes in algorithm: to provide pediatric patients with well matched kidneys from donors of optimal age (teenagers and young adults) in a short time frame to minimize the growth and developmental delay as well as the morbidity associated with ESRD and dialysis.

Additional Attachments

- Current Allocation Policy Diagrams

**OPTN/UNOS Kidney and Pancreas Transplantation Subcommittee on
Kidney Allocation and KPSAM
Ann Arbor, Michigan
February 11, 2004**

Subcommittee Participants:

Alan Leichtman, M.D.
Mark Stegall, M.D.
James Wynn, M.D.
Daniel Hayes, M.D.
Francis Delmonico, M.D.
Ruth McDonald, M.D.
Dale Distant, M.D.
Winfred Williams, M.D.
Susan Saidman, Ph.D
Ginny McBride, RN, BS, CPTC
Mike Dreis (via telephone)
Monica Lin (via telephone)

UNOS Staff Present:

Cindy Sommers, Esq.
Jason Byrd, Esq.
Erick Edwards, Ph.D
Maureen McBride, Ph.D

SRTR Staff Present:

Robert Wolfe, Ph.D
Fredrich Port, Ph.D, M.D.
Mary Guidinger
Randy Sung, M.D.
Sarah Miller
Keith McCullough
Ann Rodgers
Valerie Ashby

OPTN/UNOS Kidney Pancreas Transplant Committee
Subcommittee Meeting on Allocation Policy
SRTR/URREA Simulated Allocation Model (SAM)
Ann Arbor, Michigan
February 11, 2004

- 9:00 Overview of the structure and functions of the Simulated Allocation Models (SAM) - Robert Wolfe
- 9:30 Review of KPSAM
1. Predictors of waitlist mortality - Fritz Port
 2. Patient history matching – Robert Wolfe
 3. Kidney and pancreas allocation rules – Anne Rodgers
 4. Placement models – Keith McCullough
 5. Post-transplant allograft failure – Mary Guidinger
 6. Post-transplant mortality – Mary Guidinger / Keith McCullough
 7. Validation strategy – Robert Wolfe
- Noon Lunch
- 12:30 Future directions for allocation policy
1. Final rule – Ginny McBride / Cindy Sommers
 2. Allocation to foster net benefit – Robert Wolfe
 - a. waitlist and post-transplant survivals
 - b. other measures of benefit
 - c. Examples: liver (MELD) and lung
 3. Defining and reducing disparity in access – Dale Distant / Alan Leichtman
 - a. geography
 - b. race
 - c. insurance
 4. Simplification of allocation algorithm – James Wynn / Dan Hayes
 5. Special pediatric issues – Ruth McDonald
 6. Minority issues and defining equity – Win Williams / Dale Distant
 7. Priority based on antigen frequency (Eurotransplant) Susan Saidman / Frank Delmonico
 8. Sensitized recipients – Susan Saidman / Mark Stegall
- 3:00 “Brainstorming” Future directions for modeling and allocation
1. Data quality
 2. New / supplemental data sources
 3. Collection of new data elements
 4. Quality of life / morbidity
 5. Quality adjusted life years / discounted life years
 6. Resource utilization / hospitalizations
 7. Islet allocation
 8. Patient level predictive equations
 9. Other

Kidneys and Pancreata in KPSAM Follow National Patterns in First 6 Months of 2001

<u>Kidneys</u>	<u>Actual KPSAM</u>	
Discards	794	731
Transplants	4017	4217
Pediatric	168	135
ABO identical	3806	3980
0 ABDR Mismatch	609	579
0 BDR Mismatch	657	613
0 DR Mismatch	1345	1314
1 DR Mismatch	1591	1747
2 DR Mismatch	1060	1156

<u>Kidney-Pancreas</u>	<u>Actual KPSAM</u>	
Discards	25	14
Transplants	443	454
Pediatric	1	1
ABO identical	424	440

<u>Pancreas</u>	<u>Actual KPSAM</u>	
Discards	181	169
Transplants	202	224
Pediatric	9	7
ABO identical	158	220

SRTR

Deaths in KPSAM are Similar to Jan-Jun 2001 Patterns

		<u>Actual KPSAM</u>	
<u>Waitlist</u>	Kidney	1713	1589
	Pancreas	14	18
	Kidney-Pancreas	118	106
<u>Post-Transplant</u>	Kidney	79	139
	Pancreas	3	4
	Kidney-Pancreas	10	35

SRTR

Geographic Disparity-Waitlisting

Possible Remedies

- Candidate transportation benefits
- Outreach to underserved areas
- Professional education on survival and morbidity with LD, preemptive, and early transplantation (ASN, AMA, ANNA, American College of IM, etc.)
- Medical School curricula
- Standardized referral form
- Enforceable CMS standards on referral that are tied to dialysis reimbursement rates
- Federal regulation of Medicaid program transplant-related benefits

SRTR

Racial / Ethnic Disparity-Waitlisting

Possible Remedies

- CMS oversight of dialysis center referral patterns
- Mandatory, national, standardized education materials for dialysis patients
- Professional education
- Study of transplant center waitlisting patterns among referred patients
- Standardized candidate evaluation form
- Insurance reform

SRTR

Geographic Disparity-Transplantation

Possible Remedies

- **Facilitate candidate multiple listing**
- **Transplant centers participate in > one OPO**
- **Larger allocation areas**
- **HRSA / Donor Hospital Collaborative**
- **Enforceable national OPO performance standards**
- **Deceased and living donor incentives and recognition**

SRTR

Racial / Ethnic Disparity Transplantation

Possible Remedies

- **Assign points for uncommon HLA Ag**
- **Calculate waiting time from date of first dialysis**
- **Facilitate multiple listing**
- **Eliminate economic disincentives for living donation**
- **Minority community donor outreach programs**
- **Insurance reform**

SRTR

Disparity by Insurance-Waitlisting

Possible Remedies

- **Base dialysis reimbursement rates on transplant referral rates**
- **Standardize Medicare Intermediary interpretations of transplant benefits**
- **Survey Medicaid benefits – establish best practices – Federal regulation of Medicaid program transplant-related benefits**
- **Lifelong Medicare coverage of immuno-suppressant medications**
- **Transplant benefits as Medicare COP for HMOs**

SRTR

Disparity by Insurance-Transplantation

Possible Remedies

- **Calculate waiting time from date of first dialysis**
- **Lifelong Medicare coverage of immuno-suppressant medications**
- **Transportation, lost wages, expense benefits for Living Donors**

SRTR

Policy	Exceptions
3.5	Physician judgment governs acceptance decision
3.5.1	ECD definition
3.5.2	Except for zero MM, O only to O
	Except for zero MM, B only to B
3.5.3	Sharing of zero MM SCD and ECD kidneys is mandatory
3.5.3.1	Zero Ag MM definition includes genotypic and phenotypic identity
3.5.3.2	Data on all DD must be entered into OPTN system
	Preprocurement tissue typing is expected (Policy 2.7)
	If no pre-prcmnt TT, ECD allocation proceeds (Policy 3.5.1.2)
	If no pre-prcmnt TT, host OPO provides written explanation
3.5.3.3	Mandatory sharing zero Ag MM, unless kidney and non-renal Txp
	Offers subject to time limits
	Decision on which kidney to share rests with host OPO
3.5.3.3.1	Allocation sequence if >1 ABO identical candidate with zero AG MM
3.5.3.3.2	Allocation sequence if >1 ABO compatible candidate with zero AG MM
	Reorder allocation if owe > 9 short-terms debts, or do not meet long-term debt obligations
	Allocate to debtor OPOs in inverse order of highest number of payback debts
3.5.3.4	If kidney+non-renal Txp, must only share one kidney
3.5.3.5	Host DSA has 8 h to notify the Organ Center of SCD kidney or ECD SPK
	Host DSA has 4 h to notify the Organ Center of ECD Kidney or ECD SPK
	After first offer, Organ Center has 4 h to place SCD kidney or SPK
	Center has lesser of 1 hour or time remaining to 4 hour limit to accept SCD kidney
	Acceptance of SCD kidney declined by host OPO does not generate a pay back
	After first offer, Organ Center has 2 h to place ECD kidney or SPK
	Center has lesser of 1 hour or time remaining to 2 hour limit to accept ECD kidney
3.5.4	If PRA>80%, must offer zero Ag MM panc with kidney to candidates listed for SPK
3.5.4.1	If >1, PRA>80%, zero Ag MM candidate, tie breaker is waiting time
3.5.5	Payback mandatory for zero Ag MM, or voluntary kidney+non-renal, or voluntary PRA>80%
	When owe two kidneys of same ABO type, payback with next ABO identical donor >5, <60
	Kidneys from donors <6, >59 may be offered as paybacks
	Offer payback to OPOs with two or more ABO identical credits, starting with oldest outstanding debt
3.5.5.1.1	OPO's with ≥4 debts in a blood type, must pay back (continued next line)
	unless local simultaneous transplantation of kidney with heart, lung, liver or zero MM SPK
3.5.5.1.2	OPO's with ≥4 debts in a blood type, may not accept a MM kidney shared with a SPK
3.5.5.2	Allocate SCD kidneys locally to prior living donors before payback obligation
3.5.5.3	Long-term debt was accumulated prior to implementation of 3.5.5.3, short-term after
	OPO's choice whether to apply payback to short- or long-term debt
3.5.6	In general kidneys are allocated local, regional, national
3.5.6.1	Allocated locally unless shared as zero Ag MM, or as payback, or through a voluntary sharing arrangement
3.5.6.2	Regional sharing by point total for both the first and any back-up candidates, applies to SCD and ECD
3.5.6.3	National sharing by point total for both the first and any back-up candidates, applies to SCD and ECD
3.5.6.4	UNOS Regions
3.5.7	Adult kidneys will be allocated singly unless meet two of: donor > 60, admission crcl <65, (continued next line)
	rising serum cr and > 2.5 at retrieval, hx longstanding Htn or DM, or GS >15% <50%
	Allocate by 3.5.6 and 3.5.11
3.5.8	ECD kidneys to candidates who have agree to receive them, allocated by 3.5.6 and 3.5.11
3.5.9	Minimum information/tissue for kidney offer
3.5.10	Recipient center can't change preservation mode until it is certain that center will use the kidney
3.5.11	All active ABO compatible candidates will be assigned points for every SCD donor
3.5.11.1	Unless <18, waiting time begins when an active listed patient meets minimal criteria, i.e.
	measured or calculated crcl <20 ml/min, or initiation of dialysis
	If < 18, waiting time begins with waitlisting
3.5.11.1.1	Candidates receive one point per year waiting, and
	The candidate waiting longest gets one point and others a proportionate fraction of a point
3.5.11.2	2 points for a zero HLA-DR MM, 1 point for a one HLA-DR MM
	Donors with HLA_Dr blank are considered homozygous and can be allocated as a zero HLA-DR MM
3.5.11.3	Assigned 4 points if PRA > 79% on the serum sample that is used for the crossmatch
3.5.11.4	No regional or national medical urgency points, local can be assigned if cooperative medical decision
3.5.11.5	Age < 11, 4 points. 11 to < 18, 3 points. Points assigned when registered and retained until reach 18
3.5.11.5.1	Kidneys not to zero MM, renal + non-renal, prior LD, or PRA>80% local*, must go to < 18 surpassed goals
	*if otherwise rank higher than all other listed patients based upon points assigned
	If more than one < age 18 with surpassed goal, allocate in descending order of point total
3.5.11.5.2	Goals 0-5 at listing, 6 months; 6-10 at listing 12 months; 11-17 at listing 18 months
3.5.11.6	Prior living donors assigned 4 points
	At local level prior LD receives first priority for MM kidneys with exception of kidney + non-renal.
	If >1 prior LD, waiting time would be tie breaker
3.5.12	ECD to candidates waitlisted for ECD, ABO compatible, and active on waitlist
3.5.12.1	Unless <18, waiting time begins when an active listed patient meets minimal criteria, i.e.
	measured or calculated crcl <20 ml/min, or initiation of dialysis
	If < 18, waiting time begins with waitlisting
3.5.12.1.1	Candidates receive one point per year waiting, and
	The candidate waiting longest gets one point and others a proportionate fraction of a point

BOTH KIDNEY & PANCREAS PROCURED FROM DONOR

NATIONAL/0 ANTIGEN MISMATCHED KIDNEY/PANCREAS CANDIDATES WHO ARE HIGHLY SENSITIZED (i.e., PRA >/= 80%)

- Local (Time Waiting)
- Regional (Time Waiting)
- National (Time Waiting)

Exception: Kidney Allocated with a Non-renal Organ other than the Pancreas

KIDNEY

PANCREAS

NATIONAL/0 ANTIGEN MISMATCHED ISOLATED KIDNEY CANDIDATES

Standard Donor Kidneys

Expanded Criteria Donor Kidneys

- Identical Blood Type
 - Stratified by Local, Regional, and National: PRA; Payback Status; Age (Points)
- Compatible Blood Type
 - Stratified by Blood Type: local, Regional, and National: PRA; Payback Status; Age (Points)

Exception: Kidney Allocated with a Non-Renal Organ

NATIONAL/0 ANTIGEN MISMATCHED ISOLATED PANCREAS CANDIDATES

- Local (Time Waiting) **Exception:** Highly Sensitized Patients Listed for Kidney/Pancreas or Isolated Pancreas Transplantation
- Regional (Time Waiting)
- National (Time Waiting)

LOCAL/MISMATCHED CANDIDATES

Standard Donor Kidneys

Expanded Criteria Donor Kidneys

- Points with Priority for Prior Living Organ Donors and Pediatric Patients at Time Thresholds

Exception: Payback Kidney Offers, Kidney Allocated with a Non-Renal Organ

LOCAL/MISMATCHED CANDIDATES

- Donor <= 50 Yrs & BMI <= 30* *Donor > 50 Yrs or BMI > 30*
- Isolated Pancreas Candidates (Time Waiting), OR
 - Combined Kidney/Pancreas Candidates (Time Waiting), OR
 - Combined Solid Organ-Islet Candidates (Time Waiting)
- Then, Clinical Islet Candidates (Need and Time Waiting)

REGIONAL/MISMATCHED CANDIDATES

Standard Donor Kidneys

Expanded Criteria Donor Kidneys

- Points with Priority for Pediatric Patients at Time Thresholds

REGIONAL/MISMATCHED CANDIDATES

- Donor <= 50 Yrs & BMI <= 30 (See Note Below)* *Donor > 50 Yrs or BMI > 30*
- Isolated Pancreas Candidates (Time Waiting)
 - Combined Kidney/Pancreas Candidates if Kidney Available (Time Waiting)
- Note:** Facilitated Allocation System may be accessed through UNOS Organ Center after 5 hours or if organ retrieval is imminent.

NATIONAL/MISMATCHED CANDIDATES	
<ul style="list-style-type: none"> Standard Donor Kidneys Points with Priority for Pediatric Patients at Time Thresholds 	<ul style="list-style-type: none"> Expanded Criteria Donor Kidneys Time Waiting

NATIONAL/MISMATCHED CANDIDATES	
<ul style="list-style-type: none"> Donor \leq 50 Yrs & BMI \leq 30 (See Note Below) Isolated Pancreas Candidates (Time Waiting) Combined Kidney/Pancreas Candidates if Kidney Available (Time Waiting) 	<ul style="list-style-type: none"> Donor > 50 Yrs or BMI > 30 Clinical Islet Candidates (Need and Time Waiting)
<p>Note: Facilitated Allocation System may be accessed through UNOS Organ Center after 5 hours or if organ retrieval is imminent</p>	
LOCAL/MISMATCHED CANDIDATES	
<ul style="list-style-type: none"> Donor \leq 50 Yrs & BMI \leq 30 Clinical Islet Candidates (Need and Time Waiting) 	<ul style="list-style-type: none"> Donor > 50 Yrs or BMI > 30
REGIONAL/MISMATCHED CANDIDATES	
<ul style="list-style-type: none"> Donor \leq 50 Yrs & BMI \leq 30 Clinical Islet Candidates (Need and Time Waiting) 	<ul style="list-style-type: none"> Donor > 50 Yrs or BMI > 30 Isolated Pancreas Candidates (Time Waiting) Combined Kidney/Pancreas Candidates If Kidney Available (Time Waiting)
NATIONAL/MISMATCHED CANDIDATES	
<ul style="list-style-type: none"> Donor \leq 50 Yrs & BMI \leq 30 Clinical Islet Candidates (Need and Time Waiting) 	<ul style="list-style-type: none"> Donor > 50 Yrs or BMI > 30 Isolated Pancreas Candidates (Time Waiting) Combined Kidney/Pancreas Candidates If Kidney Available (Time Waiting)

OPTN/SRTR Data Working Group Additional Transplant Endpoints Summary Proposal

Background

To date, in order to evaluate the benefits of transplantation, the transplant community has been focused on patient and graft survival rates as the transplant outcomes of most interest. However, there are many other outcomes, commonly referred to as “additional transplant endpoints” that may be useful, either for the purpose of developing allocation algorithms or for assessing transplant system/program performance, or for both. For example, there may be some instances, such as in kidney and lung transplantation, where improving patient quality of life and functional status, rather than or in addition to prolonging life or patient survival, may play a role in the ultimate decision to receive an organ. Those who are involved in allocation policy development may wish to incorporate knowledge of relative degree of benefit in areas other than simply length of life into their decision making process. Such decisions should probably not be made entirely based upon data regarding death and graft survival, but also upon other outcomes data.

Therefore, the ultimate goal for exploring additional transplant outcome measures, is to enable the OPTN committees to consider them during the course of policy development, analyses and perhaps identifying patients who can most benefit from transplantation.

The OPTN/SRTR Data Working Group (DWG) would like to present this summary proposal to the Data Advisory Committee as well as other OPTN committees involved in allocation policy for their discussion and feedback.

Categories of Outcomes

In their meeting on April 3, 2003, members of the DWG identified major categories of additional endpoints, shown in the diagram below, that may be useful in evaluating the role of transplantation in decreasing patient morbidity and burden of disease, thereby improving patient quality of life and functional status.

Major categories of outcomes or Additional Transplant Endpoints

A	B	C	D	E
<u>Mortality</u>	<u>Morbidity</u> *Heart Attacks * GI bleeds *Other Events Requiring Hospitalization	<u>Disability</u> *Pain and Suffering *Functional Status	<u>Psychological Distress</u> *Anxiety *Depression	<u>Resource Use</u> *Inpatient and ICU Hospitalizations *Ambulatory Care

These categories of outcomes are highly correlated, and information about one will yield information about the others.

Methodology to Obtain Data on Additional Transplant Endpoint

Morbid events and use of resources: These can be measured fairly objectively by analyses of patient hospitalization data before and after transplantation. The Data Working Group recognizes, that although the current OPTN data on post transplant hospitalizations are valuable and of good quality, these data alone are not collected in sufficient detail to allow optimal analyses. In addition, the collection of hospitalization data in the OPTN/UNOS database is limited currently to the post-transplant period; information regarding hospitalizations while patients are on the waiting list is not available. Also, transplant programs following patients may not be aware or may not provide information regarding hospitalizations at other hospitals. Therefore, additional

and independent sources of data with more comprehensive patient hospitalization information are essential for conducting valid studies of resource utilization.

The DWG has identified two possible additional sources of data for obtaining more comprehensive inpatient hospitalization data:

a) CMS data: Available only for kidney and kidney pancreas patients with Medicare as their primary insurance carrier. A proposal has been submitted by the DWG to HRSA to obtain patient identified hospitalization data for a cohort of Medicare beneficiaries on the national waiting list for a renal transplant.

b) Hospitalization data from state registries: These registries are maintained by non-profit agencies affiliated with the Department of Health in each state and have inpatient and sometimes outpatient level discharges, hospital and nursing facility cost and utilization, and facility demographic and administrative databases and reports, available for public use. Formal data requests and proposals have been submitted by UNOS and negotiations are currently underway with the states of Virginia and Pennsylvania, which have expressed some interest in providing patient identified hospitalization data for a cohort of transplant candidates and recipients in their states.

Disability and Functional Status: Health Related quality of life and functional status represent a dimension of outcomes which aim to measure an individual or a group of patients' own perceptions of health and ability to function on a daily basis. Data collected on these measures may be used in conjunction with measures of resource use and morbid events to evaluate the overall impact of transplantation on reducing burden of illness.

A Functional Status subcommittee of the DWG was formed to assess the quality of the data and validity of the current mechanisms by which data on functional and employment status are gathered and reported by the transplant centers to the OPTN. Based on reports provided by UNOS and SRTR staff the sub-committee and later on, the full committee concluded that the OPTN data on functional and employment status are valuable and should continue to be collected. However, the subcommittee also agreed that in order to have an accurate assessment of the role of transplantation on patients physical well being, daily activities and overall quality of life, it is important to collect data directly from patients rather than providers, using a randomly selected cohort of patients as a sample.

In their meeting on September 9, 2003, members of the Data working Group unanimously approved the Functional Status subcommittee's proposal to implement a pilot study to collect functional status and quality of life data directly from patients, by conducting a survey of a randomly selected cohort of patients, using a health related quality of Life questionnaire.

The main objectives of the pilot study were identified as follows:

- 1) To obtain epidemiological data on functional status which may be poorly represented at this time, in order to fill in the gap with respect to resource use and hospitalization.
- 2) To study the co-linearity among the outcome measures and whether they are largely independent of each other.
- 3) To be able to ultimately predict the expected outcome of a particular patient, in relation to different treatment interventions.

The general consensus was that it would be best if the pilot study were conducted by the OPTN, perhaps under the auspices of the Data Working Group, rather than by outside agencies such as NIH. Three main options were discussed for the administration of the study 1) NIH type, clinical trial experimental study model, where the OPTN would ask a sample of transplant centers to oversee the completion of a quality of life survey questionnaire by their patients and also administer a functional status scale such as the Karnofsky scale, on each patients at various times during a patient's evaluation, treatment and follow-up. 2) Direct patient contact model, where

the OPTN would obtain address and or phone numbers of a randomly selected sample of patients from their transplant centers, and either mail the patients a questionnaire or ask them to complete the survey by calling them on the phone. 3) Field staff model, where trained data collectors from primary sampling units located at various geographic areas throughout the country would actually visit the patients in their homes and administer a questionnaire and a Karnofsky scale at the time of their meeting. There are a number of survey research firms that employ these types of field staff with specific training in administering survey instruments.

The subcommittee agreed that model number two might be the best implementation approach, although option three was not entirely excluded. Each option may require individual patient consent and institution specific IRB approval from the centers. HRSA representatives to the DWG, agreed to investigate whether it would be possible to obtain a general IRB exemption from the Office of Human Research and Protection, which would cover the data elements collected through the pilot study by the OPTN.

Three sub-groups were formed: a) a survey instrument subgroup responsible to identify a questionnaire to be used in the pilot study, b) a statistical sub-group to develop a comprehensive analytical/statistical plan for the study, including the sample size, method of random sample selection and other analytical issues related to the survey and c) a scientific sub-group responsible for the scientific oversight of the study.

The study cohorts would include a sample of transplanted patients and patients on the waiting list who have not yet been transplanted, from each organ type. Transplanted patients would be surveyed at four time intervals: 1) baseline (immediately before transplant), 2) one month 3) six months and 4) one year. Patients not yet transplanted would be surveyed at 1) baseline (at time of wait list registration), 2) lesser of six months or median time to removal from the wait list and 3) twice the amount of time at time point 2.

Duration of the Study

The study will aim to be completed within three years.

Analytical/Inferential Request #4

Update the analysis of the impact of preferentially giving 11-17 year old donor kidneys to pediatric recipients (0-17). The original analysis used all adults as the reference group. Break the adults into smaller groups (18-34, 35-49, 50-64, 65+) and use one of the subgroups as the reference group.

Study Population

The analysis includes 39,682 patients who received their first deceased donor kidney-only transplant during the study period (1/1/1996-12/31/2001).

Analytical Approach

The relative rate of graft failure was calculated as the time from transplantation until death or graft failure, censoring at the earliest of last known follow-up date, maximum date for which we expect follow-up information, or 12/31/2002. Cox models were fit to ascertain the relative rate of graft failure and were adjusted for recipient sex, recipient race, recipient BMI, year transplanted, PRA, ABO blood type, diagnosis group, time on dialysis, donor sex, donor race, cold ischemic time, donor cause of death, number of HLA mismatches, number of pre-transplant transfusions, double kidney transplant, donor history of diabetes or hypertension.

The first model included pediatric recipients only, and in addition to the variables listed above included a donor age indicator for whether or not the donor was age 0-10, 11-17, or 18+. The second model included all recipients and in addition to the variables listed above, included indicators for recipient age groups defined as follows: 0-17 (pediatric), 18-34, 35-49, 50-64, and 65+.

Results

Table 4.1 shows the number (and percent) of recipients by age of recipient and donor.

Table 4.1: Number and Percent of Recipients by Age of Recipient and Donor

Recipient Age	Pediatric Donor (0-11)		Adolescent Donor (11-17)		Adult Donor (18-59)		Older Adult Donor (60+)	
	N	%	N	%	N	%	N	%
Pediatric <18	196	7.2	271	5.9	990	3.4	13	0.4
Adult 18-34	606	22.4	868	18.8	4,708	16.4	284	8.0
Adult 35-49	934	34.5	1,683	36.4	10,160	35.3	853	24.0
Adult 50-64	808	29.8	1,473	31.9	10,466	36.3	1,687	47.4
Adult 65+	167	6.1	328	7.1	2,468	8.6	719	20.2
Total	2,711	100.0	4,623	100.0	28,792	100.0	3,556	100.0

During the study period, 4,352 (94.1%) adolescent donor (age 11-17) kidneys went to adults and 271 (5.9%) adolescent donor kidneys went to pediatric (<17) recipients.

Table 4.2: Relative Rate of Kidney Graft Failure for Pediatric Recipients Only

Donor Kidney	RR of Graft	
	Failure	p-value
Pediatric <11	0.86	0.39
Pediatric 11-17	0.82	0.17
Adult 18+	1.00	Ref

*Adjusted for recipient sex, recipient race, recipient BMI, year transplanted, PRA, ABO blood type, diagnosis group, time on dialysis, donor sex, donor race, cold ischemic time, donor cause of death, number of HLA mismatches, number of pre-transplant transfusions, double kidney transplant, donor history of diabetes or hypertension.

Overall, 1,470 pediatric patients received kidney transplants during the study period. Table 4.2 shows that the rate of graft failure for pediatric recipients of adolescent donor kidneys was not significantly lower than the rate of graft failure for pediatric recipients of adult donor kidneys (RR=0.82; p=0.17).

In the same time period, 4,623 patients received kidneys from adolescent donors. The rate of graft failure for pediatric recipients of adolescent donor kidneys was significantly higher than the rate of graft failure for adult recipients (age 35-49) of adolescent donor kidneys (see Table 4.3 below).

Table 4.3: Relative Rate of Kidney Graft Failure for Recipients by Donor Age and Recipient Age

Recipient Age	Pediatric Donor (0-11)		Adolescent Donor (11-17)		Adult Donor (18-59)		Older Adult Donor (60+)	
	RR*	p-value	RR*	p-value	RR*	p-value	RR*	p-value
Pediatric <18	1.53	0.0062	1.48	0.0043	1.67	<.0001	2.68	0.0171
Adult 18-34	1.54	<.0001	1.29	0.0039	1.48	<.0001	2.12	<.0001
Adult 35-49	1.47	<.0001	1.00	Ref.	1.26	<.0001	1.90	<.0001
Adult 50-64	1.56	<.0001	1.14	0.1057	1.39	<.0001	2.16	<.0001
Adult 65+	2.20	<.0001	1.45	0.0025	1.92	<.0001	2.70	<.0001

*Adjusted for recipient sex, recipient race, recipient BMI, year transplanted, PRA, ABO blood type, diagnosis group, time on dialysis, donor sex, donor race, cold ischemic time, donor cause of death, number of HLA mismatches, number of pre-transplant transfusions, double kidney transplant, donor history of diabetes or hypertension.

While it appears that pediatric recipients of adolescent donor kidneys do slightly better than pediatric recipients of adult kidneys, amongst recipients of adolescent donor kidneys, pediatric recipients and adult recipients age 65+ have significantly lower graft survival than adult recipients age 35-49. These data do not support preferential allocation of adolescent donor kidneys to pediatric recipients.

III. Regional Comments:

REGIONAL COMMENT SUMMARY

PROPOSAL 6: Proposed Modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) (Kidney and Pancreas Transplantation Committee)

Sponsoring Committee: Kidney and Pancreas Transplantation

Description: The proposed modifications, originally developed by the OPTN/UNOS Joint Kidney and Pancreas, Pediatric Transplantation, Minority Affairs and Histocompatibility Subcommittee, would increase from 2 to 6 the total allocation points awarded to pediatric candidates who have a zero DR mismatch with a standard criteria deceased kidney donor. The additional points would not apply in determining priorities among zero antigen mismatched patients, prior living organ donors, or patients listed with OPOs receiving kidney payback offers. The modifications also would not apply to expanded criteria donor (ECD) kidney allocation. The intent is to increase the number of transplants of well-matched kidneys into pediatric candidates while maintaining relatively short pediatric candidate waiting time to transplant, and thus, minimize long-term sensitization in pediatric candidates who most likely will require subsequent transplants during their lifetimes. The proposal is supported by both the OPTN/UNOS Kidney and Pancreas Transplantation and Pediatric Transplantation Committees.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	10 yes, 1 no, 3 no opinion			
2	5/07/04	31 yes, 0 no, 1 no opinion			
3	3/26/04	17 yes, 0 no, 0 no opinion			
4	4/2/04	29 yes, 0 no, 1 no opinion			
5	4/30/04	29 yes, 5 no, 2 no opinion			
6	4/2/04	53 yes, 0 no, 0 no opinion			
7	4/23/04	17 yes, 0 no, 0 no opinion			
8	4/2/04	22 yes, 1 no, 2 no opinion			
9	4/21/04	17 yes, 0 no, 1 no opinion			
10	4/30/04	19 yes, 0 no, 0 no opinion			
11	3/26/04	16 yes, 1 no, 3 no opinion			

COMMENTS:

Analytical/Inferential Request #1

The Pediatric Committee requests that the SRTR consider, in any analyses of the kidney allocation policy that use the utilitarian measure of total life years gained, the effects on pediatric patients.

We have received clarification from the OPTN that this is not a specific data request. The SRTR recognizes that a utilitarian measure could have an impact on pediatric patients and other patient subgroups, and will examine the effects on any potentially impacted patient subgroup in future allocation analyses.

Analytical/Inferential Request #2 (Revised)

Analyze the impact of preferentially allocating pediatric donor kidneys (0-17) to pediatric recipients (0-17). What is the impact on the number and percent of adult and pediatric patients that would be transplanted? Compare the outcomes of pediatric patients receiving pediatric donor kidneys to pediatric patients receiving adult donor kidneys. Compare the outcomes of pediatric patients receiving pediatric donor kidneys to adult patients receiving pediatric donor kidneys. (Separate adults into age groups 18-34, 35-49, 50-64, 65+).

Study Population

The analysis included 39,682 patients who received their first deceased donor kidney-only transplant during the study period (1/1/1996-12/31/2001).

Analytical Approach

We calculated national statistics such as number of pediatric donors, and number of pediatric donor kidneys that currently go to adult vs. pediatric recipients. Also, we looked at the number of pediatric patients waiting for a kidney.

Graft survival times were calculated as the time from transplantation until death or graft failure, censoring at the earliest of last known follow-up date, maximum date for which we expect follow-up information, or 12/31/2002. Cox models were fit to ascertain the relative rate of graft failure. The first model included pediatric recipients only, and in addition to the variables listed below included a donor age indicator for whether or not the donor was 17 or younger (pediatric). The second model included all recipients of pediatric donor kidneys, and in addition to the variables listed below, included indicators for recipient age groups defined as follows: 0-17 (pediatric), 18-34, 35-49, 50-64, and 65+.

Adjustment variables:

Recipient sex, recipient race, recipient BMI, year transplanted, PRA, ABO blood type, diagnosis group, time on dialysis, donor sex, donor race, cold ischemic time, donor cause of death, number of HLA mismatches, number of pre-transplant transfusions, double kidney transplant, donor history of diabetes or hypertension

Results

Table 2.1 shows the number (and percent) of recipients by age of recipient and donor.

Table 2.1: Number and Percent of Recipients by Age of Recipient and Donor

Recipient Age	Pediatric Donor (<18)		Adult Donor (18+)	
	n	%	n	%
Pediatric <18	467	6.4	1003	3.1
Adult 18-34	1474	20.1	4992	15.4
Adult 35-49	2617	35.7	11013	34.1
Adult 50-64	2281	31.1	12153	37.6
Adult 65+	495	6.7	3187	9.8
Total	7334	100.0	32348	100.0

During the study period, 6867 (93.6%) pediatric donor kidneys went to adults and 467 (6.4%) pediatric donor kidneys went to pediatric recipients.

The numbers in Table 2.2 were reported in the 2002 Annual Data Report produced by the SRTR.

Table 2.2: Kidney Waiting List at the End of 2001

	n	%
Pediatric <18	701	1.4%
Adult 18-34	7395	14.5%
Adult 35-49	16799	32.8%
Adult 50-64	20052	39.2%
Adult 65+	6197	12.1%

Overall, 1470 pediatric patients received kidney transplants during the study period. The rate of graft failure for pediatric recipients of pediatric donor kidneys was not significantly lower than the rate of graft failure for pediatric recipients of adult donor kidneys (RR=0.83; p=0.14).

In the same time period, 7334 patients received kidneys from pediatric donors. The rate of graft failure for pediatric recipients of pediatric donor kidneys was significantly higher than the rate of graft failure for adult recipients (age 35-49) of pediatric donor kidneys. (See Table 2.3)

Table 2.3: Relative Rate of Kidney Graft Failure for Recipients of Pediatric Donor Kidneys

	RR of Graft	
	Failure	p-value
Pediatric <18	1.36	0.0072
Adult 18-34	1.20	0.0074
Adult 35-49	1.00	ref
Adult 50-64	1.11	0.0871
Adult 65+	1.47	<.0001

While it appears that pediatric recipients of pediatric donor kidneys do slightly better than pediatric recipients of adult kidneys, amongst recipients of pediatric donor kidneys, pediatrics and adults age 65+ have significantly lower graft survival than adults age 35-49. These data do not support preferential allocation of pediatric donor kidneys to pediatric recipients.

**OPTN/UNOS Joint Kidney/Pancreas-Pediatric-Minority Affairs-Histocompatibility
Subcommittee
Conference call January 13, 2004**

Discussion points re agenda item #3 (Reconsideration of Prospective Crossmatch Criteria for Kidney and Pancreas Transplant Candidates)

Previous standard (prior to June, 2003 board meeting):

H. Renal and Pancreas Organ Transplantation

H3.000 Crossmatching

H3.100 Crossmatching must be performed prospectively.

Current standard (proposed by KPT committee, approved at June, 2003 board meeting)

H3.100 ~~Crossmatching must be performed prospectively.~~ Crossmatches are not mandatory for all kidney and pancreas transplant candidates. For example, patients documented as historically unsensitized, and who have no intervening sensitizing events, may be transplanted without a final crossmatch. However, laboratories must perform a prospective crossmatch if so requested by the transplant center and dictated by clinical circumstances.

Standard proposed by the Histocompatibility committee, out for public comment in fall, 2003

H3.100 ~~Crossmatches are not mandatory for all kidney and pancreas transplant candidates. For example, patients documented as historically unsensitized, and who have no intervening sensitizing events, may be transplanted without a final crossmatch. However, laboratories must perform a prospective crossmatch if so requested by the transplant center and dictated by clinical circumstances.~~ The laboratory must be capable of performing a prospective crossmatch and must do so when requested by a physician or other authorized individuals. Histocompatibility laboratories must have a joint written policy with their transplant program(s) on transplant candidate crossmatching strategies.

Due to opposition by KPT and other committees, as well as some public comment, the proposal was withdrawn at the November board meeting. But now Histo and KPT need to work together to come up with an alternative.

The following ideas are the results of discussions both within the Histo committee and with Alan Leichtman that occurred at various times last year. I hope we can use these as the first step in determining what we should propose and send out for public comment this spring, to be voted on at the June board meeting.

I would propose that the lab standard be the same as the one the Histo committee proposed last fall, i.e.

H3.100. The laboratory must be capable of performing a prospective crossmatch and must do so when requested by a physician or other authorized individuals. Histocompatibility

laboratories must have a joint written policy with their transplant program(s) on transplant candidate crossmatching strategies.

This would allow the lab standard to deal specifically with laboratory practice. The more detailed crossmatch requirements, which would be required of the labs as well as the clinicians, would be proposed as a policy change.

Possible options for the policy are as follows:

Option 1. Revised wording proposed by the Histo committee. This makes crossmatching a requirement, either prospectively or retrospectively:

The laboratory must be capable of performing a prospective crossmatch and must do so when requested by a physician or other authorized individuals. A crossmatch is required. The crossmatch must be performed prospectively unless the histocompatibility laboratory and the transplant program(s) have a joint written policy defining the circumstances under which the required crossmatch is performed perioperatively. Histocompatibility laboratories must have a joint written policy with their transplant program(s) on transplant candidate crossmatching strategies.

Option 2. Less restrictive wording for the policy could say something like:

A prospective crossmatch is mandatory for sensitized patients, and the definition of a sensitized patient must be stated in a joint written policy. Histocompatibility laboratories must have a joint written policy with their transplant program(s) on transplant candidate crossmatching strategies for both sensitized and unsensitized patients.

Option 3. We could develop a policy that lays out details like how often screening should be done, which methods should be used for XM, and what patient sensitization history is needed. However, these vary considerably from center to center. A subcommittee of the Histocompatibility committee (Karen Nelson et al) is in the process of completing a 4 page paper with guidelines on the kind of information that should be included in the joint policies to be developed by transplant centers and labs.

Proposed Modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch)**Summary**

The proposed modifications, originally developed by the OPTN/UNOS Joint Kidney and Pancreas, Pediatric Transplantation, Minority Affairs and Histocompatibility Subcommittee, would increase from 2 to 6 the total allocation points awarded to pediatric candidates who have a zero DR mismatch with a standard criteria deceased kidney donor. The additional points would not apply in determining priorities among zero antigen mismatched patients, prior living organ donors, or patients listed with OPOs receiving kidney payback offers. The modifications also would not apply to expanded criteria donor (ECD) kidney allocation. The intent is to increase the number of transplants of well-matched kidneys into pediatric candidates while maintaining relatively short pediatric candidate waiting time to transplant, and thus, minimize long-term sensitization in pediatric candidates who most likely will require subsequent transplants during their lifetimes. The proposal is supported by both the OPTN/UNOS Kidney and Pancreas Transplantation and Pediatric Transplantation Committees.

Please note that the exhibit submitted with the public comment proposal (Exhibits D-F) are not included with this briefing paper, but can be found in the March 15, 2004 OPTN/UNOS Public Comment Release.

I. Background

Current OPTN/UNOS policy assigns four points to patients who are less than 11 years old and three points to patients who are 11 years old or older and less than 18 years of age. The purpose of these point assignments is to expedite access to deceased donor kidneys for pediatric transplant candidates. This is appropriate because young children and adolescents experience unique problems associated with dialysis and disruption to expected growth and development processes due to renal failure. Early reversal of the condition through transplantation can avoid the special problems of dialysis and ameliorate many of the adverse effects of end stage renal disease which confront these patients. Rapid treatment provides the best opportunity for reversing the growth and development deficits and preventing lifelong adverse consequences.

OPTN/UNOS policy expressly defines time thresholds to reach the objective of transplantation for children. These thresholds are listed in OPTN/UNOS Policy 3.5.11.5.2, and are as follows: within 6 months of listing for candidates 0-5 years old, within 12 months of listing for candidates 6-10 years old, and within 18 months of listing for candidates 11-17 years old. Pediatric candidates who surpass their transplant goal without receiving a transplant are assigned highest priority for kidney allocation, with exceptions for zero antigen mismatched patients, prior living organ donors, kidney payback offers, highly sensitized patients with higher priority, and patients in need of combined kidney/pancreas transplantation if preference is assigned to these multiple organ candidates locally. The spirit of the policies is to have pediatric patients transplanted before or by their respective time goals. If the goal date is exceeded, additional priority is assigned to increase their opportunity for timely transplantation.

The OPTN/UNOS Pediatric Transplantation Committee has for some time been studying impacts from the policy assigning additional priority in kidney allocation to children who have reached their time goals to transplant without receiving a transplant. Though the data demonstrate some improvement in overall transplant rates within pediatric time goals after implementation of the policy, this is largely due to increases in living donor kidney transplantation rather than deceased donor kidney transplantation and many pediatric candidates still are not receiving a transplant within their time goals. A separate proposal sponsored by the Kidney and Pancreas Transplantation Committee, also included in the public comment distribution, was recommended to address issues of timely transplantation for pediatric candidates on the kidney waiting list.

In November 2002, the OPTN/UNOS Board of Directors approved modifications to the national system of standard criteria donor kidney allocation to eliminate points for HLA similarity between potential donor and recipient pairs at the B locus, and modify the number of points assigned for HLA similarity between potential donor and recipient

pairs at the DR locus. Two points are currently assigned for a 0 HLA DR mismatch and 1 point is assigned for a 1 HLA DR mismatch. Points awarded for matching at the B locus were eliminated based upon data demonstrating that matching at this locus no longer contributes significantly to intermediate-term graft survival rates, as well as expected reductions in disparities among patient ethnic groups in access to kidney transplantation due to greater commonality of HLA antigens among potential donor and candidate pools at the DR locus. The objective was, therefore, to reduce disparities in kidney transplantation due to commonality of antigens between donors and patients with little or no adverse effect upon patient transplant outcomes.

During the development of this policy, a joint subcommittee among the OPTN/UNOS Kidney and Pancreas Transplantation, Pediatric Transplantation, and Minority Affairs Committees was convened to examine potential impacts of the proposal upon pediatric transplant candidates. The Joint Subcommittee initially discussed this issue on September 26, 2003. An analysis reviewed by the Joint Subcommittee showed data based on kidneys transplanted into pediatric recipients between July 1, 2000, and June 30, 2003. The purpose of the analysis was to analyze the sensitization by HLA mismatch level for pediatric recipients. In general, the data showed that approximately 91% of pediatric kidney recipients are receiving kidneys with three or more HLA mismatches. This raised concerns that children were not receiving well-matched kidney transplants even under the former policy assigning substantially more priority for HLA matching.

An additional analysis was presented comparing kidney transplant outcomes for pediatric recipients by HLA mismatch level. The study population included all recipients who received their first deceased donor, kidney-only transplant between March 6, 1995, and March 31, 2001. The analysis examined the importance of an HLA DR mismatch in children compared to adults to determine if differences exist in graft survival rates. Frequencies were tabulated for recipients by age group and mismatch status. In addition, two-year unadjusted survival estimates (with 95% confidence intervals) by age and mismatch status were calculated using the Kaplan-Meier estimator. Graft survival times were calculated as the time from transplantation until death or graft failure, censoring at the earliest of last expected follow-up date, last date for patient follow-up (2 years after transplant date), date of re-transplant (within 2 years of first transplant), or March 31, 2003. In general, the analysis showed that within recipient age groups, graft survival was generally highest for recipients transplanted with a zero HLA ABDR mismatch and decreased according to DR (non-zero AB) mismatch. The exception to this trend was found in recipients within the 11 to 17 age group. In addition, the effect of age on overall survival within each mismatch status group was statistically significant ($p < .001$).

II. Policy Proposal

The Joint Subcommittee considered the trade-off that exists for children between the objectives of (1) receiving a rapid transplant to address debilitating effects of dialysis and renal failure upon growth and development, and (2) receiving a well-matched transplant to improve transplant outcomes and avoid sensitizing these patients who will need a lifetime of transplants. It may be that pediatric patients presently are receiving less well-matched kidney transplants because they are not staying on the waiting list long enough to be offered better matched deceased donor kidneys. This situation may be further exacerbated under the current system because it assigns less emphasis for HLA DR matching; priority for points assigned for waiting time and age at listing will, therefore, assume greater importance in determining organ offers.

The Joint Subcommittee discussed the option of assigning additional points for pediatric candidates for matching at the DR locus. One concern with such a proposal is that the additional points will more than likely result in fewer zero antigen mismatched kidney transplants because the pediatric candidates will be transplanted before getting the optimally matched offers. An advantage is that children would receive better quality organ offers in terms of commonality of antigens between donor and candidate, at least at the HLA DR locus, both before and after meeting their time goals to transplant. This would be expected to improve organ placement efficiency, as well as transplant outcomes for children. It may come at the expense of somewhat longer waiting times for pediatric candidates as physicians have the opportunity to compare the benefit of a more rapid transplant for their patients versus a transplant with a better HLA DR match.

The Joint Subcommittee initially discussed assigning additional points for children for both a 1 and 0 DR mismatch. Although some additional priority could be assigned for a 1 DR mismatch, a much greater priority would be assigned for a 0 DR mismatch. The Joint Subcommittee also discussed for future study assigning extra points to

children with 0 mismatches at the HLA DR locus when they also are mismatched with the donor at the HLA A or B loci. Matching at the HLA A and B loci may be more important for reducing the chances of sensitization for a subsequent transplant. Some Members were wary of a system that awards points for HLA A and B matching since there is no significant outcome benefit at this match level and the result of historical HLA matching priority in kidney allocation has been to disadvantage minority patients. Minority pediatric candidates might be harmed by such a proposal. Further consideration has, therefore, been deferred pending availability of modeling data to assess any such harm.

The Joint Subcommittee continued its discussion of this issue during its January 13, 2004, meeting. An analysis was presented examining the effects of awarding pediatric candidates more points for DR matching in order to allow them to be positioned high enough on the list so as to receive offers for better-matched kidneys in a time frame that keeps in mind the OPTN/UNOS goals for transplant. The study population consisted of candidates listed for a kidney-only transplant who were active on the waiting list on March 31, 2003. The number of waiting time and age points were calculated for each candidate as if the candidate would have received an organ offer on March 31, 2003. The numbers of ABO blood type O adult and pediatric candidates competing for an organ were shown within each OPO and nationally by the total number of allocation points.

Table 4.1 shows the distribution of waiting time and age points assigned to adult and pediatric candidates with ABO blood type O and PRA less than 20% on the waiting list by OPO. This table was provided as a realistic example of the number of competitors for an organ since organs are distributed within blood type for blood types O and B and candidates with PRA greater than 20% would have higher expectations for a positive crossmatch against a potential donor. Point columns include candidates with the number of points shown in the column heading as well as candidates possessing a higher number of points. Table 4.2 shows the national distribution of waiting time and age points for the same group of candidates. Table 4.3 shows the same information as Table 4.1, except that it considers candidates with ABO blood type O with PRA less than 80%, rather than PRA less than 20%. Table 4.4 is similar to Table 4.2, but it too considers candidates with ABO blood type O with PRA less than 80%.

The data show that there were 2,849 adult candidates with ABO blood type O and a PRA level less than 20% with at least four points, compared to 190 pediatric candidates. There were 822 adult candidates with the same characteristics and at least six points compared to 46 pediatric candidates.

It was suggested that a change to the number of allocation points awarded for 0 DR matching might be the appropriate means toward achieving the goal of better matched kidneys for pediatric candidates. First, the Joint Subcommittee considered a recommendation to increase the number of points awarded to pediatric candidates based on a 0 DR mismatch from 2 to 4. However, Members of the Joint Subcommittee were concerned that this modest increase might result in quicker transplants for pediatric candidates but not in better-matched kidneys. Based on the data, pediatric candidates with ABO blood type O and PRA less than 20% still compete with 822 adult candidates at the 6 (or more) allocation point level. Additional points for DR matching should be considered for pediatric candidates in order to ensure they will receive priority when the better-matched organ offers become available over adult candidates with longer waiting times. Therefore, the Joint Subcommittee considered the recommendation to award a total of 6 points to pediatric candidates for a 0 DR mismatch. Members of the Joint Subcommittee agreed that the additional pediatric points should only be applied to the allocation algorithm for standard criteria donor kidneys.

Some Members noted their concern over how highly sensitized candidates would be affected by a change to the policy for DR points for children. Unsensitized pediatric candidates could receive an advantage even over highly sensitized adult candidates who have a negative crossmatch with the donor kidney. This could further diminish opportunities for highly sensitized candidates to receive transplants. However, other Members of the Joint Subcommittee acknowledged that there are inherent trade-offs in terms of allocation priority among patients. An additional consideration is pediatric candidates who receive poorly-matched kidneys today are likely to become the next generation of highly sensitized candidates. Modifying the system to increase the number of well-matched kidneys transplanted into pediatric candidates now could result in a smaller sensitized population in the future.

After further discussion, the Joint Subcommittee unanimously agreed to recommend the proposal awarding a total of 6 points to pediatric candidates who are a 0 DR mismatch with the kidney donor. The goal of the proposal is to improve opportunities for a pediatric candidate to receive a well-matched kidney within a reasonable length of

time. This proposal addresses the negative impacts renal failure and dialysis have on critical growth and development for pediatric candidates. Better matching improves outcome and avoids sensitization, which are vital issues for pediatric candidates who may need a lifetime of transplants.

At its January 20-21, 2004, meeting, the Kidney and Pancreas Transplantation Committee was informed of the Joint Subcommittee proposal by Ruth McDonald, M.D. There was concern noted that causes of increased sensitization in children following receipt of a poorly-matched kidney transplant may not be fully understood. A white paper on the topic will be available for review by the Committee at its next meeting. However, studies reviewed by the Kidney/Pancreas Transplantation Committee in developing the proposal to eliminate points for matching at the HLA B locus show that for patients overall who receive even optimally HLA matched kidney transplants there is an increase in PRA following failure of the transplant. Additional levels of mismatch confer additional risk of increased sensitization and these differences are statistically significant. For children, such results can be particularly problematic as they grow and seek additional opportunities for transplant.

Some Members of the Committee felt that education of pediatric surgeons is the more appropriate means for addressing this issue, rather than a modification to national allocation policy. A change to allocation policy will not prevent centers and surgeons from utilizing medical judgment, which could include wait time on the list, in considering the appropriateness of organ offers for their pediatric candidates. In time, with educational efforts, the system could evolve to provide better-matched kidneys to pediatrics if this is, in fact, the preferred outcome. These Members suggested that the current national allocation point system already provides an adequate number of points for pediatric candidates and should be given additional time to reach a point of equilibrium. The Committee as a whole did not agree with this position and, instead, agreed with the Joint Subcommittee that the proposal would improve opportunities for pediatric candidates to receive well-matched kidneys within a reasonable length of time, (1) improving outcomes and avoiding sensitization, which are vital issues for pediatric candidates who may need a lifetime of transplants, and (2) addressing the negative impacts renal failure and dialysis have on critical growth and development for pediatric candidates.

Application of the proposal to the allocation system was considered by the Committee. The Committee agreed that the additional points would only apply to standard criteria donor kidneys, not expanded criteria donors (ECDs). It is expected that, in general, ECD kidneys are not the most appropriate organs for transplantation into pediatric candidates. The Committee further determined that the additional points for DR matching for children should not apply in establishing priorities among zero antigen-mismatched patients, prior living organ donors, or patients listed with OPOs receiving kidney payback offers. Members stated there is no compelling justification to assign children the proposal's higher priority when they are being prioritized among patients all of whom have the same highest level of match, *i.e.*, a 0 ABDR mismatch. Prioritization among prior living organ donors was excluded due to small likelihood that children would be included in this group as well as considerations unique to this category of candidates. Prioritization among patients eligible for payback offers also was excluded as these are national level shares and the Committee felt that they should not be impacted. The vote of the Committee for the proposal overall was 21 For; 2 Against; 1 Abstention.

The Committee agreed that additional data will be helpful in its final assessment, along with public comment, of the proposal. At its next meeting, the Committee will further examine the effect of DR matching on patient allograft survival separated by deceased and living donors, as well as, the relationship for children between time on dialysis and transplant outcomes. In addition, the Committee will review data analyzing the pediatric candidates who exceed their time to transplant goals, including PRA levels and areas where they are listed, the pediatric candidates who receive kidneys with greater than a 0 DR mismatch, and the pediatric candidates who are sensitized. The analyses will focus on deceased kidney donor recipients. However, the Committee agreed that the proposal should not be held up for these analyses, as sufficient data exists to move the proposal forward. Therefore, the Committee agreed to submit the proposal for public comment by a vote of 24 For; 0 Against; 0 Abstentions.

During its January 22, 2004, meeting, the Pediatric Transplantation Committee reviewed the proposal approved by the Kidney and Pancreas Transplantation Committee and, by unanimous vote, joined the Kidney and Pancreas Committee in supporting it.

* **RESOLVED, that the following modifications to Policy 3.5.11.2 (Quality of Antigen Mismatch) shall be distributed for public comment:**

3.5.11 The Point System for Kidney Allocation. When information about a standard donor is entered into the UNOS Match System, all patients who have an ABO blood type that is compatible with that of the donor and who are listed as active on the UNOS Patient Waiting List will be assigned points and priority as follows:

3.5.11.1 Time of Waiting. [No Changes]

3.5.11.1.1 Time of Waiting Points. [No Changes]

3.5.11.2 Quality of Antigen Mismatch. Points will be assigned to a patient based on the number of mismatches between the patient's antigens and the donor's antigens at the DR locus. An antigen mismatch occurs when a donor antigen would be recognized by the recipient as being different from the recipient's own antigens. Quality of match points are assigned as follows:

- 2 points if there are no DR mismatches, as defined in the table below, and the patient is 18 years old or older at the time of listing. 6 points if there are no DR mismatches, as defined in the table below, and the patient is less than 18 years old at the time of listing; provided, however, that 2 points will be assigned if there are no DR mismatches regardless of age at time of listing in determining priorities among zero antigen mismatched candidates, prior living organ donors, and candidates listed with OPOs receiving kidney payback offers, or;
- 1 points if there is 1 DR mismatch as defined in the table below.

UNOS HLA Mismatch Definitions*

Mismatch Category	# HLA Locus Mismatches		
	A	B	DR
0 ABDR MM	0	0	0
0 DR MM	0	1	0
	0	2	0
	1	0	0
	1	1	0
	1	2	0
	2	0	0
	2	1	0
	2	2	0
1 DR MM	0	0	1
	0	1	1
	0	2	1
	1	0	1
	1	1	1
	1	2	1
	2	0	1
	2	1	1
	2	2	1

- Antigens that UNOS considers to be equivalent for matching purposes are currently shown in Appendix C of the UNOS Computer User's Manual.

There is a pair of antigens at each HLA locus. Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed "homozygous" at that locus (i.e., When only one of the antigens in the pair at an HLA locus is identified, the other antigen is presumed to be identical). For example, a donor typed as A2, A-(blank) would be considered A2, A2. In the following example, the recipient would receive 2points for having a zero, DR mismatch (no

mismatches at DR locus) because the recipient would not recognize any DR donor antigens as foreign.

Donor Phenotype	Recipient Phenotype
A23, A- (blank)	A1, A9
B7, B8	B7, B8
DR, DR4	DR1, DR4

3.5.11.3Panel Reactive Antibody. [No Changes]

3.5.11.4Medical Urgency. [No Changes]

3.5.11.5Pediatric Kidney Transplant Candidates. [No Changes]

3.5.11.5.1 Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals. [No Changes]

3.5.11.5.2 Pediatric Goals for Transplanting Kidney Transplant Candidates. [No Changes]

3.5.11.6Donation Status. [No Changes]

3.5.12 The Point System for Expanded Criteria Donor Kidney Allocation. [No Changes]

[No Further Changes]

III. Public Comment Responses:

The proposal was issued to a mailing list of approximately 8,162 individuals and organizations for a comment period of 45 days beginning March 15, 2004, and ending April 29, 2004. As of April 29, 2004, 84 responses have been submitted to UNOS regarding this policy proposal. Of these, 39 (46.43%) supported the proposal, 5 (5.95%) opposed the proposal, and 40 (47.62%) had no opinion. Of the 44 who responded with an opinion, 39 (88.64%) supported the proposal and 5 (11.36%) opposed the proposal. All 11 Regions supported the proposal, including 4 unanimously. Comments on the proposal received to date and the Committee's responses are set forth below.

Prior to the May 2004 Committee meeting, the OPTN/UNOS Joint Kidney and Pancreas, Pediatric Transplantation, Minority Affairs and Histocompatibility Subcommittee met to discuss the proposal and public comments received. The Joint Subcommittee reviewed the final data analysis from the SRTR, 5/7/04, evaluating the effect of DR matching on pediatric patient and graft survival and the effect in the pediatric population of prior mismatch level on subsequent sensitization. The study cohort for this analysis is comprised of pediatric kidney candidates (<18years) who received their first deceased donor kidney transplant with at least one HLA mismatch during the study period of 3/6/1995 and 6/30/2001, with follow-up for the study extended until 12/31/01. Albin Gritsch, MD and Bill Harmon, MD, SRTR noted that it is difficult to reach a conclusive interpretation of the data due to the small numbers comprising the cohort. The data, as they are, do not show the graft survival advantage in pediatric patients when comparing 1 mismatch and 2 mismatch to 0 mismatch at the A, B, and DR loci that is seen in the entire group (adult and pediatric candidates combined). Ruth McDonald, MD further noted that, though the numbers may be further reduced, it may be of interest to separate out younger pediatric candidates (0-11years) from the adolescent group (12-17years) given the added complications of compliance, etc noted with adolescent recipients. Dr. Harmon noted that, for all kidney recipients (adult and pediatric) combined, there is an approximate 1.25 Relative Risk benefit with DR matching. Dr. Harmon further noted that the question this data analysis intended to address is whether there is a difference in advantage or disadvantage with DR matching, a biological histocompatibility difference, in the pediatric population. The Joint Subcommittee agreed that the small numbers in this study cohort do not allow for conclusive answers regarding this issue.

The Joint Subcommittee agreed that a continuing issue in pediatric kidney transplantation is balancing waiting for a well-matched kidney with the benefit of meeting time to transplant goals in order to prevent growth and development delays. Dr. Gritsch reviewed the SRTR analysis evaluating the effect on the pediatric recipient/candidate population of prior (1st transplant) mismatch level on subsequent sensitization levels. Susan Saidman, MD noted that, the PRA data reviewed would not include class II antibody information since UNOS has started only recently to collect this information on the data forms. The Joint Subcommittee agreed that, with only the historical PRA data available for this analysis, DR matching at first transplant would be expected to show no impact upon subsequent sensitization. Results from this analysis are, therefore, difficult to interpret. Dr. Gritsch noted that in Table 1.2 of the final SRTR data analysis, the +10.6 increase in change in PRA for the category Time Since Failure of 1st Transplant (per year) suggests that the longer pediatric candidates wait from the time of failure of first transplant to the time of listing for 2nd transplant the more the rate of sensitization will increase. Karen Nelson, PhD suggested that during the time interval between transplants, candidates stop immunosuppression therapy/medications. Dr. Nelson further suggested that patients may be responding to tissue remnants (post-nephrectomy) from the first transplant during this time off of immunosuppressants. It was noted by the Joint Subcommittee that it is difficult to determine from this data whether pediatric candidates become increasingly sensitized the longer they wait for transplant, or if they wait longer for transplant because they are sensitized.

Dr. Gritsch reviewed the data on race/ethnicity, blood type, and sensitization in Tables 1.2 and 1.3 of the SRTR final analysis, 5/7/04. The Joint Subcommittee noted that the data suggest increased sensitization among black pediatric patients and pediatric patients in blood group B. Dr. Harmon noted that the increased risk may be attributed to longer waiting times on the transplant list for patients with blood type B; however, this analysis did not include data on time waiting on the list. Nathan Goodrich, SRTR noted that the small number of patients in the study cohort did not allow for clear interpretation of the analysis results. The Subcommittee noted that race/ethnicity was among the factors adjusted for in the SRTR data analysis. It was further noted by the SRTR that within the adult kidney transplant candidate population there was no apparent difference in change in PRA between blood types. Given that the number of pediatric patients in the cohort with blood type B is small (n=40), Hui-Hsing Wong, MD suggested reviewing the race/ethnicity of the patients in this group. Dr. Wong noted that if all the patients with blood type B in this study were of one race or ethnicity group, it would be difficult to adjust for this factor in the analysis. Dr. Harmon noted that children and adolescents are more than likely not different from adults in histocompatibility of blood type. Dr. Harmon suggested that the results from the analysis may be due to the lack of statistical significance with the small numbers of pediatric patients in the study cohort instead of a statistical trend specific to race or blood type.

The Joint Subcommittee discussed whether or not the data reviewed offered enough statistical evidence to move forward with the Joint Subcommittee developed public comment proposal to assign four additional points to pediatric kidney candidates based on 0 DR matching. Dr. Harmon noted that the intent of the proposal was to further balance the issue of matching and wait time for pediatric kidney candidates. Currently, pediatric candidates receive less well-matched kidneys. It is suggested that this is attributable at least in large part to assigned allocation priority at time of listing and then once time-to-transplant goals are surpassed. The proposal now out for public comment would allow pediatric kidney candidates increased opportunity to receive better-matched kidney offers and maintain time goal priority. Dr. Harmon noted that, given the small numbers of pediatric kidney candidates, there is currently no significant data to support the proposal based on biological advantage, however, there is also no data to suggest that pediatric candidates differ from adults in receiving benefit from DR matching. The Joint Subcommittee further noted that there may be limited studies on the benefit of DR matching in pediatric kidney candidates given the substantial number of parent living kidney donors. It was noted by the Joint Subcommittee that, in the case of parent living kidney donors, the laboratory protocol for transplant is different than for a deceased kidney donor, thus, there may not be the same data available for living kidney donor transplants. Moreover, previous data has suggested that recipients of living donor kidneys do better than recipients of deceased donor kidneys regardless of matching; therefore, this data may not be applicable to the analysis of the impact of DR matching in pediatric deceased donor kidney recipients.

Dr. Leichtman discussed whether pediatric kidney candidates would be better served by receiving additional priority for being < 18years and thus improving their access to a greater fraction of all kidney offers or would young children and adolescent candidates be better served by receiving assigned priority points for age and assigned priority points for matching. Dr. Leichtman suggested that as long as currently assigned pediatric priority is maintained, it would only be helpful for pediatric kidney candidates to be assigned additional priority for matching.

The Joint Subcommittee agreed, given the discussion above and the 90% approval rate of public comment responses, to support the proposal to assign additional priority points to pediatric candidates for 0 DR matching and present the proposal to the Board of Directors in June 2004. The support of this proposal was unanimous within the Joint Subcommittee with the exception of one individual who was opposed to this proposal moving forward and noted that there were not sufficient data to support the proposal in its presentation to the Board of Directors. Dr. Frank Delmonico further noted that supporting a proposal without sufficient evidence may set a difficult precedent for future policy development. Moreover, using HLA DR mismatch as a factor in allocation for children, could suggest to physicians that they should wait for DR matched organ offers before accepting organs for their pediatric patients. In the interim, they may miss opportunities for other younger, for example, donor kidney offers that actually are preferable to the DR matched organ offer. Dr. Gritsch noted that currently, given the small numbers of pediatric candidates, data on the effect of DR matching in pediatric kidney recipient survival and sensitization is not statistically significant, however, given the evidence and logic of DR matching benefit in adults the proposal to assign priority for pediatric matching should go forward.

There also was discussion regarding the benefit of assigning preference for children for HLA DR matching in light of the data showing no statistical significance upon graft survival, versus assigning a more absolute priority that would at least help address concerns regarding children waiting beyond their time goals to transplant. Again, there is trade-off between the two goals of improved matching, which may have clinical significance despite lack of statistical significance, and shorter waiting times for children.

Dr. Takemoto noted that Table 2 in the OPTN data analysis, *Pediatric Patients Who Have Surpassed Their Time to Transplant Goals*, seems to illustrate the issue of the small percentage of pediatric kidney candidates receiving 0 DR mismatch deceased donor kidneys. Only 7.4% (n=22) of pediatric patients who were transplanted between 1/1/02 and 12/31/03 (Total n=296), and had surpassed their time goals at time of transplant, received a 0 DR mismatch donor kidney.

The Joint Subcommittee also discussed the possibility of allocating adolescent donor kidneys preferentially to pediatric kidney candidates. Table 2.2 in the SRTR Final Data Analysis, 5/7/04, suggests that pediatric deceased donor kidney recipients have the best survival rate when transplanted with an adolescent donor kidney although the improvement is not statistically significant. Dr. McDonald suggested that pediatric candidates be prioritized for 0 DR matching and adolescent donors. Dr. Wong requested, for the next Joint Subcommittee meeting, the review of data on the number of times pediatric kidney candidates appeared on the match run but did not receive a 0 mismatch offer because an adult kidney candidate had greater priority for and accepted the offer. Dr. Delmonico also requested that an analysis of the number of times pediatric candidates bypassed an adult 0 mismatch candidate on a match run list be added to the above requested OPTN descriptive data analysis; the analysis will look at the trends in this data from the past five years.

Dr. McDonald suggested moving forward with the current proposal assigning four additional points to pediatric kidney candidates for 0 DR matching and, in addition, assign priority to pediatric kidney candidates for adolescent and young adult donor kidney offers. Dr. McDonald recommended that the proposal for additional assignment of priority to pediatric candidates for pediatric donor kidney be put forth separately in the August 2004 public comment cycle and that the current proposal regarding DR matching move forward to be presented to the Board of Directors at the June 2004 meeting. The SRTR Final Analysis of 5/7/04 included a graph following Table 3.3 that further illustrates that 11-17year old deceased donor kidneys offer pediatric candidates the best graft survival rate. Dr. Wong suggested breaking out the age group of 18-34 years to see if younger adult donor kidneys offer the same survival benefit to pediatric candidates as adolescent donor kidneys. Dr. Leichtman requested the OPTN to prepare and distribute to the Joint Subcommittee a histogram of deciles of donors by age for further discussion of definition of 'ideal' donor for pediatric kidney candidates. Dr. Harmon noted that the risk of donors over 35years compared with under 35years for pediatric recipients is approximately 1.24 RR benefit for the pediatric candidate to receive an 18-34year old deceased donor kidney as compared with a 35-49 year old deceased donor kidney. Dr. Harmon noted that this is the same benefit conferred, based on adult and pediatric (combined) recipient data, from a 0 DR mismatch compared with a 2 DR mismatch. Dr. McDonald and Dr. Leichtman recommended increasing priority for 0 DR mismatch offers to pediatric kidney candidates beginning at the local level.

Maureen McBride, PhD, OPTN reviewed the data analysis, *Pediatric Patients Who Have Surpassed Their Time to Transplant Goal*, with the Joint Subcommittee. Table 1 of the analysis shows the characteristics of pediatric

candidates who have surpassed their time to transplant goals and were still waiting for a kidney transplant on April 30, 2004. Dr. McBride outlined several of the results of the analysis including:

- With the exceptions of Regions 6 and 8, there are candidates in each age group who have surpassed their goals currently waiting for transplant. The majority of the patients are in Region 5 (CA, NV, AZ, UT), the region with the largest waiting list.
- The majority of the patients are blood type O. Specifically, 55% of the 0-5 year old candidates, 59% of the candidates aged 6-10, and 55% of the 11-17 year old candidates are blood type O.
- Over two-thirds of the youngest pediatric candidates are not sensitized (Peak and Current PRA 0-19%). However, among the adolescent candidates, 28% have a Peak PRA \geq 80%, and 19% have a current PRA \geq 80%.
- Twenty percent of the candidates aged 0-5 have had a previous transplant, compared with 32% of the candidates aged 6-10, and 46% of the 11-17 year old candidates who have surpassed their goals.
- Fewer than 40% of the candidates who surpassed their goals are white. Eighteen percent of the 0-5 year old candidates are Black and 25% are Hispanic. Among the 6-10 year old candidates, 26% are Black and 30% are Hispanic. Finally, among the adolescents, 35% are Black and 20% are Hispanic.
- Overall, 30 patients currently waiting have not received any offers. Most have received 1-10 offers. Over 20% of the adolescent candidates have received more than 40 offers.

The Joint Subcommittee noted that the Pediatric Committee has previously reviewed reasons/turndown codes for deceased donor kidney offers to pediatric candidates. Approximately one-third of the offers were turned down for donor quality, other turndown reasons included issues of size/weight. The Joint Subcommittee requested a histogram of turndown reasons, a descriptive analysis of number of offers and reasons for declining offers by OPO/Transplant Center/Region, and a comparative analysis of race/ethnicity of pediatric kidney candidates who have surpassed their time goals and race/ethnicity of the total waitlist. Dr. Leichtman recommended reconvening the Joint Subcommittee after the May Committee meetings but prior to the June 2004 Board of Directors meeting in order to review the data analyses requested.

During the May 19-20, 2004, Committee meeting, Albin Gritsch, M.D., summarized the efforts and findings of the Joint Subcommittee for the Committee. Since the Joint Subcommittee met, some Members had expressed concerns with the proposal going forward to the Board at the June 2004 meeting. First, the data could be viewed as tenuous. Second, the likelihood of this proposal being followed by a subsequent proposal with respect to pediatric priority at the fall Board meeting could diminish the real concern the Committee has with appropriately allocating kidneys to pediatric candidates. Perhaps the more beneficial option is to devise a more comprehensive approach to resolving the pediatric transplant access issues, gathering supportive data, and presenting the approach at one Board meeting.

Before a comprehensive approach is developed, some Members stated that the OPTN/UNOS Pediatric Transplantation Committee should determine and specify the goal(s) they want to achieve with respect to pediatric transplantation. One suggested goal was allocation of ideal donor kidneys (aged 18-34) to pediatric candidates.

One possible approach for consideration is to limit pediatric candidate access to local donors aged less than 35 years before reaching their time to transplant goals. The pediatric candidates would still retain six points for a zero DR mismatch to help ensure better-matched kidneys are offered to pediatric candidates. If the pediatric candidate surpasses their time to transplant goal, the donor pool could be expanded from local to Regional to provide additional organ offer opportunities.

After further discussion, the Committee agreed to withhold this proposal from the Board of Directors with the intent that a more comprehensive approach to pediatric allocation priority will be developed in the near future. The Committee vote was unanimous. The Committee also agreed for the Joint Subcommittee to continue this discussion, develop the goals for pediatric allocation and strategy for achieving those goals.

I. Individual Comments:

Comment 1:
vote: Oppose

UU-9

On what basis is DR selected as the only relevant locus. The policy should include a 0 mismatch at any locus.

Committee Response:

The Committee appreciates the response. After further discussion, the Committee agreed to withhold this proposal from the Board of Directors with the intent that a more comprehensive approach to pediatric allocation priority will be developed in the near future.

Comment 2:

vote: Support

Approve with comment: The role of HLA matching in the adolescent age group is difficult to assess because of non-compliance issues. Decisions about how important HLA matching is should be based on studies involving older patients but applied to pediatric patient populations with extra measure, as appropriate for their increased benefits a per this proposal.

Committee Response:

The Committee appreciates the response. After further discussion, the Committee agreed to withhold this proposal from the Board of Directors with the intent that a more comprehensive approach to pediatric allocation priority will be developed in the near future.

Comment 3:

vote: Support

ASHI supports this proposal to increase from 2 to 6 the total allocation points awarded to pediatric candidates who have a zero DR mismatch with a standard criteria deceased kidney donor. If over time this policy proves to be beneficial to pediatric patients, we would suggest considering extending the policy to award additional points for zero B/DR mismatches.

Committee Response:

The Committee appreciates the response. After further discussion, the Committee agreed to withhold this proposal from the Board of Directors with the intent that a more comprehensive approach to pediatric allocation priority will be developed in the near future.

Comment 4:

vote: Support

It does not seem right that those age 18-24 are given the same priority as those age >65 since the potential benefit for these younger patients is not much different from pediatric patients.

Committee Response:

The Committee appreciates the response. After further discussion, the Committee agreed to withhold this proposal from the Board of Directors with the intent that a more comprehensive approach to pediatric allocation priority will be developed in the near future.

Comment 5:

vote: Support

The ASPN support the policy change that would increase from 2 to 6 the total allocation points awarded to pediatric candidates who have a zero DR mismatch with a standard criteria deceased kidney donor. We agree with the goal of increasing the number of transplants of well-matched kidneys into pediatric candidates while maintaining relatively short pediatric candidate waiting time to trasplant. Better matching would hopefully extend the graft half-life and minimize the long-term sensitization in oediatric candidates who most likely will require subsequent transplants during their lifetimes. We applaud the UNOS Committees' efforts to enhance transplant opportunities for pediatric candidates. The ASPN appreciates the UNOS Committees' efforts to improve the quality of health care outcomes and delivery in the ESRD patient population.

Committee Response:

The Committee appreciates the response. After further discussion, the Committee agreed to withhold this proposal from the Board of Directors with the intent that a more comprehensive approach to pediatric allocation priority will be developed in the near future.

Comment 6:

vote: Support

The ASPN supports the policy change that would increase from 2 to 6 the total allocation points awarded to pediatric candidates who have a zero DR mismatch with a standard criteria deceased kidney donor. We agree with the goal of increasing the number of transplants of well-matched kidneys into pediatric candidates while maintaining relatively short pediatric candidate waiting time to transplant. Better matching would hopefully extend the graft half-life and minimize the long-term sensitization in pediatric candidates who most likely will require subsequent transplants during their lifetimes. We applaud the UNOS Committees' efforts to enhance transplant opportunities for pediatric candidates.

Committee Response:

The Committee appreciates the response. After further discussion, the Committee agreed to withhold this proposal from the Board of Directors with the intent that a more comprehensive approach to pediatric allocation priority will be developed in the near future.

II. Comments from Other Committees:

Ethics Committee - The Committee found the proposal ethically acceptable based on current and historical practice.

Histocompatibility Committee - Support (14/0/0)

Patient Affairs Committee - The Committee supports the proposed policy by a vote of 15-0-1

III. Regional Comments:

REGIONAL COMMENT SUMMARY

PROPOSAL 6: Proposed Modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch) (Kidney and Pancreas Transplantation Committee)

Sponsoring Committee: Kidney and Pancreas Transplantation

Description: The proposed modifications, originally developed by the OPTN/UNOS Joint Kidney and Pancreas, Pediatric Transplantation, Minority Affairs and Histocompatibility Subcommittee, would increase from 2 to 6 the total allocation points awarded to pediatric candidates who have a zero DR mismatch with a standard criteria deceased kidney donor. The additional points would not apply in determining priorities among zero antigen mismatched patients, prior living organ donors, or patients listed with OPOs receiving kidney payback offers. The modifications also would not apply to expanded criteria donor (ECD) kidney allocation. The intent is to increase the number of transplants of well-matched kidneys into pediatric candidates while maintaining relatively short pediatric candidate waiting time to transplant, and thus, minimize long-term sensitization in pediatric candidates who most likely will require subsequent transplants during their lifetimes. The proposal is supported by both the OPTN/UNOS Kidney and Pancreas Transplantation and Pediatric Transplantation Committees.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	10 yes, 1 no, 3 no opinion			
2	5/07/04	31 yes, 0 no, 1 no opinion			
3	3/26/04	17 yes, 0 no, 0 no opinion			
4	4/2/04	29 yes, 0 no, 1 no opinion			
5	4/30/04	29 yes, 5 no, 2 no opinion			
6	4/2/04	53 yes, 0 no, 0 no opinion			
7	4/23/04	17 yes, 0 no, 0 no opinion			
8	4/2/04	22 yes, 1 no, 2 no opinion			
9	4/21/04	17 yes, 0 no, 1 no opinion			
10	4/30/04	19 yes, 0 no, 0 no opinion			
11	3/26/04	16 yes, 1 no, 3 no opinion			

COMMENTS:

Example List of Transmittable Diseases and Medical Conditions to Report

From Policy 2.2.7.1 for tests to be performed on all potential donors:

- Hepatitis screen; including HBsAg, HBcAb, and Anti-HCV;
- VDRL or RPR;
- FDA licensed Anti-HIV I/II;
- Anti-HTLV I/II;
- Anti-CMV;
- Blood and urine cultures (that pose potential risk for recipients)

From Donor Referral Data –Eligibility Requirements

- Tuberculosis
 - HIV infection with specified conditions
 - Creutzfeldt-Jacob Disease
 - Herpetic septicemia
 - Rabies
 - Reactive HbsAg
 - Any retro virus infection
 - Active malignant neoplasms (except primary CNS tumors and skin cancers)
 - Hodgkins' disease *† Non-Hodgkin's lymphoma*
 - Multiple myeloma
 - Leukemia
 - Miscellaneous carcinomas
 - Aplastic anemia and granulocytosis
 - Fungal and viral meningitis
 - Viral encephalitis
 - Gangrene of the bowel
 - Positive serological or viral culture findings for HIV
- (basal cell, squamous cell)*
Non-permissible skin cancers
 ① Melanoma
 ② Merkel Cell
 ③ Cutaneous Kaposi's

Other

- Smallpox
- EBV
- Chagas
- SARS
- WNV

ADDITIONAL COMMENTS PROVIDED BY
 MYRON KAUFFMAN, MD
 UNOS MEDICAL DIRECTOR

Example List of Transmittable Diseases and Medical Conditions to Report

From Policy 2.2.7.1 for tests to be performed on all potential donors:

- Hepatitis screen; including HBsAg, HBcAb₁ and Anti-HCV;
- VDRL or RPR;
- FDA licensed Anti-HIV I/II;
- Anti-HTLV I/II;
- Anti-CMV;
- Blood and urine cultures (that pose potential risk for recipients)

From Donor Referral Data –Eligibility Requirements

- Tuberculosis
- HIV infection with specified conditions
- Creutzfeldt-Jacob Disease
- Herpetic septicemia
- Rabies
- Reactive HbsAg
- Any retro virus infection
- Active malignant neoplasms (except primary CNS tumors and skin cancers,
- Hodgkins' disease
- Multiple myeloma
- Leukemia
- Miscellaneous carcinomas
- Aplastic anemia and granulocytosis
- Fungal and viral meningitis
- Viral encephalitis
- Gangrene of the bowel
- Positive serological or viral culture findings for HIV

Other

- Smallpox
- EBV
- Chagas
- SARS
- WNV

Response from Jay Fishman, MD, Massachusetts General Hospital, Infectious Disease Unit, to the Example list of Transmissible Diseases and Medical Conditions to Report.

I have trouble with the disorder of the "exclusion list". It could be simplified based on syndrome. Similarly, the cancer list should include the list of subtypes: active malignant neoplasms and miscellaneous carcinomas (except primary CNS tumors and skin cancers), but including Hodgkins' disease, multiple myeloma, leukemia, and aplastic anemia and granulocytosis. My list is below.

Common Infectious Exclusion Criteria for Organ Donors*

Active Infectious Disease

Unknown infection of central nervous system (encephalitis, meningitis)

Herpes simplex encephalitis or other encephalitis

H/o JC virus infection

West Nile virus infection

Cryptococcal infection of any site

Rabies

Creutzfeldt-Jacob disease

Other fungal or viral encephalitis

Untreated bacterial meningitis (need proof of cure)

Infection with HIV (serologic or molecular)

Active viremia: herpes, acute EBV (mononucleosis)

Serologic (with molecular confirmation) evidence of HTLV-I/II

Active hepatitis A, B

Infection by: Trypanosoma cruzi, Leishmania, Strongyloides, Toxoplasmosis

Active Tuberculosis

SARS

Untreated pneumonia

Untreated bacterial or fungal sepsis (e.g. candidemia)

Untreated syphilis

Multi-system organ failure due to overwhelming sepsis, Gangrenous Bowel

*Must be considered in the context of the individual donor and recipient

ECD Mortality: OPO waiting Time by Race and Age

DA Distant, VB Ashby, FK Port, AB Leichtman,
RA Wolfe, and RM Merion

SUNY HSC, Brooklyn, NY,
University of Michigan, Ann Arbor, MI, and
SRTR / URREA, Ann Arbor, MI,

SRTR

Background

- Transplantation is the preferred therapy for kidney failure compared to dialysis, offering improved quality of life and reduced death rates (Wolfe, 1999).
- However, acceptance of a particular organ offer depends upon the particular combination of donor and candidate characteristics (Ojo, 2001; Merion, 2002).

SRTR

Background

- Distinctions in Kidney Donor quality have been recently codified into Expanded Criteria Donors (ECD) having a relative risk of graft failure of 1.7 or greater vs. ideal Kidney Donors.
- ECD kidneys are now allocated to a separate list of recipients willing to accept ECD kidneys as well as Standard Criteria Donor (SCD) kidneys.

SRTR

Background

- Waitlisted patients are thus faced with a choice of an ECD kidney now vs. additional waiting time (WT) and an SCD kidney later.

SRTR

Hypothesis

- On average, ECD transplant is beneficial if the waiting time (WT) to a SCD transplant is long. (Benefit as measured by mortality risk.)

SRTR

Objective: Evaluation of ECD Option

- Comparison of
 - ECD: Mortality following an ECD transplant
 - WT+SCD: Mortality while waiting for and after an SCD transplant
- This study compares the mortality for these two options.

SRTR

Data Methods

- National data from OPTN/SRTR
- Patients placed on the kidney waitlist, 1995-2002
- Sample size

	N
Waitlisted	114,602
Deceased Donor Transplant	38,470
Standard Criteria Donor	32,476
Expanded Criteria Donor	5,994
- Censor at living donor transplant (n=14,635) or end of study (6/30/2003)

SRTR

Statistical Methods

- Time to death was modeled using time-dependent Cox regression models censored at living donor transplant or end of study.
- Adjusted for candidate age, race, gender, year waitlisted, ethnicity, ESRD cause, peak PRA, organ procurement organization (OPO) of listing, blood type, comorbidities present at waitlist, dialysis modality, and time from first dialysis to waitlist.
- Waiting time to transplant for the OPO of registration (<1350 days; >1350 days) was assigned as a patient-level covariate.

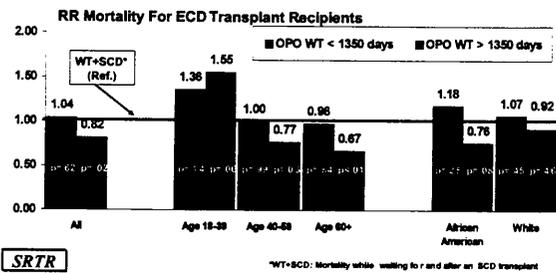
SRTR

Number of OPOs and Registrants by Waiting Time

OPO Waiting Time	Number of OPOs	Number of Registrants
< 1350 days	39 (66%)	52,929 (46%)
≥ 1350 days	20 (34%)	61,673 (54%)

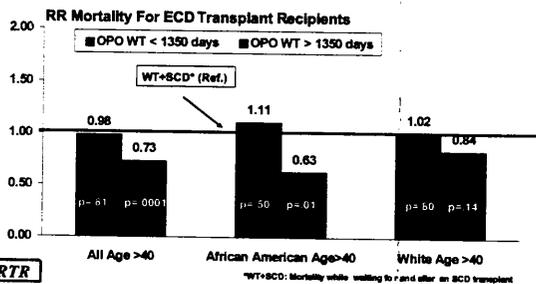
SRTR

Long Term Relative Mortality Risk for ECD Transplant Recipients vs. WT+SCD*, 1995-2002



SRTR

Long Term Relative Mortality Risk for ECD Transplant Recipients vs. WT+SCD* Age >40, 1995-2002



SRTR

Summary

- Among those listed at OPOs with long waiting times, mortality risk reduction by ECD was significant and of greater magnitude (RR=0.82, p<0.01).
- Among those listed at short waiting time OPOs, there was not a significantly lower mortality risk for any group (RR>1.0).
- Candidates age 18-39 had higher mortality risk with an ECD kidney at both short and long waiting time OPOs (RR=1.36 and 1.55, respectively), although these elevated risks were not statistically significant.

SRTR

Conclusions

- These analyses suggest that ECD kidneys should be offered to selected candidates in OPOs with long waiting times.
- Candidates listed at short waiting time OPOs, where rates of SCD kidney transplantation are higher, should be counseled that no survival benefit from ECD transplant can be demonstrated at this time.
- This comparison depends on current terms of time to SCD transplant.

SRTR

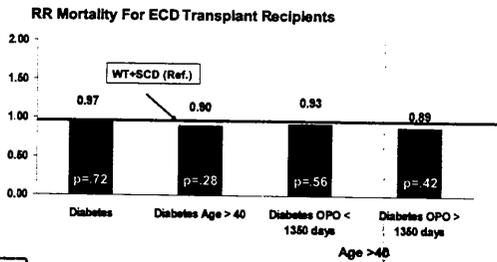
ECD Mortality: OPO Waiting Time by Race and Age

DA Distant, VB Ashby, FK Port, AB Leichtman, RA Wolfe, and RM Merion

SUNY HSC, Brooklyn, NY,
University of Michigan, Ann Arbor, MI, and
SRTR / URREA, Ann Arbor, MI,

SRTR

Long Term Relative Mortality Risk for ECD Transplant Recipients vs. WT+SCD* for Patients with Diabetes, 1995-2002



SRTR

*WT+SCD: Mortality while waiting for and after an SCD transplant

WW-3



Since 1984 — sharing organs, sharing data, sharing life.

700 North 4th Street, Richmond, VA 23219
P.O. Box 2481, Richmond, VA 23218
tel: 804-782-4800
fax: 804-782-4187
www.unos.org

Walter Graham, Executive Director

MEMORANDUM

To: Alan B. Leichtman, MD
Chair, Kidney/Pancreas Transplantation Committee

From: John M. Holman, Jr., MD, PhD
Chair, OPO Committee

Subject: Organ Transport Containers

Date: January 12, 2004

The ABO Joint Subcommittee requested that the OPO Committee review Policies 5.5 (Standard Organ Packaging Specifications) and Policy 5.5.3.1 regarding the rigid container for housing the organ during transport. The ABO Joint Subcommittee opined that the reuse of disposable organ packages should be prohibited, and also found that the standardization of packaging organs would help to promote greater safety.

In response to the request by the ABO Joint Subcommittee and in order to assist in its deliberations, the OPO Committee conducted a survey of the organ specific and pediatric committees regarding their thoughts on whether the re-use of organ transport containers should be prohibited; whether the use of coolers should be eliminated, and if a protective rigid container should be used for all organs (Attachment A). In addition, the Committee reviewed documentation by the Policy Compliance Department regarding specific packaging and shipping incidences that occurred in the past year (Attachment B).

The Committee drafted the following recommendations, but asks that the Kidney/Pancreas Transplantation Committee weigh in on these recommendations, which will be taken into consideration when preparing a final proposal to the Board. The Committee will also take into consideration the recommendations to Policy 5.2 (Standard Labeling Specifications) from the previous meeting of the Kidney/Pancreas Transplantation Committee.

Proposed Recommendations

- The re-use of disposable transport boxes should be prohibited due to the integrity of the box being compromised during the removal of labels.
- Coolers should be allowed for non-commercial transporting when the organ recovery team is taking the organ with them from the donor hospital to the transplant center. The re-use of coolers should be allowed; all labels from the previous donor organ must be removed before reusing the cooler.
- If the organ is to be commercially shipped, such as with a courier service, commercial airline or charter service, the organ should be packaged in a disposable transport box, as outlined in Policy 5.5 (Standard Organ Package Specifications), to comply with OSHA and federal transportation regulations that would require a sealed, leak-proof container.

XX-1

President
Russell H. Wiesner, M.D.

Vice President
Robert A. Metzger, M.D.

Vice President
Patient & Donor Affairs
Paul B. Oldam, B.S.S.

Secretary
Marc I Lorber, M.D.

Treasurer
Dean F. Kappel, M.S.W.

Immediate Past President
Clyde F. Barker, M.D.

Regional Councilors
George S. Lipkowitz, M.D. (1)
Andrew S. Klein, M.D. (2)
Shirley D. Schlessinger, M.D., FACP (5)
Kristene K. Gugliuzza, M.D. (4)
John P. McVicar, M.D. (5)
Douglas L. Wood, M.D. (6)

Christopher P. Johnson, M.D. (7)
Cass Franklin, M.D., FACS (8)
Frank S. Symak, M.D. (9)
Mark D. Pescovitz, M.D. (10)
P. R. Rajagopalan, M.D. (11)

At Large Board Members
Margo L. Akerman, M.S.
The Hon. Antonio Benedi
Ronald W. Busuttill, M.D., F.n.D.
Anthony M. D'Alessandro, M.D.
John Davis
Richard J. DeStefano, M.D.

Melissa J. Domzger, I.D.
Barry S. Friedman, RN, BSN, MBA CPTC
Rose Marie Gray-Finnell, ARRT (R)
Jackie L. Johnson, MSW, LICSW
Lloyd H. Jordan, Jr., CPA
Bertram L. Kasiske, M.D.
Sharon C. Kieley, M.D., MPM
Helen W. Leslie, RN, CPTC
Donna L. Luebke, RN, MSN, CNP
Stephen M. Oelrich
Fisher Padilla, M.S.W.
W. Steves King, M.D.
Sandra Rosen-Bronson, Ph.D.

Margaret J. Schaeffer, RN, CPTC
Nancy L. Senst, RN, BSN, CPTC
Charles F. Shield, M.D.
Judy J. Tisdale, Ph.D.
Adriana Zeevi, Ph.D.

Past Presidents
C. Melville Williams, M.D., 1984-85
Oscar Salvaterra, Jr., M.D., 1985-86
John C. McDonald, M.D., 1986-88
H. Keith Johnson, M.D., 1988-89
Robert I. Cotry, M.D., 1989-90
James S. Wolf, M.D., 1990-91

Robert Mendez, M.D., 1991-92
R. Randal Bollinger, M.D., Ph.D., 1992-95
Douglas J. Norman, M.D., 1995-94
Margaret D. Allen, M.D., 1994-95
Bruce A. Lucas, M.D., 1995-96
James F. Burdick, M.D., 1996-97
Lawrence G. Hunsicker, M.D., 1997-98
William W. Pfaff, M.D., 1998-99
William D. Payne, M.D., 1999-2000
Patricia A. Adams, M.D., 2000-2001
Jeremiah G. Turcotte, M.D., 2001-2002

Executive Director Emeriti

480

Should the <u>re-use</u> of disposable transport outer containers (corrugated boxes, coolers) be prohibited?	Should the standard packaging requirements of the outer container for transporting the organs be a corrugated box (eliminate coolers)?	Should a protective, inner rigid container be required to house an organ? If not, for which organs?	Comments
<p>Liver Transplantation Committee</p> <p>YES. The shipping containers are a relatively small cost considering the value of an organ and the costs of procuring one. Used boxes may not have the strength due to moisture and/or handling. They may also have markings, labels, addresses, and other information that is retained from previous use and could cause serious errors to occur. There may be an increase in contaminants/infectious agents being introduced into the operating theatre. (even a first-use container should not be brought into the inner core area of an O.R.)</p>	<p>In general, I would say yes if the organ is to be shipped. If the organ is going from the donor hospital back to the OPO or the organ is going with the recovery team back to their transplant center, a cooler should be acceptable as long as it is appropriately labeled. Any time an organ is handled by a courier, it should be in a corrugated box and packaged in accordance with UNOS standards.</p> <p>The NOTE: regarding the policy language approved by the Board and currently out for public comment; It is not appropriate for this OPO for extra renal organs when the standard practice is for visiting extra renal teams to package their own organs. They are also in control of that organ once it leaves the O.R. The Host OPO staff would have to intervene with the visiting recovery team in order to ensure that they labeled, packaged and transported the organ appropriately. This would create a burden for the OPO staff who are attending to the kidneys and other</p>	<p>My response: <u>YES (and NO)</u>. Yes if the organ will fit. It makes good sense for protection and sterile transfer in the O.R. As far as I am aware, there is no rigid inner container specifically designed for housing organs. Nalgene jars, Tupperware, and Rubbermaid containers seem to be what is in use. If the question is whether or not there should be a "standardized" container or method for each organ, I would say yes. Nalgene jar for kidneys and pancreas. Some suitable size container for hearts (Tupperware or Rubbermaid). Triple abdominal bags seem to work well for lungs and livers due to size issues. My NO response applies to these organs due to size. If they are placed in a rigid container, the outer box will have to be so large that it will be a challenge to transport on most charter aircraft we are using. (Tissue bone boxes are a good example. They are very difficult to fit into small jets and turbo props when the tissue team has to fly) It would take a box at least that size to house a rigid lung or liver container. I definitely support the notion that</p>	

Should the <u>re-use</u> of disposable transport outer containers (corrugated boxes, coolers) be prohibited?	Should the standard packaging requirements of the outer container for transporting the organs be a corrugated box (eliminate coolers)?	Should a protective, inner rigid container be required to house an organ? If not, for which organs?	Comments
<p>Liver Transplantation Committee</p> <p><u>YES.</u> The shipping containers are a relatively small cost considering the value of an organ and the costs of procuring one. Used boxes may not have the strength due to moisture and/or handling. They may also have markings, labels, addresses, and other information that is retained from previous use and could cause serious errors to occur. There may be an increase in contaminants/infectious agents being introduced into the operating theatre. (even a first-use container should not be brought into the inner core area of an O.R.)</p>	<p>In general, I would say yes if the organ is to be shipped. If the organ is going from the donor hospital back to the OPO or the organ is going with the recovery team back to their transplant center, a cooler should be acceptable as long as it is appropriately labeled. Any time an organ is handled by a courier, it should be in a corrugated box and packaged in accordance with UNOS standards.</p> <p>The NOTE: regarding the policy language approved by the Board and currently out for public comment; It is not appropriate for this responsibility to be on the HOST OPO for extra renal organs when the standard practice is for visiting extra renal teams to package their own organs. They are also in control of that organ once it leaves the O.R. The Host OPO staff would have to intervene with the visiting recovery team in order to ensure that they labeled, packaged and transported the organ appropriately. This would create a burden for the OPO staff who are attending to the kidneys and other</p>	<p>My response: <u>YES (and NO).</u> Yes if the organ will fit. It makes good sense for protection and sterile transfer in the O.R. As far as I am aware, there is no rigid inner container specifically designed for housing organs. Nalgene jars, Tupperware, and Rubbermaid containers seem to be what is in use. If the question is whether or not there should be a "standardized" container or method for each organ, I would say yes. Nalgene jar for kidneys and pancreas. Some suitable size container for hearts (Tupperware or Rubbermaid). Triple abdominal bags seem to work well for lungs and livers due to size issues. My NO response applies to these organs due to size. If they are placed in a rigid container, the outer box will have to be so large that it will be a challenge to transport on most charter aircraft we are using. (Tissue bone boxes are a good example. They are very difficult to fit into small jets and turbo props when the tissue team has to fly) It would take a box at least that size to house a rigid lung or liver container. I definitely support the notion that</p>	

	<p>issues. It would also be unlikely that a lung or heart team would want to lose precious minutes having their organs packaged or checked by the Host OPO staff. If this becomes UNOS Policy, OPO's will be asking the teams to sign "hold harmless" agreements with the teams as they leave the O.R. since we cannot guarantee that the organ will subsequently be handled in a manner that does not compromise it.</p> <p>Yes</p>	<p>whatever we use, it should be standardized nationwide in order to improve practice and minimize errors.</p>	
<p>Yes</p>	<p>kidney, pancreas</p>		
<p>Yes, if reusing has really meant the loss of organs for transplantation in the past. As unbelievable as this is, the system must be idiot-proofed.</p> <p>No</p>	<p>No. I see no evidence presented that the type of container (provided it fulfills requirements) affects organ quality.</p> <p>No</p>	<p>No. I know of no data that says this is advantageous for either liver or bowel grafts. I cannot comment on the need in other organs.</p>	
<p>No</p>	<p>No</p>	<p>All organs should have a rigid container.</p>	
<p>Due to the fact that reuse of the outer containers could potentially cause confusion as to the ABO type of the donor, the outer containers should probably be new each time.</p> <p>The re-use should not be prohibited. Proper labeling needs to be done, and can be done accurately even when a box or cooler is re-used.</p>	<p>Standard packaging should also probably be uniform nationally, therefore, corrugated boxes would be best.</p>	<p>I do not think an inner rigid container is necessary for the packaging of all organs, ie. livers, etc.</p>	
<p>The re-use should not be prohibited. Proper labeling needs to be done, and can be done accurately even when a box or cooler is re-used.</p>	<p>I am unsure why coolers are used instead of boxes. Unless there is a strong medical reason why boxes shouldn't be used. Use of boxes for all organs should be the standard.</p>	<p>If boxes are used, a rigid container will be necessary inside the box. If coolers continue to be used, they will serve as a rigid, protective container - makes sense.</p>	
<p>Pediatric Transplantation Committee</p>			
<p>If the only way to ensure organ wastage is by prohibiting the re-use of containers, I would support it. Do we have any data on how many organs are wasted every year due to this? One factor that needs to be taken into</p>	<p>There absolutely should be a standardized packaging method adopted. The specific recommendations should be based on available data, if any, regarding the most optimal and safe way to</p>	<p>Again, a single standardized packaging method, one that would suit the transport of all organs, if such a method is available, would be the way to go to avoid errors and confusion. The specific pros and cons</p>	

<p>consideration is how expensive the containers are? If they are not very expensive, I would be even more in favor of eliminating re-use</p>	<p>transport organs.</p>	<p>for not using a rigid container for lungs or livers should be requested from those organ specific committees..if there are no disadvantages, and cost is not a major issue, I'd support standardizing the use of an inner rigid container for them too.</p>	
<p>Yes</p>	<p>It is not clear if coolers meet the 200 lb. burst strength requirement. If so, then there would be no need to limit it to corrugated containers.</p>	<p>Yes. If size is a concern, an alternative container should be designed.</p>	
<p>No, re-use should be allowed in my opinion. What should be prohibited is the inadequate "de-identification" after use for one organ/donor and before the next</p>	<p>Whatever offers optimal organ conservation should be allowed. I don't know enough about differences in this regard between coolers and corrugated boxes etc. or why livers and lungs don't need a rigid inner container.</p>	<p>Whatever offers optimal organ conservation should be allowed. I don't know enough about why livers and lungs don't need a rigid inner container.</p>	
<p>The disposable containers should not be re-used.</p>	<p>Yes, eliminate coolers.</p>	<p>I believe that a protective inner rigid container is not required for liver, kidney or intestine.</p>	
<p>Reuse of outer containers would be okay, not coolers</p>	<p>Yes.</p>	<p>No. No advantage over triple bagging and surrounded by ice</p>	
<p>I endorse the committees recommendation that outer transport container re-use should be prohibited.</p>	<p>A corrugated box makes sense and I endorse this recommendation.</p>	<p>I have to defer to more expert opinions than mine. This having been said, uniformity in packaging might help to eliminate the improper use of packaging for organs other than lung/liver/pancreas and in this regard I would tend to support the concept.</p>	

Kidney/Pancreas Transplantation Committee

<p>As a transplant nephrologist, I do not have enough first-hand experience with organ transportation to provide specific suggestions. However, whatever method is finally chosen, one would hope that it:</p> <p>a) Completely eliminates any chance of human error causing confusion, such as dual labels on the outside.</p> <p>b) Completely eliminates any chance of cross-contamination, such as from improper sterilization</p> <p>c) Guarantees the best possible environment for organ survival</p> <p>d) Does NOT increase the hassles for the harvesting team or delay harvest (appropriate container not available on time)</p> <p>e) Does NOT add significant additional costs</p> <p>f) Fixes ONLY what is broken and does not result in additional rules that look nice on paper but may not really add value.</p>			
			<p>An inner, rigid container is not necessary for all organs, only pancreas and kidneys, if not being transported by the transplant team. Most of the time, livers arrive (sterile bagged x 3) in a cooler, and a private</p>
		<p>I see no reason for the OPO to box ALL organs (especially kidneys) if the retrieving surgeon is bringing back the organs with him to the transplant center (in a cooler). Boxing organs takes extra time, and most</p>	
<p>I don't think it is necessary to prohibit the reuse of corrugated boxes or coolers, we have had no problems with either container. The only stipulation might be to ensure the reused box is intact and in good shape</p>			

<p>(we've never received one in disrepair).</p>	<p>surgeons are not happy about hanging around waiting for this process. However, in circumstances in which kidneys and pancreas are transported without coming back with the surgeon, the corrugated box is absolutely necessary.</p>	<p>plane or courier is dispatched to transport the organ. Kidneys, as you know, travel commercially with the Samsonite Gorilla, so they need all the support they can get!</p>	
<p>Yes</p>	<p>Standardize sending coolers, but leave the option for a procuring team to bring their own cooler to transport an organ regardless of type. It is up to the cost containment guidelines of the organization and the transplant center to ensure proper transport of the organ they procure.</p>	<p>Standardize transport coolers to include protective inner lining.</p>	
<p>Thoracic Transplantation Committee</p>	<p>No, coolers do not come in contact with body fluids, and are readily cleaned. To ban their reuse would add an additional, unnecessary expense.</p>	<p>If the current practice is followed there should not be a problem. Hold people accountable for following current practice.</p>	
<p>No, a corrugated box is less durable and more easily damaged during transport. With exposure to ice, water etc. it will be subject to loss of integrity - none of which are an issue with coolers.</p>	<p>No, a corrugated box is less durable and more easily damaged during transport. With exposure to ice, water etc. it will be subject to loss of integrity - none of which are an issue with coolers.</p>	<p>Yes. We use a small, circular plastic jar with a coarsely threaded cap. It is easy to use even when gloved. The plastic bags fit easily inside and ice can be added. The container provides a sterile environment that is easily opened in the recipient operating room. I suspect that such a system can be used for all organs.</p>	
<p>I see no problem with continuing to use coolers for outside packaging. The inner packaging is not reusable. I can foresee some problems with disposable packaging with corrugated boxes that do not have the same thermal protection to prevent ice melt during transport through hot</p>	<p>I see no problem with continuing to use coolers for outside packaging. The inner packaging is not reusable. I can foresee some problems with disposable packaging with corrugated boxes that do not have the same thermal protection to prevent ice melt during transport through hot</p>		

<p>No</p> <p>I do not see why a box cannot be reused if appropriate.</p> <p>I have no idea of the scope of this problem. How many organs have been "wasted"? Why, mislabeling, trauma or what? Wouldn't it be better to mandate a blank container than go through the nonsense and expense of buying new "boxes" every time?</p>	<p>climates. This issue should probably be discussed at the Thoracic Committee meeting.</p> <p>No</p> <p>I think that a corrugated box can meet all the requirements for transport.</p> <p>We don't need an inventory of boxes. Coolers are durable and economical because they can be stored.</p>	<p>No</p> <p>Do we now use a rigid box? It seems it would be protective, and if so for all organs.</p> <p>Similarly, what evidence is there that we have a problem with the current organ container standard?</p>	
<p>Committee - Unknown</p> <p>Since identifying information must be secured to the outermost surface of the transport box perhaps the reuse of corrugated boxes with old identifying information still in place should be prohibited. Plastic coolers with the information securely affixed by an attached plastic envelope, where the envelope can be completely emptied and new information replaced, should not be a problem. If by "cooler" we mean the Styrofoam container within the corrugated box, then I have no objection to its reuse. The institution of standardized packaging for transport would probably make the policy writing easier. Then I would agree that corrugated boxes should not be reused.</p>		<p>I agree with the policy as currently stated. The size of livers and lungs makes it somewhat more difficult, although not impossible, to use a rigid container.</p>	

The Policy Compliance Department is aware of two situations that occurred this year as a direct result of an OPO reusing an organ shipping box.

Scenario #1: An OPO received an import kidney/heart combination for transplant. The heart failed upon reperfusion. OPO 0 reallocated the kidney outside of its own service area. The OPO repackaged the kidney for shipping reusing both a kidney shipping box and plastic liner from a previous imported kidney. The plastic liner contained a label identifying a different Donor and ABO Group from that of the organ contained within. When the importing OPO received the kidney, the kidney was discarded due to the conflicting information on the labels. This kidney was from an eleven-year-old donor.

Scenario #2: A transplant center received an import kidney from an OPO. The shipping box contained two different Donor IDs numbers, two different ABO Blood Groups and one was labeled Right kidney while the second label identified the Left kidney. The shipping box had been reused from a previous case. The labels from the previous case remained on the box. The transplant center and OPO were able to resolve this without discarding the kidney.

Other labeling issues *this* year.

- An OPO failed to label 3 of 4 blood tubes accompanying a liver.
- An OPO shipped a kidney with the two conflicting Donor IDs and ABO types on the inner label. Apparently the person who preprinted the labels at the OPO mistaking understood the wrong Donor ID and ABO "O". The coordinator became aware of the correct Donor ID and ABO "AB" in the OR. She created new labels showing the correct ID and that the ABO was "AB". She put the bright yellow sticker with the "wrong" ABO and ID on the Styrofoam box and kidney bag. She then put a white sticker with the correct ABO of "AB" and ID # on top of the yellow stickers on both the styro box lid and kidney bag. The Transplant center could see the incorrect yellow sticker when they opened the box.

RE: Rigid container

I have cited an OPO once for not using a rigid container for shipping pancreata. That OPO was of the understanding that "no one" uses a rigid container for pancreata. I just happened on this since I usually only ask OPO staff to demonstrate packing a kidney.

Margaret M. Kearns, R.N.
Compliance Auditor
United Network for Organ Sharing (UNOS)

This survey will be sent out tomorrow. The OPO Committee will forward the scenarios and aggregated responses to the organ specific committees for input. The OPO Committee will take any recommendations into consideration at its March meeting.

Dear OPO Executive Director:

Earlier this year, the OPTN/UNOS ABO Joint Subcommittee requested that the OPO Committee consider the necessity of defining the role and responsibilities of the "coordinating OPO." We are interested in your response to four scenarios listed below in order to thoughtfully and appropriately address this request, but first want to provide you with some background information.

According to a section of Policy 3.2.3 (Match System Access): For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. Thus, if the original designee is ultimately unavailable to receive the transplant, the organ is released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local level must be done according to the match run.

The OPO Committee conducted a survey of OPOs to determine the degree to which OPOs serve as the clearinghouse for organ offers/imports. Of the 47 OPOs that responded to the survey, 30 responded that they act as the coordinating OPO, 4 OPOs responded that they did not, and 13 OPOs indicated that they act as the coordinating OPO for some of their transplant centers or for certain organs, such as kidneys.

The Committee then identified four potential scenarios for managing organ offers/imports. Please send your comments to the questions outlined below for each of the following four scenarios to Debbie Seem, OPO Committee Liaison, at seemdl@unos.org by **Wednesday, December 31**.

For each of the four scenarios, please provide the following information:

- What do you anticipate the impact might be, if any, on your OPO related to such issues as financial impact or workload?
 - What are the disadvantages or advantages to this approach for your OPO?
 - What issues would need to be addressed before implementing this approach?
 - Any other pertinent comments?
1. The OPO serves as the clearinghouse for all organ offers/imports.
 2. In instances where the intended recipient is not able to receive the organ transplant, a transplant candidate identified at the receiving transplant center could serve as "local" back-up for the organ. (Note: This approach conflicts with current policy. In current policy "local" is defined as the OPO or the approved ALU. Implementing this scenario would require changing the definition of "local" in policy).
 3. In instances where the intended recipient is not able to receive the organ transplant, and the policy definition of "local" does not change, the transplant center serves as the proxy for the OPO and performs a local match run and organ placement.
 4. In instances where the intended recipient is not able to receive the organ transplant, the UNOS Organ Center performs the match run and organ placement.

If you have any questions, please do not hesitate to contact me at john.holman@hsc.utah.edu or Debbie Seem at 804-782-4845 or at the email address listed above. Thank you in advance for your participation.

Sincerely,
John Holman, Jr., MD, PhD
OPO Committee Chair

MEMORANDUM

Walter Gnanam, Executive Director

To: Alan B. Leichtman, MD.
Chair, Kidney/Pancreas Transplantation Committee

From: John M. Holman, Jr., MD, PhD
Chair, OPO Committee

Subject: Role and Responsibilities of the Coordinating OPO

Date: January 12, 2004

The ABO Joint Subcommittee requested that the OPO Committee consider the necessity of defining the role and responsibilities of the "coordinating OPO" in regard to when the organ is offered and accepted by a transplant center and then not transplanted into the patient for whom it was accepted. The Subcommittee recognized this practice varied widely across the country.

According to Policy 3.2.3 (Match System Access), "[f]or all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a patient who ultimately is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local level must be done according to the match run."

The Committee conducted a survey of OPOs to determine the degree to which OPOs serve as the clearinghouse for organ offers/imports to patients at transplant programs within their donor service area. Of the 47 OPOs that responded to the survey, 30 responded that they act as the coordinating OPO, 4 OPOs responded that they did not, and 13 OPOs indicated that they act as the coordinating OPO for some of their transplant centers or for certain organs, such as kidneys.

A subsequent survey was conducted that outlined four scenarios for managing organ offers/imports. OPOs were asked to provide information on the impact, (if any), and advantages and disadvantages of each approach. Although explained in detail in the attachment, the scenarios are briefly outlined below.

- Scenario 1: The OPO serves as the clearinghouse for all organ offers/imports.
- Scenario 2: In instances where the intended recipient is not able to receive the organ transplant, a transplant candidate identified at the receiving transplant center could serve as "local" back-up for the organ.
- Scenario 3: In instances where the intended recipient is not able to receive the organ transplant, and the policy definition of "local" does not change, the transplant center serves as the proxy for the OPO and performs a local match run.
- Scenario 4: In instances where the intended recipient is not able to receive the organ transplant, the UNOS Organ Center performs the match run and organ placement.

At its next meeting, the OPO Committee will draft a response to the Board regarding the necessity of defining the role and responsibilities of coordinating OPOs, and if yes, what the role and responsibilities should be. The Committee requests that the Kidney/Pancreas Transplantation Committee consider the charge of the ABO Joint Subcommittee and survey results and provide recommendations to the OPO Committee for consideration in its deliberations.

President:
Russell H. Wiesner, M.D.

Vice President:
Robert A. Metzger, M.D.

*Vice President
Patient & Donor Affairs:*
Paul B. Oldam, B.S.S.

Secretary:
Marc I. Lorber, M.D.

Treasurer:
Dean F. Kappel, MSW.

Immediate Past President:
Clyde E. Barker, M.D.

Regional Councilors:
George S. Lipkowitz, M.D. (1)
Andrew S. Klein, M.D. (2)
Shirley D. Schlessinger, M.D., FACP (5)
Kristene K. Gugliuzza, M.D. (4)
John P. McVicar, M.D. (5)
Douglas E. Wood, M.D. (6)

Christopher P. Johnson, M.D. (7)
Cass Franklin, M.D., FACS (8)
Frank S. Szmalc, M.D. (9)
Mark D. Pescovitz, M.D. (10)
P. R. Rajagopalan, M.D. (11)

At Large Board Members:
Margo L. Akerman, M.S.
The Hon. Antonio Benedi
Ronald W. Busuttill, M.D., Ph.D.
Anthony M. D'Alessandro, M.D.
John Davis
Richard J. DeSanto, MA

Melissa I. Doniger, J.D.
Barry S. Friedman, RN, BSN, MBA, CPTC
Rose Marie Gray-Finnell, ARRT (R)
Jackie L. Johnson, MSW, LICSW
Lloyd H. Jordan, Jr., CPA
Bertram L. Kasiske, M.D.
Sharon C. Kiehl, M.D., MPM
Helen W. Leslie, RN, CPTC
Donna L. Luebke, RN, MSN, CNP
Stephen M. Oelrich
Esther Padilla, M.S.W.
W. Steves Ring, M.D.
Sandra Rosen-Bronson, Ph.D.

Margaret J. Schaeffer, RN, CPTC
Nancy L. Senst, RN, BSN, CPTC
Charles F. Shield, M.D.
Ludy J. Trisdale, Ph.D.
Adriana Zeevi, Ph.D.

Past Presidents:
G. Melville Williams, M.D., 1984-85
Oscar Salvaterra, Jr., M.D., 1985-86
John C. McDonald, M.D., 1986-88
H. Keith Johnson, M.D., 1988-89
Robert J. Corry, M.D., 1989-90
James S. Wolf, M.D., 1990-91

Robert Mendez, M.D., 1991-92
R. Randal Bollinger, M.D., Ph.D., 1992-95
Douglas I. Norman, M.D., 1995-94
Margaret D. Allen, M.D., 1994-95
Bruce A. Lucas, M.D., 1995-96
James F. Burdick, M.D., 1996-97
Lawrence G. Hunsicker, M.D., 1997-98
William W. Pfaff, M.D., 1998-99
William D. Payne, M.D., 1999-2000
Patricia L. Adams, M.D., 2000-2001
Jeremiah G. Turcotte, M.D., 2001-2002

Executive Director Emeritus:
Gene A. Piers

YY-2 450

	What do you anticipate the impact might be, if any, on your OPO?	What are the advantages to this approach for your OPO?	What are the disadvantages to this approach for your OPO?	Any other comments?
<p>The OPO serves as the clearinghouse for all organ offers/imports.</p>	<p>Workload and financial impact not an issue</p>			
<p>OPO #1 serves as clearinghouse for all organs except for thoracic</p>				<p>OPO responsibility to have control of all organ offers. All offer comes to OPO Call Center and thoracic offers sent directly to the transplant center</p>
<p>OPO #2 receives all import offers</p>				<p>Works with 3 centers. Have separate staff to receive and coordinate offers.</p>
<p>OPO #3</p>		<p>Assurance that local allocation algorithms are being adhered to. OPO will place more organs due to vested interested.</p>	<p>OPO personnel resource intensive. OPO SAC's to transplant programs will increase. Allocation policies might be overlooked when placing organs from marginal/DCD donors.</p>	
<p>OPO #4 receives import offers</p>	<p>No adverse impact on current financial or workload issues</p>			
<p>OPO #5 receives kidney offers only</p>	<p>Would have to hire at least 3 placement coordinators to back up on-call person in order to handle extra-renal volume.</p>		<p>Slows down offers and acceptance of organ offers. Regarding the shift in the medicare cost report, when the OPOs gets involved in allocation of extra renal organs, the overhead costs are shifted from kidneys to the extra renals, which has huge cost considerations for local transplant centers and the OPOs SACs. The increase in work load and the financial impact.</p>	<p>Receive approx. 1000 kidney offers per year. Have significantly increased our thoracic utilization by offers discussed directly with transplant surgeons. Would only support this approach if DonorNet was made mandatory and all donor information was posted on the internet. Serves 7 transplant centers. Averages 1,000 pancreas call per year.</p>
<p>OPO #6 receives all import calls with exception of 1 heart program</p>	<p>Financial/ work load implications have been significant. Indirect costs related to the importation of each organ has risen significantly since 2001, of which some relates to the staff hired to field calls and coordinate the imports.</p>	<p>Have aggressive pancreas tx programs and receive large number of offers not patient specific. Allocation based on a local list run by the OPO, and therefore maintains fairness of the allocation system. Another advantage - process runs smoothly for the tx centers, and the OPO has an awareness of what organs are imported for which centers. Also, our OPO provides preservation services for most of our transplant centers, so it makes sense that the coordination of fly-outs is done by our staff.</p>		
<p>OPO #7 serves as clearinghouse for all organ offers</p>		<p>Since we receive offers from other OPOs functioning in the clearinghouse roles, standardization helps us in receiving and then offering information on import organ offers.</p>		<p>Defining roles and creating general standards or at a minimum, guidelines, would be helpful for the risk mgmt, quality and service improvement, and standardization reasons.</p>

	What do you anticipate the impact might be, if any, on your OPO?	What are the advantages to this approach for your OPO?	What are the disadvantages to this approach for your OPO?	Any other comments?
OPO #8 does not accept offers for extra-renal organs	One of the largest OPOs. Change would have significant impact on operations and finances. Would require additional staff, training, additional billing, the creation of charts for each organ offer and additional reporting to UNOS.		Medicare recently determined OPOs to count each imported organ as a full organ for cost report purposes. Proposal to require OPOs to accept all import offers would, in our case, shift costs to extra-renal organs (increasing their costs) while decreasing the amount that Medicare would reimburse for kidneys. (Added layer) would provide increased opportunity for error as well as add placement time. Would be two systems for placing extra-renal organs; procurement coordinators making offers on local donors and Call Center placement staff handling import offers, which could lead to confusion.	Estimate that importing 100 organs would decrease Medicare reimbursement by \$620,000, increase extra-renal fees by \$780,000, and increase overall costs by \$300-500,000 (additional staff and other resources). Proposal would take some time to implement. Policies and procedures would need to be written, staff hired, training etc.
OPO #9 serves as clearinghouse for all import offers	No financial or workload impact.			
OPO #10 has many tx centers that take heart & liver offers	In the past year or so, our OPO began taking all kidney offers, which increased workload on employees. If we took all organ import offers, it would require us to significantly increase the staff in our call center.		Would also be a major change for the transplant center staff who prefer to get the heart and liver offers directly.	
OPO #11	Negligible - this is the current model we employ.	Potential advantage of this model is that it ensures a third party "check and balance" on the organ allocation process.	Adds a third party (our OPO) between the offering OPO and the tx center, thereby increasing the number of "information hand-offs" and therefore increasing the risk of incomplete or incorrect information transfer.	Smaller OPOs might need to add resources for 24/7 communications. Some smaller OPOs currently outsource this function, thereby adding to the complexity of information transfer. Policy mandating OPO serves as clearinghouse may lead to more such outsourcing. Protocols for communication would need to be addressed before implementation.
OPO #12	Increased workload on existing coordinators.	Could be source of revenue for OPO (as it is for ours)	Issues surrounding timing, knowledge of OPTN/UNOS policies, etc.	
OPO #14	Would add up to two FTEs maybe more. Huge increase in workload. In fact, it may cause the use of full time staff sitting in a call center			

	What do you anticipate the impact might be, if any, on your OPO?	What are the advantages to this approach for your OPO?	What are the disadvantages to this approach for your OPO?	Any other comments?
OPO #15 takes all import offers	Currently no impact. If transplant centers become major importers, it would effect staffing immensely.		Act as a middle man and sometimes the relay of information is not as fluid as it could be.	
OPO #16 takes all import offers		Our coordinators are perhaps more in tune with organ placement issues that the offering OPO is encountering. We view this role as a significant part of our mission and think that it aids in promoting transplant center relationships with our staff.		

	What do you anticipate the impact might be, if any, on your OPO?	What are the advantages to this approach for your OPO?	What are the disadvantages to this approach for your OPO?	Any other comments?
In instances where the intended recipient is not able to receive the organ transplant, a transplant candidate identified at the receiving transplant center could serve as "local" back-up for the organ. (Note: This approach conflicts with current policy.)				
OPO #1		Usually, cold time is an issue so it could be advantageous for the importing OPO to place the organ as long as they utilized the original matchrun from the host OPO and provided the printout back to the host OPO for submission to UNET.	Best outcome could be to have the host OPO place the organ but the receiving OPO could transport it to another transplant center.	
OPO #3		Will maximize organ usage. Increased graft outcomes due to decreased CITs. Cost savings to the transplant system, i.e. less ATN.	More urgent patients at other centers will be passed-up. Not in line with a national sharing system for most medical needy.	
OPO #4	Logistically the easiest of the four alternatives, and would simplify our workload somewhat, saving some expense, but nothing material.		Foresee creation of tension and dissension among the transplant centers, including accusations of "gaming the system," if this were implemented. There is also the issue of a "patient driven" allocation system, rather than a "center driven" system.	We recommend against this alternative because of the absence of control by an organization other than the transplant center.
OPO #5		Makes sense in decreasing ischemia time.	Suspect that transplant centers will immediately begin gaming the system by accepting more organs with no intention of actually transplanting the intended recipient.	
OPO #6	Would decrease the work load for the OPO staff	In theory, it makes sense to have the back-up be from the same center, particularly for hearts, lungs, livers and possibly pancreas because of the need to limit CIT. For kidney and possibly pancreas imports, where there may be more time to allocate to a back-up patient from the list, allocating from a list makes the most sense.	Would be hard for UNOS to oversee the practice and ensure centers are not accepting organs inappropriately for one candidate, with the intent to transplant another candidate further down the list.	A monitoring system or policy should be put in place prior to implementation
OPO #7		In OPOs whose tx ctrs still heavily rely on HLA matching for kidney, by forcing allocation backup to the entire list, you potentially and likely increase CIT on the organs and possibly negatively impact outcomes (thus, tx center as local back-up is an advantage). For extrarenals, no changes should occur.		For kidney or k/p offers, we support the change in that if the initial offer comes to an identified specific recipient from the current local list, but the intended recipient is unable to be transplanted, and local backup is granted to the local OPO by the original "host" OPO, the backup recipient should be at that local center, based on the match run.

	What do you anticipate the impact might be, if any, on your OPO?	What are the advantages to this approach for your OPO?	What are the disadvantages to this approach for your OPO?	Any other comments?
OPO #8				We would support this policy if: the current policy were changed to make it "legal"; the decision to do this was elective on the part of the "host" OPO; the organ had not left the "host" area (i.e., turned down in the OR); and the policy would assure that "debt" status was not adversely affected.
OPO #10			Giving it unconditionally to the first accepting center would do a disservice to the other patients waiting at the top of the list. Other result might be that centers may accept an organ for one patient, knowing that if they cannot ultimately use it for that patient, they can use it for another patient waiting at their particular center.	This approach is unnecessary in our area where we can re-locate an organ within a reasonable amount of time. If we cannot, the new transplant centers will decline and the organ will stay where it would be best used within the given timeframe.
OPO #11	Minimal	Less CIT.	Tx ctr has opportunity to 'game' the system. Also, if there is more than one local program, the program getting to back up the organ may be advantaged over the other local programs, especially those with smaller lists.	How will allocation violations be monitored in a timely manner?
OPO #13		Advantageous to us because of numerous transplant programs and lack of enough tissue typing materials, and logistics causing extended preservation times.		
OPO #16		Could assist in minimizing the cold time on imported offers. Allowing the "same center" to back up would help minimize CIT and tx centers are aware of "local" patients that could be brought in to receive the transplant.		
OPO #17	Might reduce workload.		Could include more non-local recipients and fewer local recipients.	Would require careful monitoring at a national level (not by the OPO) to prevent receiving transplant centers from using "bait and switch" techniques of having "intended recipients" that are used merely to attract organ offers but who never really get transplanted because the organ(s) offered to them are consistently shifted to other recipients on the center's list.

	What do you anticipate the impact might be, if any, on your OPO?	What are the advantages to this approach for your OPO?	What are the disadvantages to this approach for your OPO?	Any other comments?
<p>In instances where the intended recipient is not able to receive the organ transplant, and the policy definition of "local" does not change, the transplant center serves as the proxy for the OPO and performs a local match run and organ placement.</p>				
OPO #1				<p>Host OPO should be offered the organ back for placement if the intended recipient is unable to be transplanted and cold time is not an issue. Host OPO needs to be responsible to whether the receiving OPO is allowed to use internally. If the transplant center keeps the organ for placement, the same UNET matchrun should be utilized rather than some internal local matchrun from another database. Again, the host OPO would need to receive all documentation from that placement in order to complete UNET</p>
OPO #3		<p>Advantages are not apparent in this model.</p>	<p>Lack of vested interest on behalf of transplant center to place organ if no local matches. Possible increase in organ discards. Possible increase in OPO SAC's due to organ discards. Delays in providing OPO required data for reporting to UNOS. Possible abuse of organ allocation algorithms. Transplant personnel not experienced organ donation, may misrepresent donor organ.</p>	
OPO #4			<p>Has many of the same issues as scenario #2. It may complicate the issue of record keeping. It could raise logistical problems, as not all transplant centers may be equipped to arrange transportation, or even to access the UNOS match runs.</p>	
OPO #5			<p>I don't believe the transplant programs are prepared to do this. Their personnel do not have much experience doing match runs or organ placement.</p>	<p>OPO is in the best position to do this. I support the originating OPO, unless the local OPO is involved in receiving all out of region offers.</p>

	What do you anticipate the impact might be, if any, on your OPO?	What are the advantages to this approach for your OPO?	What are the disadvantages to this approach for your OPO?	Any other comments?
OPO #6			Same concerns for this scenario as in #2. Additional disadvantage relates to the transplant centers' limited working knowledge of allocation policies (i.e. tx staff don't routinely allocate organs; they aren't aware of all of the nuances of the system), contact information for other transplant centers, and process for transporting the organ.	This scenario would be the least desirable of those presented by the committee.
OPO #7				Do not think this is a good idea. The OPO needs to maintain control of this process.
OPO #8			We would have the same concerns as scenario #2. Transplant centers do not have the resources (faxes, computers, staff on site) nor trained staff to do this. Transplant centers would be given access to each other's match run lists. (Probably not a good idea). This scenario would be highly prone to errors.	
OPO #10			Unnecessary and complicated. Very unlikely that our transplant centers would be willing/able to do this.	
OPO #11	Major.		Seems risky. Would only help in cases where the transplant center actually had a backup pt. The local transplant center would need to be skilled in the use of UNet to ensure all existing system safeguards are maintained (e.g. ensure intended recipient is on the match run, etc.) Tx coordinators unfamiliar with the proper procedure for performing match run.	This approach could increase the risk of improper organ allocation due to lack of familiarity of tx center staff with the organ allocation system.
OPO #12	Saves time to have the local center act as proxy, taking the exchange of information back and forth out of the equation.			In essence, seems to be the same as local back up. If transplant center using the organ to benefit the best patient, the only purpose of a match run is to verify that the patient matches and verify waiting time. How will possible match run violations be addressed, and will it penalize the OPO that gave the proxy to the tx center?
OPO #13			Most centers have no access to the match runs and do not have adequate personnel to offer organs to other OPOs/centers.	

	What do you anticipate the impact might be, if any, on your OPO?	What are the advantages to this approach for your OPO?	What are the disadvantages to this approach for your OPO?	Any other comments?
OPO #14				
OPO #15			This would cause the smaller centers to be on the short end of the sharing. Large centers would have no reason to decline an organ.	This is how we handle this now, although it does potentially allow for the organ to be used in a patient not on the list. Our tissue typing runs renal lists.
OPO #16			This would be logistically tough for all involved since our centers all handle call differently. I am not certain this would be politically favored by either center. We are viewed as more neutral.	
OPO #17	This is not a workload issue for the OPO.		May be a competency issue among transplant centers in their ability and/or willingness to perform these tasks.	

	What do you anticipate the impact might be, if any, on your OPO?	What are the advantages to this approach for your OPO?	What are the disadvantages to this approach for your OPO?	Any other comments?
In instances where the intended recipient is not able to receive the organ transplant, the UNOS Organ Center performs the match run and organ placement.				
OPO #1		In terms of renals, UNOS has always been a valuable resource for kidney placement, with most being 0-antigen mismatches or marginal kidneys. That allows more time for our staff to focus on other donor-related issues.		Could be a back-up option but the host OPO should always be primary for extra-renals. With automation, placement can move faster.
OPO #3		Adherence to allocation policies due to neutral party placing organs. Reporting of data to OPO in a timely fashion. OPO personnel can better be utilized. Potential SAC cost savings to OPO.	Delays in organ placement due to organ placement volumes handled by Organ Center. Organ Center not as aggressive as OPOs in placing extended and DCD organs due to following allocation algorithms.	This would be the best scenario of the four as an impartial party would be placing the organs. However, there would need to be trained staff in adequate numbers to accomplish this as well as policy reform that would expedite the placement of all organs, including both extended and DCD donors. Anticipated that the costs to OPOs and transplant facilities would increase for these services. However, if more organs are placed this cost increase would be minimal.
OPO #4	Makes our workload marginally easier, but not significantly.		Better than scenarios #3 or #2 as it removes any "gaming of the system."	
OPO #5				Good solution if the originating OPO cannot perform this function.
OPO #6	Would decrease the OPO workload.		Adding the Organ Center would add an extra layer to an already complex system. If the original allocation was done from one OPO to another, it would make sense to have the re-allocation done by the accepting OPO.	
OPO #7			Don't think this needs to be automatic. Currently, this occurs frequently when the next recipient is not in that initial OPO. If the host OPO grants local backup, then the importing OPO can work off the match run or rerun one just for that OPO and allocate accordingly - depends on if extrarenal or not.	
OPO #8			UNOS does not have the trained resources available to undertake this effort.	

	What do you anticipate the impact might be, if any, on your OPO?	What are the advantages to this approach for your OPO?	What are the disadvantages to this approach for your OPO?	Any other comments?
OPO #10		This would add cold time on our already "marginal" organs.	We feel that we can do a diligent search for a recipient either locally or nationally in a more reasonable timeframe than UNOS.	We can do a diligent search for a recipient either locally or nationally in a more reasonable timeframe than UNOS.
OPO #11	Would slightly reduce the organ placement workload at the OPO level, but not by much.		One advantage the OPO has with its own tx programs is local relationships, knowledge of systems, and general familiarity with the process - all of which makes for a more efficient placement process - this would be negated. Also, organ placement by UNOS organ center may be less efficient.	Would not suggest this model if the goal is to minimize organ wastage.
OPO #12	Depends on which organ is being transplanted.	Transplant center couldn't 'game' the system	UNOS could not do it quickly enough for organs with limited CIT's, especially if the organ is out of the body (heart, lung). Would result in increased CIT and possible organ wastage.	Unsure why UNOS or transplant center would have to rerun a PTR, instead of continuing down the list as originally printed.
OPO #13			Sometime due to ischemic times, strict adherence to the match run list can cause organs to be discarded, while too many offers are being made, and turned down.	Would place a significant additional burden on the Organ Center, causing the Organ Center staff to be expanded
OPO #15		This is one way to address issues where multiple tx centers are "local." UNOS would have to expedite their placement however, because often these organs are recovered.		
OPO #16				If the kidney is to remain in town, we view our role as the party responsible for allocation and I would ask that the OPO be included in the process.
OPO #17	This would substantially decrease the OPO workload.			

<p>Other Comments</p>	<p>Any change to the existing procedures for placing organs could have significant impact on certain organizations. A change would require training, the addition of resources, could negatively impact Medicare reimbursement and most seriously, could cause delays in placement and potentially organ discards. (8)</p> <p>Your request is a little confusing to me. If you are evaluating whether or not current policy needs to be changed since there are a number of programs either unable or unwilling to comply, I would suggest that the policy remain in force "as is". It appears from your previous surveys that the majority of OPO's (30) act as the clearinghouse and comply. Those that do not should modify their processes to be in compliance with the UNOS/OPTN policy since it applies to all transplant centers, HLA Labs and OPO's. (9)</p> <p>These types of questions take on different meaning based on the context. If the goal of "defining the role of the coordinating OPO" is to reduce the risk to patients of incorrect organ allocation, the questions will be best answered in a certain way. This applies for other contexts as well, such as the goal of minimizing organ wastage, or minimizing violation of UNOS policies. In closing, we think it is important to clarify the context and goals for this undertaking, and to follow a guiding principle of minimizing unneeded information "hand-offs". (11)</p>
------------------------------	--

From: Alan Ting
Sent: Tuesday, November 04, 2003 3:48 PM
To: -Cindy Sommers; Jason Byrd
Subject: FW: Pancreas donor match list



Pancreas Issue

Jason & Cindy,

I have attached an email that also addresses this issue. I have had other calls/emails from members with questions/comments similar to what Linda says in her email. I think it may be time for the KPT Committee to revisit this issue, and if they still support it, to put it in policy where members can see it.

What do you think?

Thanks,

Alan

-----Original Message-----

From: Linda.Cagle@UCHSC.edu [mailto:Linda.Cagle@UCHSC.edu]
Sent: Tuesday, November 04, 2003 1:14 PM
To: Alan Ting
Subject: Pancreas donor match list

Hi Alan,

It was nice seeing you at the ASHI meeting in Miami. I came back to some cold, wet miserable weather in Denver--but we need the moisture.

We were called on 4 pancreas offers last night and one of our coordinators was trying to explain to the surgeon how the matching of a pancreas donor to a recipient includes both the recipient and previous kidney donor HLA typing for up to 12 antigens. The surgeon wanted to know how long this matching process has been in effect and I could not find anything in the policies, not even a reference for including the previous kidney donor HLA when listing a pancreas candidate.

Can you give me the date when this went into effect? And a reference? Thanks for your help!

- > Linda R. Cagle, CLDir, CHS
- > ClinImmune Labs
- > Tel: 303-724-1315
- > Fax: 303-724-1316
- > e-mail: linda.cagle@uchsc.edu
- > www.uchsc.edu/sm/cihl

> CONFIDENTIALITY NOTICE

> This electronic message transmission contains information from ClinImmune Labs, and this information is confidential. If you are not the intended recipient, be aware that disclosure, copying, distribution or use of all or any portion of the content of this information is prohibited, except by authority of the sender. If you received this transmission in error, please notify us as soon as possible by e-mail and delete the original message. Thank you.

Jason Byrd

From: Alan Ting
Sent: Friday, January 11, 2002 4:33 PM
To: -Cindy Sommers
Subject: Pancreas Issue

Cindy,

The following KP resolution was approved by the Board in November 1994, and implemented in April 1996:

*** Resolved, that the UNOS computer matching system for pancreas allocation shall be modified so that mismatches that are shared between the kidney and pancreas donors will be considered as matches. Pancreata that do not meet the mismatch criteria for a particular recipient will not be offered to that patient.

Probably not too many people are aware of this programming, and it has caused some confusion with some centers. The problem is: If a member adds a pancreas candidate who has had a previous kidney transplant that is still functioning the member is asked to enter the previous kidney donor's HLA antigens. If the member does this the above resolution is in enacted, although the member is probably unaware of it since this "pancreas allocation policy" is not in Policy but only occurs in UNet programming. Would it be worthwhile asking the KP Committee to relook at this "policy" and if they agree that it is still valid (I doubt that there will be consensus!) could they recommend a policy addition so that more members are aware of it.

Am I making sense?

Thanks,

Alan

*Alan Ting, PhD
Research Department
UNOS
(804) 323-4305
(804) 330-8535 (Fax)
www.unos.org*

ZZ-2

1 497

15. UNOS Mismatch Criteria for Candidates Registered for Pancreas Transplantation Following a Kidney Transplant. At its January 24, 1997, meeting, the Committee considered whether the national protocol that allows mismatched antigens identified with a recipient's kidney donor to be considered acceptable antigens for subsequent pancreas offers should apply in determining eligibility of the recipient for zero antigen mismatched organ offers. In response to this issue, the Committee considered the origins of the underlying protocol.

Effective April 15, 1996, the UNOS Pancreas Match Program was modified to prompt for additional information regarding a pancreas candidate's prior kidney transplant, if applicable. At the time of listing a pancreas candidate, the individual entering the patient's information is now asked if the patient has received a prior kidney transplant; if so, if the kidney is still functioning; if so, to identify the mismatched antigens of the kidney donor and that candidate. This information is not required to list a patient. The purpose of the modification is to enhance transplant opportunities for kidney recipients who require a sequential pancreas transplant, including opportunities for zero antigen mismatched organ offers. Subsequent to implementation of this protocol, UNOS modified the national allocation algorithm for pancreata to require sharing for any patient on the Waiting List for whom there is a zero antigen mismatch with the donor.

The Committee discussed whether there is a difference in outcomes between patients receiving sequential pancreas after kidney transplants based upon the shared kidney antigens and those receiving pancreas transplants following kidney transplants based upon their own antigens. Preliminary data are attached as Exhibit P. The Committee requested additional outcome data for further discussion at its next meeting.

Analysis of the Impact of Shared HLA Mismatches on Pancreas after Kidney Graft Survival

Purpose: To assess whether using a "shared mismatch" algorithm for computing HLA mismatch level yields similar results to the conventional HLA mismatch algorithm.

Cohort: All pancreas recipients transplanted between October 1, 1987 and December 31, 1995 who had also received a prior kidney transplant which was still functioning at the time of the pancreas transplant (N=232).

Methods:

- (i) Univariate tabulations of conventional and shared mismatch levels.
- (ii) Multivariate analysis of 1-year pancreas graft survival using logistic regression to determine if the transplants which are conventionally mismatched but not mismatched using the shared algorithm have similar survival to transplants with 0 conventional mismatches.

Results:

(i) Univariate results

Locus	HLA Mismatch level	N	%
A	0 conventional MM	56	24.1
	0 shared MM, > 0 conventional MM	21	9.1
	>0 shared MM, > 0 conventional MM	151	65.1
	missing	4	1.7
B	0 conventional MM	52	22.4
	0 shared MM, > 0 conventional MM	6	2.6
	>0 shared MM, > 0 conventional MM	170	73.3
	missing	4	1.7
DR	0 conventional MM	57	24.6
	0 shared MM, > 0 conventional MM	17	7.3
	>0 shared MM, > 0 conventional MM	153	65.9
	missing	5	2.2

(ii) Logistic regression results:

Due to the very small number of PAK transplants with a functioning kidney at the time of transplant, who also had known 1 year graft status (N=210), a p-value of 0.15 or less was considered to be significant. After adjusting for the impact of donor age and donor gender (the only non-HLA risk factors which were significant), 0 shared mismatches at either the B or DR locus were found to be not significantly different from 0 conventional mismatches at the same loci (p=0.3 and 0.9, respectively), but there was a significant increase in the odds of graft failure for the recipients of transplants which had 0 shared A mismatches when compared to those with 0 conventional A mismatches (p=0.11). The impact of 1 or 2 mismatches at each locus was similar for both the traditional and shared mismatch algorithms.



Network
for
Organ
Sharing

Suite 500
P.O. Box 13770
Richmond, Virginia 23225-8770
804 • 330 • 8500
Fax 804 • 330 • 8517

Executive Director
Walter K. Graham

Vice President
James H. Black, M.D.
Secretary
Lawrence C. Hanks, M.D.
Treasurer
W. Daniel Parker, MHA, FAHA
Immediate Past President
Margaret D. Aiken, MD

MEMORANDUM

To: Kidney Transplant Program Directors
Pancreas Transplant Program Directors
Kidney Transplant Clinical Coordinators
Pancreas Transplant Clinical Coordinators
OPO Executive Directors

From: Douglas A. Heiney, Director
Department of Membership and Policy Development

Re: Mismatch Criteria for Candidates Registered for Pancreas
Transplantation Following Kidney Transplantation

Date: April 8, 1996

Regional Councillors
William E. Hammon, MD (1)
Timothy R. Staver, MD (2)
James J. Wann, MD (3)
Goran B. G. Kiranadani, MD, PhD (4)
J. Thomas Rosenthal, MD (5)
James D. Perkins, MD (6)
William D. Payne, MD (7)
Jackson Foster, MD (8)
Charles M. Miller, MD (9)
Jery C. Rosenberg, MD, PhD (10)
Patricia L. Adams, MD (11)

At Large Board Members
Mango Akerman, MS
Rosco E. Andriola, Esq
Philip H. Berry, Jr., MD
Kimberly Y. Brooks
Suzanne Lane Conrad, RN, MHA, CPTC
Christine J. Gilmore, RN, BSN
Marvone D. Hunter, Esq
Dean F. Kappel
Mary S. Leffell, PhD
James L. Locke, MD
Theodora D. Monroe, MA
Kenneth P. Montsaga, M.D., MPH
John M. Newmann, Ph.D., MPH
Dale G. Renlund, MD
Cynthia H. Rodriguez, LVN
Lawrence L. Schkade, Ph.D.
Lynn H. Skelbaugh
Peter Sastny, M.D.
Frank P. Stuan, Jr., M.D.
Manakkam Suthanthiran, M.D.
Charles Washington, Ph.D.
Phyllis G. Weber, R.N., CPTC
Manuel Zapata

Past Presidents
G. Melville Williams, M.D., 1964-85
Oscar Salvatierra, Jr., M.D., 1985-86
John C. McDonald, M.D., 1986-88
H. Keith Johnson, M.D., 1988-89
Robert J. Cory, M.D., 1989-90
James S. Wolf, M.D., 1990-91
Robert Mendez, M.D., 1991-92
R. Randal Bollinger, M.D., Ph.D., 1992-93
Douglas J. Norman, M.D., 1993-94

Executive Director Emeritus
Gene A. Pierce

In an effort to enhance transplant opportunities for kidney recipients who require a sequential pancreas transplant and have been added to the pancreas waiting list, the UNOS pancreas match-run program will be modified so that mismatched antigens identified with a recipient's kidney donor will be considered as acceptable antigens for any subsequent pancreas offer. **This program modification will be effective April 15, 1996.**

The modified program will take into account a candidate's antigens and all of the kidney donor's mismatched antigens that are entered on the computer system. Mismatches that are common to a recipient's kidney donor and a pancreas donor will be considered as matches and the candidate will appear on the match-run print out for all pancreas donors who meet these mismatch criteria. **Use of these modified mismatch criteria is optional. Transplant programs will not be required to enter the kidney donor's mismatched antigens when registering a candidate on the pancreas waiting list.** For those programs that elect to participate, the kidney donor's mismatched antigens can be entered and maintained through the non-renal maintenance program beginning April 15, 1996.

If you have questions with regard to this program modification, please contact the information technology help-line at (804) 330-8658.

Effective April 15, 1996, the Non-Renal Maintenance program for registering-Pancreas candidates to the UNOS Waiting List will prompt for additional information regarding prior kidney transplant. When adding or modifying a pancreas candidate, you will be prompted if candidate received a prior kidney transplant. Please respond with a "Y" or "N". If the response is "Y", you are asked if the Kidney is still functioning. Please respond with a "Y" or "N". If the response is "Y", you are prompted to enter the mismatched antigens of the kidney donor and that candidate.

Note: Transplant centers are not required to enter this information.

Below is example of the new screen prompts:

 Enter Required Donor Weight Measurements:

```

WEIGHT
MIN MAX UNIT
=== === =
==> 100 900 L
  
```

```

A1 A2 B1 B2 DR DR ACPT
== == == == == == =
=> 2 30 8      4      0
  
```

Candidate will accept Pancreas procured by another team <"Y"es or "N"o> : Y
 Candidate will accept organ from HCV POSITIVE donor ? <"Y"es or "N"o>: N

Prior Kidney Transplant ? <"Y"es or "N"o> : Y
 Kidney still functioning ? <"Y"es or "N"o> : Y

Kidney Donor's Mismatched Antigens:

```

A1 A2 B1 B2 DR DR
== == == == == ==
=> 1      22      11
  
```

 The report program has also been modified to include the new pancreas data.

Below is an example:

PA/KP/PI ANTIGENS REPORT:

NAME	BG	ORG	A1	A2	B1	B2	DR1	DR2	MSMAT CODE	PA OTH	KI TXC	KI FNC	PREV KI				DONR HLA	
													A1	A2	B1	B2	DR	DR
BLISS MARTIN	O	PA	02		60	62	04	13	0	Y		2	60	62	4	13		
CALDWELL LIS	O	PA	26	26	38	38	04	04	0	Y								
GREWING MARK	O	PA	02	32	35	61	01		0	Y								
HARTL ADOLPH	O	PA	24	29	44	39	01	03	0	Y	Y	Y	24	29	44	39	1	3
HARTMAN STEV	O	PA	02	11	62	61	04	13	0	Y	Y	Y	2	11	44	61	8	13
KNEPFLER KAT	O	PA	03	31	14	47	04	07	0	Y								

LARSON DOUG	O	PA	2	32	44		4	12	0		Y	Y	Y	2	32	44	7	2	12	—
MURPHY CHRIS	O	PA	02	30	08	18	03		0		Y									
NICHOLS WM	O	PA	2		8	62	3	4	0		Y	Y	Y	2		8	62	3	4	
PERRIN PAT	O	PA	01	24	08	39	01	03	0		Y									
RIPA ELIZABE	O	PA	01	02	08	49	04	06	0		Y	Y	Y	1	2	8	49	4	6	

The Pancreas Match program will include all kidney donor mismatched antigens as acceptable antigens for new donor/potential recipient HLA matching. For example, if a candidate has an additional 4 kidney donor mismatched antigens, the 6 donor antigens will have a chance of matching to 10 candidate antigens (6 for the candidate plus 4 kidney donor mismatched antigens) thereby enhancing the candidates chance for a better match.

The Pancreas Match printout will display two additional fields, "ACCP" and "REGID" after the SSN. Any acceptable antigens (kidney donor mismatched antigens) stored for candidates will print next to "ACCP A: ... B:... DR:...". The "REGID" is the candidate unique registration ID. It has been added for future use.

Below is an example of a pancreas match results print out.

ENTER PRINT OPERATION (U FOR MENU):

DATE: 10-APR-96 TIME: 09:15 EASTERN

UNOS PANCREAS MATCH RESULTS

BASED ON MNOP DONOR:

RUN NUMBER: 2

DONOR ID	UI	DONOR NAME	AGE	SR	BG	A1	A2	B1	B2	DR	DR	AVAIL	ORGANS	KS
JDJ085	MC O	1 32 8	0	Y	MC O	1	32	8	60	4	PA			

BR	DI	CHEST	DONOR
(MM)	(CM)	HCV	
100L	N		N

O ABRD MISMATCH OPO

OR	NAME	CNTR	BG	T	A	MIN	MAX	ENTRY	DATE	A1A2B1B2DRDR	ABR	TELENUM	Y	GT	P
PA	WILLIAMS MAR	MNUM O	2		0	999	8	295	132 860 3 4 000	800 247 4273	Y	Y			
		SSN:530268192								REGID:1207699	ACCP A: 1	A:32 B: 8 B:60 DR: 3 DR: 4 RC: _____			
PA	PITTI EDNA	MNUM A	2		0	999	112995	24321362	3 7 000	800 247 4273	Y	Y			
		SSN:027383814								REGID:1252161	ACCP A: 1	A:31 B: 8 B:60 DR: 3 DR: 4 RC: _____			