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OPTN/UNOS POLICY OVERSIGHT COMMITTEE
SUMMARY

I. Action Items for Board Consideration:

- None.

II. Other Significant Items:

link

- The Committee reviewed ten proposals that were circulated for public comment in February 2008, and made recommendations for the sponsoring committees to consider as the proposals are finalized (Item 2, Page 3).

link

- The Committee received an update on the new national kidney allocation system (Item 3, Page 6).

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- The Committee reiterated its support for the kidney paired donation proposal (Item 4, Page 9).

link

- The Committee reviewed recent and current projects of the Liver and Intestinal Organ Transplantation Committee that may address geographic variations (Item 5, Page 9).

link

- The Committee discussed the proposal for rewriting OPTN/UNOS policies (Item 6, Page 10).

link

- The Committee discussed its role in the review of alternative allocation systems (Item 7, Page 11).

link

- The Committee will investigate the appropriate pathways for policy proposals that have not fit into the current policy and bylaw paradigm (Item 8, Page 11).

link

- The Committee's Annual Data Review will be conducted in July 2008. (Item 9, Page 12).

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- The Living Donor Data Task Force has met via teleconference to discuss the purposes for which living donation-related data are needed and to recommend appropriate approaches for obtaining and/or reporting data for each purpose (Item 10, Page 12).

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REPORT OF THE POLICY OVERSIGHT COMMITTEE

TO THE BOARD OF DIRECTORS

Richmond, Virginia

June 19-20 2008

Janis M. Orlowski, M.D., Chair

1. Review of Committee Actions, December 2005 – present. Janis Orlowski, MD, Committee chair, noted that the meeting materials included a summary of the Committee's actions over the last two and a half years, including completing the data reduction project and review of all existing policies (**Exhibit A**).

2. Review of Proposals Circulated For Public Comment. The Committee discussed the ten proposals that were circulated for public comment in February 2008. Because the Committee had conducted an initial review of these proposals in January 2008, each policy was assigned to one reviewer, rather than two. Reviewers were asked to use the following questions as guidance:

   - Are the policy goals objective and measurable?
   - Do the goals further the mission, strategic plan and long term goals of the OPTN and HHS program performance goals?
   - Are the goals are scientifically based?

   A. Proposal to Limit Mandatory Sharing of Zero Antigen Mismatch (0ABDRmm) Kidneys to Children and Sensitized Adult Candidates. Mary Kelleher, B.S., M.S., reviewed this proposal from the Kidney Transplantation Committee. The goals of the proposal are to reduce payback debts, shorten cold ischemic times for kidneys, and improve the efficiency of the OPTN kidney allocation system. Dixon Kaufman, MD, provided additional data to the Committee (**Exhibit B**) that highlight the impact of the current policy on access to transplant. These data suggest that eliminating mandatory 0ABRDmm shares at the national level for unsensitized adults should reduce ethnic barriers to transplant candidates, as unsensitized white candidates receive proportionately many more national 0ABDR kidneys than African Americans. This change should also improve pediatric access to kidneys. Thus, the policy change would be a "step in the right direction" towards more equitable organ allocation. Keeping the current policy could be seen as retaining these variations in minority access. Ken Andreoni, MD, cited an SRTR study that concluded that the increase in graft survival from national 0ABDRmmtransplants is offset by the reduced survival benefit of payback kidneys.

   The Committee discussed the formulation of the proposal, and asked whether its members and the Kidney Committee did a thorough job of assembling all the evidence that would support the proposal. Public commenters expressed strong opinions that could have been mitigated with the inclusion of additional analyses. The data may have been so well known to the Kidney Committee that members assumed that it was common knowledge, and therefore was not included in the proposal. The Committee can provide support for policy development by helping to identify and strengthen the evidence basis for proposals.

   The Committee remained in support of the proposal, but recommended that the proposal be revised to include additional supporting evidence. The perception that the primary goal of the

policy is to eliminate paybacks needs to be corrected, with the stated goals of (1) improving net benefit to patients and (2) correcting inequities caused by the current system. Members opined that the current policy would not be acceptable by today's standards. The question that needs to be answered is: Is there continued benefit to the current system of national sharing of 0ABDRmm kidneys to all candidates regardless of sensitization?

B. Proposal to Allow an Additional Method for Waiting Time Reinstatement for Pancreas Recipients. The Committee has reviewed this several times since October 2007. All public comments received were in support of the proposal. The Committee maintained its support of the proposal.

C. Proposal to Change the Bylaws to Require Written Notification (or Disclosures) to Living Donors from the Recipient Transplant Programs. W. Kenneth Washburn, M.D. reviewed this proposal from the Living Donor Committee, which would require that recipient transplant programs must provide written notification to living organ donors within ten business days following their donation date to include:

- The telephone number that is available for living donors to report concerns or grievances through the OPTN;
- Disclosure that the recipient transplant center is required to submit Living Donor Followup (LDF) forms to the OPTN for a minimum of two years; and
- The plan for obtaining living donor data for completion of follow-up forms.

The Committee reiterated its previous comments that the notification should be provided to potential living donors earlier in the process, perhaps when consent for evaluation is obtained. This is consistent with many individual and regional comments on the proposal. This would also be consistent with the requirement that that transplant candidates must be notified within ten business days of the patient's being placed on the waiting list (i.e., pre- rather than post-transplant). The information could be provided after donation as well. The Committee also suggested that the notifications procedure and contact information should be placed on the OPTN and UNOS websites.

D. Proposal to the Change the Bylaws to Include Restoration of Membership Privileges Following an Adverse Action. Cedric Sheffield, M.D., reviewed this proposal from the Membership and Professional Standards Committee (MPSC). Committee members expressed concern about the use of the word 'may' in: "the MPSC may consider requests during its regularly scheduled meetings." The questions raised are: Can the MPSC refuse a center's request for review after 12 months? Is the burden on the center to make sure the process is moving along? Is there a limit to how long this process can linger on beyond 12 months? UNOS staff explained that the intent was that the process cannot begin earlier than 12 months, after substantial demonstration of compliance with the corrective action plan. Committee members asked whether there any circumstances under which a plan of action may not require 12 months. In general, Committee members felt that the policy language is confusing.

Due to the nature of the proposal, goals and metrics are not easy to define. UNOS staff will develop a list of review questions that will be more applicable to the development of Bylaw proposals.

E. Proposal to Change the Elector System for Histocompatibility Lab Members and Medical/Scientific Members. Dr. Orlowski reviewed this proposal from the MPSC, which will

permit each histocompatibility laboratory and each medical/scientific member a single vote in OPTN/UNOS affairs and removes the need for separate national elections for both the histocompatibility member and medical/scientific member electors. This proposal simplifies a complicated system. The Committee was generally in support if the proposal, but would like to know the total number of electors and the percentage change in voting members this proposal would bring about.

F. Proposal to Change Organ Time Limits to Organ Offer Limits for Zero Antigen Mismatched (0ABDRmm) Kidneys, Pancreata, and Kidney/Pancreas Combinations. Jeff Orlowski, MS, CPTC, reviewed this proposal from the Operations Committee. The proposal would allow OPOs to make 0ABDRmm organ offers through DonorNet® rather than requiring that they be placed by the Organ Center. The intent is to have a process that can be applied consistently across OPOs and can be monitored by UNOS staff. The primary metrics identified to assess the policy include: the number of 0ABDRmmorgans offered, placed, and transplanted; the number of match runs required to place 0ABDRmmorgans; the cold time of 0ABDRmmorgans of the Organ Center vs. through DonorNet®; the placement time of 0ABDRmmorgans; number of 0ABDRmmorgans placed through the Organ Center vs. through DonorNet®. The policy is clearly worded. Mr. Orlowski commented that the system should be programmed to stop making offers at the required level (10 offers) and prompt the OPO personnel as to whether they want to continue. Otherwise the system is capable of moving quickly through 10 offers and putting the OPO in the position of inadvertently sharing a kidney when they will not receive a payback. If paybacks are reduced or eliminated, then this will not be an issue.

Mr. Orlowski also commented that sections of the policy that still involve time (e.g., "OPOs must offer kidneys within 8 hours of procurement") must be more clearly delineated from what must now happen based on the number of offers. Finally, he noted that the DonorNet® system records which individuals ran the match (based upon the login), which OPO offered the organ, and which center accepted the organ, with the exact times for each. Thus, it is unnecessary to require that the OPO fill out a "Kidney Payback Accounting Sheet" or risk losing their payback. The transplant centers know when they accept a 0ABDRmm kidney that it incurs a payback; the system should automatically log the payback as soon as the kidney has been accepted. The policy must be modified to require the DonorNet® system to do the accounting or there will be no incentive for the OPO to place through DonorNet® when using the Organ Center allows the debt to be automatically recorded.

G. Proposal to Require Transplant Centers to Inform Potential Recipients About Known High Risk Donor Behavior. Dr. Kaufman reviewed this proposal from the Executive Committee. The policy was approved by the Executive Committee in December 2007, prior to public comment, in order to address potential patient safety issues after reports that several transplant recipients contracted HIV from a donor. The policy requires transplant centers to inform potential organ recipients about any known high risk behavior by the donor. In the cases reported, there was no documentation that the recipients were aware of the high-risk status of the donor. This proposal also brings OPTN/UNOS policy in line with the CMS Conditions of Participation.

Dr. Kaufman noted that some aspects will require decision-making outside OPTN/UNOS purview. For example the policy states that "All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV)." However, OPOs prefer to use nucleic acid testing, which is not approved by the FDA. Committee members also expressed concerns that the criteria for high risk are not detailed enough (e.g., "Inmates of correctional systems" and "hemodilution") and may be outdated. Dr. Orlowski recommended that the policy include a reference to the CDC guidelines

rather than incorporating them into the policy, because if the CDC makes changes, then the policy will be out of date. Other Committee members felt that the policy title is too wordy, and could perhaps be shortened to "Reporting of Potential Recipient Diseases or Medical Conditions."

H. Proposal to Change How 0-10 Year-Old Donor Livers and Combined Liver-Intestines are Allocated. Maryl Johnson, M.D., reviewed this proposal from the Pediatric and Liver and Intestinal Organ Transplantation Committees. The policy's goals and metrics were stated in the proposal, and the policy is clearly worded. She commented that those policies related to allocation of livers, intestines, and liver-intestines should note up front which policies must be followed for each type of allocation. The Committee was supportive of the proposal.

I. Proposal to Change Allocation of Pediatric Lungs and Allow Creation of a Stratified Allocation System for 0-11 Year Old Candidates. Simon Horslen, M.D., reviewed this proposal from the Pediatric and Thoracic Organ Transplantation Committees. The policy's goals and metrics were stated in the proposal. The policy is well-worded, well-organized and meets several of the objectives of the Final Rule. No modeling was used in the development, but the Committee reviewed much data during the policy development process. The proposal would impact a very small number of candidates. The Committee was supportive of the proposal.

J. Proposal to Allocate Pediatric Donor Hearts More Broadly. James Wynn, MD, reviewed this proposal from the Pediatric and Thoracic Organ Transplantation Committees. Dr. Wynn noted that the proposal would:

- Allocate pediatric and adolescent donor hearts to candidates under the age of 18 preferentially;
- Allocate pediatric and adolescent donor hearts to sicker candidates across a large geographic area (local plus zone A); and
- Consolidate the allocation of all hearts from donors less than 18 into a single algorithm.

The intent of the proposal is to reduce pediatric waiting list deaths. As with the previous proposal, this change would involve a small number of candidates. The primary metrics identified to assess the policy are death rates among various candidate groups and utilization of hearts from donors less than 11 years of age. Committee members noted that "pediatric" and "adolescent" are defined differently across allocation policies. Dr. Wynn asked why a pediatric organ donor is defined as an individual who is 0-17 years of age, and noted that changing the definition to 'an individual who is less than 18 years of age' would be more precise. The Committee was supportive of the proposal.

3. New National Kidney Allocation System. The Committee received an update on the development of a new kidney allocation system. Dr. Andreoni reported that the HHS Office for Civil Rights (OCR) has not determined whether the inclusion of age in the LYFT score calculation constitutes age discrimination under the Age Discrimination Act of 1975. Age is currently a strong indicator of outcome after transplant. Christopher McLaughlin, OPTN Project Officer, reported that HRSA is working with the OCR to answer their questions.

The Committee discussed comments and questions submitted by the American Society of Transplant Surgeons (ASTS), the Patient Affairs Committee, and OPTN/UNOS Board Members. Dr Andreoni stated that some of the comments indicate that there is confusion about terminology, such as life years following transplant (LYFT), the donor profile index (DPI), the kidney allocation score (KAS), and how each relate to create the new allocation system. One recurrent question was how the proposed

policy compares to the current policy. To address this question, Alan Leichtman, MD, SRTR representative, described the current kidney allocation system and the simulations of the proposed system in terms of medical criteria, waiting time, PRA, and donor quality. Both are similar in that they each use these factors, but in different ways.

Dr. Leichtman provided an example of a hypothetical average 30-year old candidate, whose remaining life might be 18 years with a deceased donor kidney transplant or 12 years with dialysis. In this case, the LYFT will be 6, equal to the extra years of life with transplant. This hypothetical candidate's LYFT would be higher if his or her expected survival on dialysis is shorter than 12 years or if the post-transplant is expected to be longer than 18 years. Robert Wolfe, PhD, with the SRTR, explained the difference between the DPI and the donor risk index (DRI). Both rank donor organs from least ideal to most ideal. However, DPI tells you what percentage of organs are less ideal than the organ being offered (0.2 means 20% of organs are worse). The DRI tells you how much better or worse the organs are when compared to each other. The DPI is scaled so that the donors are ranked on a scale of longevity from 0 to 1.

One recurrent theme of the questions related to the potential impact of LYFT on recipient age at transplant. Dr. Leichtman presented several graphs that demonstrate that there is a great deal of overlap in the KAS in patients of different ages. Figure 1 demonstrates that overlap exists for organs with different DPIs. Figure 2 shows, that, for an organ with a DPI of 0.3 (better than average), there is more of a trend in KAS with age, although the overlap between adjacent decades remains large. For an organ with a DPI of 0.7 (worse than average), the distribution is fairly uniform.

Figure 1

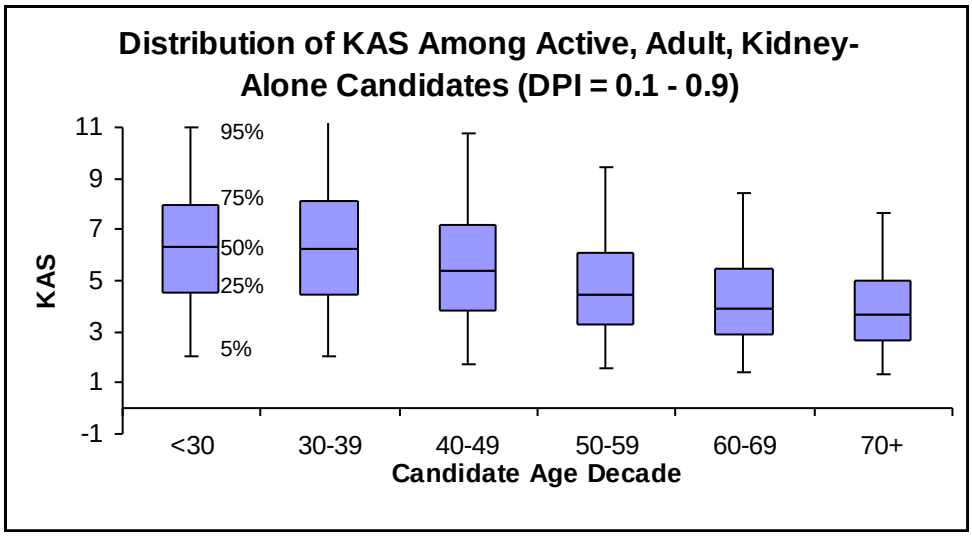
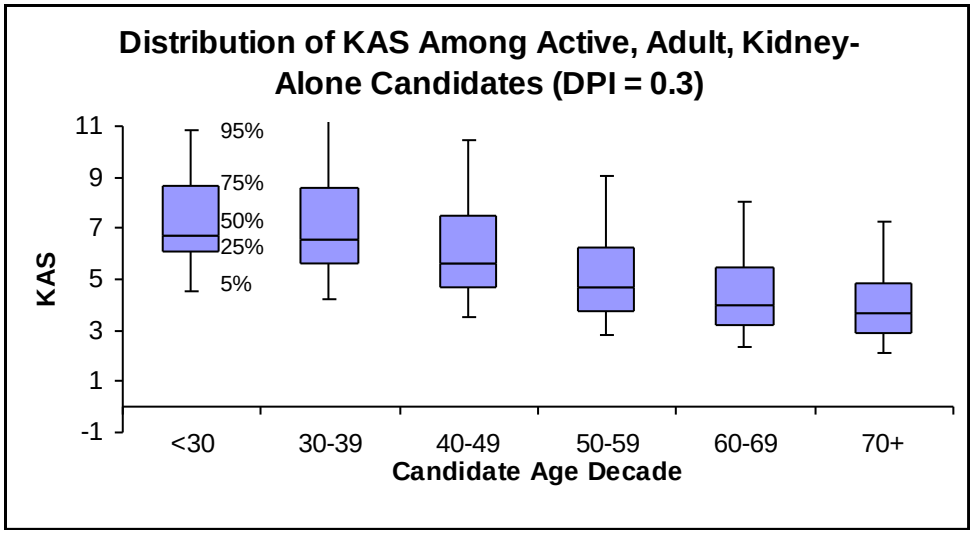


Figure 2



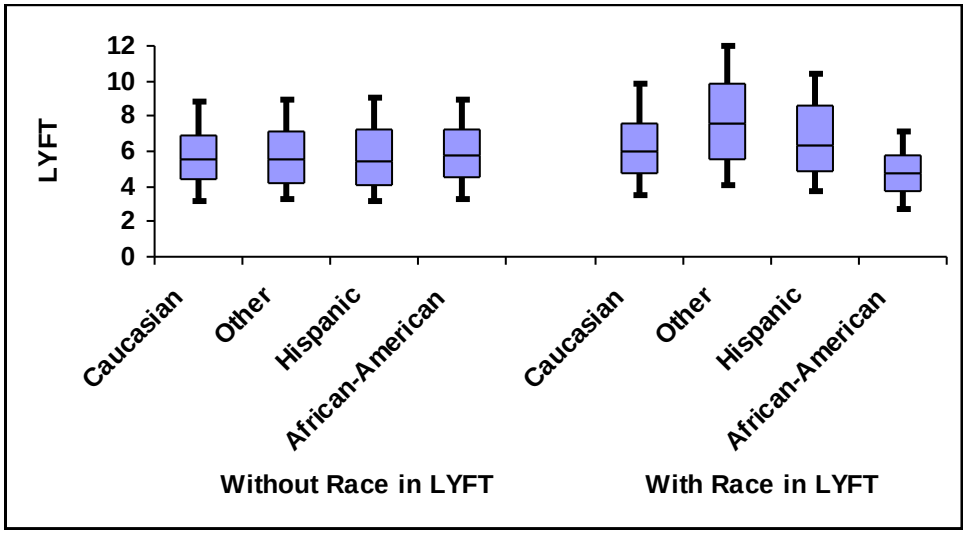
Questions also centered on the "predictability" of the proposed system, and whether patients will understand when they might expect to get an offer. The SRTR is developing tools that could be used to inform candidates on their expected waiting times based on candidate blood type and donor service area, for organs of varying DPIs. The Committee asked whether this information might alter candidate behavior. For example, candidates who expect to have a short waiting time for a good organ might choose not to seek a living donor. The Kidney Transplantation Committee (Kidney Committee) discussed this, and chose to cap the LYFT score's contribution to the KAS formula to 80%. The Committee acknowledged that a great deal of education will be required so that patients and their families will understand the implications of the DPI and LYFT so they can make the best decision for their individual situation. The consent process will have to include a conversation about choosing an appropriate/acceptable range of DPI scores for the candidate.

The questions demonstrated a range of feelings about the role of utility in the KAS, with commenters arguing that it is emphasized either too much or too little. Dr. Leichtman responded that the KAS is intended to achieve a variety of goals. The SRTR simulations suggest that, compared to the current system, the proposed system will lead to more aggregate years of life, as well as improved access for minorities, sensitized candidates and Blood Type B candidates. The system that was projected to increase life years the most might not accomplish these other goals, and therefore the Kidney Committee chose a system that would balance these issues of utility and equity. Some options that were modeled actually provided worse outcomes than the current system.

The ASTS asked about the exclusion of race from the LYFT calculation. Dr. Leichtman stated that the SRTR was instructed by the Kidney Committee to consider variables in the LYFT calculation that a) were collected by the OPTN; b) objective and measureable; and c) have statistical and clinical relevance. Completeness and validity of the data elements were considered. The Kidney Committee felt that self-reported race was not measurable or objective, so there was little discussion about race. Dr. Leichtman felt that there is a lot of confusion about what the Kidney Committee actually discussed. He stated that there is no difference in patient survival post-transplant for African

Americans. The SRTR provided the distribution of LYFT scores by race, with and without race in the model, shown in Figure 3.

Figure 3



The Kidney Committee's proposed metrics for assessing the policy were provided in the draft public comment proposal. Data will be evaluated every 6 months, and the first round of data will be provided as soon as sufficient time has elapsed after policy implementation. Committee members suggested that the Kidney Committee develop educational materials for patients, similar to what was done for LAS and MELD. The Committee remains comfortable endorsing proposal.

4. Kidney Paired Donation (KPD). In October 2006, the Committee agreed by unanimous vote that the Board should approve the concept of a national live donor paired kidney exchange program. The Committee reviewed the main components of the proposal again in April 2008. The Kidney Committee plans to send the public comment proposal that was circulated in 2006 to the Board in June 2008, with the following revisions:
   - To include three-way matching as well as two-way matching; and
   - To allow donor and candidate preferences (travel, age, etc) to screen out potential matches.

   Additional elements (e.g., altruistic donor chains) will be circulated for public comment separately. The Kidney Committee will partner with Living Donor, Patient Affairs and Ethics Committees to address patient/donor safety in the KPD system. The Committee maintained its support of the paired donation proposal.

5. Geography Study. In June 2006, the Board approved the following resolution from the Committee:

   ** *RESOLVED, that the OPTN undertake a study to address geographic variations in organ allocation*.

   During the January 2008 meeting, the Committee agreed to begin by reviewing the goals and metrics identified by the organ-specific Committees (and approved by Board) in 2004. The Committee thought that it would make sense to begin its work with the Liver and Intestinal Organ

Transplantation Committee (Liver Committee), which had already formed a subcommittee on broader sharing.

UNOS staff members identified nine recent and current projects of the Liver Committee that may address geographic variations. This inventory will allow the Committees to assess what further work should be undertaken. Dr. Washburn reviewed these initiatives of the Liver Committee related to geography (**Exhibit C**):

- Investigating sharing for MELD/PELD scores >29 regionally
- Investigating sharing for all MELD /PELD scores regionally (eliminate local allocation)
- Investigating the applicability of net survival benefit to liver allocation
- Review of Waiting List Mortality for Status 1A/1B by DSA, Region, and population density
- Proposal for a National Review Board (NRB)
- Definitions for up to 7 (more) standardized MELD/PELD exception diagnoses
- Fall 2008 HCC Consensus Conference
- Changes in priority for Liver-Intestine Candidates
- Recommendations for national sharing of pediatric donors for pediatric status 1A recipients

Each of these has been linked to the Liver Committee's goals and metrics. The first two projects are aimed at reducing post-transplant mortality. The Liver Committee felt that the threshold of MELD/PELD 29, currently used in Region 8, is arbitrary, and therefore has asked the SRTR to model allocation of livers regionally using the current MELD/PELD threshold of 15. The Liver Committee has been looking into the use of net benefit for liver allocation for a year and a half, with the intent to optimize the use of deceased donor livers. Separate analyses provided to the Liver Committee have demonstrated much higher mortality for Status 1A/1B candidates in some regions than in others. The Liver Committee has asked for simulation modeling using alternative distribution units (e.g., concentric circles, population density). Several of the proposals are aimed at reducing regional variations in the MELD/PELD exceptions. Finally, the last two proposals are intended to improve access for combined liver-intestine and pediatric candidates.

One Committee member asked why the Liver Committee is still focusing on regions as the unit of allocation, as they are arbitrary geographic boundaries. Dr. Washburn noted that regional allocation is the next logical step beyond the OPO, although the Liver Committee may investigate the use of concentric circles or population-based distribution units. This progression can be seen as "evolution versus revolution" in terms of redrawing traditional distribution boundaries.

6. Proposal for Rewriting OPTN/UNOS Policies. The Committee has completed its review of existing polices and made recommendations for revisions. UNOS Policy Analysts have proposed an approach to begin rewriting all OPTN/UNOS policies. The primary goals of this project are to:
    - Ensure that the intent of each policy is clearly articulated;
    - Ensure that all polices are easy to understand, and that requirements for compliance are clear; and
    - Create a unified structure and format for OPTN policies.

The new format will include key elements, such as a statement of purpose, potential metrics for assessment, policies for listing and removing candidates, policies for management of candidates while on the waiting list, all donor information necessary for organ allocation, and the sequence for organ allocation. Other proposed new features include a table of contents, an index/cross-reference, a glossary of terms, and flow charts/diagrams of allocation sequence. A set of rules will be developed to promote ongoing consistency as policies are revised in the future. Committee members asked if the policies could include the history of the policy and what the committee intended the policy to accomplish.

The proposed path forward is to begin rewriting the kidney allocation policies; this will test the template for the new policy structure. The policies for liver allocation and the transplantation of non-resident aliens will be revised next, in parallel.

7. Review of Alternative Allocation Systems (AAS). The Committee chairs received a memorandum from Timothy Pruett, MD, OPTN/UNOS President, stating that all AASs will be undergoing review by the Committees and Board. All areas with an AAS must complete and submit a brief application for the AAS to continue. The memorandum noted that "Due to the impending kidney allocation system, at this time, sponsors of a kidney AAS or kidney/pancreas AAS, do not need to submit this new application." The proposed process complies with requirements of the OPTN Final Rule, which states that an AAS must be time-limited and follow a research design. Each member with an AAS has been sent a customized CD that will allow them to complete the application more easily. Edward Garrity, MD, incoming Chair, noted that the Thoracic Organ Transplantation Committee reviewed all thoracic AASs over the last few years, and only three remain. Two are related to geographic anomalies. However, these may not have stated goals or a time frame. It was noted that most of the liver AASs involve broader sharing of organs, and do not have stated time limits. The OPTN may need to develop a mechanism for incorporating these into policy. Alternatively, since 7 of 11 Regions have an AAS for broader sharing for livers, perhaps the national policy could be modified to incorporate Regional sharing.

8. Definitions and Mechanisms for "Non-policies." During the last years, the Committee has reviewed several policy proposals that have not fit into the current policy and bylaw paradigm, such as the Organ Availability Committee's proposal to promote renal perfusion and the Living Donor Committee's Consent and Medical Evaluation Resource Documents. The Committee has stated that these types of guidelines or recommendations, which are not enforceable, should not be approved as "policy." UNOS Policy staff has recommended that the OPTN develop new pathways and mechanisms to accommodate areas of innovation in transplantation that do not fit into policy or bylaws.

   Many Committee members felt that the OPTN should not be developing these types of guidelines, which are the purview of the professional societies. However, in some cases the transplant community may identify a need (e.g., living donor consent guidelines), and may ask committees to "fill the void." UNOS has put a process in place to evaluate proposals early in the development process, to identify whether they are within the OPTN/UNOS purview, and whether other committees and/or the professional societies should be involved. The Committee can also play a role in initiating

discussions with the societies. Mr. McLaughlin suggested that the Committee should identify what criteria must be met for a proposal to become policy, versus a guideline or resource document, and that these criteria should be included in the Bylaws.

9. Annual Data Review. Ann Harper, Committee liaison, has been creating an inventory of potential committee requests for new data elements. The ongoing Committee review of the SRTR's methodology for its center-specific report may also result in requests for new data elements. All requests for new data elements must meet at least one of the Principles of Data Collection (PODC), as approved by the Board in December 2006. During the July 2008 meeting, the SRTR will report on its findings regarding the collection of malignancy data. Dr. Orlowski asked that UNOS staff assess the effect of data reduction, to determine if any data elements that were removed are included in the inventory of requested data elements.

10. Living Donor Data Task Force (LDDTF). Robin Pierson, MD, informed the Committee that the LDDTF had met several times via conference call. The calls have focused on the group's charge, the completeness of OPTN data about living donors, and other sources of living donor data (**Exhibit D**). The LDDTF's charge is to "To identify the purposes for which living donation-related data are needed and to recommend appropriate approaches for obtaining and/or reporting data for each purpose." The LDDTF is reviewing other living donor data collection efforts, such as the New York Center for Liver Transplantation, the Living Organ Donor Network, and the NIH-sponsored A2ALL the RELIVE studies.

Policy Oversight Committee		**Meeting Date: 04/15/2008**
NAME	**POSITION**	
Janis Orlowski, M.D.	Chair	X
Ray Gabel	At Large	
Simon Horslen, M.D.	At Large	X
Maryl Johnson, M.D.	At Large	X
Dixon Kaufman, M.D., Ph.D.	At Large	X
Mary Kelleher, B.S., M.S.	At Large	X
Felicia LeClere, Ph.D.	At Large	
Jeffrey Orlowski, M.S., C.P.T.C.	At Large	X
Richard Pierson, III, M.D.	At Large	By telephone
Henry Randall, M.D.	At Large	X
Cedric Sheffield, M.D.	At Large	X
Judy Jones Tisdale, Ph.D.	At Large	
W. Kenneth Washburn, M.D.	At Large	X
James Wynn, M.D.	At Large	X
Monica Lin, Ph.D.	Ex Officio, non Voting	By telephone
Christopher McLaughlin	Ex Officio, non Voting	By telephone
Robert Merion, M.D.	Ex Officio, non Voting	X
Robert Wolfe, Ph.D.	Ex Officio, non Voting	By telephone
Alan Leichtman, M.D.	SRTR Liaison	X
Guests		
Edward R. Garrity, MD	Incoming Chair	X
UNOS Staff		
Ann Harper	Policy Analyst/Committee Liaison	X
Erick Edwards Ph.D.	Assistant Director, Research	X
Mary D. Ellison, Ph.D., M.S.H.A	Assistant Executive Director, Federal Affairs	X
Karl J. McCleary, Ph.D., MPH	Director, Policy, Membership, and Regional Administration, Committee Liaison	X
Ciara Gould, MSPH	Liaison, Kidney Transplantation Committee	By telephone
Elizabeth Sleeman, MHA	Liaison, Pancreas Transplantation Committee	By telephone
Shandie Covington	Liaison, Pediatric Transplantation Committee	By telephone

December 14, 2005 (Inaugural meeting)

- The Committee reviewed its charge as provided for in the OPTN contract, and approved the POC's Charter. To provide further context for the committee's work, HRSA and UNOS staff members presented the following topics:
  - An Overview of the OPTN Final Rule (Walter Graham - UNOS)
  - The Principles and Practice of Modeling for Policy Development in the OPTN (Michael Dries, PharmD, MPH - HRSA)
  - An Overview of HRSA Program Goals and the Model for Improvement. (Ann Harper – UNOS)
  - The Process for Requesting Additional Data and Analyses by the OPTN and SRTR (Erick Edwards, PhD - UNOS)

- The Committee began work on the data reduction project and reviewed:
  1. The OPTN Principles of Data Collection (Erick Edwards, PhD – UNOS)
  2. The Recommendations of the AST/ASTS Task Force and its guiding principles for data (Michael Abecassis, MD – ASTS).

  - The Committee agreed that the timeline for the project would culminate in final recommendations submitted to the Board in June 2006, so that changes to the forms could be incorporated into the 2007 OMB cycle.

- The Committee established a foundation for future work, including the process for reviewing OPTN policies.

February 24, 2006

- Mary D. Ellison, PhD, MSHA, gave an overview of the new OPTN Policy Development Process and Project Development Life Cycle.

- The Committee approved a timeline for review of existing polices and a process for reviewing new policy proposals. Two primary reviewers will be assigned to each proposal as it moves through the development process. The reviewers would identify concerns and brief the Committee about the proposals.

- The Committee endorsed a request by the Pancreas Committee to modify the definition of "transplant" as described in Policy 7.1.1 (Reporting Definitions) to include infusion of islet cells within the definition of organ transplant.

- The Committee received an initial progress report from the Kidney Allocation Review Subcommittee (KARS). After reviewing the concept of NLSB and the initial objectives of the KARS committee, the POC had several requests/ recommendations for the KARS and Kidney Committees:

- Public comment should be brought into the process early; the POC understands that a public forum is planned.
- There is general agreement that the objectives are being met; however, the POC would like to continue to see the details of the proposal as they are developed.
- The POC asked for details of a transition plan from the current policy to the new policy; this would include a strategy for alternative allocation systems and paybacks.

- Janis Orlowski, MD (chair) provided an update to the Committee on the Forms Working Group, which met by teleconference on February 6, 2006 and February 21, 2006. The timeline was revised in order to gather comments from all the stakeholders prior to circulating a proposal for public comment, but the June 2006 deadline for Board submission was retained.

May 10 and June 20, 2006

- Janis Orlowski, MD, (Chair), provided an overview of the Data Reduction Project:
  - Recommendations had been received from HRSA, CMS, USRDS, UNOS, SRTR, ASTS/AST Task Force, and eight OPTN Committees (Kidney Transplantation, Pancreas Transplantation, Liver and Intestinal Organ Transplantation, Thoracic Organ Transplantation, Pediatric Transplantation, Patient Affairs, Minority Affairs, Organ Availability, and Transplant Coordinator Committees).
  - On May 3 and 8, 2006, the POC Data Reduction Working Group met to review all recommendations to date, and to make a proposal to the full Committee. Representatives from all of the OPTN data "stakeholders" (HRSA, USRDS, CMS, OPTN, SRTR, and the ASTS/AST Task Force) were invited to participate in these meetings.
  - A proposal submitted for public comment on May 20, 2006, to run through June 19, 2006.
  - The Committee met on June 20, 2006 to review comments and to make a final recommendation.

- Mary S. Leffell, PhD, Vice-chair of the Histocompatibility Committee, presented a proposal from the Histocompatibility Committee that would replace Panel Reactive Antibody (PRA) with a calculated probability of incompatible donors, based on a candidate's defined unacceptable antigens. The POC was supportive of this concept with the following recommendations:
  - The policy should state that designation of unacceptable antigens is the responsibility of the center.
  - As the concept is being pursued, the Histocompatibility Committee should recognize the complexity of this with respect to policy changes (i.e., policies that cite PRA), capital expenditures, training, etc. and develop a transition plan.

- The Committee received a request from a transplant surgeon to review Policy 3.7.10 (Sequence of Adult Heart Allocation), which was approved by the Board in November 2005 and scheduled for implementation in June 2006. The surgeon had concerns about the policy and the process used to develop it. After hearing from the surgeon, as well opposing viewpoints from the chair and vice-

chair of the Thoracic Committee, Committee members were asked to make a recommendation, and voted unanimously to deny the request to review this policy.

August 16, 2006

- The Committee was provided with the following information/updates:
  - Overview of Committee Charge
  - Orientation to the roles and responsibilities of the SRTR
  - Status of HHS Program Goals for the OPTN
  - Report from the June 2006 Board of Directors Meeting.

- The data reduction proposal was approved by the Board on June 29, 2006. This included a reduction of items on the Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), and Transplant Recipient Follow-up (TRF) forms; a restriction on immunosuppressive data to the first year post-transplant only; and a reduction in the number of post-transplant malignancy data elements.
  - The Board approved a modification to Policy 7.1.3 in June 2006 that would eliminate the requirement to follow patients after their graft has failed.
  - The Board voted that "the OPTN will address within six months what limited elements other than patient and graft survival will be required for follow up after five years."

- The Committee reviewed five proposals that were to be submitted to the Board for approval in September 2006. For each of these proposals, an Executive Summary was provided that described the intent/goals of the proposal, use of analytic or simulation modeling in the development process, and whether the proposal addressed any of the HRSA program goals or OPTN strategic goals. These are shown in Table 1.

- The Committee discussed the path forward for review of existing OPTN/UNOS policies, with the liver allocation policy to be the first to undergo review.

October 16, 2006 meeting and November 3, 2006 call

- The Committee was provided with the following information/updates:
  - Status of HHS Program Goals for the OPTN
  - President's Report: Strategic Plan

- The Committee reviewed twenty-one proposals during its October 16, 2006 meeting and November 3, 2006 conference call. These are shown in Table 2.

- The Committee made recommendations for data elements to be retained after 5 years post-transplant. The proposal was circulated for public comment in November 2006. The Committee continued work Policy 7.1.3 (Reporting Definitions), which defines the length of post-transplant follow-up.

- The Committee received an update on proposed changes to the kidney allocation policy. The POC will have topical discussions at upcoming meetings to discuss proposed transition plans, the ongoing ethical deliberations, and other areas of debate.

- The Committee reviewed a presentation that had been provided to the Minority Affairs Committee (MAC) on July 26, 2004 that outlined both the OPTN and federal public comment processes. One of the MAC's goals for the year was to collaborate with the POC to improve the public comment process. Committee members were asked to work with staff and the MAC to continue studying this process.

January 24, 2007 Meeting

- The POC formalized the recommendation that a limited set of data elements shall be required for validation of the Transplant Recipient Follow-up (TRF) form after 5 years post-transplant. This proposal was circulated for public comment in November 2006 and was widely supported.

- The POC unanimously supported changes to the data collection forms proposed by the Pediatric Committee, but asked for a recommendation for length of follow-up for pediatric transplant recipients.

- The Committee reviewed the SRTR's preliminary analysis of ascertainment of patient death following graft failure, which is related to the modification to Policy 7.1.3 that would eliminate the requirement to follow patients after their graft has failed.

- The Committee reviewed three policy proposals. These are shown in Table 3.

- The Committee began its review of Policy 3.6 (Allocation of Livers).

- The Scorecard subcommittee presented its initial proposals for a policy development scorecard.

- The Committee voted unanimously to recommend that the "Policy Tracker," which includes a summary of the POC's recommendations, should be circulated for all members to sign on a semiannual basis.

May 17, 2007 Meeting

- The Committee was apprised that Board approved the POC's proposal for follow-up after 5 years post transplant in March 2007.

- The Committee reviewed six proposals that involved data collection, and made recommendations with input from the Ad Hoc Data Management Group. These are shown in Table 4.

- The Committee concluded its review of Policy 3.6 (Allocation of Livers) as well as Policy 3.11 (Intestinal Organ Allocation).

- The Committee asked that a joint OPTN Committee be established to evaluate the use of living donor data.

- The Committee asked that the OPTN undertake a study to address geographic variations in organ allocation.

- In March 2007, the Board approved a resolution that, that until the Board reconsiders policies regarding reallocating organs when a DCD donor progresses to brain death, the Board will not consider reallocation to be a violation of OPTN policy. The POC again expressed its support of a policy that clarifies what should occur when a DCD converts to brain death, and made the following observations for the TCC to consider the following:

  - Some DCD donors can be expected due to their clinical course to deteriorate to brain death. That situation presents the opportunity for more organs to be procured. The POC advises that OPOs utilize that period of time to see if the donor makes the transition from DCD to brain death. This may also allow for allocation to more urgent patients
  - There should be a definite point when the list cannot be re-run. For some OPOs, it may be the recovery team going out, but for others that may not be an "event," so this may require a specific time frame related to the operating room.
  - The policy should also include a statement of purpose, such as to increase number of organs available per donor and/or to allocate organs to more urgent patients.

- The Committee reviewed the SRTR's final analysis of ascertainment of patient death following graft failure, which is related to the modification to Policy 7.1.3 that would eliminate the requirement to follow patients after their graft has failed. The Committee planned to address any necessary changes to the policy language during the July 2007 meeting.

- The Scorecard subcommittee presented its proposal for a policy development scorecard, which the Committee planned to begin using in July.

July 24, 2007 Meeting

- After a review of progress towards the OPTN program goals, the Committee requested "that the HHS Secretary's Advisory Committee on Transplantation (ACOT) review: (1) the current HHS Program Goals for the OPTN for organs transplanted per donor, (2) the data used to establish these goals, and (3) how these goals might be impacted by the standards set by CMS."

- The Committee reviewed six policy proposals. These are shown in Table 5.

- The SRTR presented an inventory of SRTR studies related to geographic differences in access to transplantation.

- The Committee completed its review of Policy 3, Appendix B (Indications for Liver Transplantation in Children). The reviewer, Simon Horslen, MD, felt that Appendix 3B is inaccurate and obsolete. By unanimous vote, the Committee recommended to delete the appendix.

October 16, 2007 meeting and December 5, 2007 Conference Call

- The Committee was provided with the following information/updates:
  - Review of Committee Charge/Goals
  - Update on Prior Committee Recommendations

- The Committee finalized its work on Policy 7.1.3, and unanimously approved the following modification to the policy, which will be submitted to the Board in February 2008:
  7.1.3. Each organ transplant must be followed until graft failure.

- The Committee reviewed several proposals that are being developed by other OPTN committees and have not been circulated for public comment:

  1. The Committee received an update on the development of a new national kidney allocation system. That this proposal is still in the development process.
  2. The Kidney Committee proposed a change to the kidney allocation system that would eliminate mandatory sharing for zero antigen mismatched (0ABDR MM) kidneys except for pediatric and sensitized candidates. The Kidney Committee intends to circulate this for public comment in February, 2008. The POC supported the proposal in concept.
  3. The POC reviewed a memorandum from the Pancreas Committee regarding reinstatement of waiting tome for pancreas recipients with immediate graft thrombosis resulting in non-function, requiring retransplant. With several considerations noted, the Committee was generally in support of the proposal.
  4. The POC reviewed a memorandum from the Pancreas Committee regarding accounting for the pancreas in a multiple organ transplant when the pancreas is procured for technical reasons

only. The Committee felt that cost and accounting issues should be resolved between CMS and HRSA before the Committee could offer its support.

- The Committee began its review of Policy 3.7 (Allocation of Thoracic Organs), and recommended that the OPTN establish a small working group with representation from the Liver-Intestine, Kidney, and Thoracic Committees to undertake review of policies related to multiple organ transplant allocation.

- The Committee discussed the path forward for the geographic variation study.

- The Committee reviewed the SRTR Analysis Plan for developing OPO performance metrics. The task force activity described in the Committee's July 2007 resolution will be put on hold pending this request and further communication with OMB

- The POC met by telephone on December 5, 2007 to discuss the Resource Document for the Medical Evaluation of Living Kidney Donors, distributed for public comment on November 11, 2007. The Committee accepted the proposal in concept, with the following caveats:
  - The language should more clearly outline the intent of the document;
  - Some issues still remain regarding the specific details of the proposal, such as:
    - The implied need for the donor to have disability insurance;
    - The list of viruses that the donor must be screened for (such as HTLV);
    - The blood pressure and metabolic evaluation seems excessive;
    - The proposal still contains details (e.g., ABO blood typing X2) that make it appear to be prescriptive.

January 15, 2008 meeting

- The Committee reviewed 9 proposals that were planned for public comment distribution in February 2007, and provided initial feedback.

- The Committee reviewed 3l proposals that are being developed by other committees but are not yet ready for public comment:

  - Proposal for Allocation of Organs from Non-Directed Living Donors;
  - Proposal for a New National Kidney Allocation System; and
  - Proposed Modification to Policy 3.2.7 (Pancreas Waiting List Criteria).

- The Committee completed its review of Policies 3.7 (Allocation of Thoracic Organs); 3.3 (Organ Distribution: Acceptance Criteria); 3.4 (Organ Distribution: Organ Procurement, Distribution and Allocation); and 6 (Transplantation of Non-Resident Aliens)

- The Committee developed a path forward for its study of geographic variations in organ allocation, and will begin working with the Liver and Intestinal Organ Transplantation Committee.

- The Ad Hoc Data Management Working Group (AHDMWG) reviewed and approved three requests for patient-level data, although one was controversial with two of six members voting against the request.

- The Committee reviewed enhancements to the public comment process that are being introduced in February 2008

Table 1. Summary of Proposals Reviewed by the POC, August 16, 2006

Proposal	Sponsoring Committee	POC: Support?	POC Comments
Proposed Modifications to OPTN/UNOS Policy 3.7.8 (ABO Typing for Heart Allocation)	Pediatric Transplantation	Yes	
Proposed Modification to OPTN/UNOS Policy 3.3.6 (Center Acceptance of Organ Offers)	Transplant Coordinators	No	The TCC is asked to provide an estimate of the number of times that a DCD donor progresses to neurological death, the impacts of the proposal on waiting patients and donor families, and the potential to create disincentives for centers to accept DCD donors.
Proposed Modifications to OPTN/UNOS Policy 3.2.4 (Match System Access)	OPO	Yes	
Proposed Modifications to Policies 7.1.1 and 7.1.2 (Reporting Definitions)	Pancreas	Yes	
Definition of Imminent Death (not final)	OPO	N/A	The POC was generally supportive of the draft definition

Table 2. Summary of Proposals Reviewed by the POC, October 16, 2006

Proposal	Sponsoring Committee	POC: Support?	POC Comments
Policy 3.3.6 (Center Acceptance of Organ Offers)	Transplant Coordinators	No	Collect data and evaluate Timeframe for reallocation
Policy 3.4.1 (Time Limit for Acceptance) and Policy 7.6.1 (Entry and Validation of Offers)	Operations	Yes	- 2 additional metrics - Documentation
Proposal for a National Kidney Paired Donation (KPD) Program	Kidney	Yes	
Proposed Allocation System for Broader Sharing for Livers in Region 8	Liver/ Intestinal	Yes	-Time-limited research design - Specific goals
Policy 3.6.4.2 (Pediatric Candidate Status)	Liver/ Intestinal	Yes	
New Policy 3.11.4.2 (Combined Liver-Intestine Organ from Donors 0-10 Years of Age)	Liver/ Intestinal	Yes	- Clarify policy l - Remove paybacks
Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC))	Liver/ Intestinal	Yes	- Total diameter 9? - Lower boundary - Biopsy issue
Proposed Modifications to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation)	Liver/ Intestinal	Yes	- Track by DSA - Timeframe for review
Policy 3.6.4.1 (Adult Candidate Status) and Policy 3.6.4.2 (Pediatric Candidate Status)	Liver/ Intestinal	Yes	-Clarify language and statement of objectives - Quantitative goals
Bylaw Appendix B Attachment 1, Section VI (Transplant Surgeon and Physician) and Section XII (Transplant Programs)	Liver/ Intestinal	Yes	
Policy 3.7.2 (Geographic Sequence of Thoracic Organ Allocation)	Thoracic	Yes	
Policy 2.2 (Evaluation of Potential Donors)	MPSC	Yes	
Policy 3.6.2.2 (Liver Allocation to Candidates Willing to Accept an Incompatible Blood Type)	Liver	Yes	May prevent offers to less sick children who could benefit
Policy 3.6.4.7 (Combined Liver-Intestine Candidates)			
Policy 3.7.6 (Lung Allocation)	Thoracic	Yes	Monitor on quarterly basis
Policy 3.8.1 (Pancreas Organ Allocation),	Pancreas	Yes	
Policy 3.5.11.3 (Panel Reactive Antibody)	Histocompatibility	Yes	
Recommended Histocompatibility Guidelines	Histocompatibility	Yes	
Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer)	Organ Availability	Yes	
Policy 3.8.2 (Waiting Time Adjustment)	Pancreas	Yes	
Appendix B of the OPTN Bylaws	OPO	Yes	

Table 3. Summary of Proposals Reviewed by the POC, January 24, 2007

Proposal	Sponsoring Committee	POC: Support?	POC Comments
Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer))	Organ Availability	No	The POC strongly recommends that the OAC put forward a proposal to standardize the biopsy technique that does not mandate additional data collection.
Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials	Operations	Yes	The POC requests that that the portion of the policy dealing with interactions between a single operating room suite be stricken or changed.
Policy 3.1 (Organ Distribution: Definitions).	Operations	Yes	The POC requests that the Operations Committee require those in the OR to verify the unique linkage between the donor and the recipient.

Table 4. Summary of Data-Related Proposals Reviewed by the POC, May 17, 2007

Proposal	Sponsoring Committee	POC: Support?	POC Comments
Proposed Modifications to Data Elements for Pediatric Candidates and Recipients on UNet℠ Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) Forms	Pediatric Transplantation	Yes	
Policy 7.1.5 (Reporting Definitions) and OPTN/UNOS Policy 7.3.2 (Submission of Organ Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms)	Living Donor	Yes	
Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data)	Living Donor	Yes	Limit the reporting requirement to two years, the current requirement for living donor follow-up
Modifications to the UNet℠ Living Donor Registration (LDR) and Living Donor Follow-up (LDF) Forms.	Living Donor	Yes	
Proposed Modifications to Data Elements on UNet℠ Deceased Donor Registration (DDR) Form.	Organ Availability	Yes	POC asked that the OAC define for each organ the clinical questions/hypotheses that will be answered using these data and outline a plan for use of the data.
Proposed Imminent Neurological and Eligible Death Definition Data Elements	OPO	Yes	POC requested several modifications

Table 5. Summary of Proposals Reviewed by the POC, July 24, 2007

Proposal	Sponsoring Committee	POC: Support?	POC Comments
Request for Incorporating CPRA into an Existing Alternative System for Kidneys	Histocompatibility	Yes	Supports. POC asks that participants provide criteria for defining unacceptable antigens.
Proposed Modifications to OPTN/UNOS Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer)	Organ Availability	No	Does not support.
Proposed Modifications to OPTN/UNOS Policy 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth (HPDGH), and Reporting of Potential Recipient Diseases or Medical Conditions, including Malignancies, of Donor Origin)	Operations	Yes	Supports, with minor clarifications.
Proposed Modifications to OPTN/UNOS Policy 7.4 (Submission of Organ-Specific Transplant Recipient Follow-up Forms)	Operations	No	Does not support at this time. The Operations Committee is asked to demonstrate: 1. The mechanism by which the data will get to the recipient transplant centers; 2.Whether or not there is science to support the belief that organs from the same donor are likely to cause death or organ failure in other recipients; and 3. Some estimate of compliance rate for the current reporting period of within 2 weeks.
Guidelines for the Medical Evaluation of Living Kidney Donors and Guidelines for the Consent of Living Donors	Living Donor	No	Does not support.

Table 6. Summary of Proposals Reviewed by the POC, October 16, 2007 and December 5, 2007

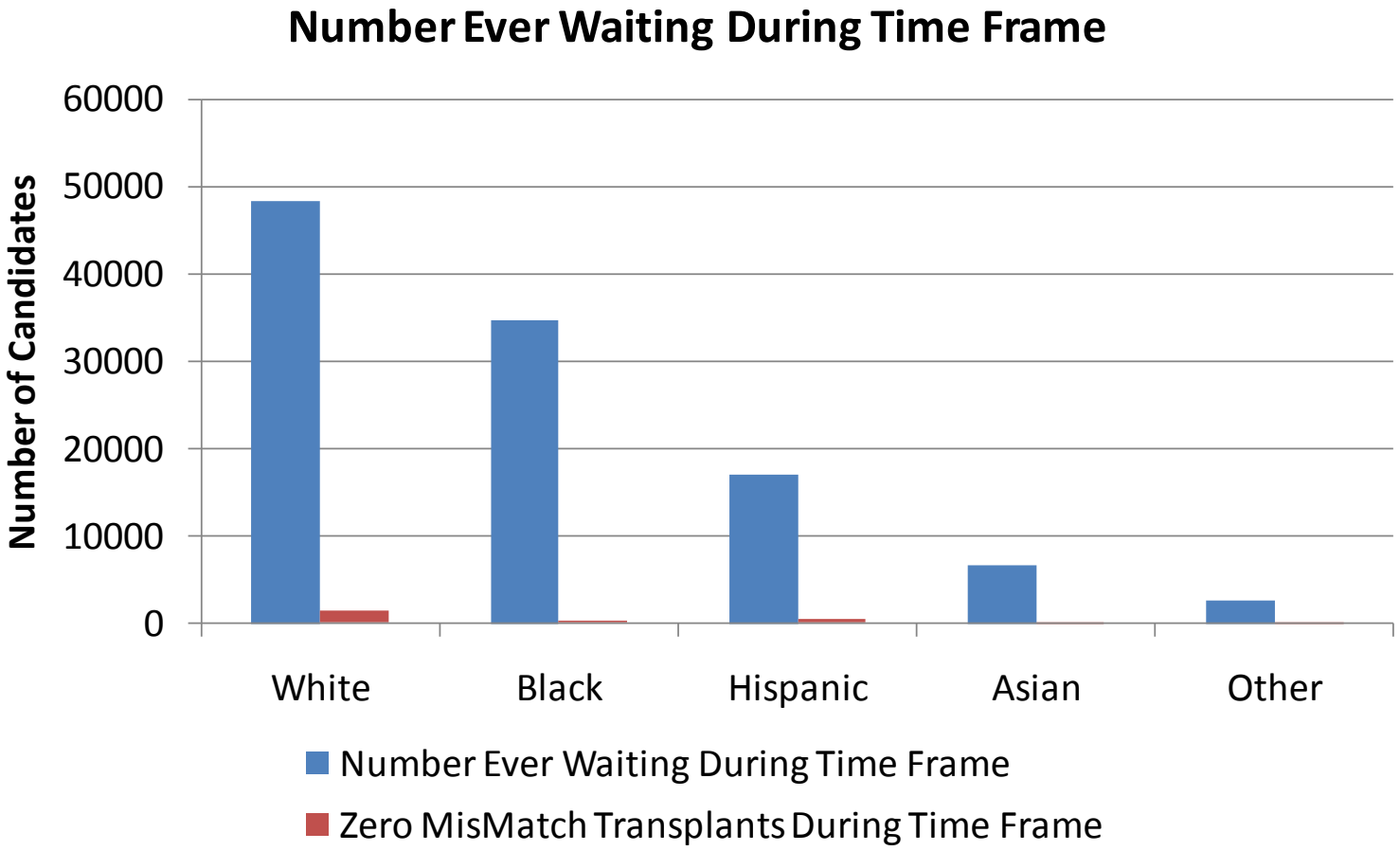
Proposal	Sponsoring Committee	POC: Support?	POC Comments
Bylaws, Appendix B, Transplant Hospitals; Section B. Survival Rates; and Section C "Inactive Membership Status"; and Attachment I, Section II, "Inactive Program Status"; and to the UNOS Bylaws, Attachment I, Section II "Inactive Program Status" and Attachment II, Section XIII, C, (10) "Survival Rates."	MPSC	Yes	POC asked that UNOS counsel review this in terms of the jurisdiction that applies for due process and peer review, which varies from state to state
Resource Document for the Medical Evaluation of Living Kidney Donors	Living Donor	Yes, with caveats	The language should more clearly outline the intent of the document. Some issues remain regarding the specific details of the proposal, such as: - The implied need for the donor to have disability insurance; - The list of viruses that the donor must be screened for (such as HTLV); - The blood pressure and metabolic evaluation seems excessive; and - The proposal still contains details (e.g., ABO blood typing X2) that make it appear to be prescriptive.

Table 7. Summary of Proposals Reviewed by the POC, January 15, 2007 (preliminary review)

Proposal	Sponsoring Committee	POC: Support?	POC Comments
Proposal to Allocate Pediatric Donor Hearts More Broadly	Pediatric/Thoracic	No Vote	POC suggested that the Pediatric Committee provide metrics that would demonstrate whether the proposal meets the goal of decreased pediatric waiting list deaths
Proposal to Change Allocation of Pediatric Lungs and Allow Creation of a Stratified Allocation System for 0-11 Year-Old Candidates	Pediatric/Thoracic	No Vote	POC suggested that the Pediatric Committee provide metrics that can demonstrate whether the proposal meets the goal of decreased pediatric waiting list deaths.
Proposed Changes to How 0-10 Year-Old Donor Livers and Combined Liver-Intestines Are Allocated	Pediatric/Liver and Intestinal	No Vote	Clearly outline the allocation sequence for donors age 0-10, 11-17 and 17 and older
Proposal to Change Organ Time Limits to Organ Offer Limits for Zero Antigen Mismatched (0ABDRmm) Kidneys, Pancreata, and Kidney/Pancreas Combinations	Operations	No Vote	OPOs should be informed that, if they choose to place these offers through DonorNet® rather than through the Organ Center, they risk losing a payback Sections of the policy that still involve time (e.g., OPOs must offer kidneys within 8 hours of procurement) be clearly delineated from what must now happen based on the number of offers.
Proposal to Eliminate Mandatory Sharing of 0ABDR Kidneys for Unsensitized Adult Candidates	Kidney	Yes	
Proposed Modifications to Allow an Additional Method for Waiting Time Reinstatement for Pancreas Recipients	Pancreas	Yes	
Informed Consent for HIV Donors	Operations	No vote	The POC asked that the Operations Committee and Disease Transmission Advisory Group provide some guidance regarding OPO and transplant center responsibility for disclosure to/consent from recipients for non-CDC "high risk" donors.
Modification of Bylaws Appendix-B, Section II, G "Patient Notification	Living Donor	No Vote	Should this be provided potential donors as part of the work-up and consent process, or just prior to surgery, rather than after the donation?
Proposed Changes to the Bylaws to Restore Full Membership Privileges Following an Adverse Action	MPSC	No Vote	

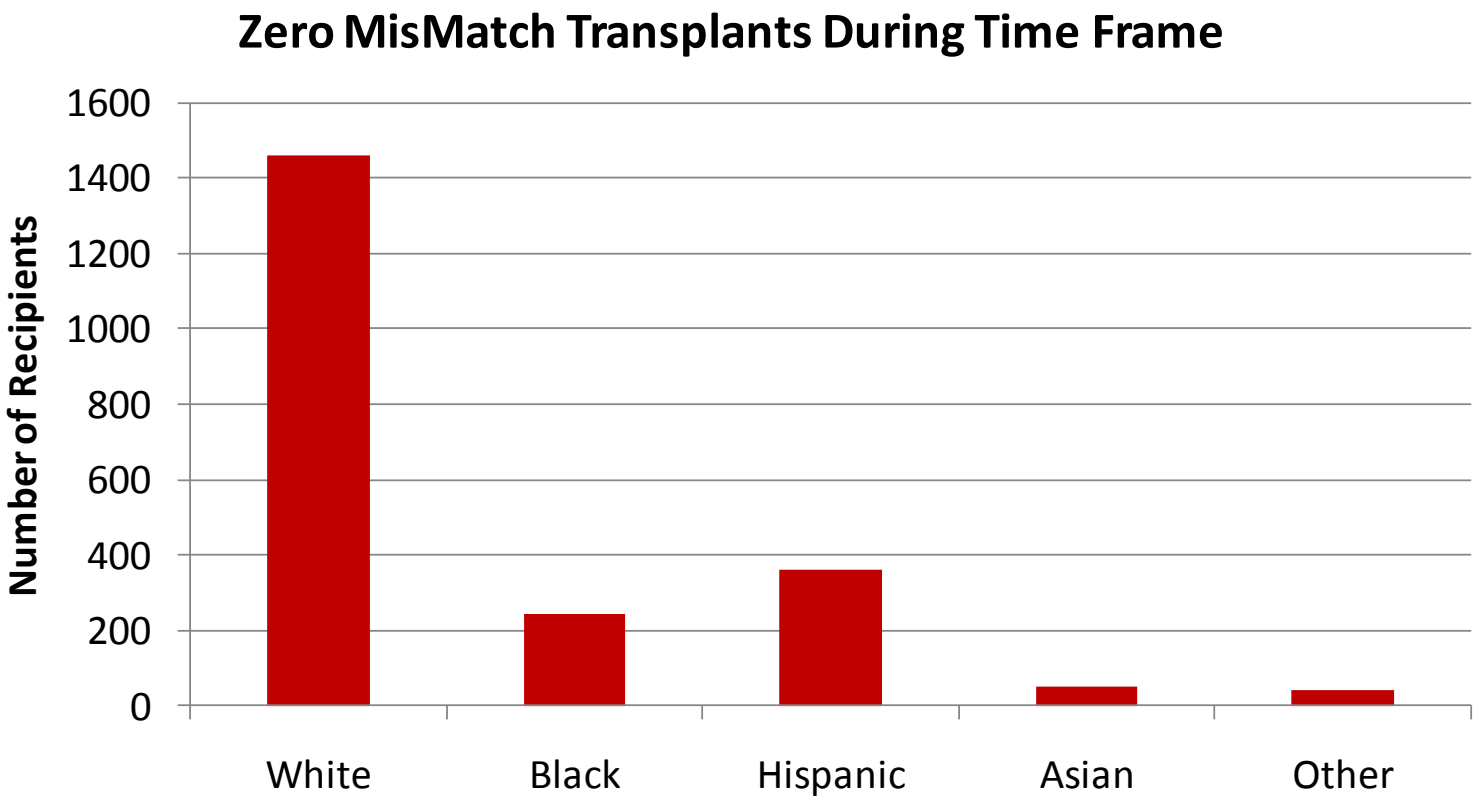
United Network for Organ Sharing
Zero Mismatch Kidney Transplants 1/1/05 - 6/30/06

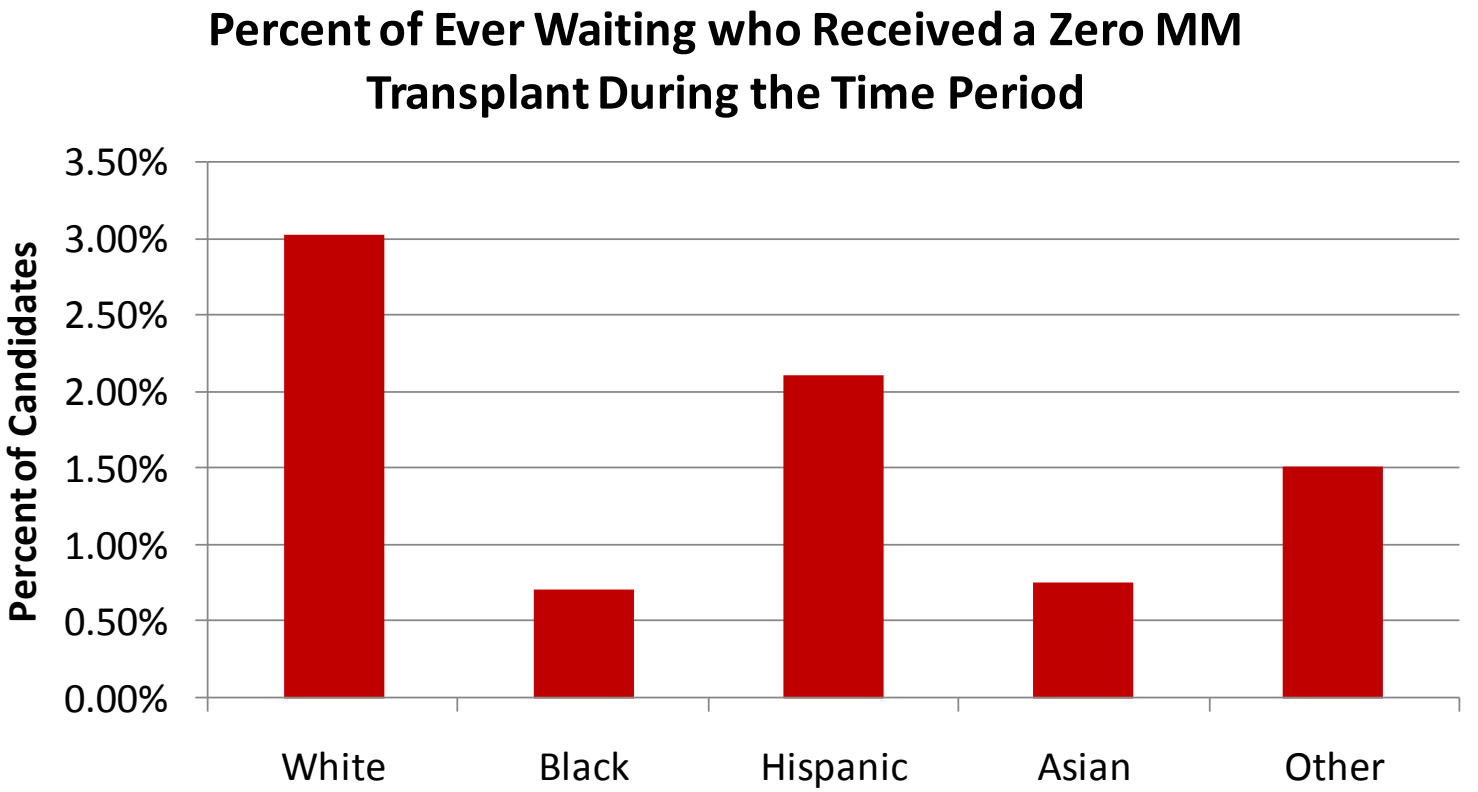
ETHNICITY CATEGORY	Number Ever Waiting During Time Frame	Zero MisMatch Transplants During Time Frame	Payback Kidney Transplants During Time Frame	Percent of Ever Waiting who Received a Zero MM Transplant During the Time Period	Percent of Ever Waiting who Received a Payback Kidney During the Time Period
White	48229	1459	236	3.025%	0.489%
Black	34635	246	146	0.710%	0.422%
Hispanic	17077	360	50	2.108%	0.293%
Asian	6689	51	28	0.762%	0.419%
Other	2632	40	14	1.520%	0.532%



Source: The OPTN Data as of March 28, 2008
Data subject to change based on future data submission or correction.

United Network for Organ Sharing
Zero Mismatch Kidney Transplants 1/1/05 - 6/30/06





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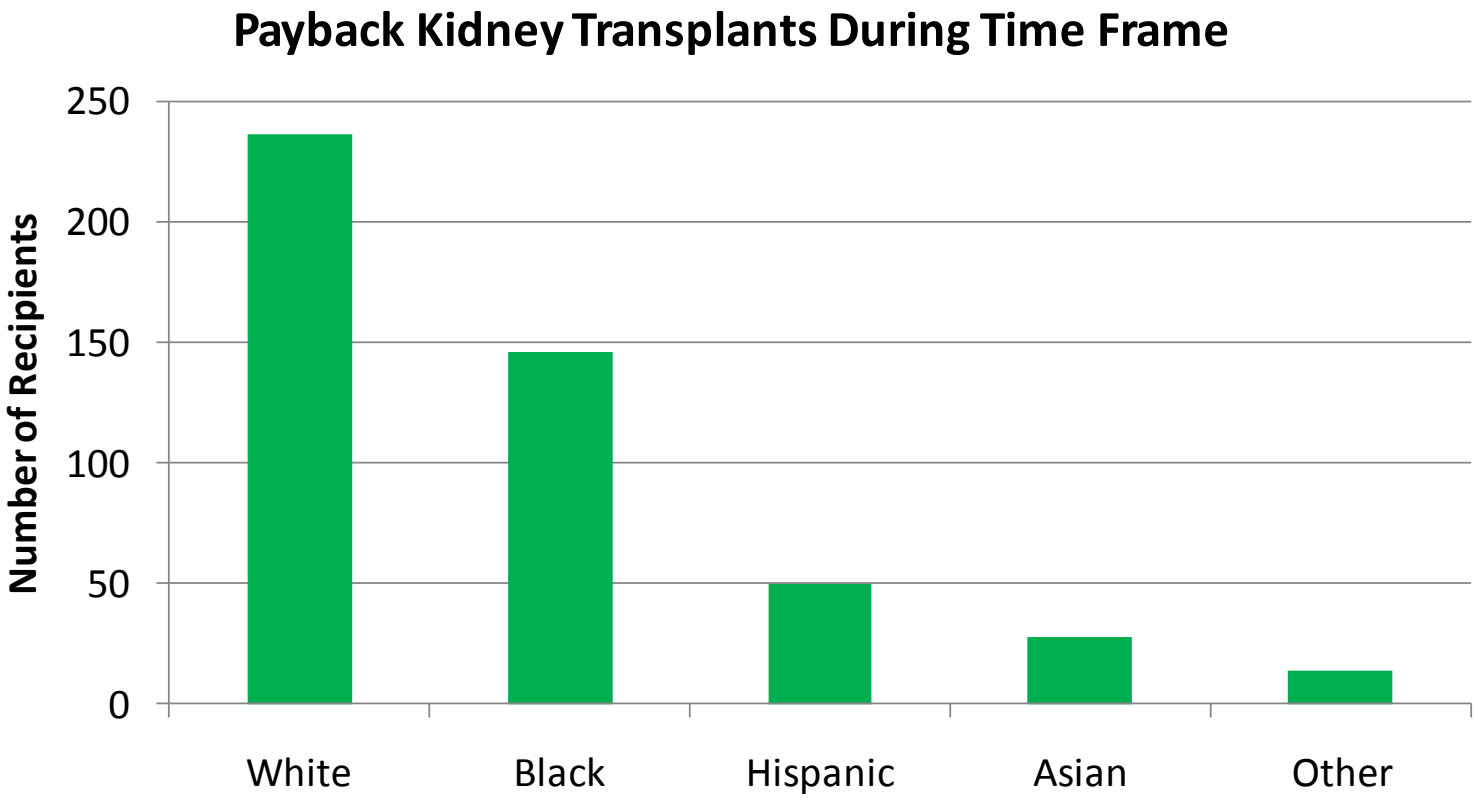
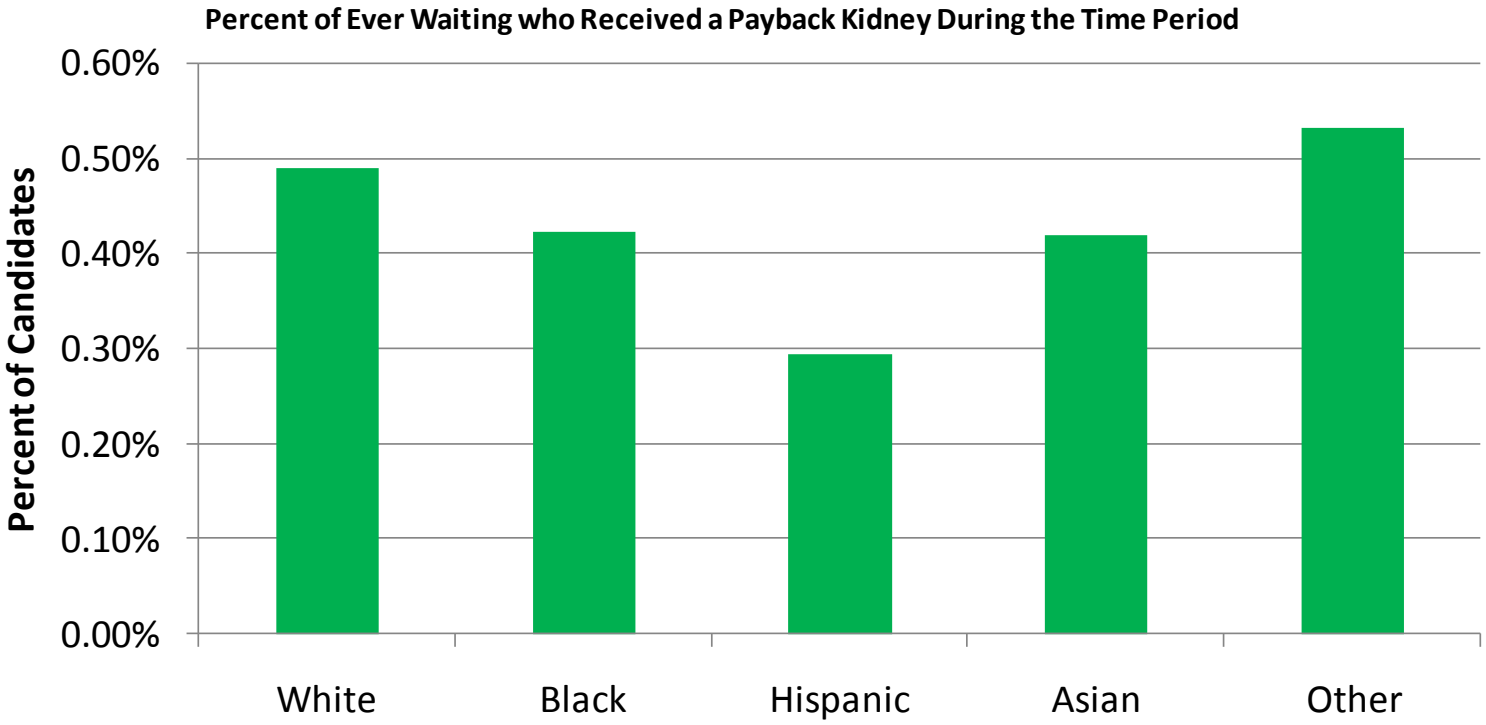
Zero Mismatch Kidney Transplants 1/1/05 - 6/30/06





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United Network for Organ Sharing
Zero Mismatch Kidney Transplants 1/1/05 - 6/30/06

			Share Type																							
			Local								Regional								National							
			PRA								PRA								PRA							
	All		Missing		0-20%		21-79%		80-100%		Missing		0-20%		21-79%		80-100%		Missing		0-20%		21-79%		80-100%	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
All	2,156	100.0	10	100.0	234	100.0	39	100.0	26	100.0	9	100.0	142	100.0	28	100.0	26	100.0	68	100.0	1,041	100.0	259	100.0	274	100.0
Ethnic Background																										
White	1,459	67.7	1	10.0	152	65.0	28	71.8	20	76.9	7	77.8	86	60.6	13	46.4	13	50.0	43	63.2	728	69.9	176	68.0	192	70.1
Black	246	11.4	2	20.0	19	8.1	6	15.4	2	7.7	.	.	10	7.0	3	10.7	5	19.2	9	13.2	114	11.0	40	15.4	36	13.1
Hispanic	360	16.7	5	50.0	54	23.1	4	10.3	3	11.5	1	11.1	35	24.6	11	39.3	7	26.9	11	16.2	158	15.2	32	12.4	39	14.2
Asian	51	2.4	2	20.0	3	1.3	.	.	1	3.8	1	11.1	8	5.6	.	.	.	.	3	4.4	24	2.3	4	1.5	5	1.8
Other	40	1.9	.	.	6	2.6	1	2.6	.	.	.	.	3	2.1	1	3.6	1	3.8	2	2.9	17	1.6	7	2.7	2	0.7

Source: The OPTN Data as of March 28, 2008
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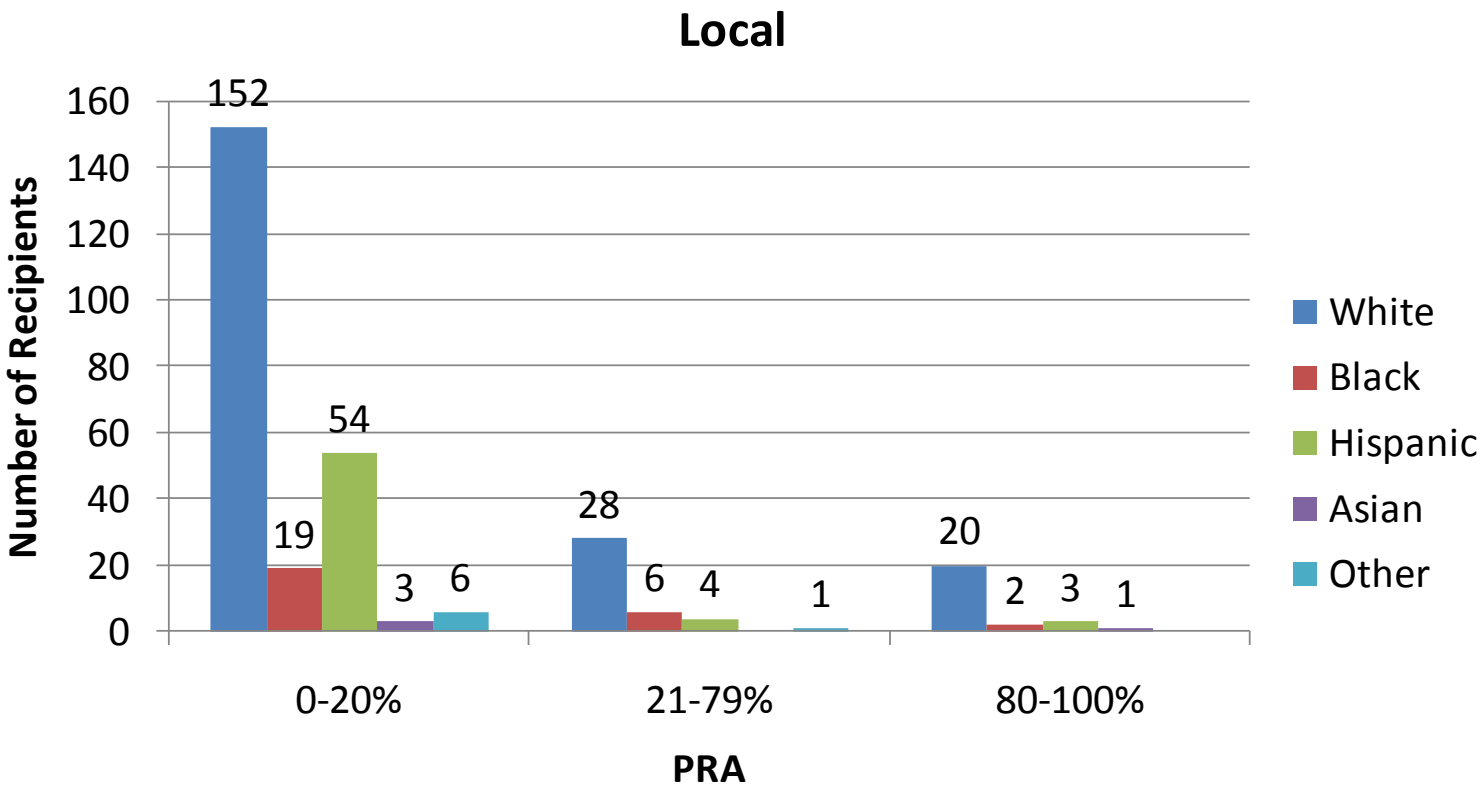
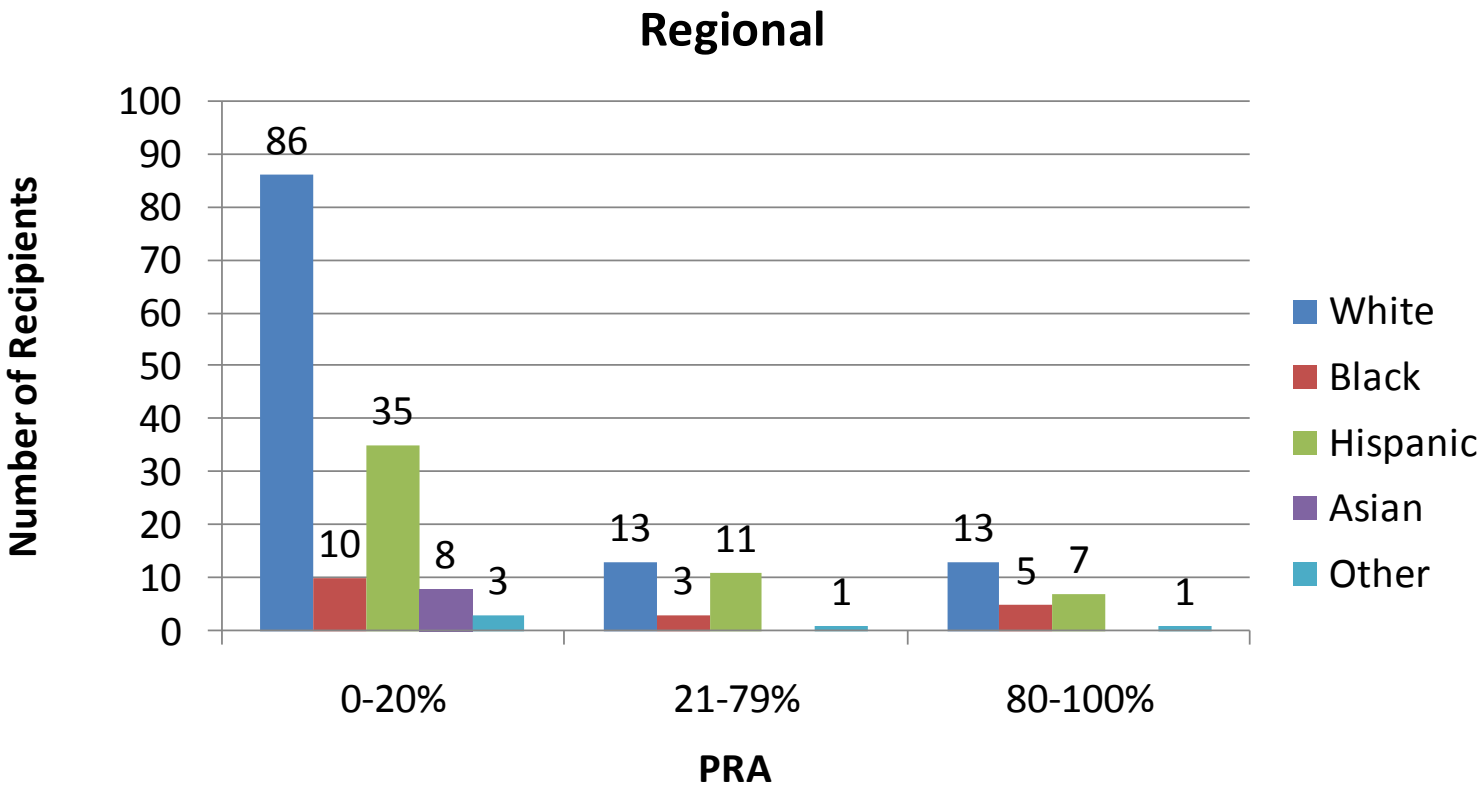
United Network for Organ Sharing
Zero Mismatch Kidney Transplants 1/1/05 - 6/30/06





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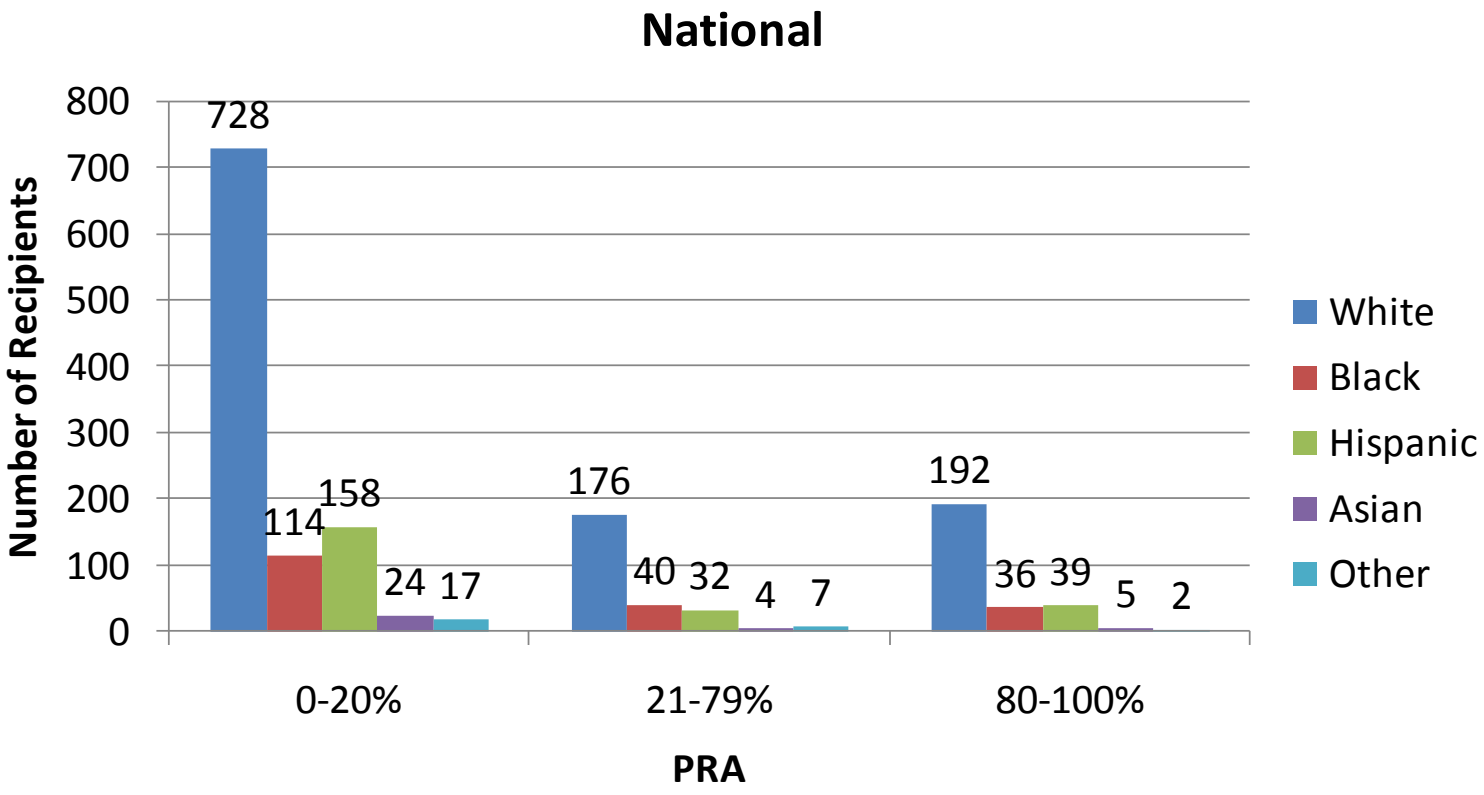
Zero Mismatch Kidney Transplants 1/1/05 - 6/30/06



Source: The OPTN Data as of March 28, 2008
Data subject to change based on future data submission or correction.

United Network for Organ Sharing
Percent of Kidney Waitlist Candidates of Each Ethnic Group
Who Received a Zero Mismatch Transplant
During the Time Frame

Table 1. Percent of Kidney Waitlist Candidates of Each Ethnic Group Who Received a *Local* Zero Mismatch Transplant

	PRA			
Ethnicity	Missing	0-20%	21-79%	80-100%
White	0.05%	0.44%	0.47%	0.32%
Black	0.22%	0.08%	0.11%	0.03%
Hispanic	0.52%	0.45%	0.19%	0.15%
Asian	0.54%	0.06%	0.00%	0.16%
Other	0.00%	0.32%	0.32%	0.00%

Table 2. Percent of Kidney Waitlist Candidates of Each Ethnic Group Who Received a *Regional* Zero Mismatch Transplant

	PRA			
Ethnicity	Missing	0-20%	21-79%	80-100%
White	0.38%	0.25%	0.22%	0.21%
Black	0.00%	0.04%	0.06%	0.08%
Hispanic	0.10%	0.29%	0.52%	0.34%
Asian	0.27%	0.16%	0.00%	0.00%
Other	0.00%	0.16%	0.32%	0.31%

Table 3. Percent of Kidney Waitlist Candidates of Each Ethnic Group Who Received a *National* Zero Mismatch Transplant

	PRA			
Ethnicity	Missing	0-20%	21-79%	80-100%
White	2.34%	2.13%	2.96%	3.09%
Black	1.00%	0.51%	0.75%	0.60%
Hispanic	1.14%	1.32%	1.51%	1.90%
Asian	0.81%	0.49%	0.52%	0.78%
Other	1.54%	0.91%	2.27%	0.63%

Based on UNOS OPTN data as of April 4, 2008
Data subject to change due to future data submission or correction

Geography Study: Inventory of Projects Undertaken by the Liver and Intestinal Transplanation Committee
April 15, 2008

Background

In June 2007, the Board approved the following resolution from the POC:

> "*RESOLVED, that the OPTN undertake a study to address geographic variations in organ allocation.*"

During the January 2008 meeting, the POC discussed two approaches to move forward with this work: (1) ask each committee how they would like to proceed and begin to partner with each committee or (2) begin work with the Liver Committee, as they have already formed a subcommittee on broader sharing, and their allocation system is relatively stable at this point. The Committee agreed to explore both pathways, beginning work with the Liver Committee while asking for the other organ-specific Committee's input.

As a first step, UNOS staff has identified recent and current projects of the Liver committee that may address geographic variations. This inventory will allow the POC and Liver Committee to assess what further work should be undertaken. Further, the goals and metrics of liver allocation policy established by the Liver Committee in 2004 will be used as a way to assess whether the committee is meeting its stated goals with respect to addressing geographic variations.

Liver Committee Projects

A. Investigating sharing for MELD/PELD scores >29 regionally. Since May 2007, livers in Region 8 have been offered first to Regional candidates (i.e., a combined list of local and Region 8 candidates) with a MELD/PELD score of 29 prior to those with lower MELD scores. An assessment of the first 6 months of the policy is currently in process.

B. Investigating sharing for all MELD /PELD scores regionally (eliminate local allocation). As an extension of the proposal described in (A), the SRTR has been asked to model a policy that would offer organs to patients listed with a MELD/PELD score using the Region as the initial distribution unit. The Committee reviewed LSAM for results using a MELD/PELD threshold of 29 for regional sharing in March 2006, and have asked that the SRTR model the following, to be reviewed at the July 2008 meeting:

    Local Status 1A

    Regional Status 1A

    Local Status 1B

    Regional Status 1B

Regional MELD/PELD > 15

Regional MELD/PELD < 15

National Status 1A

National Status 1B

All other MELD/PELD

C. Investigating the applicability of net survival benefit to liver allocation. The Committee has asked the SRTR to model a system which bases allocation on net survival benefit, rather than the MELD and PELD scores. The modeling and identification of covariates for both pre- and post-transplant survival models are being finalized. The LSAM model will be used to compare transplant benefit and MELD-based allocation. The SRTR has been asked to model the current allocation system in which candidates (non-Status 1) are ranked according to net benefit rather than MELD/PELD, and consider various weighting formulas in the net benefit equation that would advantage pediatric candidates. These results will be compared to those of the current system as simulated in LSAM.

D. Review of Waiting List Mortality for Status 1A/1B by DSA, Region, and population density. During the March 4, 2008 meeting, the Committee reviewed data on waiting list mortality rates for Status 1 candidates, broken out by reason for Status 1, as well as separate rates for Status 1A/1B candidates, by region. The Committee noted that larger regions seem to have a relatively low mortality rate (for Status 1 candidates) and questioned whether there is a any correlation between mortality rates in Status 1A and the population density and/or donor procurement rates in the regions and wait list mortality. This information will be provided to the full committee during the July 2008 meeting. The SRTR has been asked to model various alternative distribution units, such as a group of regions, for the sharing of Status 1A candidates with fulminant failure.

E. Proposal for a National Review Board (NRB). The Committee is evaluating the applicability of a NRB to help address the variations in MELD exception scores across the UNOS regions.

F. Definitions for up to 7 (more) standardized MELD/PELD exception diagnoses. The Committee is evaluating the applicability of assigning standard MELD/PELD scores for certain diagnoses to help address the variations in MELD exception scores across UNOS regions. The list of diagnoses being examined was based on recommendations from the MESSAGE conference in 2005.

G. Fall 2008 HCC Consensus Conference. There is a lot of variation in how HCC candidates are being evaluated and listed across the country. The Committee agreed that a consensus conference is needed to evaluate current studies/research and develop recommendations that can be utilized across the UNOS regions.

H. Changes in priority for Liver-Intestine Candidates. The Committee is working with the Pediatric Committee to create national sharing of livers and liver-intestines. A proposal is currently out for public comment.

I. Recommendations for national sharing of pediatric donors for pediatric status 1A recipients. A proposal is currently out for public comment.

Relationship to Goals and Metrics

In 2004, the Liver Committee established a set of goals and metrics as displayed in Attachment 1. Regarding geography, the committee made the following statement:

> "Geographic criteria are not patient-specific and therefore are not to be emphasized in organ allocation or distribution. However, the Committee recognizes that scientific studies have continued to document the potential negative effects of increasing cold ischemic time on liver graft survival. Therefore, in order to maximize transplant benefit, some form of sharing boundary is necessary given current organ preservation limitations. The impact of distribution units used in liver and intestinal allocation should be evaluated in the context of patient-specific liver transplant benefit criteria."

Recent and ongoing Liver Committee projects are mapped against these s goals and metrics in Tables 1 and 2.

Table 1. Liver Committee Goals	**Project**
Reduced waiting list mortality	A,B, C, D, H, I
Increased post-transplant survival	C
Reduced post-transplant morbidity and burden of disease	
Increased quality of life	
Allow optimal patient access for transplantation	A, B, C, D, E, F, H, I
Efficient placement of organs	H
Enhanced utilization of extended-criteria donors	

Table 2: Metrics	**Project**
Pre- and post-transplant graft and patient survival;	C
Listing, transplant, death and removal rates for various patient groups (e.g., diagnostic groups, allocation score ranges, demographic and geographic groups);	D, E, F, G, I
Indicators of morbidity and quality of life, as measured by available data and current methodologies;	
Risk of progression of disease	F, G, I
Distances traveled by patients for their transplant care.	D

DRAFT MINUTES

Living Donor Data Task Force

January 29, 2008

Conference Call

Introductions and Background

On this inaugural call of the Living Donor Data Task Force (LDDTF), participants introduced themselves and provided background regarding their involvement with living donation. The meeting slides are provided as **Exhibit A**.

Mary Ellison, PhD, MSHA, reviewed the recent history of the OPTN's involvement with living donation. Prior to 2005, the OPTN had been collecting living donor follow-up data for 1 year post donation. The OPTN contract issued in September 2005 extended this requirement to 2 years. In January 2006, HHS published a notice in the Federal Register soliciting comments on the OPTN's oversight of living donor guidelines. In June 2006, the Secretary of HHS directed OPTN to develop living donor policies that would have the same force as other policies developed by the OPTN. In June 2007, the OPTN/UNOS Board approved a resolution from the Policy Oversight Committee stating that, "Resolved, that a joint OPTN Committee be established to evaluate the use of living donor data." As a result, the LDDTF is being asked to take an objective look at the various needs for living donor data, and to propose an appropriate approach for each need.

Robert Gaston, Chair, noted that Task Force consists of 19 members with varied expertise with living donation. Members are involved with:

- OPTN/UNOS Living Donor and Policy Oversight Committees, Kidney Paired Donation Working Group, and Board of Directors;
- ASTS, AST;
- Adult to Adult Living Donor Liver Transplantation Cohort Study (A2All), Renal and Lung Living Donors Evaluation Study (RELIVE), NYCLT, LODN, NKF; and
- Clinical, Social Work/Psychology, patients and donors.

The idea behind creating the LDDTF was to assemble an expert group with "all the answers present in the room." Members are not necessarily representing a specific entity (i.e., AST, OPTN), but are asked to bring their experience and expert opinions to the group. The LDDTF will meet primarily by conference calls, with the hope that its work can be finalized within 6 months, and with recommendations going to the Board in November 2008.

Background/Data

Dr. Gaston noted that donors, patients, transplant centers, and others have many questions about living donation, especially relating to risks, costs, psychosocial impacts, etc. There are many questions for which there are no data. OPTN data is limited for addressing many important questions, due primarily to lack of long-term follow-up data. Part of the challenge for the LDDTF will be deciding which gaps in the data that the OPTN should be responsible for and which would more appropriately be undertaken by others.

Ann Harper, LDDTF liaison, reviewed the data currently collected on the living donor registration and follow-up forms. Committee members asked for the specific dates that the OPTN began collecting living donor data on its forms (i.e., when the registration and follow-up forms were implemented), as well as copies of the living donors forms, with explanations of what certain terms mean (e.g., "lost to follow-up" versus "not seen").

Ms. Harper presented slides showing the percentage of donors that donated in 2005 but whose last known date of follow-up was less than 330 days post-transplant. There was considerable variation by transplant center. The LDDTF also reviewed slides showing how often a question on the one year follow-up form was marked as "unknown", for variables such as weight, diabetes, creatinine, blood pressure, hypertension, readmission, and complications. Task Force members asked for a tabulation of the degree of follow-up that is available on this cohort of donors (i.e., what percentage are actually being followed at various time points).

Path Forward

Prior to the call, the LDDTF members were asked to submit questions that are often asked about living donation. These questions were categorized into the following broad topics:

- Questions About the Donation Process
- Short-Term Risks
- Long-Term Risks
- Recovery / Return to ADLs
- Donor Follow-Up
- Psychosocial Impacts
- Costs/Insurance
- Questions Specific to Paired Donation

The suggested path forward is that the LDDTF review these questions and to develop proposals or recommendations related to obtaining data for each topic. Those members involved with currently available sources of living donor data (i.e., A2ALL, RELIVE, LODN) were asked to provide an overview of what data those studies will provide. It was suggested that the purpose of data collection should be

defined first (e.g., what is the purpose of collecting short and long-term data) and then the group can determine how (and by whom) these data should be collected. The group discussed the possibility of breaking into smaller groups assigned specific tasks. Several task force members expressed a preference for the group continuing to meet as a whole instead of breaking into smaller groups.

A request was made that all questions about living donation submitted to Ann are circulated to the entire group.

Living Donor Data Task Force **January 29, 2007** **Conference Call**
Robert Gaston, M.D., Chair
Bob Merion, M.D.
Robin Pierson, M.D.
Gigi Spicer, R.N.
Tom McCune, M.D.
Arthur Matas, M.D.
Cheryl Jacobs, ACSW
Felicia LeClere, Ph.D.
Samantha DeLair
Mary Amanda Dew, Ph.D.
Judy Jones Tisdale, Ph.D.
John Roberts, M.D.
Kim Olthoff, M.D.
Jane Zill, LICSW
Dolph Chianchiano
Ruth Ann Hanto, RN, MPH, CPTC
Mark Barr, MD
Betsy Walsh, JD, MPH
Unable to Attend
Connie Davis, MD
Matt Cooper, MD
HRSA Staff
Bernard Kozlovski, MD
UNOS Staff
Ann Harper
Mary D. Ellison, PhD, MSHA
Jennifer Wainright, MPH
Lee Bolton, RN, ACNP

DRAFT MINUTES

Living Donor Data Task Force

February 22, 2008

Conference Call

Minutes from January 29, 2008 Conference Call. The minutes were distributed to the task force just prior to the call on February 22, 2008. Members were asked to review them and submit any revisions to Ann Harper.

Task Force Charge. The Committee discussed its charge, which is to "To identify the purposes for which living donation-related data are needed and to recommend appropriate approaches for obtaining and/or reporting data for each purpose." The charge elaborated on the initial resolution to the Board from the Policy Oversight Committee that "…a joint OPTN Committee be established to evaluate the use of living donor data." The effort would thus go beyond what data are appropriate for the OPTN to collect and report. For example, if data are needed that are outside the OPTN's purview, the group could identify other sources for those data.

Living Donor Data Collection Timeline. During the call on January 29, 2008, members asked for a timeline for OPTN collection of living donor data. Beginning in October 1987, the OPTN began to collect the donor name, gender, age and relationship to the recipient on the Donor Histocompatibility Form. The Living Donor Registration (LDR) form was created in October, 1990, and included donor name, relationship to the recipient, serology data, and some basic demographic information. In April 1994, the donor SSN was added to LDR. The six month and one year Living Donor Follow-up (LDF) forms were implemented in October, 1999. This included the donor's status and cause of death information, rehospitalizations, complications such as dialysis and bile leaks, and lab values such as creatinine and bilirubin. The LDR was expanded at that time to include pre-discharge complications, donor education level and source of payment. In June, 2004, the OPTN began to collect additional data about the donor's pre-donation insurance and functional status, and the LDR was expanded to include more details on complications, including vents occurring in the first 6 weeks post-donation. Additional changes to the LDR and LDF are to be implemented in March 2008. These changes will include more information about the center's attempts to contact the donor and a 2-year follow-up form.

Data Completeness. The Task Force reviewed data describing forms submission and the level of completeness at 6 weeks, 6 months, and 1 year for selected variables. For the 6,433 individuals who donated a kidney in 2006, 12% had an LDR only, 17.6% have 6-month follow-up, and 69.9 had 1 year follow-up. However, these data were provided with the caveat that, in some cases, a patient may be marked as 'alive' but the date provided on the LDF may be the same date provided on the registration form (e.g., discharge date) or an earlier LDF. Looking at reported complications, the LDR had a very low rate of 'not reported.' However, the rate of those with 'unknown' or 'missing', or 'no form' increased to

approximately 20% for these complications at 6 months, and 50% at 1 year. The data for liver donors appeared to be more complete, but was subject to the same caveats regarding the actual date of follow-up.

Members asked whether these data have been used in published studies, and questioned the validity of research using these data, at least beyond the data collected on the LDR. The event rates are likely to be accurate in the early period, but possibly not for the long term. Further, as these events are known to be rare, centers may not expend a lot of resources looking for donors. Thus, one cannot assume that the lack of a report on a donor means that no adverse event has occurred. As these data have been collected for many years, at some cost to the OPTN and centers, it is important to understand the usefulness of the data. UNOS staff will assemble all the papers that have used these data for the Task Force.

Specific concerns to be Addressed by Data. Dr. Gaston described the issues that the community is most concerned about ("what are we most afraid of?"), including:

1. Pre-Donation Issues
    - Are donors being properly evaluated?
    - Is the risk of donation properly assessed and communicated to potential donors?
2. Perioperative complications
3. Long-term complications
    - Cardiovascular Disease
    - Renal Disease
    - Surgical complications
4. Psychiatric Complications
    - Quality of Life
5. Financial Implications
    - Life, health and disability Insurance and employability

Members discussed whether the LDDTF is interested in data related to outcomes or process. Information related to process (how are donors evaluated? are risks communicated? etc.) is not currently included on the LDR. Regarding outcomes and risks, while the short term risk to the average kidney donor from surgery is estimated to be 1 in 3000, the operative risk for a less than idea donor is not known. The long- term complications less well understood, and the community is interested in 5, 10, and 20 years outcomes, rather than outcomes at 1-2 years.

There are essentially two issues for the LDDTF to tackle:

- "What would we like to know?"
- What should the OPTN collect?

The LDDTF is asked to step back and answer these in view of the fact that data are needed, and in light of the history of the effectiveness of OPTN data collection for living donors. The LDDTF should recommend what approaches should be taken to provide long-term outcomes data. One approach could be to make recommendations for what should be collected at 6 weeks to allow complete understanding of the factors that contribute to long-term adverse events. The LDDTF could recommend that meta-analyses be conducted using what has already been published.

Members noted that the OPTN has collect donor SSN since 1994, and could utilize OPTN waiting list data as well as SSDMF and ESRD data to provide some insights into long-term events, keeping in mind that the mean time that kidney patients return to the waiting list is 18 years. This would provide a large denominator, and could be run annually. Finally, the LDDTF could produce a white paper that would include the following:

1. What's happened with the data collected up to this point?;
2. What would we like to have?;
3. What it is feasible for the OPTN to do and do well?; and
4. Summary recommendations.

Sources of Data. For the next calls, the LDDTF will hear from those involved with A2ALL , RELIVE, NYCLT and LODN.

LDDTF SharePoint Site. A SharePoint™ site will be made available to the LDDTF that would be a repository for articles, minutes, slides, and resources, and would allow for discussion threads and collaboration on projects.

Living Donor Data Task Force **February, 22, 2007** **Conference Call**
Robert Gaston, M.D., Chair
Matt Cooper, MD
Robin Pierson, M.D.
Gigi Spicer, R.N.
Tom McCune, M.D.
Arthur Matas, M.D.
Samantha DeLair
Mary Amanda Dew, Ph.D.
John Roberts, M.D.
Jane Zill, LICSW
Dolph Chianchiano
Ruth Ann Hanto, RN, MPH, CPTC
Mark Barr, MD
Betsy Walsh, JD, MPH
Unable to Attend
Connie Davis, MD
Judy Jones Tisdale, Ph.D.
Cheryl Jacobs, ACSW
Bob Merion, M.D.
Kim Olthoff, M.D.
HRSA Staff
Bernard Kozlovski, MD
Christopher McLaughlin
UNOS Staff
Ann Harper
Mary D. Ellison, PhD, MSHA
Jennifer Wainright, MPH