

**OPTN/UNOS Minority Affairs Committee
Report to the Board of Directors
November 18-19, 2008
St. Louis, MO**

Summary

Action Items for Board Consideration

- None

Other Significant Items

- The Committee has formed a Subcommittee on Referral to the Waitlist and Transplant that is reviewing evidence and other activities being undertaken by centers to improve referral and wait listing rates. (Item 7, Page 9)
- The Committee wishes to update the Board on the Dialysis Facility Public Comment Survey Project (Item 8, Page 14)
- The Committee continues to study factors related to geographic variation in organ allocation. (Item 12, Page 18)
- The Committee proposes to pursue publication of a review article summarizing all of the data and issues it has examined over the last decade. (Item 14, Page 21)

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Pang-Yen Fan, MD, Chairman
Henry Randall, MD, Vice-Chairman

This report includes items addressed by the Minority Affairs Committee at its meetings held on March 11, May 9 and July 18, 2008.

1. Summary of Board of Directors Meetings during its March 11 meeting, the Committee received a brief update on relevant actions from the February meeting of the Board of Directors held in Orlando, Florida. The item of primary interest to the Committee was the removal of the Living Donor Medical Evaluation Resource Document from Board consideration. It was noted that the item was removed from the agenda due to recently raised editorial and technical comments from the transplant community and from HRSA. HRSA and the Living Donor Committee are in the process of reworking the document for consideration at the June Board meeting. The board approved the revised document in June 2008.

In July, Ms. Parker updated the Committee on relevant Board actions from the June Board meeting held in Richmond, Virginia. The items of primary interest to the Committee were:

- Board approval of the proposal to limit mandatory sharing of zero antigen mismatch kidneys to children and sensitized adult candidates
- Approval of the proposal to require transplant centers to inform potential recipients about known high risk donor behavior.
- Executive Committee approval of a resource document for evaluating potential living donors.
- Board approval of a pilot project for the National Kidney Paired Donation program.

2. New Member Orientation. At its meeting on July 18, 2008, the Committee was provided with comprehensive orientations on the following subject areas for the benefit of new members:

- *Introduction to OPTN/UNOS Committee Service*
- *OPTN/UNOS Regulatory and Contractual Framework*
- *UNOS Research Committee Support*
- *Update on Progress Toward Reaching the HHS Donor-Related Goals*
- *Overview of the OPTN/UNOS Policy Development Process*
- *SRTR Orientation*
- *UNOS Information Technology Orientation*

3. OPTN/UNOS Strategic Planning. During the July meeting, Dr. Fan updated the Committee on the development and identification of several overarching strategic planning goals, including related annual goals for each committee. The annual goals were developed by the incoming and outgoing President with staff input. The goals include previous committee priority activities not yet completed as well as areas the OPTN leadership believes to be important for the coming year. The Committee was informed that the goals should continue to form the primary basis of committee activity over the next year.

4. Update on Development of a New Kidney Allocation System. In 2005, the OPTN/UNOS Board of Directors charged the Kidney Transplantation Committee with revising the kidney allocation system following a comprehensive 360 review. For the past several years, the Minority Affairs Committee

(MAC) has reviewed data in tandem with the Kidney Committee showing the impact of a proposed new kidney allocation system incorporating Life Years From Transplant (LYFT) on minority transplantation. The new LYFT system would rank candidates based upon objective medical criteria using their projected median survival with transplant from a specific available donor compared to survival on dialysis. The Kidney Committee has considered input from the Minority Affairs Committee in its deliberations and has recommended the inclusion of various factors that have the potential to improve transplantation for minority candidates.

During the March 11, 2008 meeting Alan Leichtman, MD of the SRTR, briefly updated the committee on results from the latest Kidney Pancreas Simulated Allocation Model (KPSAM) showing the specific components included in the new kidney allocation proposal. The Committee was informed that Run 28 was selected as the architecture for the new kidney allocation proposal. Silas Norman, MD, MAC liaison to the Kidney Committee, provided the committee with a summary of the discussions of the Kidney Committee during its development of the proposal. Dr. Norman reported that in attempting to develop the final proposal, the Kidney Committee was challenged with addressing competing interests of various patients groups, each hoping to receive benefit from the new system. In its deliberations only medical factors that were measurable, calculable, and monitorable were included. Factors that did not meet these criteria (gameability, for example) were excluded. He acknowledged that the Kidney Committee is aware of the desire of the Minority Affairs Committees to evaluate the performance of the system over time and address issues with regard to geography.

Dr. Norman remarked that a few additional decisions remain before a final system is proposed, including how to transition to the new system as well as how to incorporate donation by cardiac death (DCD) organs into the system. Additionally, one element of the proposal, limiting mandatory sharing to highly sensitized and pediatric candidates, has been issued as a separate proposal for the February public comment cycle. The Committee was informed that the proposed timeline for the kidney proposal includes another public forum and public comment cycle to allow for additional input into the system. However, distribution of the final proposal has been delayed due to review by the Department of Health and Human Services Office of Civil Rights (OCR) to determine whether the kidney allocation schema incorporating LYFT constitutes age discrimination.

Following discussion, it was noted that the first few iterations of the proposal were neutral in terms of any perceived benefit for minority candidates. However, the last two simulations demonstrate more of a beneficial and encouraging shift in organs directed toward African Americans. He noted that the new system will not solve all of the issues faced by minority groups; however, the proposal is a good first step forward. The MAC requested to be updated on the final opinion of the OCR as well as the proposal distribution date.

During the July 18, 2008 meeting, Dr. Alan Leichtman of the SRTR, presented the Committee with an overview of the computer modeling simulations used in developing the new proposed system for the benefit of new members beginning their service on the committee. **(Exhibit A).**

The current deceased donor kidney allocation algorithm allocates 15% of expanded criteria donor (ECD) kidneys based upon waiting time alone and 85% of standard criteria donor (SCD) kidneys based upon a point system. In the current system:

- 5% of kidneys are allocated to candidates listed for a kidney plus a life saving organ
- 15% of kidneys are allocated to zero HLA-A,B,DR mismatched candidates
- 65% of kidneys are allocated to HLA mismatched candidates

LYFT prioritizes both medical urgency and post-transplant survival by using the common metric of expected future years of life. In this system, kidneys with longer potential for survival are allocated

primarily to candidates with longer expected survival. LYFT is primarily a measure of utility. LYFT can be used to assess trends in outcomes of existing allocation systems and to compare the current allocation system to proposed alternative allocation systems.

There are numerous covariates included in the LYFT simulations. The specific elements include:

- Recipient Factors: age, transplant type, kidney v. simultaneous kidney-pancreas, recipient diagnosis, diabetes, polycystic disease, other, BMI, previous transplant, albumin, peak PRA, years on dialysis.
- Donor factors: HLA A, B, and DR, same Donation Service Area (DSA) as recipient v. shared across DSA, DCD, age, CMV, hypertension, weight.
- Quality of Life Adjustments: (QoL) QoL adjustment weights dialysis years by 80%, Transplant lifetime (QoL) = Years with functioning graft + 0.8 * Dialysis Years (DY) after graft failure, Non-Transplant Lifetime (QoL) = 0.8 * Dialysis Years. QoL adjusted LYFT is the difference between the adjusted lifetimes.

LYFT incorporates the following major elements which contribute toward the priority a candidate would receive in the kidney allocation system:

- *Dialysis Years (DY)*: Patients receive priority for time spent on dialysis waiting for a kidney.
- *Donor Profile Index (DPI)*: A continuous measure of organ quality which classifies kidneys based on clinical information.

More than 30 sets of allocation rules were modeled; however, only three alternatives were extensively discussed. These modeling runs include:

- Run 16a: 100% LYFT for SCD, 100% DY for ECD
- Run 18f: $LYFT \times (1-DPI) + DY \times DPI + PRA \times 4$
- Run 28: $LYFT \times 0.8 \times (1-DPI) + DY \times (0.8 \times DPI + 0.2) + PRA \times 4$

The following rules were modeled in Run 28:

- Formula for kidney allocation score = $LYFT \times 0.8 \times (1-DPI) + DY \times (0.8 \times DPI + 0.2) + PRA \times 4$
- KP candidate priority follows pancreas allocation rules, i.e. waiting time and kidney follows pancreas
- Diagnosis categories in LYFT calculation are PKD, DM and all other diagnoses
- LYFT score can be updated (based on age, dialysis years, PRA)
- ECD/SCD distinction was eliminated (although patient preference to not accept ECD kidneys was kept)
- Dialysis years were calculated since most recent initiation of dialysis
- Pediatric and adult allocations are separated. Pediatric rules remain the same as in the current system (local priority for donors <35, except for no offers from donors ≥ 35 to pediatric candidates)
- No paybacks
- No 0-HLA priority
- No 0-HLA sharing, except for PRA 80%+
- A₂/A₂B to B was applied nationally
- HLA A and B were not included in LYFT calculation

Run 28 was selected as the architecture for the new kidney allocation proposal because:

- In Run 28, the maximum amount of allocation weight that LYFT would contribute to a candidate's allocation score would be limited to 80%. With LYFT capped at 80%, DY still contributes to the LYFT score even for the highest quality category of organs, retaining some incentive to pursue living donation as an option and greater balancing the utility versus justice issue.

- Run 28 gives additional priority to highly sensitized patients (PRA 80% and above receive 4 points). This may benefit minority candidates who tend to be sensitized against more common donor antigens.
- Run 28 increases total extra years of life to 51,589 as compared to the current system, but results in a decrease in the average extra years of life as compared to Runs 16a and 18f (5.7).
- Run 28 demonstrates the smallest decrease in transplants to candidates over the age of 50 while still increasing transplants to 18-34 year old candidates
- Finally, this run also shows an improvement in the number of transplants allocated to African American candidates as compared to the current system (33% to 38%) and demonstrates greater parity between Caucasian and African American candidates (41% and 38% respectively.) (See Figure 1 below).

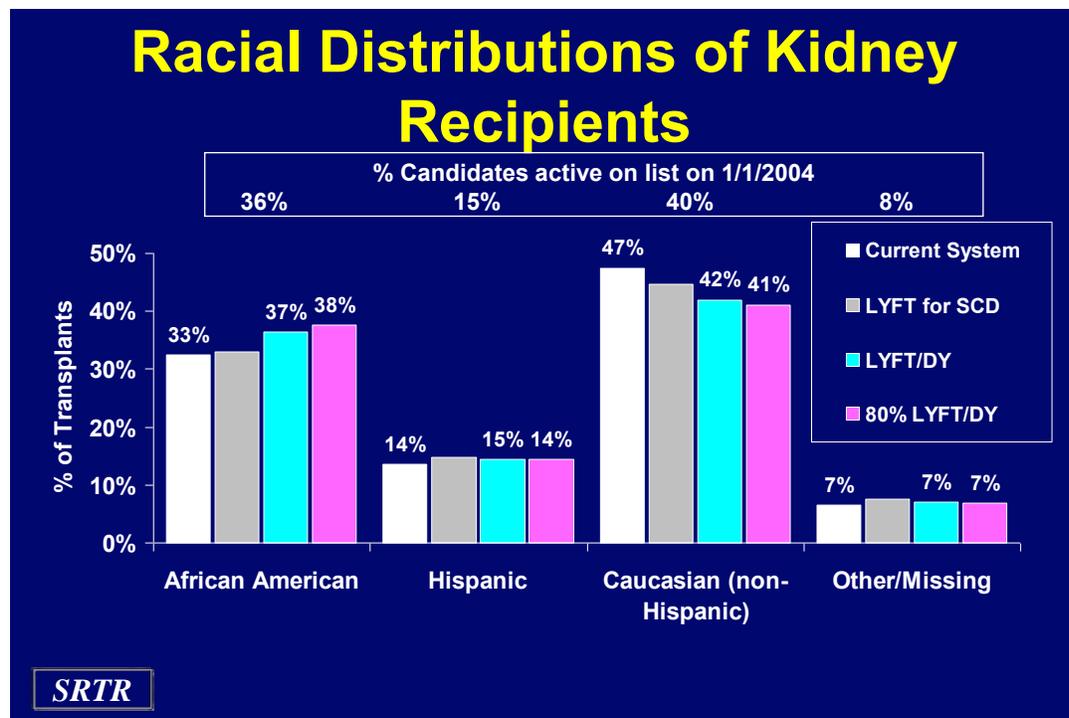


Figure 1.

Figure 2 shows overall modeling results as compared to the current system:

- LYFT for SCD adds about 11,500 incremental years of life for each year of DD kidney transplantation
- LYFT/DY adds about 4,800 years
- 80% LYFT/DY adds about 3,400 years
- All three potential proposals increase allocation to younger candidates and decrease allocation to older candidates
- LYFT/DY and 80% LYFT/DY improve access for African Americans
- 4*PRA improves access for candidates with PRA 20-80%

Expected Years of Life Per Year of Allocation

| | Current System | Simulation 16a LYFT For SCD | Simulation 18f LYFT/DY | Simulation 28 80% LYFT/DY |
|-----------------------------|----------------|-----------------------------|------------------------|---------------------------|
| Years after tx | 107,865 | 143,505 | 122,140 | 118,133 |
| Total graft yrs | 72,814 | 86,614 | 75,600 | 73,772 |
| Total extra life yrs | 48,187 | 59,691 | 52,947 | 51,589 |
| Δ years after tx | | 35,640 | 14,275 | 10,268 |
| Δ graft yrs | | 13,800 | 2,786 | 958 |
| Δ extra life yrs | | 11,504 | 4,760 | 3,402 |

SRTR

Each Δ (change) is relative to the current system

Figure 2

The Committee was also updated as to LYFT simulations including preliminary 3-year data, acceptance pattern simulations, as well as a patient waiting time calculator. The calculator was developed to help patients determine their likely score based on LYFT/DY. Dr. Norman updated the Committee on the review by the US Office of Civil Rights (OCR). He reported that the OPTN and the Kidney Committee has forwarded correspondence to the OCR offering assistance with the review. In the interim, the Kidney Committee is planning to move forward with the release of a KAS Request for Information (RFI) proposal which is expected to be distributed in the Fall of 2008.

After discussion, members of the Committee voiced the need for strong education with regard to the elements of the proposal, as well as simpler language to explain the concepts. One member of the Committee commented that population figures do not necessarily reflect what will happen to a particular individual under the proposed system. In this situation, the KAS calculator and other simulators may be important tools to provide patients with the information needed to determine whether their individual status will improve or worsen under the new system. It was remarked that prior to implementation of any new system, patient education materials would be developed to take into account all of the considerations expressed.

5. Ethnic and Demographic Characteristics of Candidates with High PRA versus those with Low PRA. During the March 11 meeting, the Committee was provided with a presentation by the SRTR showing ethnic and demographic characteristics of candidates with high versus low PRA with respect to the outcomes from the simulation runs for the LYFT-based kidney allocation system (**Exhibit B**). Sangeetha Mahedevan of the SRTR presented the information to the Committee.

The data showed that:

- Under the current national system, recipients with 80-100 and 0-10 PRA represent 48.8% and 45.2% of Caucasians respectively versus 43.7% and 42.3% in the new system;
- Under the current national system, recipients with 80-100 and 0-10 PRA represent 30.7% and 37.6% of African Americans respectively versus 34.8% and 40.9% in the new system;

- Under the current national system and under the new system, recipients with 80-100 and 0-10 PRA represent similar percentages of Hispanics ;
- Under the current national system, recipients with 80-100 and 0-10 PRA received similar percentages of zero mismatched organs;
- Under the proposed system, recipients with 80-100 PRA receive a much higher percentage of zero mismatched organs than recipients with 0-10 PRA;
- Sharing: under the current national system, recipients with 80-100 v. 0-10 PRA represent 29% v. 20%, under the proposed system they represent 24% v. 12% of recipients; and
- Pediatrics: under the current national system, recipients with 80-100 v. 0-10 PRA represent 2% v. 8%, under the proposed system they represent 2% v. 10%;

During discussion, the Committee reiterated concerns it has expressed over several meetings with regard to the variability in technologies used by histocompatibility labs to determine patient sensitization. It was noted that the system will be in flux for a year or so as the community moves toward using CPRA versus PRA to calculate sensitization, and so any information reviewed will be difficult to interpret. Even when processes and technologies become more standardized, there will still be differences in the thresholds labs use to define sensitivity. It was remarked that the Histocompatibility Committee will be reviewing preliminary data comparing CPRA versus PRA at its next meeting. The Committee expressed interest in seeing this data in July.

Review of CPRA vs. PRA.

During the July meeting, the Committee examined preliminary descriptive data recently reviewed by the Histocompatibility Committee, showing the number of candidates listed according to CPRA as compared to those listed using PRA (**Exhibit C**). The Committee is ultimately interested in determining the percentage of patients receiving priority points who have been determined to be highly sensitized using match PRA and whether the number changed after the introduction of CPRA. The Committee is hoping to gauge the implications for clinical practice in determining if the results of CPRA should be used as a contraindication to transplantation. Dr. Wida Cherikh, Ph.D, UNOS Research Liaison presented the information to the Committee.

Dr. Cherikh provided brief background on CPRA. Calculated PRA (CPRA) is a measure of a candidate's sensitization level that is based on unacceptable HLA antigens listed for candidates. The goal of CPRA is to provide a more accurate and consistent measure of patient sensitization and to improve the efficiency of organ allocation by reducing the number of predictably positive crossmatches. Because CPRA is obtained by determining the actual frequency of potential deceased donors who have one or more unacceptable antigens for a given transplant candidate, CPRA may benefit ethnic minority candidates who are sensitized to HLA antigens that are relatively common in the deceased donor population. Phase I of CPRA, which requires centers to list at least one unacceptable antigen for their highly sensitized patients to receive four additional points, was implemented in UNetSM on 12/5/2007. Phase II, which will use CPRA in the kidney allocation algorithm, is expected to be implemented in the Fall of 2009.

The data reviewed by the Committee included candidates currently eligible for sensitization points, the percentage of candidates who would potentially keep or lose those points, by ethnic group. The data show that as of June 13, 2008, 23,009 (28.4%) of the kidney waiting list candidates have at least one unacceptable antigen listed, allowing calculation of a CPRA. A small number of centers (13 out of 258) have not entered any unacceptable antigens for their candidates. Slightly less than 20% of candidates that are currently eligible for sensitization points (match PRA \geq 80%) do not have a CPRA \geq 80% to justify the points. When the CPRA is used for allocation in Phase II of the implementation, these candidates

could potentially lose these points. One committee member expressed strong sentiment that CPRA does not provide enough information to conclusively predict a positive crossmatch and that the mere presence of an antigen should not necessarily impede transplantation. CPRA, in his opinion, may needlessly prevent people who are not actually sensitized against a particular antigen, from being transplanted. He believes that antigen specificity should be used to determine the specific alleles that the patient is sensitized against. It was suggested that more data is needed to determine how to identify a good or bad antigen. The committee concluded that it was premature to infer anything about CPRA with regard to its potential impact upon minority access, but it will continue to review the data as updates are available.

6. Analysis of the Alternative Allocation System Allowing for Calculation of Waiting Time to Include Time on Dialysis, on Transplantation by Ethnicity. During its meeting on March 11, the Committee reviewed preliminary data on the pilot study allowing patients to receive credit for time spent on dialysis prior to becoming waitlisted (**Exhibit D**). On 4/29/06, two OPOs, One Legacy (CAOP) and Gift of Life (MIOP), implemented the study. Iowa Donor Network (IAOP) was added to this initiative on 1/24/2007. However, as implementation at IAOP occurred very recently, the information on this OPO was not included in the report. Dr. Alan Leichtman of the SRTR, presented the data to the committee.

The data showed that:

- There were no patterns observed in the ethnic distribution of candidates entering the waitlist before and after the policy change.
- The number of deceased donor transplants did not change significantly in these time periods, but there is some indication that the characteristics of these deceased donor recipients have changed.
- On average, there was an increase in the average years on dialysis and decrease in the average years on the waitlist for patients receiving deceased donor transplants in the period following policy implementation across all ethnicities in CAOP and MIOP.
- This trend was not observed in the OPO's where this allocation policy was not implemented.

Committee members noted that though the time period studied was limited, preliminary results were quite interesting. In Michigan, there was a slight increase in transplant rates for African Americans; though there was not a similar increase shown in California. In California, the alternative system showed more benefit for Hispanics than African Americans. The SRTR suggested that waiting times in California may be so substantial that the incremental pre-waitlist dialysis years may not have yet affected who is at the top of the list. It was suggested that the true effects of the study may not be seen for another year.

Overall, the Committee believed the data to be fairly encouraging. Results appeared to demonstrate a decrease in the average years on the waitlist across all ethnicities, as the committee had hoped would occur when the change was initially proposed. The SRTR noted that although only 3 OPOs have signed up for the study, there is more interest in the alternative system than participation would suggest as OPOs are currently limited to participating in one alternative system at a time. Dr. Fan acknowledged that the data was early but inquired if it might still be appropriate to revisit the concept as a change to the national system, especially given the delay in the release of the kidney allocation proposal. He noted that another element of the kidney proposal has already been separated from the proposal and distributed for public comment during this cycle. After brief discussion, it was suggested that a smaller, focused work group or subcommittee might be convened to review the initial data and determine if this is an approach that should be pursued at this time or delayed pending further analysis.

7. Referral to the Waitlist and Transplant. The Committee has been exploring ways to examine the factors related to referral rates and delays for patients getting onto the waitlist. Subsequently, the Committee formed a Subcommittee on Referral to the Waitlist and Transplant that is currently reviewing evidence

and other activities being undertaken by centers geared toward increasing referral and wait listing rates. The subcommittee convened on May 9 to examine various data previously reviewed by the full committee. An analysis of geographic variability in patient access to kidney transplantation in the US (1996-2005) showed large geographic differences in access to the kidney transplant waiting list and once listed, to a kidney transplant.

However, an analysis of the CMS 2728 form showing the likelihood of being informed of kidney transplantation, being placed on the kidney transplant waitlist, or of receiving a living donor transplant, revealed that approximately 73% of patients beginning renal replacement therapy for the first time (in July-Dec. 2005) were informed of their kidney transplant options (Figure 3), while 1.75 percent received a preemptive living donor transplant (Figure 4). In addition, the data showed that African Americans, Hispanics and Asians were more likely to be informed than Native Americans and Whites. (Figure 5) However, African Americans, Hispanics, Asians, and Native Americans were less likely to be placed on the waitlist or receive a living donor transplant than Whites. (Figure 6)

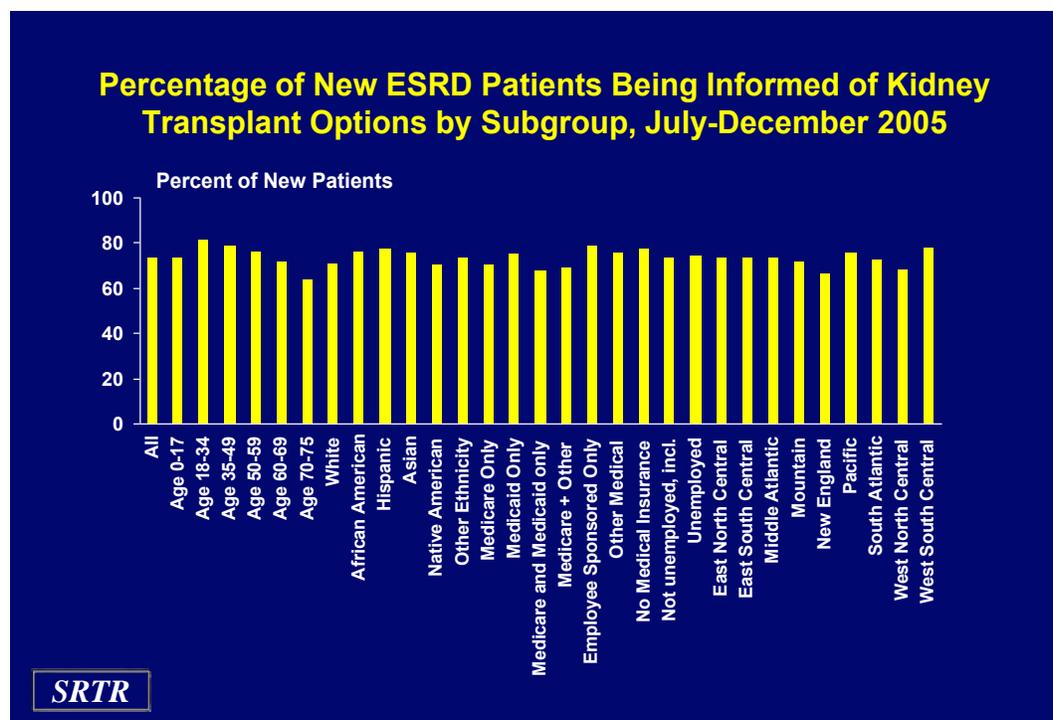


Figure 3

Percentage of New ESRD Patients Receiving a Pre-emptive Living Donor Kidney Transplant by Subgroup, July-December 2005

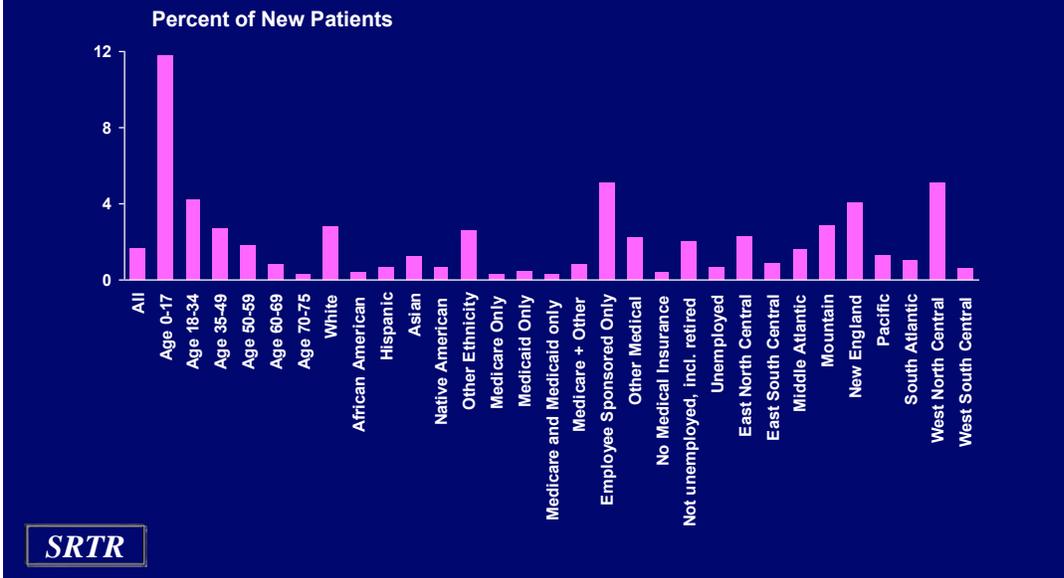


Figure 4

Adjusted Odds Ratio† of New ESRD Patients Being Informed of Kidney Transplant Options or Receiving a Living Donor Kidney Transplant by Ethnicity, Jul-Dec 2005

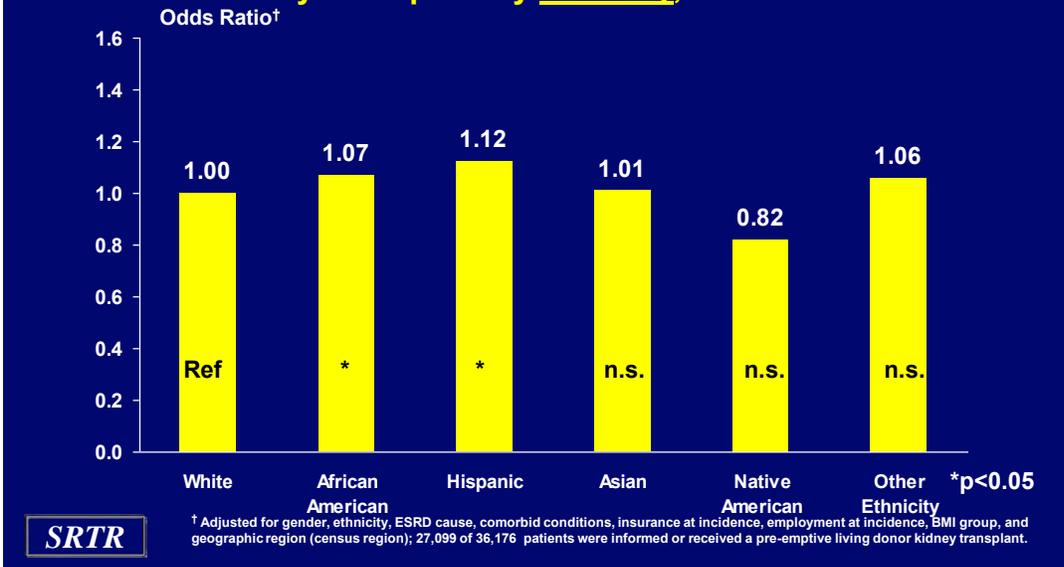


Figure 5

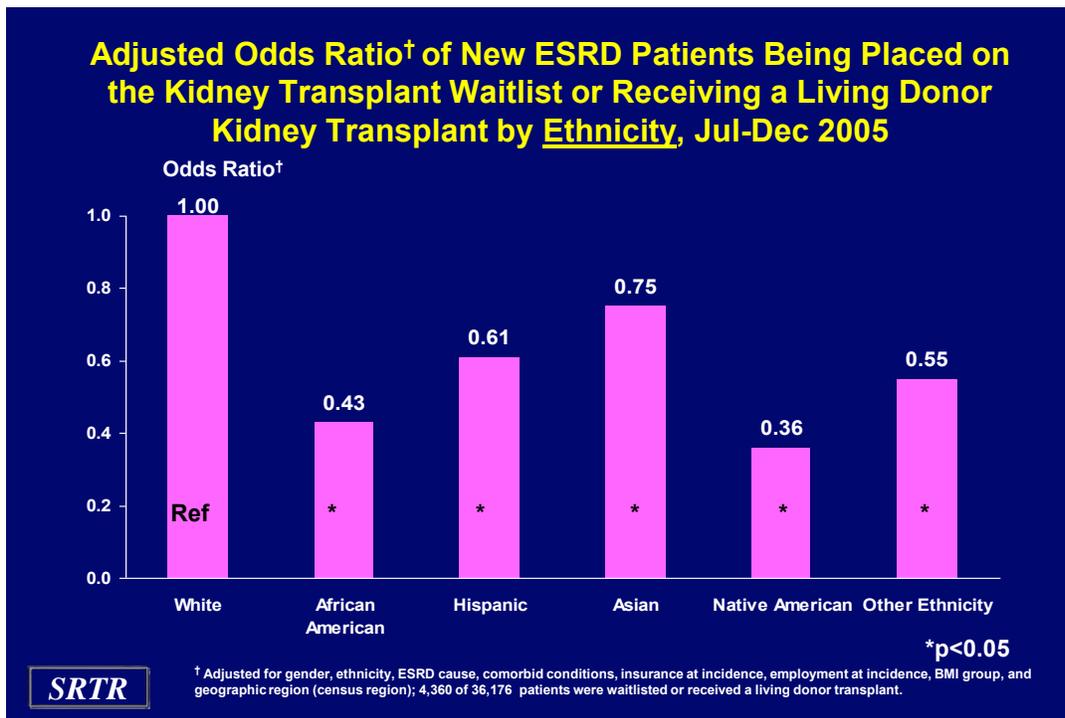


Figure 6

Subcommittee feedback highlighted the unexpected negative correlation between African Americans being informed of their transplant options and lower referral rates, with some members questioning the accuracy of the data. The subcommittee discussed various issues, including the definition of a referral, designation of the person responsible for completing the 2728 paperwork and their knowledge about whether the patient has been informed, as well as oversight of dialysis patient referrals. The subcommittee also reviewed the results of a special study conducted by the Centers for Medicare & Medicaid Services (CMS) under contract with the End Stage Renal Disease (ESRD) Network which has developed kidney transplant referral measures at the dialysis facility level to track the steps in the transplant referral process for quality improvement and public reporting.

During the July 18 meeting, the Committee discussed ways to research efforts being made in other localities to increase referral rates for all organs. Committee members informally related practices in their own centers which ranged from nephrologists routinely visiting dialysis units to review charts, to centers where there is little or no oversight mechanism in place to insure that suitable patients are referred to transplantation. The anecdotal exchange highlighted significant variation in referral practices as well as in the person designated to complete the 2728 forms. As a possible intervention, it was suggested a study protocol in which every OPO and transplant center could establish a collaborative relationship with their local dialysis units to provide some method of oversight. The specific method of oversight could vary according to the resources available. The data may identify practice patterns that could be compared to other areas to determine if they have affected wait listing and transplant rates. Study questions could be generated for additional analysis. If successful, the intervention could be piloted out to other OPOs. Additional discussion will continue at the subcommittee level to be reported back to the full committee.

Living Donation Issues

Living Donor Task Force.

At the March 11 meeting, Helen Spicer, RN, updated the committee on the work of the Living Donor Task Force. The purpose of the group is to examine long term follow-up data to help centers with various issues, including informed consent, monitoring outcomes, etc. At present, only one-year follow-up information is available in the database; however, two-year follow-up is now mandated. The second year mandate is unfunded. The Task Force has convened via two conference calls; however, there is a conflict between the amount and type of data wanted versus the available sources. Concern has also been expressed that the data might not be accurate based on interpretations of data coordinators. Additionally, the task force has also expressed concern regarding the risk of donors eventually ending up on the wait list. This is an area of risk which the Committee has also attempted to identify through the review of data. The committee requested to be updated on the progress of the work of the task force in this area.

Prior Kidney Living Donors Who Were Subsequently Placed on the Waiting List and Rate of Being Placed on the Kidney Waiting List within Five Years of Donation.

The Committee has been examining data pertaining to the safety of living donation, particularly with respect to individuals who have donated their organ and ended up on the waiting list due to end stage organ failure. The Committee has been interested in determining if the rate of being placed on the waiting list within 5-6 years is higher for previous living kidney donors who are non African-American as compared to non-African American. The committee is hoping to learn whether or not there are significantly more risks to minority donors as compared to non-minority donors. In September, the Committee reviewed a descriptive analysis using OPTN and CMS data showing 148 previous living kidney donors who were on the kidney waiting list between 1/1/1996 and 3/31/2007. 137 were identified from donation points, 3 through SSN linkage, and 8 through both donation points and SSN linkage.

At the July 18 meeting, the Committee was provided with an updated analysis including the rate of living donors being placed on the kidney waiting list within five years of the donation (**Exhibit E**). The analysis included candidates ever on the kidney waiting list between 1/1/96 and 2/29/08, who were indicated as a previous donor, or had a prior living donation record in the OPTN living donor database as matched by social security number. The analysis identified 172 previous living kidney donors who were on the kidney waiting list between 1/1/96 and 2/29/08.

Dr. Cherikh summarized the characteristics of the 172 prior living kidney donors:

- The majority (66%) of donors were less than 35 at donation with a median donor age of 31.
- 42% of donors were placed on the waiting list between 16 and 25 years post donation, with a median age of 19 years from donation to first listing.
- The median years from donation to listing was 21 years for White donors and 16 years for Black donors.
- There were 105 male donors (61%) versus 67 female (39%) donors.
- The majority of donors were White (42%) or Black (43%) with 9% Hispanic and 3% of Asian ethnicity.
- The three most common diagnosis categories at listing were glomerular disease, hypertensive nephrosclerosis and diabetes.
- The majority (68%) of donors donated to their full siblings.
- 18% were blood related children who donated to their parents.

- The majority of donors (70%) received a transplant and are still alive.
- 13% have not yet received a transplant.
- 6% received a transplant and died.

Dr. Cherikh also provided the Committee with demographic highlights of living donors placed on the kidney waiting list within 5 years of donation:

- There were two Caucasian living donors and 5 African-American living donors who returned to the waiting list.
 - The recipient and donor diagnoses of the two Caucasian donors were Malignant Hypertension and IGS Nephropathy and Hemolytic Uremic syndrome (HUS) and HUS.
 - One donor received a deceased donor transplant and the other donor received 2 living donor transplants.
 - Of the 5 African American donors, 2 were female and 3 were male.
 - The donors donated in 1997, 1998, 1999, 2001 and 2002.
 - 2 donated at age 18-34.
 - 3 donated at age 35-49.
 - 3 donated to full siblings, 1 to parent and 1 to biological relative
 - The time from donation to listing ranged from 2 - 5 years.
 - 1 donor received 2 deceased donor transplants
 - 3 donors received a deceased donor transplant
 - 1 donor received a deceased donor transplant, was relisted and is still waiting

Dr. Cherikh noted that since the overall median time for previous living donors to be placed on the kidney waiting list is 19 years, the number and the rate of being placed on the waiting list within 5 years of donation is very small. However, despite small numbers, the rate was substantially higher for Black than White donors (0.11% vs. 0.01%). The committee was informed that the next step is to link the OPTN living donor database with the CMS 2728 database to determine how many prior living donors received subsequent maintenance dialysis.

One member of the Committee found the ten-fold difference between Black and White living donors disturbing. He remarked that although the instances of hypertension in the Black community are greater than in the White population, they are four fold and not ten-fold. He further commented that there is a difference being shown that extends beyond the normal ethnic differences. It was noted that this is an ongoing area of interest that the committee will continue to examine under the enhanced follow-up of donors that will be experienced in the future.

8. Minority Affairs Committee/Dialysis Facility Public Comment Survey Project. The Committee is continuing its work on the dialysis survey project approved by the Board of Directors two years ago. The intent of the project is to collect baseline information on what the public, particularly minorities, understand about organ allocation policy and their ability to provide input on the development of these policies. The information from the survey will be used to substantiate the committee's concerns about the representativeness of public comment and its role in allocation policy to possibly support the development of initiatives designed to address public education and outreach.

During its March meeting, the committee was updated on recent activity regarding the survey project. The committee was informed of ongoing discussions with two dialysis companies regarding distribution of the survey questionnaire in their facilities. Both companies expressed concern about the project for varying reasons. One company expressed concern about the potential for disruption and distraction of their staff answering patient questions, etc. regarding the survey questionnaire. The other company

relayed a concern that their dialysis staff assistance with the survey without compensation, could be construed as a “kickback.” Since UNOS does not refer patients to dialysis, the kickback concern is unjustified, possibly resulting from a misunderstanding of the function of UNOS. However, to address both concerns, it was requested that a UNOS staff person be allowed to oversee administration of the survey onsite in each region. The questionnaire is in the process of being piloted in the Massachusetts area and committee staff is completing the required IRB paperwork to begin the study.

At the July meeting, Dr. Fan reported that the pilot test had been completed and the survey was being conducted on a limited basis in the Massachusetts area. He noted that the response rate has been very low with only twenty-two surveys collected so far. Due to the low response rate in Region 1, staff is hoping to supplement the study with two additional dialysis units in the area; however approval has not yet been received from the other dialysis company. It has been agreed that a UNOS staff auditor will be made available onsite to facilitate administration of the survey; however, committee staff is experiencing difficulty attempting to communicate with the appropriate principal staff at one of the dialysis facilities to coordinate this activity. Dr. Fan noted that IRB as well as dialysis facility approval has not yet been received to conduct the survey in Region 3; however, the IRB has responded to request clarification of specific items submitted in the application. Committee staff is working toward responding to the questions from the IRB.

9. Public Comment Enhancement Project. At the March meeting, the Committee viewed a slide presentation outlining efforts to enhance public comment with improvements to internal processes as well as expanded functionality of the public comment tool on the OPTN and UNOS websites. The Committee was also provided with a live demonstration of new features available on the site.

10. Discussion of Public Comment Proposals Distributed February 8, 2008

1. Proposal to Limit Mandatory Sharing of Zero Antigen Mismatch Kidneys to Children and Sensitized Adult Candidates (Modifications to Policy 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys))

Silas Norman, MD, provided the committee with a brief overview of the policy proposal. During discussion, members noted strong support for the proposal. Data shows that the majority of zero antigen mismatch organs are allocated to Caucasian patients because their genetic profile more closely matches other donors in the donor pool. Fewer minority patients receive these organs because they are less likely to have this genetic match. Minority candidates are also less likely to receive a transplant with a payback kidney than Caucasian candidates. Therefore, the payback system, which was created to address imbalances in the system caused by the zero mismatch policies, has actually served to disproportionately direct organs away from disadvantaged populations. If paybacks are eliminated, organs that may have previously been shipped to zero mismatched patients outside of the region could potentially be allocated locally to minority candidates.

Committee members discussed the survival advantage of zero mismatched kidneys. A member remarked that the question at hand is whether the medical benefit of sharing zero mismatched kidneys supersedes the societal benefit gained by opening distribution to other patients. It was noted that the acceptance rate for payback kidneys is very low, averaging around 7%. This is because kidneys offered as a payback are often of lesser quality than organs retained for local transplantation. It was also noted that some centers routinely turn down zero mismatch offers, significantly limiting the types of organs accepted in order to avoid incurring large payback debts. Therefore, the survival benefit of sharing zero mismatch kidneys is offset by the decrease in survival advantage of the kidneys that are offered as a payback. Additionally, some members reported that an examination of the other levels of mismatch (not zero mismatch or paybacks) shows a distribution that looks very similar to the wait list. This indicates that the policy change could help level the playing field for minority candidates.

Members reiterated a strong endorsement of the proposal, noting its potential to improve access for minority candidates. The Committee voted unanimously to approve the proposal by a vote of 14, 0, 0.

2. Proposal to Allow an Additional Method for Waiting Time Reinstatement for Pancreas Recipients (Modifications to Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients))

The Committee determined that there was no minority impact from the proposed policy.

3. Proposal to Change the OPTN/UNOS Bylaws to Require Written Notification (or Disclosures) to Living Donors from the Recipient Transplant Programs (Proposed Modifications to Appendix-B, Section II, (F) "Patient Notification" of the OPTN Bylaws and Appendix B, Attachment I, XIII, D (13) of the UNOS Bylaws)

The Committee determined that there was no minority impact from the proposed policy.

4. Proposal to the OPTN and UNOS Bylaws: Restoration of Membership Privileges Following an Adverse Action (Proposed Changes to Appendix A, Section 3.01A Paragraphs (1) and (3) and Section 5.05A, Addition of Section 5.07A.)

The Committee determined that there was no minority impact from the proposed policy.

5. Proposal to Change the Elector System for Histocompatibility Lab Members and Medical/Scientific Members: OPTN and UNOS Bylaws Article I, Sections 1.9 and 1.12; Article II, Section 2.2 and 2.4; Article VI, Section 6.1.

The Committee determined that there was no minority impact from the proposed policy.

6. Proposal to Change Organ Time Limits to Organ Offer Limits for Zero Antigen Mismatched Kidneys, Pancreata, and Kidney/Pancreas Combinations (Modifications to: Policy 3.5.3.5 (Organ Offer Limit), Policy 3.8.1.7.1 (Time Limit), and Policy 7.6.1.2 (Validation of Offers of Organs Placed through the Organ Center))

The Committee determined that there was no minority impact from the proposed policy.

7. Proposal to Require Transplant Centers to Inform Potential Recipients about Known High Risk Donor Behavior. (Proposed Revisions to Policy 4.0 - Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Recipient Diseases Or Medical Conditions, Including Malignancies, of Donor Origin)

The Committee determined that there was no minority impact from the proposed policy; however, it acknowledged the importance of promoting transparency in the system as well as improving patient safety.

The Committee voted unanimously to approve the proposal by a vote of 14, 0, 0.

8. Proposal to Change How 0-10 Year-Old Donor Livers and Combined Liver-Intestines are Allocated (Modifying Policies 3.6 (Allocation of Livers) and 3.11.4.2 (Combined Liver-Intestinal Organs from Donors 0-10 Years of Age))

The Committee determined that there was no minority impact from the proposed policy.

9. Proposal to Change Allocation of Pediatric Lungs and Allow Creation of a Stratified Allocation System for 0-11 year-old Candidates (Modifying Policies 3.7.6.2 (Candidates Age 0-11), 3.7.11 (Sequence of Adult Donor Lung Allocation) and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation))

The Committee determined that there was no minority impact from the proposed policy.

10. Proposal to Allocate Pediatric Donor Hearts More Broadly (Modifying Policies 3.7.5 (Allocation of Adolescent Donor Hearts to Pediatric Heart Candidates) and 3.7.10.1 (Sequence of Adolescent Donor Heart Allocation))

The Committee determined that there was no minority impact from the proposed policy.

11. Discussion of Public Comment Proposals Distributed on June 30, 2008

1. Proposal to Add the Factor “Change in Bilirubin” to the Lung Allocation Score (LAS) Policy Affected: 3.7.6.1 (Candidates Age 12 and Older) (Thoracic Organ Transplantation Committee)

One member of the Committee questioned why the requirement was being applied across the board to all four classes of diagnoses when the difference only seemed to affect the pulmonary group. The Committee ultimately determined that there was no minority impact from the proposed policy.

2. Proposal to Verify that Foreign Agencies Importing Organs to the United States are Legitimate and Test Organs for Transplant Safety Policies Affected: 6.4.2 (Developmental Protocols in Organ Exchange) and 6.4.3 (Ad Hoc Organ Exchange) (Ad Hoc International Relations Committee)

The Committee noted the importance of the proposal as more of these organs are being used in the United States; however, it ultimately determined that there was no minority impact from the proposed policy.

3. Proposal to Require That Living Donor Organs Only Be Recovered at an OPTN Member Institution Policy Affected: Add Policy 3.3.7 (Center Acceptance of Organs from Living Donors) (Living Donor Committee)

A member Commented on an instance where a person was willing to donate their organ but refused to go to a hospital other than where they have always received their care or which was located at a distance from their home. The member questioned how a patient would be followed in those circumstances. Another Committee member noted that among pediatric institutions which may belong to the same university system, one hospital may not be an OPTN institution but organ procurement may be performed at the non-OPTN hospital and then transferred to the affiliate institution for both pediatric and adult transplantation/donation. After brief discussion, the Committee determined that it favors language recognizing that there may be individual cases where this might be a problem. The Committee ultimately determined that there was no minority impact from the proposed policy and declined a formal vote.

4. Proposal to Modify the Bylaws Pertaining to *Conditional Approval Status for Liver Transplant Programs that Perform Living Donor Transplants* Bylaws Affected: Attachment , Appendix B, Section D, (4) Liver Transplant Programs that Perform Living Donor Liver Transplant) of the OPTN/UNOS Bylaws , (Membership and Professional Standards Committee)

The Committee determined that there was no minority impact from the proposed policy

5. Proposal to Change the OPTN/UNOS Bylaws to Better Define Functional Inactivity, Voluntary Inactive Membership Transplant Program Status, Relinquishment of Designated Transplant Program Status, and Termination of Designated Transplant Program Status Policy Affected: Appendix B, Section II, C of the OPTN/UNOS Bylaws (Membership and Professional Standards Committee)

The Committee determined that there was no minority impact from the proposed policy.

12. Review of Geographic Variation in Organ Allocation. During its March 11 meeting, the Committee was updated on efforts of the Policy Oversight Committee (POC) to study geographic variation in organ allocation. Dr. Henry Randall, vice chairman of the MAC, presented the update to the committee. The POC has reviewed data generated by various OPTN committees to identify areas with high geographic variability that can be addressed through changes in policy. He informed the Committee that the Thoracic Committee presented data showing that they could decrease waiting list mortality with increased geographical distribution. As data has shown that minorities tend to be located in Donor Service Areas (DSA's) with longer waiting times, it has been suggested by the MAC and others that this could apply to kidney allocation as well. However, other analyses performed suggest that eliminating all of the barriers might not make much difference in terms of minority access, which has confused the precise role of geography as an impediment to access. Other specific challenge areas, including listing and referral practices, etc. might be outside of the purview of UNOS. The POC has determined that its path forward at this time is to review issues identified by the organ specific committees one by one, beginning with the Liver Committee.

Wait-Listing Rate among ESRD Patients versus Deceased Donor Transplantation Rate among Waiting List Patients by State, 1996-2005.

The Committee briefly reviewed slides previously presented to the committee and recently provided to the POC, showing the concentration of minorities in area with extended waiting times. Dr. Leichtman provided the data to the Committee. One analysis divided the US into 4 quadrants consisting of the 52 states, the District of Columbia and Puerto Rico. The dots on the scatter plot demonstrate states with either a higher or lower rate of waitlisting depending on whether or not they fall above or below the relative rate (Figure 7).

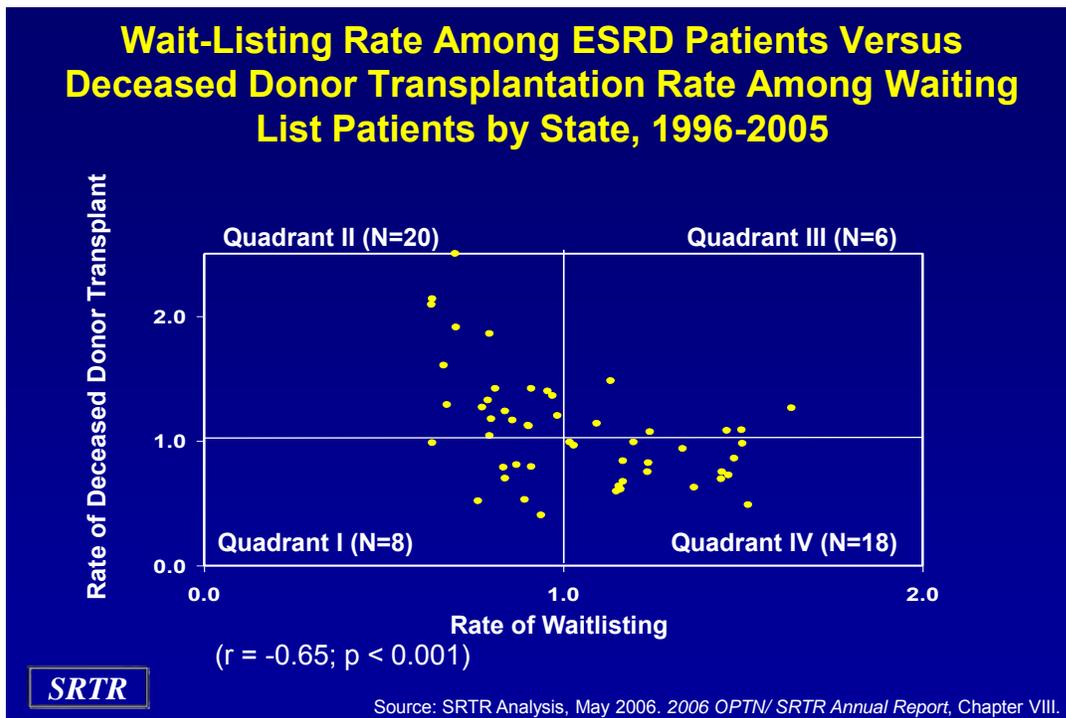


Figure 7

The analysis shows:

- There are six states in which patients with ESRD have a high likelihood of getting on the waitlist and being transplanted.
- There are 20 states where patients have a reasonable chance of being transplanted but a below average chance of being waitlisted.
- There are 18 states with a good likelihood of being waitlisted, but once waitlisted have very poor opportunity for transplantation.
- There are 8 states in which it is difficult to get on the waitlist and once waitlisted patients will wait many years for an organ.

In summary, Dr. Leichtman noted that there are two areas that need to be addressed – the opportunity to be placed on the wait list and once placed on the waitlist, the opportunity to be transplanted. In the United States there are significant barriers to both steps.

Deceased Donor Transplantation Rates Among Kidney Transplant Registrants With Various Adjustments, 2000-2005

The Committee also re-examined data demonstrating the impact of geography on transplant rates by ethnicity. Alan Leichtman, MD presented data highlights to the Committee showing that even after various adjustments, Blacks were still 17% less likely than Whites to receive a kidney transplant (Figure 8).

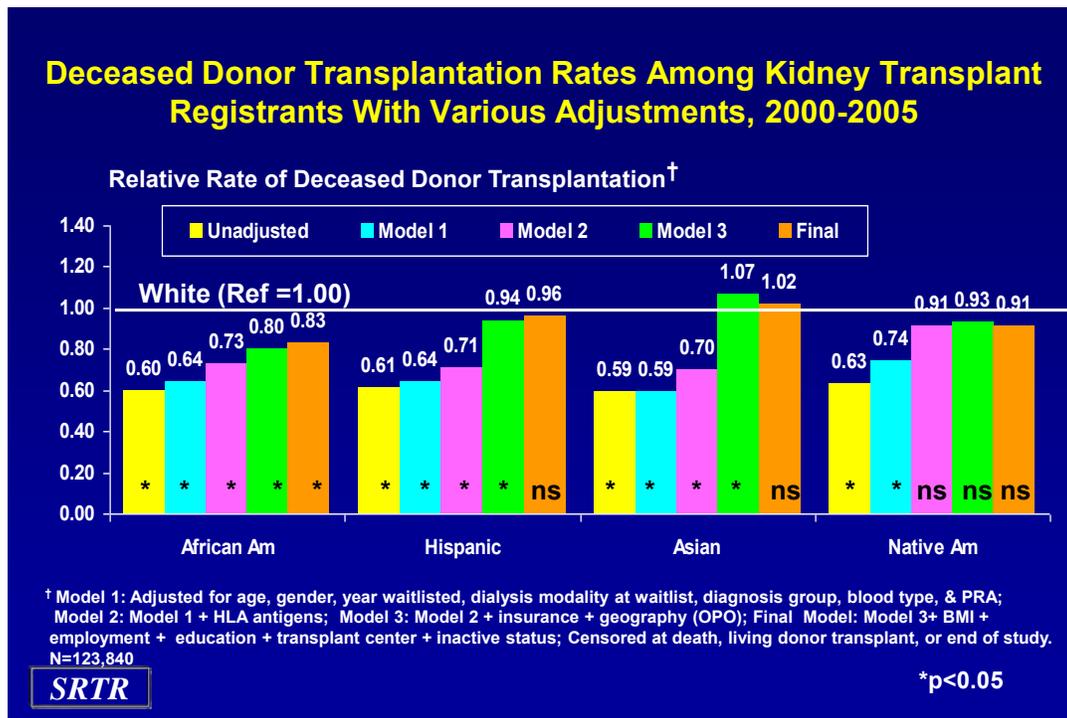


Figure 8

- Model 1 includes the basic adjustments, as well as comorbid conditions, ABO blood group, and PRA.
- Model 2 includes all of the adjustments from Model 1 with the addition of HLA.
- Model 3 includes all of the adjustments from the previous models and adds insurance and geography (OPO) as factors.
- Model 4 incorporates the adjustments from the previous models and adds BMI, Employment, Education, Transplant Center, and Inactive Status.

In summary, adjustments for all of the various factors (e.g., age, gender, diagnosis group, waitlist year, blood type, PRA, HLA, insurance, geography (OPO), BMI, employment, education, transplant center, and inactive status) substantially account for the differences in transplantation rates that were observed, indicating that these factors, most importantly differences in geography and insurance, and the difficulty in finding a deceased donor kidney that is a close tissue match, contribute to the barriers that minorities face in gaining access to transplantation. However, even taking all of these characteristics into account, there remains an unexplained 17% lower transplantation rate for African Americans compared with Caucasians.

Following the presentation, the Committee briefly discussed various initiatives that could be undertaken to improve nephrologist identification, diagnosis and referral of patients with kidney disease. It was noted that while issues related to early detection and identification of kidney disease are very important, the Committee should focus its efforts on addressing areas within its purview that impact transplantation.

Dr. Fan requested volunteers from the committee to form a Minority Transplant Referral Subcommittee charged with development of a proposal, though not one that would necessarily flow through UNOS channels. The areas to be addressed would include:

- Monitoring of patients entering the system as appropriate candidates. How can/should we monitor who is coming into the system, irrespective of their ethnicity? How do you find others who should have been referred to transplant but were not?

- Collaborations with Outside Groups. How can/should we best partner with other groups that are already trying to target referring physicians, especially those serving minority areas, especially in those 20 states showing low referral rates?

It was suggested that these and other areas be addressed via conference call with the volunteers who expressed interest in serving on the subcommittee.

13. Access to Liver and Heart Transplantation. During its July meeting, the Committee briefly reviewed and discussed the results of analyses reviewed several years ago on heart and liver transplantation (**Exhibit F**). Dr. Alan Leichtman presented the data to the Committee. The data showed differences in access to the liver waiting list by age, race and geography. However, once patients entered onto the waiting list there did not appear to be as much of a difference in the rates of transplantation. It was suggested that the MAC review an update of the liver and heart analyses to determine if the same patterns exist. The SRTR indicated that the data upon which the original analysis was based was not robust, due to the lack of a single catchment area in which to identify patients with liver or heart failure. It was recommended that the committee form a small group to assist the SRTR with reviewing discharge diagnosis codes commonly used for liver and heart failure to help in identifying other meaningful parameters that would improve the data pool of candidates.

The “Share 29” liver policy was implemented in Region 8 on 5/9/07. Under this allocation sequence, livers from adult donors would be shared regionally for adult and pediatric candidates. The Liver Committee was presented with the results of this regional sharing at its meeting on July 29, 2008 and voted to replace the current allocation with a wider, regional sharing plan which would offer livers first to those sickest patients within multistate regions rather than local delineations. The Committee is interested in reviewing the results of the descriptive data analysis prepared for the Liver Committee, especially with regard to the ethnic breakdown of some of the results.

14. MAC Comprehensive Review Article. To support the objective of building upon the body of evidence to improve minority access to transplantation, the Committee has expressed interest in publishing a comprehensive review article of all of the data it has examined over the last decade. The article will be authored by present and past committee members and chairs. The Committee is interested in publishing the article with the intent to circulate the information in the public arena so as to initiate a dialogue with a broader community than the OPTN membership. The article would add to the body of literature, encourage discussion, and attempt to substantiate or refute concerns commonly raised. The article would encompass many issues related to minority access to transplantation through various dedicated subject areas. Possible subjects would include a “then and now” review of ethnic differences in access to transplantation, waitlist rates, changes in allocation policy, advances in donation rates, impact of geography on organ allocation, and other ongoing barriers.

| MINORITY AFFAIRS COMMITTEE | | JANUARY 1, 2008 - JUNE 30, 2008 |
|---------------------------------------|----------------------------|--|
| | | MONTH |
| | | DAY |
| | FORMAT (select) | In Person |
| NAME | POSITION | Attending |
| Pang-Yen Fan, MD | Chair | X |
| Henry B. Randall, MD | Vice Chair | X |
| Diego G. Martinez | Regional Rep. | |
| Meelie A. DebRoy, MD | Regional Rep. | X |
| Gaetano Ciancio, MD, FACS | Regional Rep. | X |
| Alejandro Mejia, MD | Regional Rep. | |
| Okechukwu N. Ojogho, MD | Regional Rep. | |
| Ali s. Olyaei, PharmD | Regional Rep. | |
| Maurice E. Goodwin, ORT/NREMT | Regional Rep. | |
| Andrew C. Kao, MD | Regional Rep. | X |
| Joselito Nuqui | Regional Rep. | X |
| Silas P. Norman, MD | Regional Rep. | X |
| Gloria T. Hairston, EMT-D, CNA | Regional Rep. | X |
| Bonita Balkcom Guilford | At Large | X |
| L. Ebony Boulware, MD | At Large | X |
| Bradley H. Collins, MD | At Large | |
| Steven S. Geier, PhD, ABHI Diplomat | At Large | X |
| Judith V. Joseph, RN, BSN, CCTC | At Large | X |
| Michele M. Snyders, MSW | At Large | |
| Helen G. Spicer, RN | At Large | |
| H. Gareth Tobler, MD | At Large | X |
| Jerry Butler | BOD Liaison | X |
| Carlton J. Young, MD | Ex. Officio | X |
| Renee Dupee, Esq. (VIA PHONE) | Ex Officio | X |
| Gregory Fant, PhD | Ex Officio | |
| Valarie Ashby | SRTR Liaison | |
| Alan B. Leichtman, MD | SRTR Liaison | X |
| Sangeetha Mahadevan | SRTR Liaison | X |
| Katherine Pearson | SRTR Liaison | |

| | | |
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| Randall S. Sung, MD | SRTR Liaison | |
| Deanna L. Parker, MPA | Committee Liaison | X |
| Wida S. Cherikh, PhD | Support Staff | X |
| Dielita J. McKnight | Support Staff | X |
| Emmanuel Anum, MD | Support Staff | X |
| | | |
| Number of Committee Members Attending | | 22 |
| Total Number of Committee Members | | 34 |
| Percentage of Committee Attending | | 65% |
| Meeting Format | | 0 |
| | | |

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| MINORITY AFFAIRS COMMITTEE | SUBCOMMITTEE ON REFERRAL TO THE WAITLIST AND TRANSPLANT | JANUARY 1, 2008 - JUNE 30, 2008 |
| | MONTH | MAY |
| | DAY | 9 |
| | FORMAT (select) | Conference Call |
| NAME | POSITION | Attending |
| Pang-Yen Fan, MD | Chair | X |
| Henry B. Randall, MD | Vice Chair | X |
| Diego G. Martinez | Regional Rep. | |
| Alejandro Mejia, MD | Regional Rep. | |
| Okechukwu N. Ojogho, MD | Regional Rep. | |
| Joselito Nuqui | Regional Rep. | |
| Silas P. Norman, MD | Regional Rep. | X |
| Gloria T. Hairston, EMT-D, CNA | Regional Rep. | X |
| L. Ebony Boulware, MD | At Large | |
| Steven S. Geier, PhD, ABHI Diplomat | At Large | X |
| Charles Modlin, MD | At Large | |
| Jerry Butler | BOD - Liaison | X |
| Carlton J. Young, MD | Ex. Officio | |
| Rich Laeng, MPA | Ex Officio | |
| Gregory Fant, PhD | Ex Officio | |
| Valarie Ashby | SRTR Liaison | X |
| Alan B. Leichtman, MD | SRTR Liaison | X |
| Sangeetha Mahadevan | SRTR Liaison | X |
| | | |
| Deanna L. Parker, MPA | Committee Liaison | X |
| Wida S. Cherikh, PhD | Support Staff | X |
| Dielita J. McKnight | Support Staff | X |
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| | | |
| Number of Committee Members Attending | | 12 |
| Total Number of Committee Members | | 33 |
| Percentage of Committee Attending | | 36% |
| Meeting Format | | 0 |

| | | |
|--|------------------------|------------------|
| MINORITY AFFAIRS COMMITTEE | MONTH | JULY |
| | DAY | 18 |
| | FORMAT (select) | In-Person |
| | | |
| NAME | POSITION | Attending |
| Pang-Yen Fan, MD | Chair | X |
| Henry B. Randall, MD | Vice Chair | X |
| Diego G. Martinez | Regional Rep.1 | |
| Kenny Boyd | Regional Rep.2 | X |
| Gaetano Ciancio, MD, FACS | Regional Rep.3 | X |
| Ronald Kerman, PhD | Regional Rep.4 | X |
| R. Kelvin Satcher, MBA, CPTC | Regional Rep.5 | X |
| AJ Johnson | Regional Rep. 6 | X |
| Beth Plahn, RN, BA MHA | Regional Rep. 7 | X |
| Andrew C. Kao, MD | Regional Rep.8 | X |
| Joselito Nuqui | Regional Rep.9 | |
| Silas P. Norman, MD | Regional Rep.10 | X |
| Gloria T. Hairston, EMT-D, CNA | Regional Rep.11 | X |
| Bonita Balkcom Guilford | At Large | X |
| L. Ebony Boulware, MD | At Large | X |
| Meelie A. DebRoy, MD | At Large | X |
| Eddie Island, MD | At Large | X |
| Charles S. Modlin Jr. MD | At Large | Substitute |
| Terri Rihner, MSW, LCSW | At Large | X |
| Rachel C. Thomas, MPA, BSN, RN, CNN | At Large | |
| Roberta Wager, RN | At Large | |
| Carlton J. Young, MD | At Large | Phone |
| Jerry Butler | BOD - Liaison | X |
| Meismen Germain | Ex-Officio HRSA | X |
| Richard Laeng, MPA | Ex-Officio HRSA | |

| | | |
|---------------------------------------|-----------------------------|-----|
| Valarie Ashby, MS | SRTR Liaison | |
| Alan B. Leichtman, MD | SRTR Liaison | X |
| Sangeetha Krishnan | SRTR Liaison | X |
| Randall S. Sung, MD | SRTR Liaison | |
| Deanna L. Parker, MPA | Committee Liaison | X |
| Wida S. Cherikh, PhD | Support Staff | |
| Dielita J. McKnight | Support Staff | X |
| Karl McCleary, Ph.D, MPH | Director | X |
| Mary D. Ellison, Ph.D, MPH | AED/OPTN Project Officer | X |
| | | |
| | | |
| | | |
| Number of Committee Members Attending | | 19 |
| Total Number of Committee Members | | 25 |
| Percentage of Committee Attending | | 75% |
| Meeting Format | In-Person | 0 |

Simulation Models Integrating a Measure of Life Years From Transplant (LYFT) into the National Deceased Donor Kidney Allocation System

OPTN Minority Affairs Committee
July 18, 2008

Alan Leichtman, M.D.
Scientific Registry of Transplant Recipients
University of Michigan

SRTR

Scientific Registry of Transplant Recipients Co-investigators

- Robert Wolfe
- Keith McCullough
- Ann Rodgers
- Mary Guidinger
- Kathryn Meyers

SRTR

Kidney and Pancreas Simulation Allocation Model (KPSAM)

- KPSAM is a sophisticated computer program that can be used to
 - replicate the results of the current kidney allocation system
 - predict the consequences of proposed policy changes before they are instituted
 - allow comparisons between alternative allocation rules or algorithms
- KPSAM uses specified allocation rules and the characteristics of actual candidates and donors
 - The order of offers of organs to candidates is based on the specified allocation rules being considered
 - Data from actual candidates and donors are used to predict
 - candidate, recipient and allograft outcomes
 - probability of accepting an offer
 - Outputs include demographic and survival outcomes resulting from application of the rules under consideration

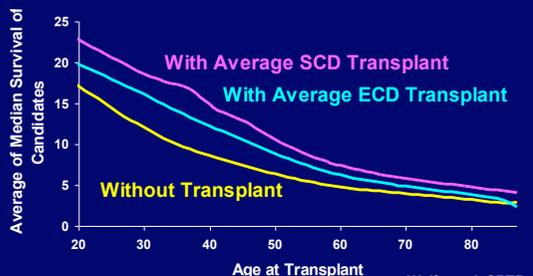
SRTR

Bottom Line

- Nearly all waitlisted chronic renal failure patients are predicted to live longer with a kidney transplant than without (dialysis alone)
- Kidney transplantation provides:
 - Not only a better quality of life, but also
 - Longer life
 - Reference: Wolfe et al NEJM 1999

SRTR

Median Expected Survival by Age Active Kidney Candidates, 1/1/2004



SRTR

Wolfe et al, SRTR simulation models

Estimated Median Waitlist (WL) and Post-Transplant (PT) Lifetimes (Years) Are Shorter Than for the U.S. Population, But Longer Than for Dialysis Population, by Diabetes Status

| age | DM | | | | non DM | | | General Population |
|-----|----------|----|----|----|--------|----|----------|--------------------|
| | Dialysis | WL | PT | KI | PT | KP | Dialysis | |
| 20 | 5 | 9 | 16 | 24 | 16 | 16 | 22 | 61 |
| 40 | 4 | 5 | 14 | 15 | 7 | 9 | 17 | 41 |
| 60 | 3 | 4 | 9 | 12 | 4 | 6 | 14 | 22 |

SRTR

Current Deceased Donor Kidney Allocation Algorithm

- Allocates 15% of (ECD) kidneys based upon waiting time, alone
- Allocates 85% (SCD) kidneys based upon a point system
 - 5% - kidney plus life saving organ
 - 15% - zero HLA-A,B,DR mismatched candidates
 - 65% - HLA mismatched candidates

SRTR

Life Years from Transplant (LYFT)

- May, 2004 OPTN Kidney Committee was charged with performing a 360° review of the existing kidney allocation algorithm
- June, 2005 reported to the OPTN Board of Directors three principal areas of concern
 - Allocation system (inequitable, inefficient, suboptimal utility)
 - Donor organ supply (HRSA Collaboratives)
 - Effects of geography on allocation equity
- OPTN Board charged the Kidney Committee with revising the kidney allocation system
- OPTN Kidney Committee began to explore integrating a measure of LYFT into the kidney allocation system

SRTR

Life Years From Transplant (LYFT)

- LYFT is the difference between two predicted lifetimes:
 - Expected lifetime without a transplant
 - Expected lifetime with a transplant from a specific donor
- Example, a hypothetical 30 year old (otherwise average) candidate's remaining life might be:
 - 18 years with a deceased donor kidney transplant
 - 12 years with dialysis
 - LYFT = 6 extra years of life with transplant
- This hypothetical candidate's LYFT would be greater if his or her expected survival
 - on dialysis would be shorter, or
 - post-transplant would be longer

SRTR

LYFT Combines Two Major Approaches to Organ Allocation

- Prioritize medical urgency
 - Higher priority if waitlist lifetime is shorter
- Prioritize post-transplant survival
 - Higher priority if post-transplant lifetimes are longer
- LYFT prioritizes both by using the common metric of expected future years of life
- LYFT can be used
 - as an element in organ allocation
 - as a metric
 - to assess trends in outcomes of existing allocation systems
 - to compare the current allocation system to proposed alternative allocation systems

SRTR

Methods: Covariates Used in LYFT

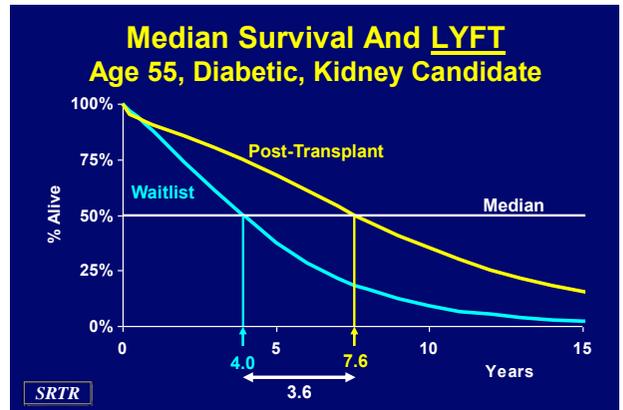
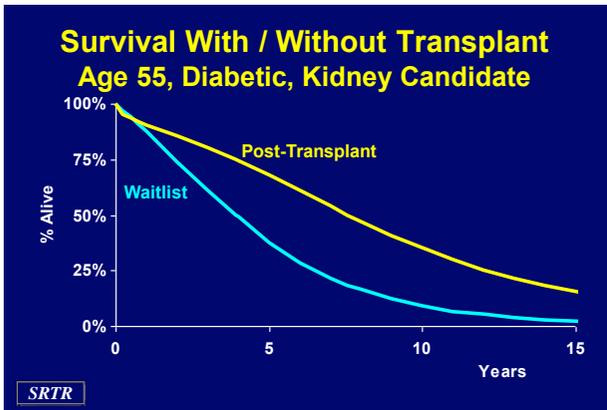
- Recipient Factors:
 - Age
 - Transplant type (kidney v. simultaneous kidney-pancreas)
 - Recipient diagnosis (diabetes, polycystic disease, other)
 - BMI
 - Previous transplant
 - Albumin
 - Peak PRA
 - Years on dialysis
- Donor factors:
 - HLA (A, B, and DR)
 - Same Donation Service Area (DSA) as recipient v. shared across DSA
 - DCD
 - Age
 - CMV
 - Hypertension
 - Weight
 - Cause of Death

SRTR

Quality of Life (QoL) - Adjusted LYFT

- QoL adjustment weights dialysis years by 80%:
 - Transplant Lifetime (QoL) = Years with functioning graft + 0.8 * Dialysis Years after graft failure
 - Non-Transplant Lifetime (QoL) = 0.8 * Dialysis Years
- QoL adjusted LYFT is the difference between the adjusted lifetimes.
- Simulations (unless otherwise noted) use QoL adjusted LYFT
- Survival is reported in non-adjusted life years

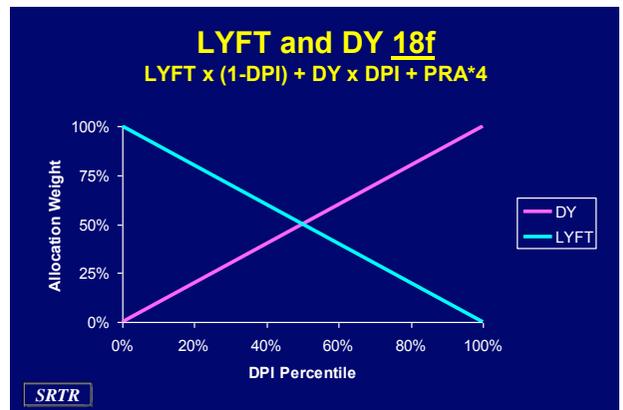
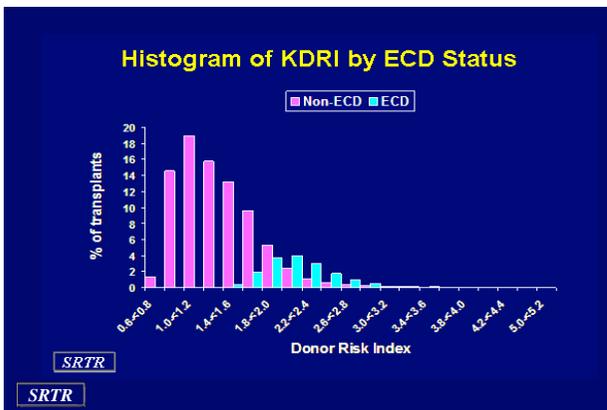
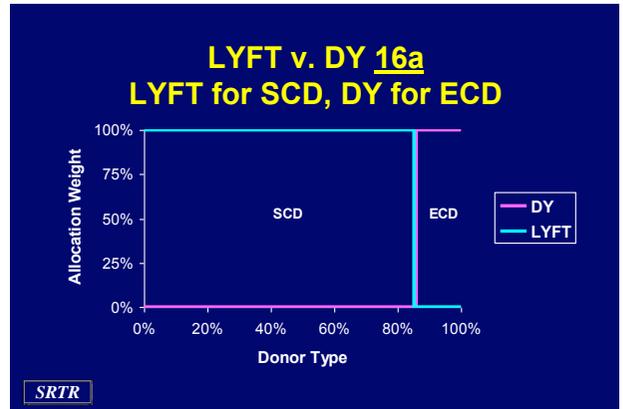
SRTR

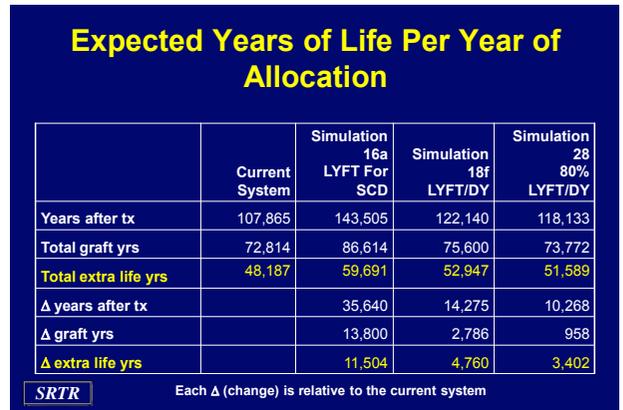
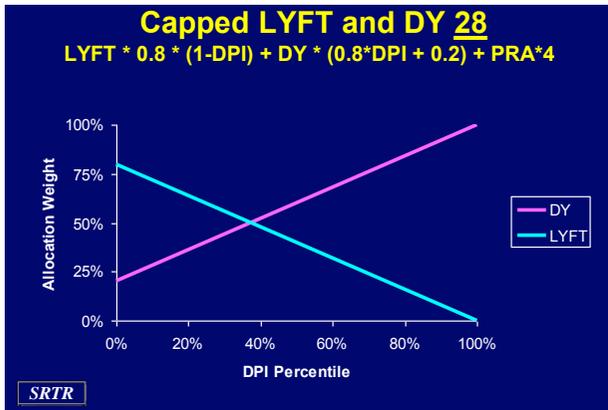


KPSAM LYFT-based Models

- More than 30 sets of allocation rules were modeled, three alternatives were extensively discussed:
 - Run 16a: 100% LYFT for SCD, 100% DY for ECD
 - Run 18f: $LYFT \times (1-DPI) + DY \times DPI + PRA^4$
 - Run 28: $LYFT \times 0.8 \times (1-DPI) + DY \times (0.8 \times DPI + 0.2) + PRA^4$

SRTR

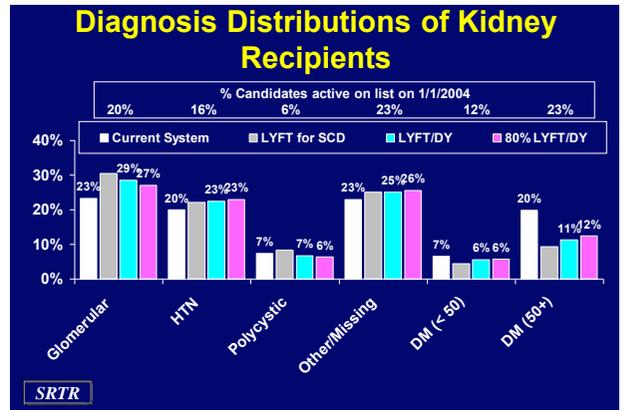
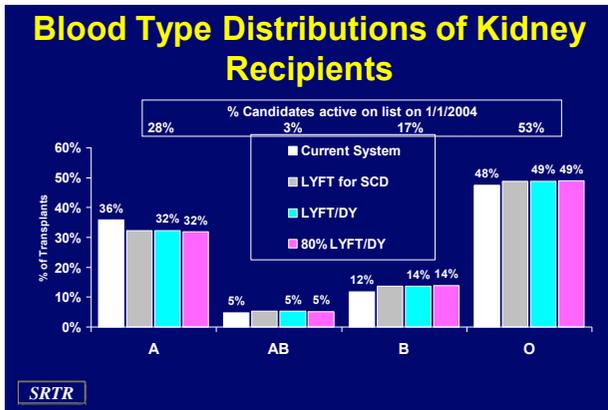
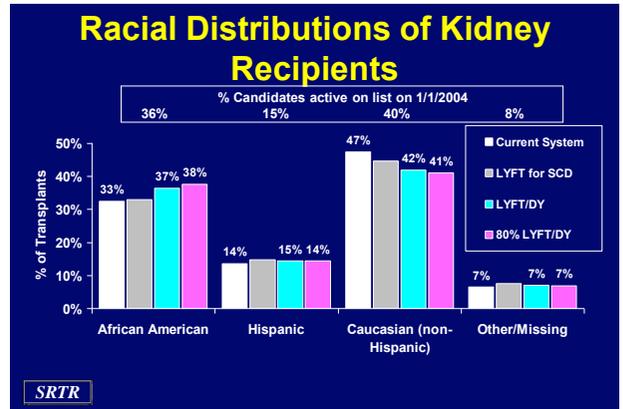




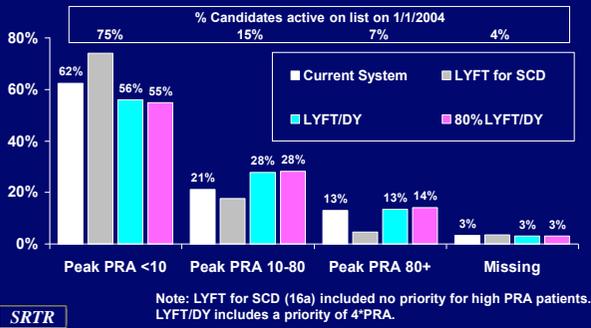
Expected Years of Life Per Transplant by KPSAM Run (2003)

| Years | Average Post-Tx Lifetime | Average Graft Lifetime | Average Extra Years of Life | Total Extra Years | KI + KP Tx |
|-------------------------------------|--------------------------|------------------------|-----------------------------|-------------------|------------|
| Run 1: Current nat. allocat. system | 11.8 | 8.0 | 5.3 | 48,187 | 9124 |
| Run 16a: LYFT for SCD | 15.0 | 9.1 | 6.2 | 59,691 | 9569 |
| Run 18f: LYFT/DY | 13.4 | 8.3 | 5.8 | 52,947 | 9111 |
| Run 28: 80%LYFT/DY | 13.1 | 8.2 | 5.7 | 51,589 | 9035 |

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PRA Distributions of Kidney Recipients

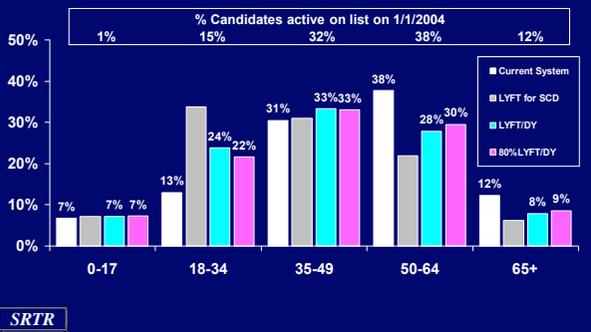


Kidney Allocation System (KAS) Proposal US DHHS Office of Civil Rights (OCR)

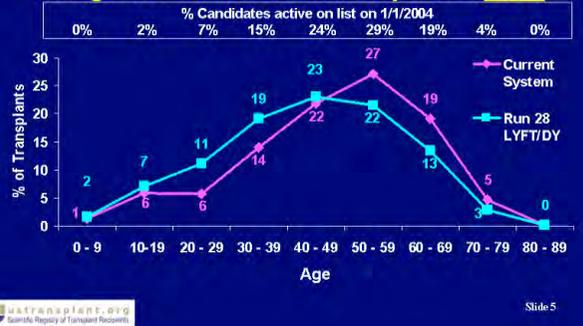
Update from 3/12/2008 Kidney Committee Meeting

- At HRSA's request, the OCR has been reviewing the projected impact of the KAS proposal on recipient age since December
- The DHHS is continuing to meet with the OCR on this issue

Age Distributions of Kidney Recipients

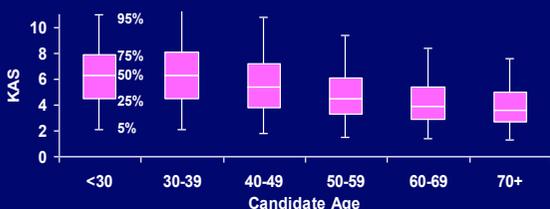


Age Distribution of All Kidney Alone Recipients Changes When Allocation Incorporates LYFT



KAS by Age Decade

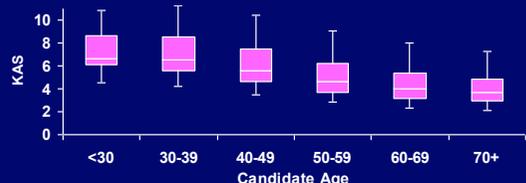
Distribution of KAS Among Active, Adult, Kidney-Along Candidates



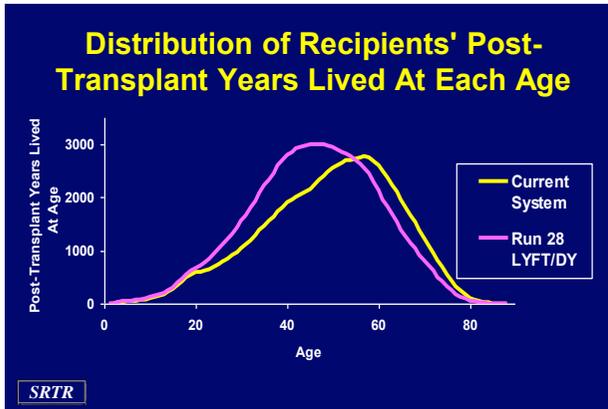
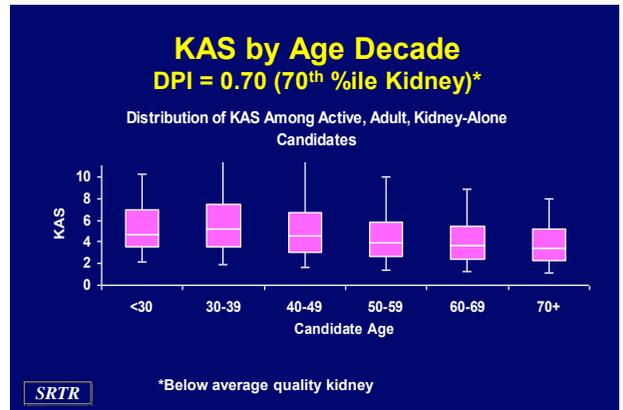
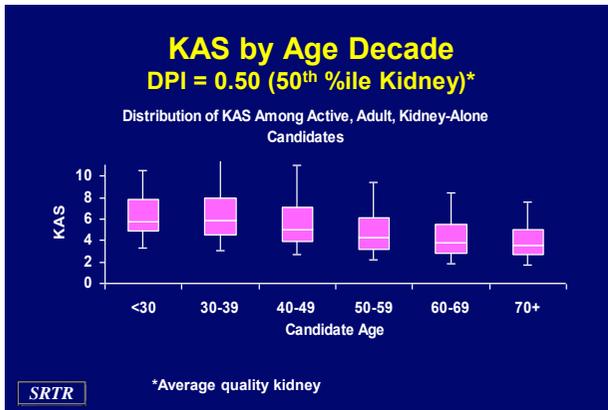
*Kidneys with DPI = 0.1, 0.3, 0.5, 0.7, 0.9

KAS by Age Decade DPI = 0.30 (30th %ile of Quality)*

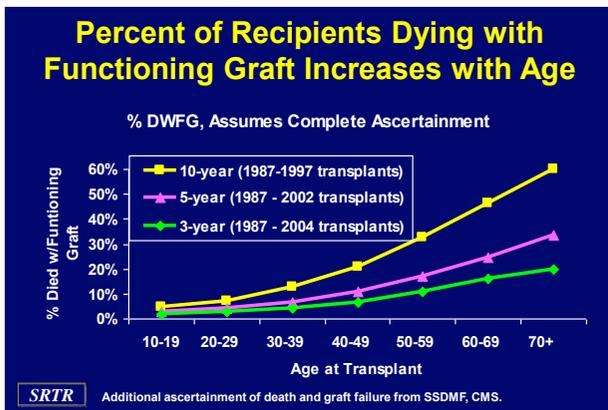
Distribution of KAS Among Active, Adult, Kidney-Along Candidates



*Good quality kidney



- ### Age Concepts
- Under the current national system: with equal wait time, age is not a factor
 - Under the proposed system: with equal KAS, age is not a factor
 - Neither system discriminates based on age if the wait time or KAS is the same
 - Age affects the chances of achieving both
 - a high KAS
 - a long wait time
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- ### Rules Modeled in Run 28
- Run 28 LYFT (capped at 80%) Blended with Dialysis Years
- Formula for kidney allocation score = $LYFT * 0.8 * (1-DPI) + DY * (0.8 * DPI + 0.2) + PRA * 4$
 - KP candidate priority follows pancreas allocation rules, i.e. pancreas allocated by waiting time and kidney follows pancreas
 - Diagnosis categories in LYFT calculation are PKD, DM, and other
 - LYFT score updates (age, dialysis years, PRA)
 - ECD/SCD distinction eliminated (although patient preference to not accept ECD kidneys was kept)
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Rules Modeled in Run 28

Run 28 LYFT (capped at 80%) Blended with Dialysis Years

- Dialysis years calculated since most recent initiation of dialysis
- Pediatric and adult allocation are separated. Pediatric rules remain same as in current system (local priority for donors < 35), except for no offers from donors > 35 to pediatric candidates
- No paybacks
- No 0 HLA priority
- No 0 HLA sharing, except PRA 80+
- A2-B and A2B-B nationalized
- HLA A and B not in LYFT calculation

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Caveats Regarding the Run 28 Rules

- The kidney allocation proposal is not yet finalized
- The rules employed in Run 28 are still under consideration by the OPTN Kidney Committee
- The rules modeled in Run 28 do not constitute the details of a final proposal

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Summary of KPSAM Modeling of Modifications of Allocation by LYFT/DY

- Compared to the current system
 - LYFT for SCD adds about 11,500 incremental years of life for each year of DD kidney transplantation
 - LYFT/DY adds about 4,800 years
 - 80% LYFT/DY adds about 3,400 years
 - All three potential proposals increase allocation to younger candidates and decrease allocation to older candidates
 - LYFT/DY and 80% LYFT/DY improve access for African Americans
 - 4*PRA improves access for candidates with PRA 20-80%

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Simulations in Progress

- 3-Year Simulations
 - Will not be as accurate
 - assumptions of unchanging listing practices and acceptance patterns will be less valid over 3 years than 1 year
 - Will be useful in evaluating size and duration of bolus effect
- Acceptance Pattern Simulations
 - Current simulations assume unchanging acceptance patterns, other assumptions can be tested
- Patient waiting time calculator

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Recipient Age over 3-Year KPSAM Run

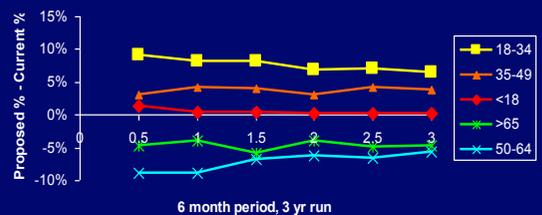
Average Age of KI Recipients



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Recipient Age Over 3-Year KPSAM Run

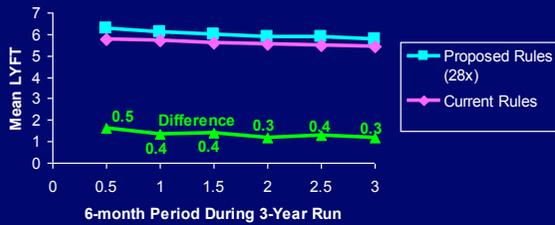
Difference in % of KI Recipients by Age Group



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LYFT Over 3-Year KPSAM Run

Benefit (LYFT) Among Kidney Recipients



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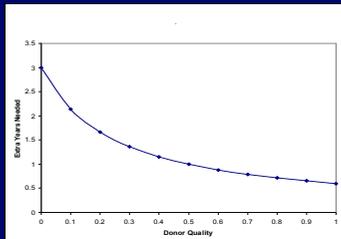
Race Over 3-Year KPSAM Run

% African American Kidney Recipients



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Example Patient DSA-Specific Waiting Time Calculator



Input:
LYFT variables,
PRA,
Dialysis years,
Blood type

Output:
Curve displaying
expected future
waiting time to
receive a kidney of
any give DPI

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Waiting Time Calculator

Example Calculator for a candidate (OPD statistics should have a look-up table)
Projects waiting time for "typical" HLA mismatch and cold time organ. does not apply to a current offer.

| Candidate Inputs: | | | | KAS parameters: | | | |
|--|----------------------|------|------------------------------------|-----------------|-----------------|---|---------------------|
| 0.5 | Dialysis Time (DT) | 0.5 | LYFT-DPI beta | 0.3 | Min DT weight | 4 | Points per 100% PRA |
| 8 | LYFT (average organ) | 0.6 | Max LYFT weight | 0.8 | Max LYFT weight | | |
| A | Blood Type | 0.13 | Wait List Death rate (approximate) | | | | |
| 0.6 | PRA | | | | | | |
| Candidate Score = $0.8 * (1 - \text{DPI}) * \text{LYFT} + (0.2 + 0.8 * \text{DPI}) * \text{DT} + 4 * \text{PRA}$ | | | | | | | |

| DPI Range | Donor Percentile Index | Cand LYFT with such a donor | OPO Median Score (Type A) Transplant | Candidate Score for such Organ | Wait Time to Median Score | Probability of survival to next X-match at this OPC | Average Years to next X-match compatible organ | Type A per year at this OPC |
|-----------------------|------------------------|-----------------------------|--------------------------------------|--------------------------------|---------------------------|---|--|-----------------------------|
| 0.0 - 0.2 | 0.10 | 11.0 | 13 | 9.1 | 13.9 | 18% | 1.3 | 4 |
| 0.2 - 0.4 | 0.30 | 9.4 | 10 | 7.9 | 4.8 | 55% | 1.0 | 3 |
| 0.4 - 0.6 | 0.50 | 8.0 | 8 | 6.7 | 2.2 | 76% | 0.7 | 2 |
| 0.6 - 0.8 | 0.70 | 6.8 | 6 | 5.5 | 0.7 | 92% | 0.7 | 2 |
| 0.8 - 1.0 | 0.90 | 5.8 | 2 | 4.3 | 0.0 | 100% | 1.3 | 4 |
| Live Donor Average MM | | -0.20 | 14.0 | | | | | |

Input: Candidate Characteristics are in Light Yellow
Input: OPO statistics for given blood type are in Blue
Calculated: Candidate Outcomes are in Gold

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Comparison of the Current Kidney Allocation System and the Kidney Allocation Score (KAS) Simulations

| Current Kidney Allocation System | | KAS Simulations |
|--|-------------------------|---|
| HLA Match - Increases allograft survival | Medical Criteria | Life Years From Transplant (LYFT) - Increases candidate survival |
| Wait time - Starts at listing or GFR < 20 | Time | Dialysis Years (DY) - Starts at initiation of dialysis |
| 4 points for %PRA > 80 | PRA | 4 * % PRA/100 |
| SCD/ECD | Donor Quality | Donor Profile Index (DPI) - Continuous measure of association with graft failure, ranging from 0 (lowest risk) to 1 (highest risk) |

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Simulation Models Integrating a Measure of Life Years From Transplant (LYFT) into the National Deceased Donor Kidney Allocation System

OPTN Histocompatibility Committee
July 9, 2008

Alan Leichtman, M.D.
Scientific Registry of Transplant Recipients
University of Michigan

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Final Analysis for Data Requests from the OPTN Minority Affairs Committee Meeting on September 28, 2007

Prepared by Alan Leichtman, MD ., Sangeetha Krishnan, MS, Keith McCullough, MS, John Kalbfleisch, Ph.D., Panduranga Rao, MD., Valarie Ashby, MA, and Robert Wolfe, Ph.D., of the Scientific Registry of Transplant Recipients (Arbor Research/University of Michigan)

Data Request Routing Information and Analysis Timeline:

- OPTN Committee request made: 10/08/2007
- Analysis plan submitted: 10/22/2007
- Draft Analysis submitted: 2/15/08
- Final Analysis submitted: 2/29/08
- Next Committee Meeting: 03/11/2008

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Analytical/Inferential Request #1: Ethnic and Demographic Characteristics of candidates with high PRA compared with those with low PRA.

Background: At the meeting on September 28, 2007 the Minority Affairs Committee (MAC) was presented with results of analyses from KPSAM simulation runs that compared life-years from transplant (LYFT) for the current national allocation system with the LYFT-based allocation systems that incorporate years on dialysis and matches groups of donors and candidates on characteristics such as LYFT, donor profile index (DPI), panel reactive antibody (PRA), age, etc. The committee would like to know about the ethnic and demographic characteristic of candidates with high PRA compared with those with low PRA.

Data Requested: With respect to the outcome from the simulation runs for the LYFT-based allocation systems the committee would like to know what the ethnic and demographic characteristics of candidates with high PRA versus those with low PRA are.

Executive Summary

Counts and percentages by PRA category of kidney recipient characteristics resulting from simulations under current national allocation policy and under the Kidney Committee's proposed LYFT blended with dialysis years allocation system.

Study Population

The simulation used actual candidates and donors from the year 2003 to simulate allocation under two sets of rules:

1. The current national allocation rules (without local variances)
2. The LYFT blended with Dialysis Years system currently under consideration as a proposal from the OPTN Kidney Committee.

Not only did each set of rules result in different organs being allocated to different candidates, but acceptance decisions (which were modeled probabilistically using candidate and donor characteristics in a logistic regression based on match run data) could vary with every run. The results presented are the averages of three separate runs under each system, each run with the same patient and donor population, with only acceptance and relisting patterns allowed to vary in between runs.

LYFT models were based on candidates and recipients from 1987 to 2006. Waitlist survival was calculated using samples of active candidates on specific dates, mirroring the candidates available for a transplant; i.e., a cross-section of active candidates on a given date. Post-transplant survival used all recipients during this period.

Analytical Approach

Results of the KPSAM model were analyzed and grouped according to the PRA score. Only kidney-alone recipients were included in the output, as the Kidney Committee has decided that kidney-pancreas

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allocation should be kept separate, following the pancreas allocation system. The cross tabulation of recipient characteristic by PRA group was calculated first as counts of received kidneys and then as percentages within each recipient characteristic group.

*Results***Table 1.1: Counts of recipients by PRA and recipient characteristic**

| | Current System | | | | | Proposed System | | | | |
|---|----------------|--------------|------------|----------------|-------------|-----------------|--------------|------------|----------------|-------------|
| | PRA 0-10 | PRA 10-80 | PRA >80 | PRA missing | Total | PRA 0-10 | PRA 10-80 | PRA >80 | PRA missing | Total |
| 2 A MM | 2437 | 856 | 540 | 102 | 3935 | 2200 | 1217 | 605 | 109 | 4131 |
| 1 A MM | 1900 | 635 | 347 | 110 | 2992 | 1847 | 960 | 437 | 112 | 3356 |
| 0 A MM | 830 | 263 | 199 | 60 | 1352 | 313 | 158 | 175 | 18 | 664 |
| 2 B MM | 3347 | 1160 | 631 | 160 | 5298 | 3087 | 1660 | 715 | 168 | 5630 |
| 1 B MM | 1183 | 391 | 290 | 60 | 1924 | 1156 | 615 | 370 | 64 | 2205 |
| 0 B MM | 637 | 203 | 164 | 52 | 1056 | 117 | 59 | 131 | 8 | 315 |
| 2 DR MM | 1849 | 638 | 409 | 80 | 2976 | 1874 | 1009 | 485 | 101 | 3469 |
| 1 DR MM | 2209 | 757 | 435 | 113 | 3514 | 2019 | 1080 | 519 | 114 | 3732 |
| 0 DR MM | 1109 | 359 | 242 | 79 | 1789 | 467 | 245 | 213 | 24 | 949 |
| 0 ABDR MM | 551 | 182 | 146 | 48 | 927 | 21 | 11 | 101 | 3 | 136 |
| Recipient African American | 1586 | 651 | 408 | 44 | 2689 | 1516 | 967 | 497 | 47 | 3027 |
| Recipient Hispanic | 704 | 230 | 131 | 53 | 1118 | 618 | 312 | 144 | 48 | 1122 |
| Recipient Caucasian | 2523 | 778 | 491 | 136 | 3928 | 1906 | 924 | 514 | 109 | 3453 |
| Recipient Other/Missing Race/Ethnicity | 354 | 95 | 55 | 38 | 542 | 320 | 132 | 61 | 36 | 549 |
| Recipient ABO = A | 1889 | 601 | 383 | 101 | 2974 | 1442 | 724 | 377 | 92 | 2635 |
| Recipient ABO = AB | 245 | 80 | 52 | 19 | 396 | 230 | 111 | 57 | 16 | 414 |
| Recipient ABO = B | 641 | 206 | 91 | 35 | 973 | 677 | 308 | 120 | 26 | 1131 |
| Recipient ABO = O | 2393 | 867 | 559 | 117 | 3936 | 2011 | 1192 | 662 | 104 | 3969 |
| Recipient < 18 | 416 | 74 | 20 | 27 | 537 | 455 | 75 | 22 | 33 | 585 |
| Recipient 18-34 | 572 | 246 | 201 | 24 | 1043 | 506 | 369 | 230 | 24 | 1129 |
| Recipient 35-49 | 1386 | 579 | 424 | 71 | 2460 | 1204 | 807 | 479 | 63 | 2553 |
| Recipient 50-64 | 2029 | 657 | 363 | 108 | 3157 | 1609 | 822 | 399 | 83 | 2913 |
| Recipient 65+ | 765 | 198 | 77 | 42 | 1082 | 586 | 262 | 87 | 36 | 971 |
| Recipient Diagnosis: Glomerular | 1097 | 433 | 340 | 57 | 1927 | 992 | 618 | 381 | 53 | 2044 |
| Recipient Diagnosis: HTN | 1034 | 370 | 201 | 48 | 1653 | 1062 | 566 | 250 | 42 | 1920 |

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| | Current System | | | | | Proposed System | | | | |
|---|----------------|--------------|-------------|----------------|-------------|-----------------|--------------|-------------|----------------|-------------|
| | PRA 0-10 | PRA 10-80 | PRA >80 | PRA missing | Total | PRA 0-10 | PRA 10-80 | PRA >80 | PRA missing | Total |
| Recipient Diagnosis: Polycystic | 402 | 124 | 60 | 23 | 609 | 384 | 167 | 71 | 21 | 643 |
| Recipient Diagnosis: Renovascular | 12 | 4 | 2 | 1 | 19 | 13 | 6 | 3 | 1 | 23 |
| Recipient Diagnosis: Other/Missing | 1097 | 415 | 302 | 66 | 1880 | 1012 | 540 | 341 | 68 | 1961 |
| Recipient Diagnosis: DM (KI recipient) | 1526 | 408 | 180 | 76 | 2190 | 897 | 437 | 170 | 55 | 1559 |
| Recipient Diagnosis: DM (KI recipient) < 50 | 361 | 118 | 48 | 19 | 546 | 210 | 128 | 46 | 14 | 398 |
| Recipient Diagnosis: DM (KI recipient) 50+ | 1165 | 289 | 131 | 57 | 1642 | 688 | 309 | 124 | 41 | 1162 |
| Shared - payback | 260 | 83 | 39 | 6 | 388 | 0 | 0 | 0 | 0 | 0 |
| Shared - nonpayback | 1014 | 383 | 317 | 84 | 1798 | 503 | 288 | 286 | 29 | 1106 |
| Total | 5168 | 1754 | 1085 | 272 | 8279 | 4360 | 2335 | 1216 | 238 | 8149 |

Table 1.2: Percentages of recipients by PRA and recipient characteristic

| | Current System | | | | | Proposed System | | | | |
|---------------------------------------|----------------|--------------|------------|----------------|-------|-----------------|--------------|------------|----------------|-------|
| | PRA 0-10 | PRA 10-80 | PRA >80 | PRA missing | Total | PRA 0-10 | PRA 10-80 | PRA >80 | PRA missing | Total |
| 2 A MM | 47.2% | 48.8% | 49.8% | 37.4% | 47.5% | 50.5% | 52.1% | 49.7% | 45.7% | 50.7% |
| 1 A MM | 36.8% | 36.2% | 31.9% | 40.5% | 36.1% | 42.4% | 41.1% | 35.9% | 46.9% | 41.2% |
| 0 A MM | 16.1% | 15.0% | 18.3% | 22.1% | 16.3% | 7.2% | 6.8% | 14.4% | 7.4% | 8.1% |
| 2 B MM | 64.8% | 66.1% | 58.2% | 58.8% | 64.0% | 70.8% | 71.1% | 58.8% | 70.1% | 69.1% |
| 1 B MM | 22.9% | 22.3% | 26.7% | 22.2% | 23.2% | 26.5% | 26.4% | 30.5% | 26.6% | 27.1% |
| 0 B MM | 12.3% | 11.6% | 15.1% | 19.0% | 12.8% | 2.7% | 2.5% | 10.8% | 3.3% | 3.9% |
| 2 DR MM | 35.8% | 36.4% | 37.7% | 29.5% | 35.9% | 43.0% | 43.2% | 39.9% | 42.1% | 42.6% |
| 1 DR MM | 42.8% | 43.2% | 40.1% | 41.6% | 42.4% | 46.3% | 46.3% | 42.6% | 47.8% | 45.8% |
| 0 DR MM | 21.5% | 20.5% | 22.3% | 29.0% | 21.6% | 10.7% | 10.5% | 17.5% | 10.2% | 11.6% |
| 0 ABDR MM | 10.7% | 10.4% | 13.5% | 17.6% | 11.2% | 0.5% | 0.5% | 8.3% | 1.1% | 1.7% |
| Recipient African American | 30.7% | 37.1% | 37.6% | 16.2% | 32.5% | 34.8% | 41.4% | 40.9% | 19.5% | 37.1% |
| Recipient Hispanic | 13.6% | 13.1% | 12.1% | 19.6% | 13.5% | 14.2% | 13.4% | 11.8% | 20.2% | 13.8% |
| Recipient Caucasian | 48.8% | 44.3% | 45.2% | 50.2% | 47.4% | 43.7% | 39.6% | 42.3% | 45.4% | 42.4% |

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| | Current System | | | | | Proposed System | | | | |
|---|----------------|--------------|--------------|----------------|---------------|-----------------|--------------|--------------|----------------|---------------|
| | PRA 0-10 | PRA 10-80 | PRA >80 | PRA missing | Total | PRA 0-10 | PRA 10-80 | PRA >80 | PRA missing | Total |
| Recipient Other/Missing Race/Ethnicity | 6.8% | 5.4% | 5.1% | 14.0% | 6.5% | 7.3% | 5.6% | 5.0% | 14.9% | 6.7% |
| Recipient ABO = A | 36.6% | 34.3% | 35.3% | 37.1% | 35.9% | 33.1% | 31.0% | 31.0% | 38.6% | 32.3% |
| Recipient ABO = AB | 4.7% | 4.6% | 4.8% | 7.0% | 4.8% | 5.3% | 4.8% | 4.7% | 6.8% | 5.1% |
| Recipient ABO = B | 12.4% | 11.7% | 8.4% | 12.9% | 11.8% | 15.5% | 13.2% | 9.8% | 11.0% | 13.9% |
| Recipient ABO = O | 46.3% | 49.4% | 51.5% | 43.1% | 47.5% | 46.1% | 51.0% | 54.4% | 43.6% | 48.7% |
| Recipient < 18 | 8.1% | 4.2% | 1.9% | 9.9% | 6.5% | 10.4% | 3.2% | 1.8% | 13.9% | 7.2% |
| Recipient 18-34 | 11.1% | 14.0% | 18.6% | 8.7% | 12.6% | 11.6% | 15.8% | 18.9% | 9.9% | 13.9% |
| Recipient 35-49 | 26.8% | 33.0% | 39.1% | 26.0% | 29.7% | 27.6% | 34.6% | 39.4% | 26.3% | 31.3% |
| Recipient 50-64 | 39.3% | 37.5% | 33.4% | 39.9% | 38.1% | 36.9% | 35.2% | 32.8% | 34.8% | 35.7% |
| Recipient 65+ | 14.8% | 11.3% | 7.1% | 15.5% | 13.1% | 13.4% | 11.2% | 7.1% | 15.0% | 11.9% |
| Recipient Diagnosis: Glomerular | 21.2% | 24.7% | 31.4% | 21.0% | 23.3% | 22.8% | 26.5% | 31.3% | 22.0% | 25.1% |
| Recipient Diagnosis: HTN | 20.0% | 21.1% | 18.5% | 17.7% | 20.0% | 24.4% | 24.3% | 20.6% | 17.7% | 23.6% |
| Recipient Diagnosis: Polycystic | 7.8% | 7.1% | 5.6% | 8.5% | 7.4% | 8.8% | 7.2% | 5.8% | 8.8% | 7.9% |
| Recipient Diagnosis: Renovascular | 0.2% | 0.3% | 0.2% | 0.4% | 0.2% | 0.3% | 0.3% | 0.3% | 0.3% | 0.3% |
| Recipient Diagnosis: Other/Missing | 21.2% | 23.7% | 27.9% | 24.4% | 22.7% | 23.2% | 23.1% | 28.1% | 28.3% | 24.1% |
| Recipient Diagnosis: DM (KI recipient) | 29.5% | 23.2% | 16.6% | 28.1% | 26.5% | 20.6% | 18.7% | 14.0% | 23.0% | 19.1% |
| Recipient Diagnosis: DM (KI recipient) < 50 | 7.0% | 6.8% | 4.5% | 7.0% | 6.6% | 4.8% | 5.5% | 3.8% | 5.7% | 4.9% |
| Recipient Diagnosis: DM (KI recipient) 50+ | 22.5% | 16.5% | 12.1% | 21.1% | 19.8% | 15.8% | 13.2% | 10.2% | 17.3% | 14.3% |
| Shared - payback | 5.0% | 4.7% | 3.6% | 2.2% | 4.7% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Shared - nonpayback | 19.6% | 21.8% | 29.2% | 30.9% | 21.7% | 11.5% | 12.3% | 23.5% | 12.3% | 13.6% |
| Total | 62.4% | 21.2% | 13.1% | 3.3% | 100.0% | 53.5% | 28.7% | 14.9% | 2.9% | 100.0% |

Scientific Registry of Transplant Recipients

Minority Affairs Committee

March 11, 2008

SRTR



Purpose

To study the ethnic and demographic characteristics of candidates with high PRA versus those with low PRA, with respect to the outcome from the simulation runs for the LYFT-based allocation systems.

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Background

- On September 28, 2007 the Minority Affairs Committee (MAC) was presented with results of analyses from KPSAM simulation runs that compared life-years from transplant (LYFT) for the current national allocation system with several LYFT-based allocation systems.
- The MAC requested incremental information about the ethnic and demographic characteristic of candidates with high PRA compared with those with low PRA as modeled in these systems.

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Methods

- The simulation used actual candidates and donors from the year 2003 to simulate allocation under two sets of rules:
 - The current national allocation rules (without local variances)
 - LYFT blended with Dialysis Years
- The results presented are the averages of three separate runs under each system.
- LYFT models were based on candidates and recipients from 1987 to 2006.

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Analytical Approach

- Results of the KPSAM model were analyzed and grouped according to the PRA score.
- Only kidney-alone recipients were included in the output, as the Kidney Committee has asked that kidney-pancreas allocation models should be kept separate, with SPK following the pancreas allocation system.

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Results

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Recipient Demographics by PRA Range Under Current National Rules and Under Proposed Kidney Allocation System

| Recipient Characteristic | Current | Proposed | Current | Proposed | Current | Proposed |
|--|----------|----------|-----------|-----------|---------|----------|
| | PRA 0-10 | PRA 0-10 | PRA 10-80 | PRA 10-80 | PRA >80 | PRA >80 |
| 0 ABO MM | 10.7% | 0.5% | 10.4% | 0.5% | 13.5% | 5.3% |
| Recipient African American | 30.7% | 34.8% | 37.1% | 41.4% | 37.5% | 40.9% |
| Recipient Hispanic | 13.6% | 14.2% | 13.1% | 13.4% | 12.1% | 11.6% |
| Recipient Caucasian | 48.8% | 43.7% | 44.3% | 39.6% | 45.2% | 42.3% |
| Recipient ABO = B | 12.4% | 15.5% | 11.7% | 13.2% | 8.4% | 9.8% |
| Recipient Diagnosis: DM (KI recipient) 50+ | 22.5% | 15.8% | 16.5% | 13.2% | 12.1% | 10.2% |

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Summary

- Under the current national system, 80-100 and 0-10 PRA have 48.8% and 45.2% Caucasians respectively v. 43.7% and 42.3% in the new system
- Under the current national system, 80-100 and 0-10 PRA have 30.7% and 37.6% African American respectively v. 34.8% and 40.9% in the new system
- Under the current national system and under the new system, 80-100 and 0-10 PRA have similar percentages of Hispanics
- Under the current national system, 80-100 and 0-10 PRA have similar percentages of 0 MM
- Under the proposed system, 80-100 PRA recipients have a much higher percentage of 0 MM than 0-10
- Sharing (80-100 v. 0-10 PRA for: current national system = 29% v. 20%, proposed system = 24% v. 12%)
- Pediatrics (80-100 v. 0-10 PRA for: current national system = 2% v. 8%, proposed system = 2% v. 10%)

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**OPTN/UNOS Histocompatibility Committee
Descriptive Data Request**

Final Report:

CPRA Analyses

Prepared for:
Histocompatibility Committee Meeting
July 9-10, 2008

By:
Ann Harper
Research Department
United Network for Organ Sharing

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Background/Purpose

The CPRA was implemented in UNetSM on 12/5/2007. Initial analyses were presented to the committee during conference calls held on January 29, 2008 and March 20, 2008. The Committee has requested ongoing updates and several refinements to the analyses.

Program Goal Addressed

To increase the number of deceased donor organs transplanted, by ensuring that the CPRA is appropriately used to provide better matched kidney offers to sensitized patients.

Committee Request

This is an update of previous analyses. The Committee asked that, when the analyses are updated for the July 2008 meeting, the Committee would like the following modifications to the CPRA analyses:

- For candidates currently eligible for sensitization points, provide the percentage of candidates who would potentially keep or lose those points, by race.
- For all graphs showing the distribution by center, sort centers by those with the most listings (on the left) to least listings (on the right).
- For graphs showing candidates who have a PRA (>0, >80) but no CPRA, provide the percentage of patients affected within each (region, center) rather than the number of candidates.

Data and Methods

CPRA and unacceptable antigen data will be analyzed for patients currently on the kidney waiting list. The percentage of patients with a CPRA, the number of patients who could potentially lose their sensitization points, and the number of centers that are not entering unacceptable antigens will be determined.

Results

Percentage of patients with CPRA

As of June 13, 2008, 23,009 candidates (28.4%) on the kidney waiting list have at least one unacceptable antigen entered, allowing the calculation of a CPRA. This is an increase from the number observed on January 28, 2008 (20,862). Results by Region are provided in Figure 1. Figure 2 displays the percentage of patients with CPRA by center. In this figure, each bar represents a center, arranged by those centers with the greatest number of candidate listings on the left and the fewest listings on the right. A total of 13 centers have no unacceptable antigens listed for their candidates.

Figure 1. Percent of Patients with CPRA, by Region

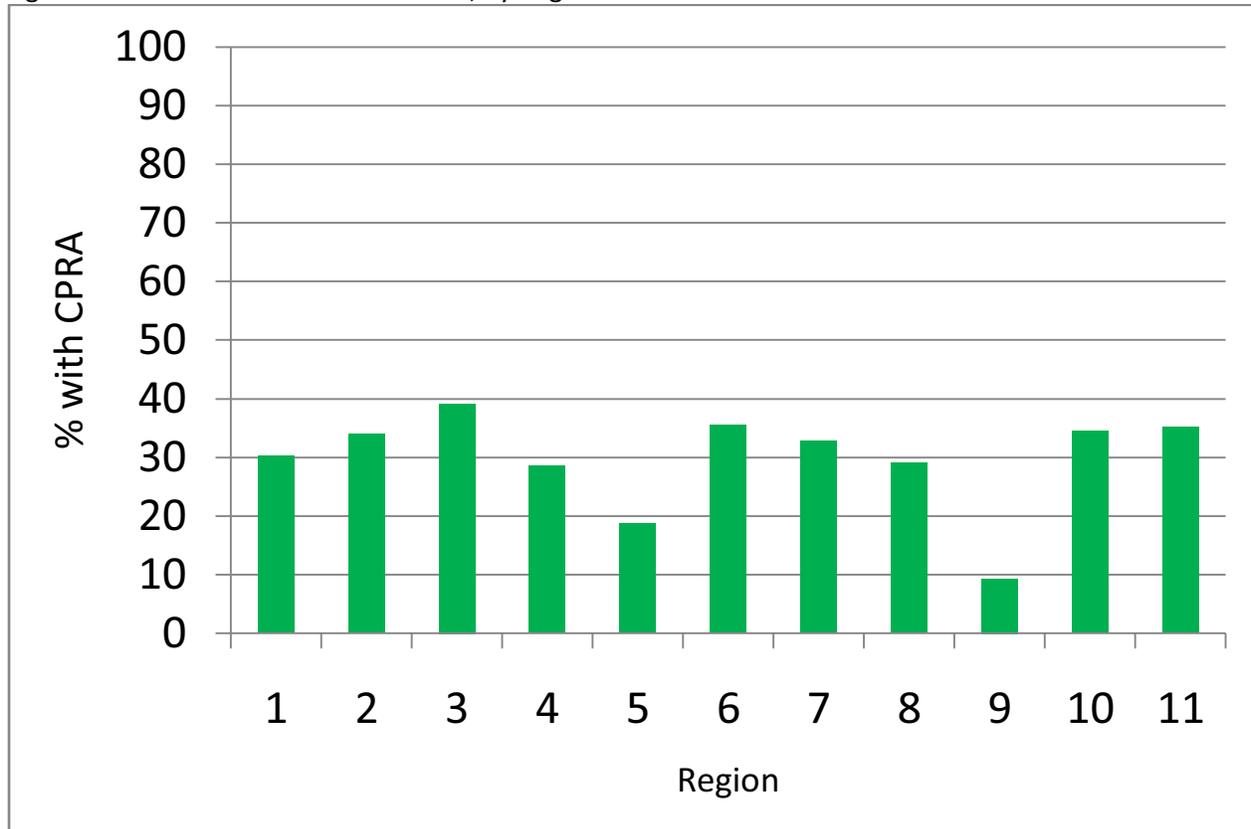
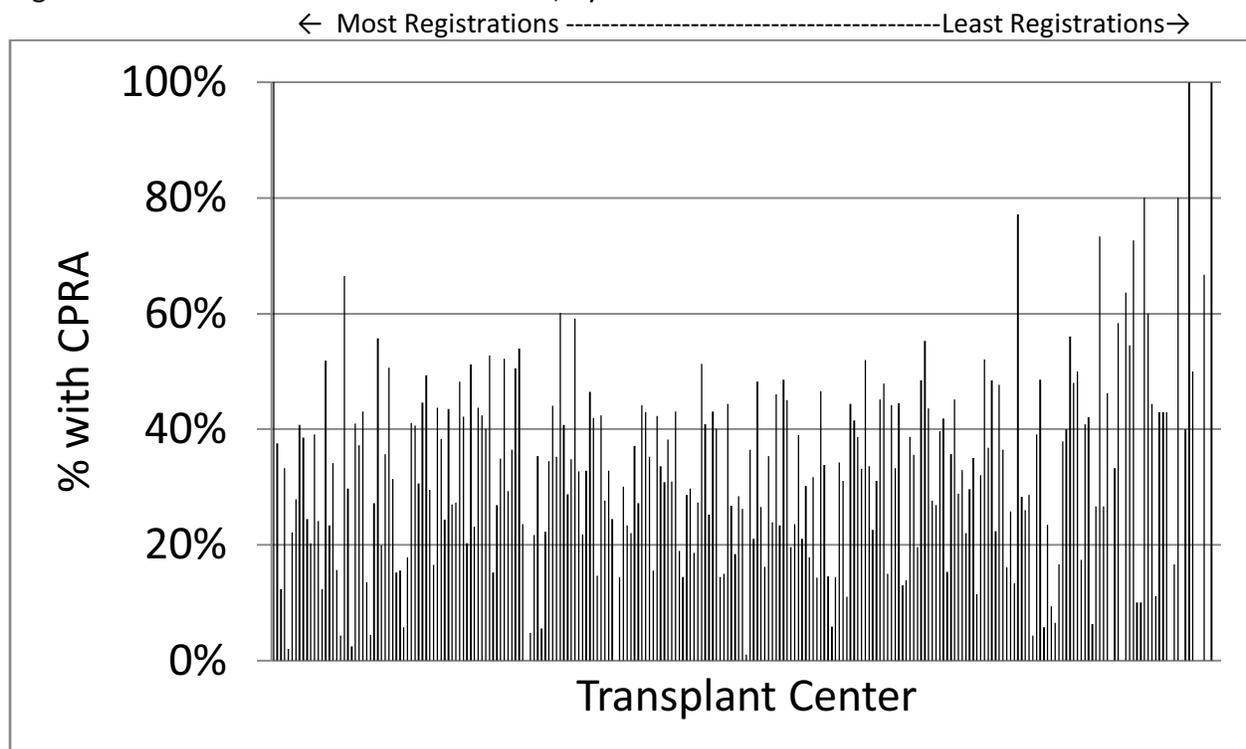


Figure 2. Percent of Candidates with CPRA, by Center



Who Might Lose Sensitization Points?

This analysis includes all candidates with a “match” PRA 80 or higher and at least one unacceptable listed antigen in UNETSM (n=10,492). The match PRA is defined as the current PRA if the waiting list record indicates that the current PRA is to be used and peak PRA if peak is indicated. These candidates are currently eligible to receive 4 points for their PRA level. Of these candidates, 1,950 (18.6%) have a CPRA of less than 80, with a mean/median CPRA of 52.9 and 58.8. Figures 3, 4 and 5 show these percentages by Region, Center, and Ethnicity. Analyses by gender and age will also be provided.

Figure 3. Patients Currently Eligible for PRA Points, by Region

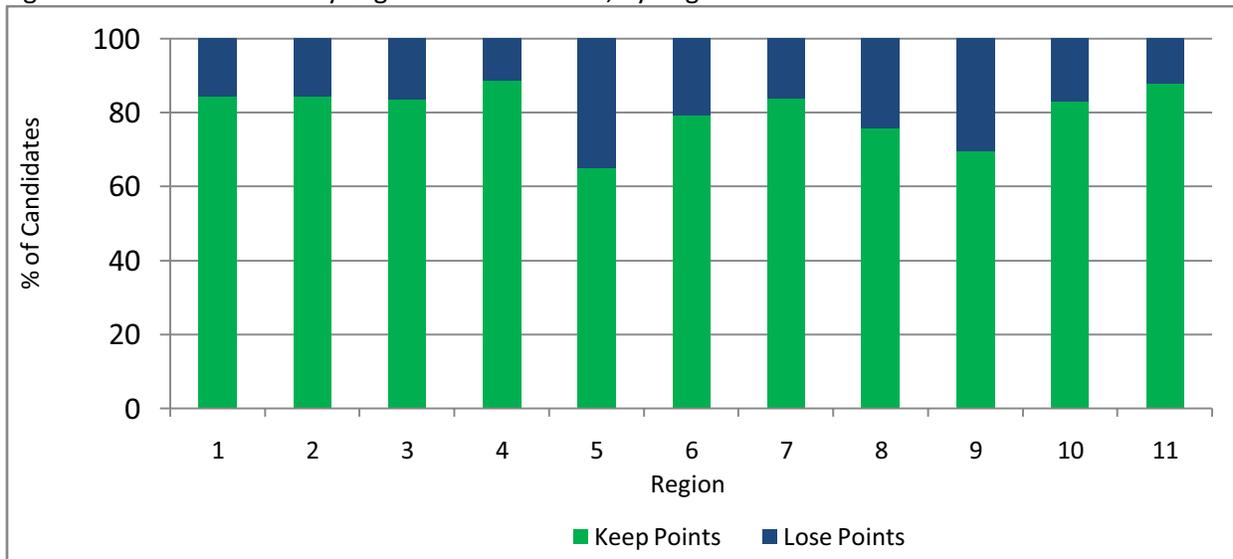


Figure 4. Patients Currently Eligible for PRA Points, by Region

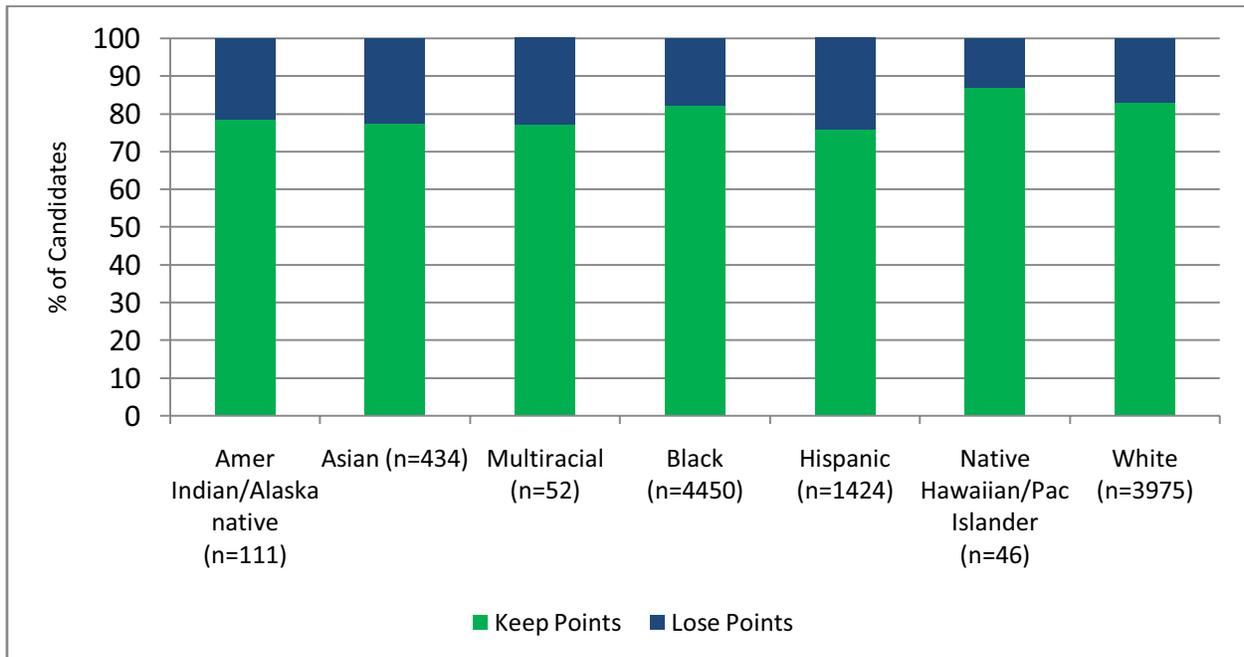
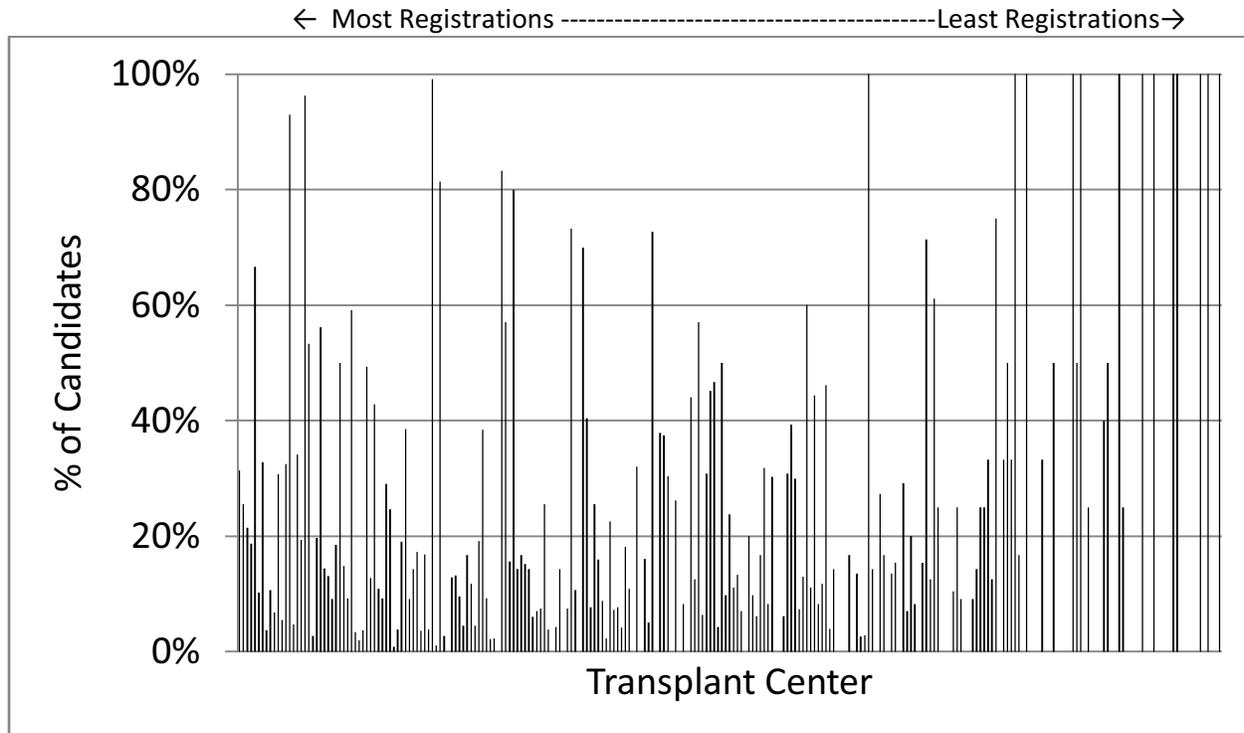


Figure 5. Patients Currently Eligible for PRA Points with a CPRA < 80, by Center



Most Recent CPRA versus CPRA as of 12/05/2007

This analysis includes all candidates who had a CPRA as of the date of CPRA implementation (n=19,957). The difference between the CPRA on that date and the most recent CPRA was computed by Region and Center (Figures 6 and 7). The mean change across all cases was small, at 1.6.

Match PRA versus Most Recent CPRA

The difference between the match PRA and the CPRA was calculated by Region and center (figures 8 and 9). On average, the match PRA was 3.9 points lower than the most recent CPRA.

Conclusions

Currently, 28.4% of candidates on the kidney waiting list have at least one unacceptable antigen listed, allowing calculation of a CPRA. A small number of centers (13/258) have not entered any unacceptable antigens for their candidates. This can have negative implications for the sensitization points awarded to candidates for their CPRA: when the CPRA is used for allocation in Phase II of the implementation, these candidates could potentially lose these points. At present, slightly fewer than 20% of candidates that are eligible for sensitization points do not have a CPRA to justify the points. However, as shown in Figures 6 and 7, centers appear to have entered additional unacceptable antigens since Phase I implementation on December 5, 2007.

Figure 6. (Most Recent CPRA) - (CPRA on 12/5/07), by Region

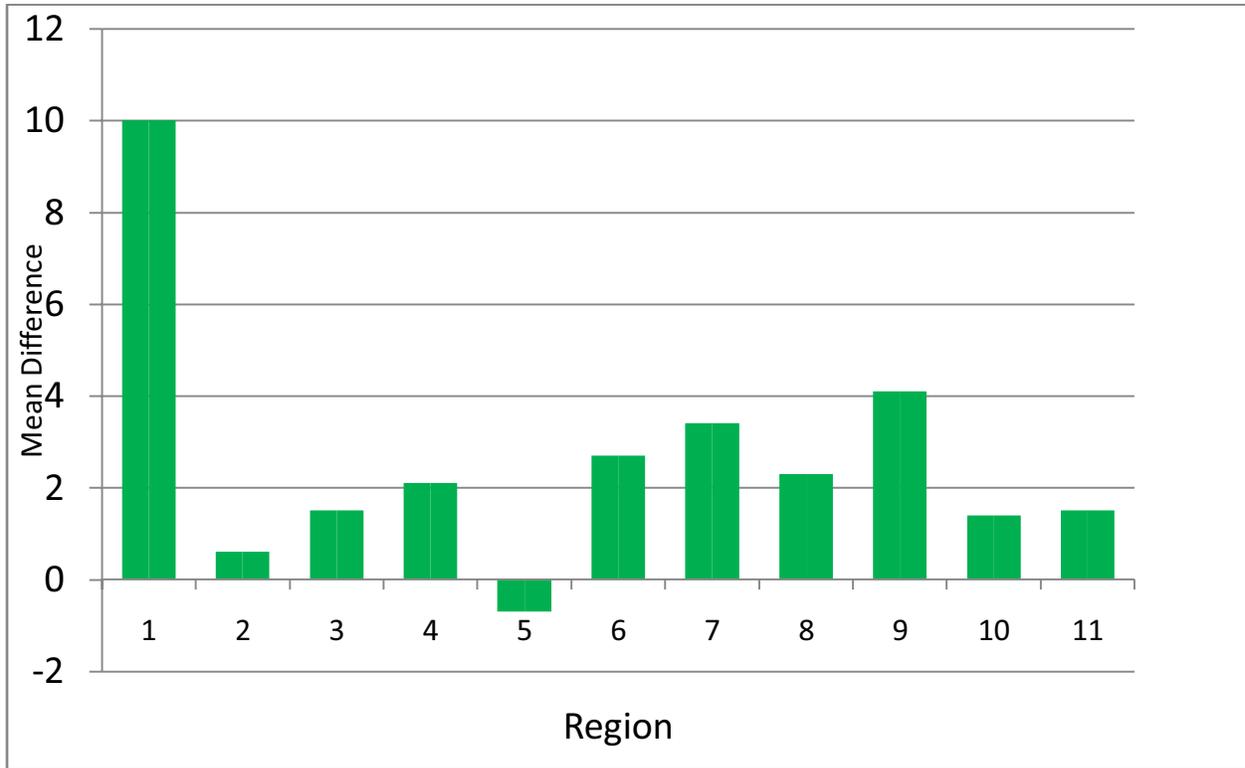


Figure 7. (Most Recent CPRA) - (CPRA on 12/5/07), by Center

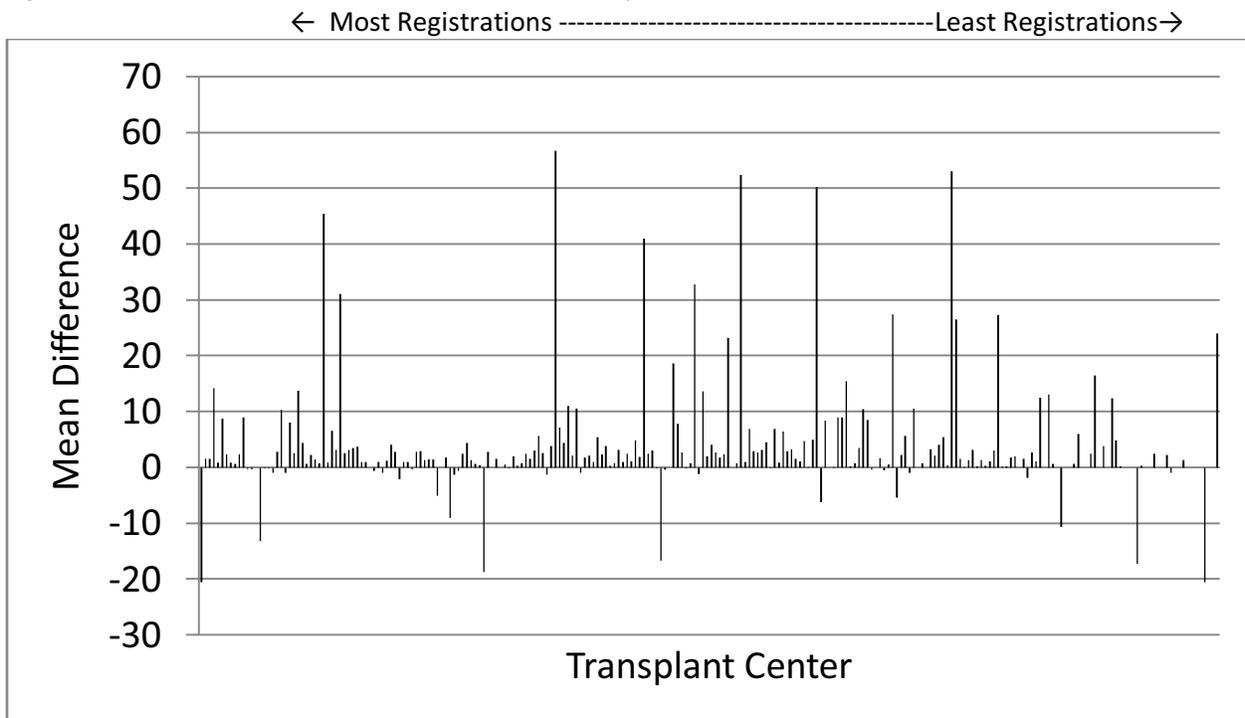


Figure 8. Match PRA – Most Recent CPRA, by Region

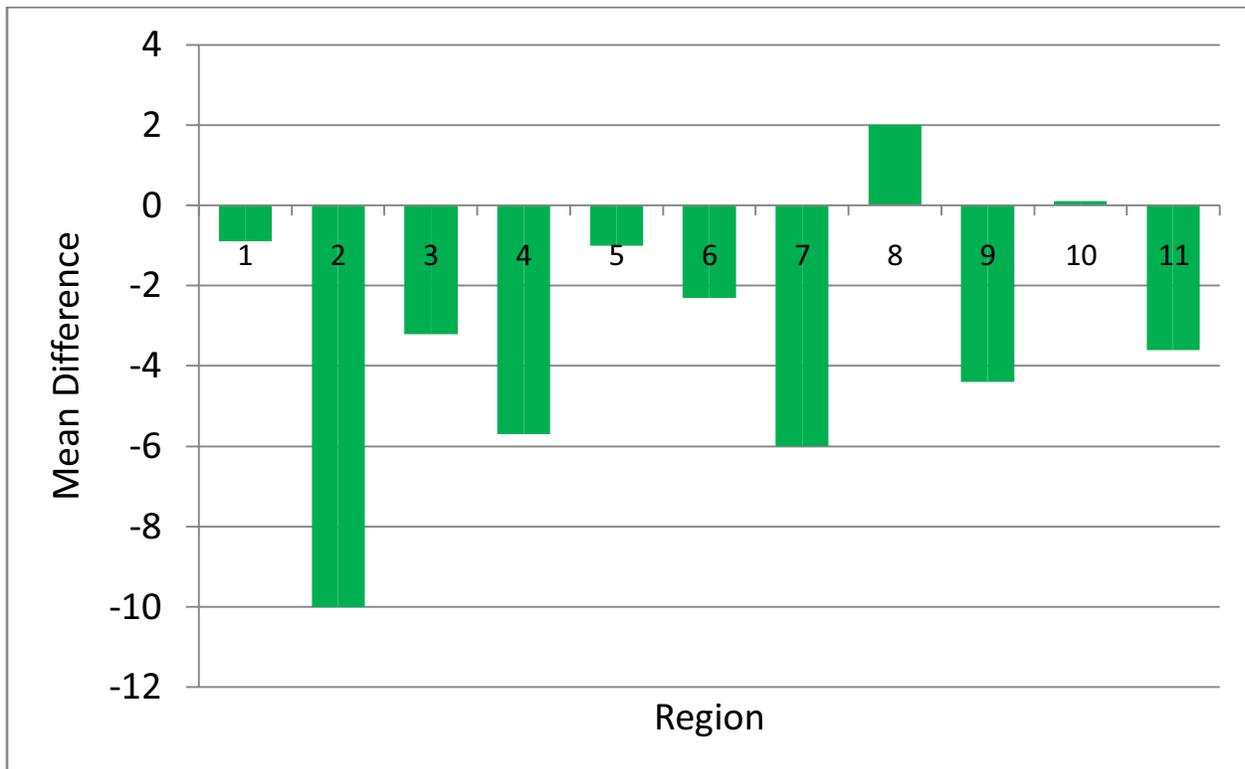
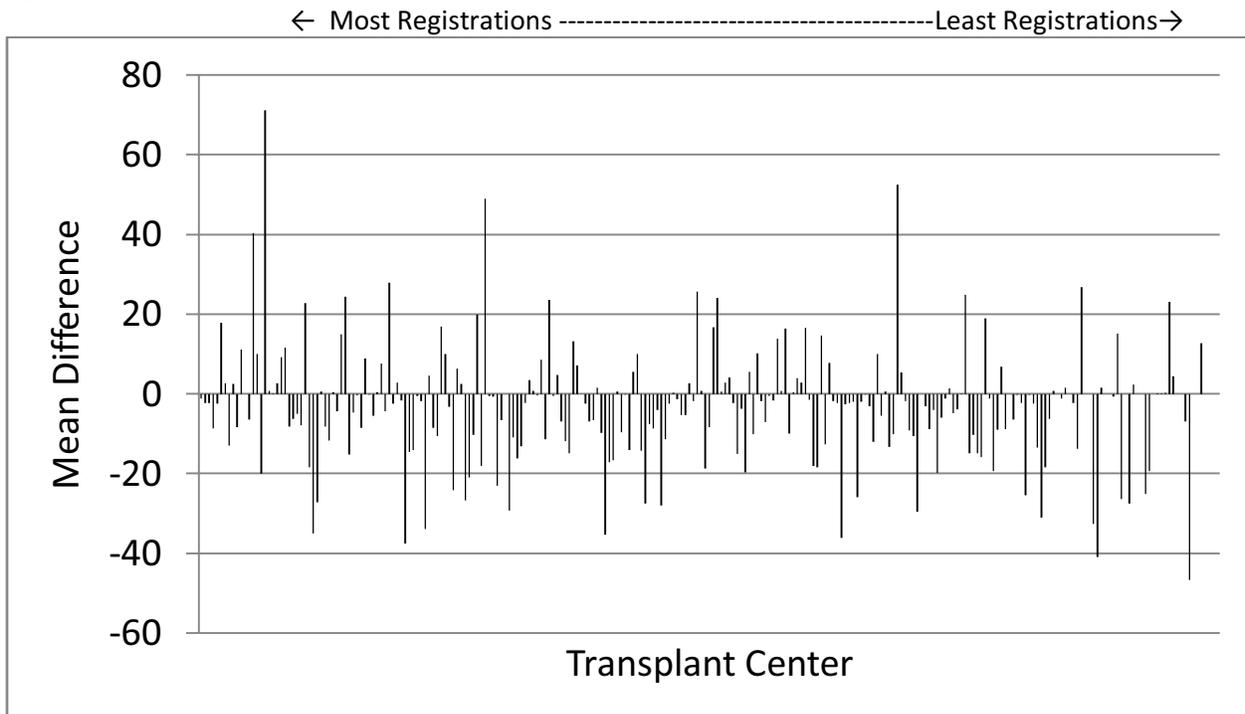


Figure 9. Match PRA – Most Recent CPRA, by Center



CPRA Analyses

Ann M. Harper, UNOS Research Dept., for the
OPTN/UNOS Histocompatibility Committee
July 8-9, 2008

OPTN



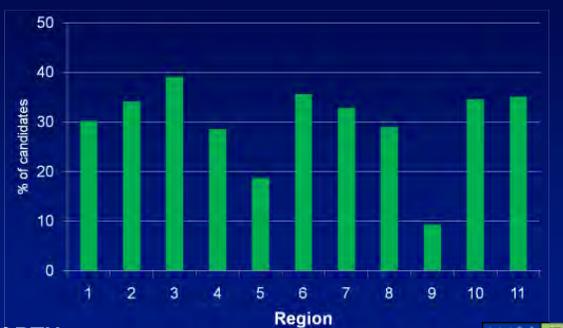
CPRA - Cohort

- Phase I of CPRA was implemented on 12/5/2007
- 80,941 registrations on the kidney WL as of 6/13/2008
- 23,009 (28.4%) with unacceptable antigens to calculate a CPRA
 - (↑ from 20,862 on 1/28/08)

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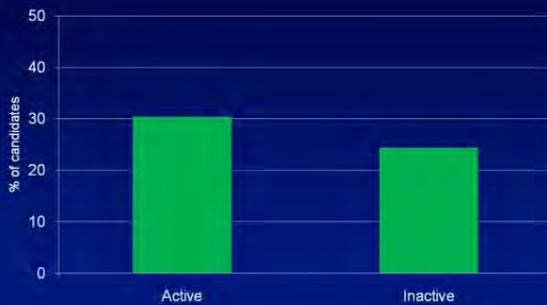
Percent of Candidates on 6/13/08 with CPRA by Region



OPTN



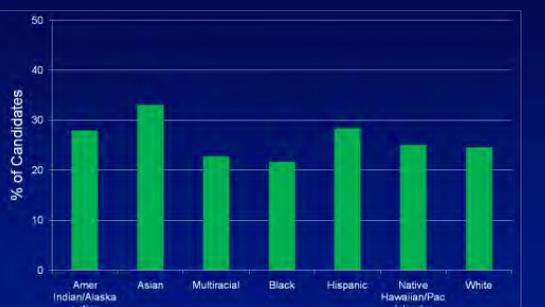
Percent of Candidates on 6/13/08 with CPRA by Waiting List Status



OPTN



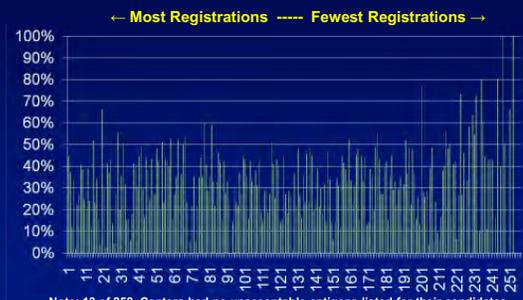
Percent of Candidates on 6/13/08 with CPRA by Ethnicity



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Percent of Candidates with CPRA, by Transplant Center



OPTN



WHO MIGHT LOSE SENSITIZATION POINTS?

OPTN



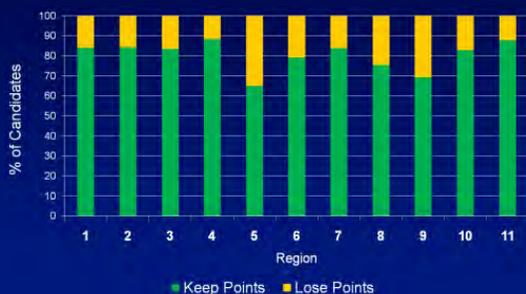
COHORT

- There were 10,492 candidates with “match” PRA \geq 80%, and with at least 1 unacceptable antigen in UNetSM
 - Match PRA is based on current PRA if “Current” is specified for PRA points or peak PRA if “Peak” is specified
- Of these, 1,950 (18.6%) had CPRA < 80% - mean CPRA=52.9%; median CPRA=58.8%

OPTN



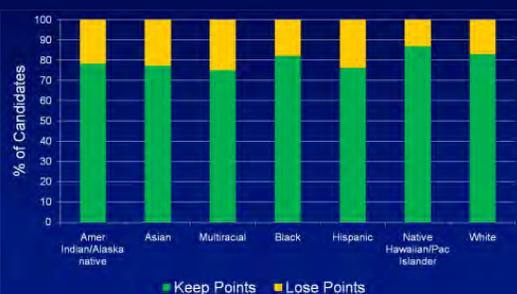
Candidates Currently Eligible for Sensitization Points by Region



OPTN



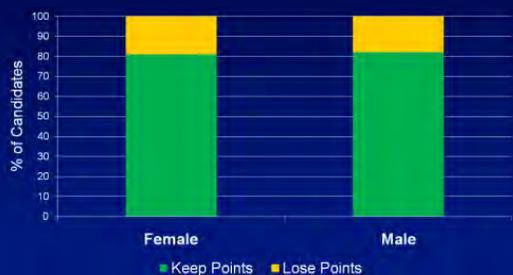
Candidates Currently Eligible for Sensitization Points by Ethnicity



OPTN



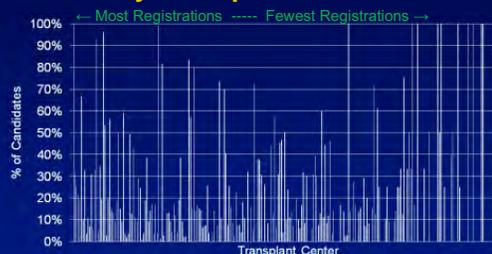
Candidates Currently Eligible for Sensitization Points, by Gender



OPTN



Candidates Currently Eligible for Sensitization Points but CPRA < 80%, by Transplant Center



OPTN



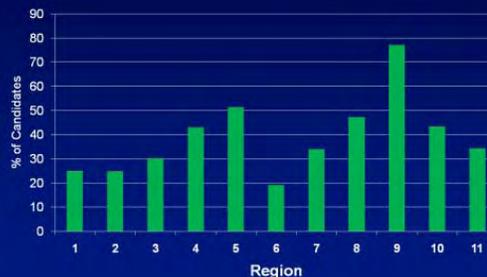
Other Analyses

- Who has a PRA but no CPRA?
- Have the CPRA values changed since 12/5/07?
- How does CPRA compare to “Match” PRA?

OPTN



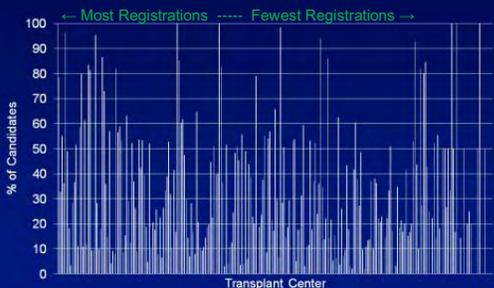
Candidates with a “Match” PRA > 0 but no CPRA, by Region



OPTN



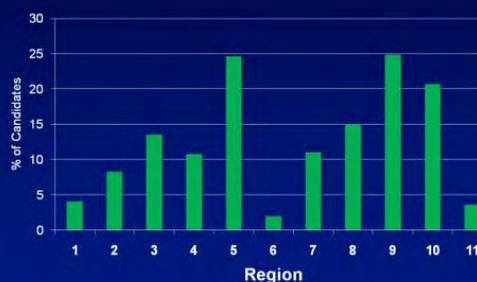
Candidates with a “Match” PRA > 0 % with no CPRA, by Transplant Center



OPTN



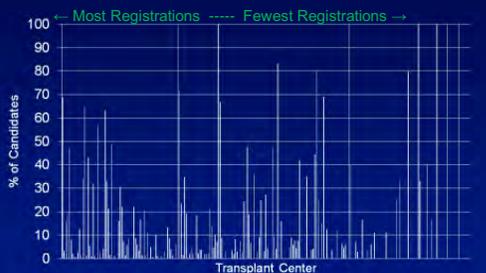
Candidates with a “Match” PRA > 80% Percent with no CPRA, by Region



OPTN



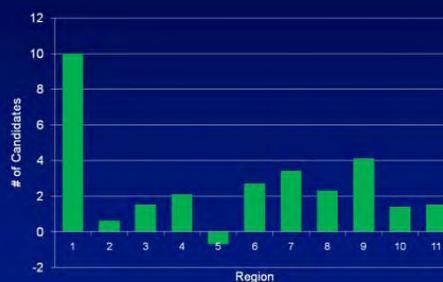
Candidates with a “Match” PRA > 80, % with no CPRA, by Transplant Center



OPTN



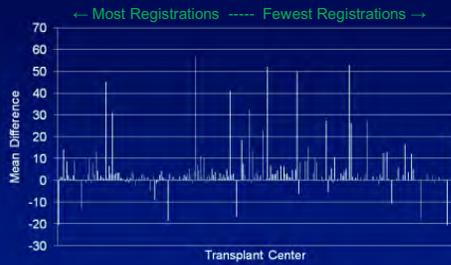
(Most Recent CPRA) - (CPRA on 12/5/07) by Region



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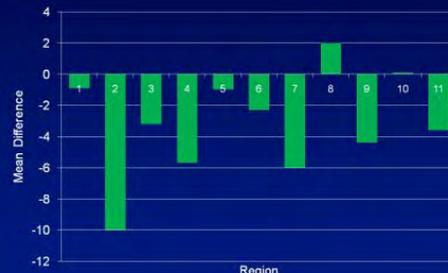
(Most Recent CPRA) - (CPRA on 12/5/07) by Transplant Center



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Match PRA - Most Recent CPRA by Region



Includes Cases where Most Recent CPRA > 0 only

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Match PRA - Most Recent CPRA by Transplant Center



Includes Cases where Match PRA > 0 only

OPTN



Final Analysis for Data Requests from the OPTN Minority Affairs Committee Meeting on September 28, 2007

Prepared by Alan Leichtman, MD., Sangeetha Krishnan, MS, Keith McCullough, MS, John Kalbfleisch, Ph.D., Panduranga Rao, MD., Valarie Ashby, MA, and Robert Wolfe, Ph.D., of the Scientific Registry of Transplant Recipients (Arbor Research/University of Michigan)

Data Request Routing Information and Analysis Timeline:

- OPTN Committee request made: 10/08/2007
- Analysis plan submitted: 10/22/2007
- Draft Analysis submitted: 2/15/08
- Final Analysis submitted: 2/29/08
- Next Committee Meeting: 03/11/2008

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Analytical/Inferential Request #2: Evaluation of Committee Sponsored Alternative Kidney Allocation System

Background: On 04/29/2006, OPO's OneLegacy (CAOP) and Gift of Life (MIOP) implemented a Committee Sponsored Alternative Kidney Allocation System to credit patients for time on dialysis in addition to time on the waitlist. IAOP was added to this initiative on 1/24/2007.

Data Requested: The committee requested for analyses of transplant rates by ethnicity in these OPOs to determine the effects of this alternative allocation system allowing calculation of waiting time from the date of first dialysis.

SRTR Note

As the committee sponsored alternative allocation system was implemented at IAOP very recently, we did not perform analyses to show the trends specifically at IAOP in this report.

Executive Summary

To observe changes in the ethnic composition of the waitlist, we looked at the number and percentage of candidates entering the waitlist in given six month periods before and after the Committee Sponsored Alternative Kidney Allocation System that took effect at CAOP and MIOP on 04/29/2006 [Table 2.1]. We compared these numbers within the OPO's where this policy change was implemented and with the rest of the country. There were no clear trends observed in the ethnic distribution of candidates entering the waitlist before and after the policy change.

The number of Deceased Donor Transplants in the 18 months prior to and after the Committee Sponsored Alternative Kidney Allocation System was implemented are shown in Table 2.2. The number of Deceased Donor Transplants did not change significantly in these time periods, but there is some indication that the characteristics of these Deceased Donor Recipients have changed. In the 18 month period prior to the policy change the average years on Dialysis for Deceased Donor Transplant Recipients in CAOP was 3.9 years and the average years on the waitlist was 2.7 years. In the year following the policy change, the average years on Dialysis for Deceased Donor Transplant Recipients in CAOP increased to 4.8 years and the average years on the waitlist decreased to 2.3 years. This increase in the average years on Dialysis and decrease in the years on the waitlist was consistent across all ethnicities in CAOP and MIOP (except Hispanics and Asians in MIOP). This trend is not observed in the OPO's where this allocation policy was not implemented.

Study Population

Registrants with no previous transplant on the list on 04/28/2004 and those entering the list between 04/29/04 and 10/31/07.

Analytical Approach

The number and percentage of new kidney waitlist candidates by ethnicity before and after the change on 04/29/2004 are presented in Table 2.1. The number of Deceased Donor Transplants prior to and after the Committee Sponsored Alternative Kidney Allocation System was implemented are shown in Table 2.2. These counts were calculated by ethnicity in CAOP, MIOP and in the OPO's where there was no change in allocation system. The average years on dialysis and average years on waitlist by OPO and ethnicity, are also shown for the Deceased Donor Transplant Recipients in Table 2.2. Table 2.3 shows the distribution of median time on dialysis, in days, for new kidney candidates prior to being waitlisted, by OPO and ethnicity.

Prepared by the Scientific Registry of Transplant Recipients

Results:

Table 2.1: Number and percent of patients on the waitlist on 4/28/2004 and added to waitlist in subsequent periods by Ethnicity

| N and % | On the WL on 04/28/2004 | Added to WL 04/29/04-10/31/04 | Added to WL 11/01/04-04/28/05 | Added to WL 04/29/05-10/31/05 | Added to WL 11/01/05-04/28/06 | Added to WL 04/29/06**-10/31/06 | Added to WL 11/01/06-04/28/07 | Added to WL 04/29/07-10/31/07 |
|-------------------|----------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|------------------------------------|----------------------------------|----------------------------------|
| CAOP | | | | | | | | |
| White | 944 22.3 | 274 24.7 | 235 26.6 | 254 27.1 | 227 26.7 | 213 24.3 | 217 21.3 | 199 21.7 |
| African American | 748 17.7 | 181 16.3 | 123 13.9 | 119 12.7 | 148 17.4 | 160 18.2 | 158 15.5 | 127 13.8 |
| Asian | 617 14.6 | 137 12.4 | 116 13.1 | 129 13.8 | 96 11.3 | 126 14.4 | 164 16.1 | 121 13.2 |
| Hispanic | 1,894 44.8 | 499 45.0 | 405 45.8 | 433 46.2 | 371 43.7 | 368 41.9 | 470 46.2 | 462 50.3 |
| Other Race | 29 0.7 | 17 1.5 | 6 0.7 | 3 0.3 | 8 0.9 | 11 1.3 | 9 0.9 | 9 1.0 |
| Total | 4,232 | 1,108 | 885 | 938 | 850 | 878 | 1,018 | 918 |
| MIOP | | | | | | | | |
| White | 665 45.1 | 246 56.0 | 233 54.2 | 261 55.9 | 312 56.9 | 285 57.0 | 260 57.9 | 256 60.5 |
| African American | 728 49.4 | 169 38.5 | 163 37.9 | 179 38.3 | 199 36.3 | 184 36.8 | 163 36.3 | 150 35.5 |
| Asian | 26 1.8 | 7 1.6 | 17 4.0 | 8 1.7 | 10 1.8 | 13 2.6 | 8 1.8 | 8 1.9 |
| Hispanic | 40 2.7 | 14 3.2 | 15 3.5 | 18 3.9 | 24 4.4 | 16 3.2 | 15 3.3 | 7 1.7 |
| Other Race | 15 1.0 | 3 0.7 | 2 0.5 | 1 0.2 | 3 0.6 | 2 0.4 | 3 0.7 | 2 0.5 |
| Total | 1,474 | 439 | 430 | 467 | 548 | 500 | 449 | 423 |
| Other OPOs | | | | | | | | |
| White | 15,651 38.4 | 4,695 47.8 | 5,212 46.8 | 5,197 48.3 | 5,373 48.3 | 5,798 48.0 | 5,761 46.6 | 6,075 46.6 |
| African American | 15,638 38.4 | 2,952 30.0 | 3,220 28.9 | 3,227 30.0 | 3,229 29.0 | 3,571 29.5 | 3,678 29.7 | 4,048 31.1 |
| Asian | 2,922 7.2 | 632 6.4 | 934 8.4 | 680 6.3 | 656 5.9 | 753 6.2 | 863 7.0 | 830 6.4 |
| Hispanic | 5,896 14.5 | 1,372 14.0 | 1,573 14.1 | 1,510 14.0 | 1,694 15.2 | 1,790 14.8 | 1,912 15.5 | 1,888 14.5 |
| Other Race | 672 1.7 | 177 1.8 | 205 1.8 | 154 1.4 | 170 1.5 | 181 1.5 | 162 1.3 | 183 1.4 |
| Total | 40,779 | 9,828 | 11,144 | 10,768 | 11,122 | 12,093 | 12,376 | 13,024 |

**Date of Policy implementation at CAOP and MIOP was 04/29/2006

Prepared by the Scientific Registry of Transplant Recipients

Table 2.2: Number of Deceased Donor Transplants and Average years on dialysis and waitlist for Deceased Donor Transplant recipients by Ethnicity and OPO (04/29/2004-10/31/2007)

| | Period1: 11/01/2004-04/28/2006 | | | Period2: 04/29/2006-10/31/2007 | | |
|-------------------------|--------------------------------|------------------------|------------------------|--------------------------------|------------------------|------------------------|
| | Number of tx | Avg. years of dialysis | Avg. years on Waitlist | Number of tx | Avg. years of dialysis | Avg. years on Waitlist |
| All | 14,479 | 3.4 | 2.1 | 15,999 | 3.5 | 2.0 |
| CAOP | | | | | | |
| White | 185 | 2.9 | 2.1 | 184 | 3.9 | 1.9 |
| African Am. | 126 | 5.1 | 3.5 | 125 | 7.1 | 2.9 |
| Asian Am. | 125 | 4.1 | 3.0 | 130 | 5.3 | 2.7 |
| Hispanic | 372 | 4.0 | 2.7 | 419 | 4.4 | 2.2 |
| Other | 10 | 3.2 | 1.7 | 7 | 5.4 | 2.5 |
| CAOP Total | 818 | 3.9 | 2.7 | 865 | 4.8 | 2.3 |
| MIOP | | | | | | |
| White | 236 | 3.1 | 2.0 | 257 | 3.4 | 1.8 |
| African Am. | 164 | 4.1 | 2.6 | 216 | 5.7 | 2.2 |
| Asian Am. | 12 | 2.3 | 1.7 | 13 | 3.1 | 2.0 |
| Hispanic | 16 | 3.3 | 2.0 | 17 | 4.6 | 2.6 |
| Other | 5 | 3.3 | 1.4 | 0 | | |
| MIOP Total | 433 | 3.5 | 2.2 | 503 | 4.4 | 2.0 |
| Other OPOs | | | | | | |
| White | 6,370 | 2.6 | 1.6 | 6,931 | 2.6 | 1.7 |
| African Am. | 4,129 | 4.4 | 2.5 | 4,634 | 4.3 | 2.4 |
| Asian Am. | 852 | 3.7 | 2.4 | 933 | 3.6 | 2.3 |
| Hispanic | 1,676 | 3.8 | 2.1 | 1,925 | 3.6 | 2.0 |
| Other | 201 | 4.0 | 2.2 | 208 | 3.5 | 2.1 |
| Other OPOs Total | 13,228 | 3.4 | 2.0 | 14,631 | 3.4 | 2.0 |

**Date of Policy Implementation at CAOP and MIOP was 04/29/2006

Prepared by the Scientific Registry of Transplant Recipients

Table 2.3: Median Number of Days from Dialysis to Waitlisting for New Candidates by Ethnicity and OPO (04/29/2004-10/31/2007)

| | Added to WL 04/29/04- 10/31/04 | Added to WL 11/01/04- 04/28/05 | Added to WL 04/29/05- 10/31/05 | Added to WL 11/01/05- 04/28/06 | Added to WL 04/29/06**- 10/31/06 | Added to WL 11/01/06- 04/28/07 | Added to WL 04/29/07- 10/31/07 |
|-------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--|--------------------------------------|--------------------------------------|
| CAOP | | | | | | | |
| White | 356 | 413 | 349 | 381 | 384 | 348 | 593 |
| Black | 522 | 544 | 597 | 600 | 646 | 478 | 735 |
| Asian | 442 | 387 | 577 | 447 | 526 | 435 | 581 |
| Hispanic | 515 | 471 | 446 | 492 | 510 | 514 | 563 |
| Other | 706 | 374 | 1687 | 468 | 515 | 336 | 334 |
| MIOP | | | | | | | |
| White | 284 | 383 | 316 | 352 | 369 | 306 | 333 |
| Black | 429 | 525 | 441 | 516 | 523 | 483 | 545 |
| Asian | 337 | 206 | 296 | 238 | 203 | 198 | 211 |
| Hispanic | 691 | 486 | 598 | 620 | 569 | 265 | 756 |
| Other | 278 | 863 | 1098 | 726 | 1193 | 1430 | 797 |
| Other OPOs | | | | | | | |
| White | 346 | 396 | 368 | 369 | 366 | 356 | 360 |
| Black | 525 | 580 | 529 | 546 | 516 | 550 | 546 |
| Asian | 373 | 489 | 376 | 337 | 394 | 405 | 321 |
| Hispanic | 466 | 529 | 461 | 470 | 473 | 435 | 440 |
| Other | 503 | 615 | 492 | 506 | 549 | 571 | 541 |

**Date of Policy change at CAOP and MIOP was 04/29/2006

Note: Pre-emptive listings are excluded from this analysis.

Background

On 04/29/2006, two OPO's- One Legacy (CAOP) and Gift of Life (MIOP) implemented a Committee Sponsored Alternative Kidney Allocation System to include the time spent on dialysis prior to wait listing in addition to time on the waitlist. IAOP was added to this initiative on 1/24/2007.

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Purpose

To analyze the effects of the alternative allocation system allowing for calculation of waiting time to include time on dialysis, on transplantation by ethnicity in the OPOs where this policy was implemented

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Methods (1)

- Data Source: OPTN/SRTR
- As the committee sponsored alternative allocation system was implemented at Iowa Donor Network (IAOP) very recently, we did not include IAOP in this report.
- The ethnic distribution of kidney waitlist candidates on the list on 04/29/2004 and subsequent new additions (in six month intervals) was determined at CAOP and MIOP and compared with other OPO's.
- The median time from dialysis to waitlisting for new candidates entering the waitlist in six month periods before and after policy implementation was calculated for each ethnic group at CAOP and MIOP and compared with the other OPO's. Pre-emptive listings were excluded from this analysis.

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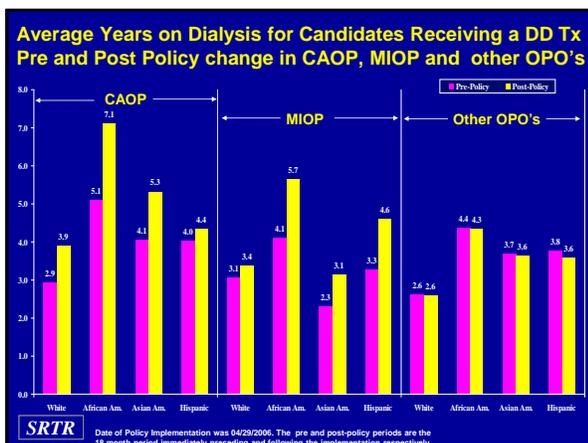
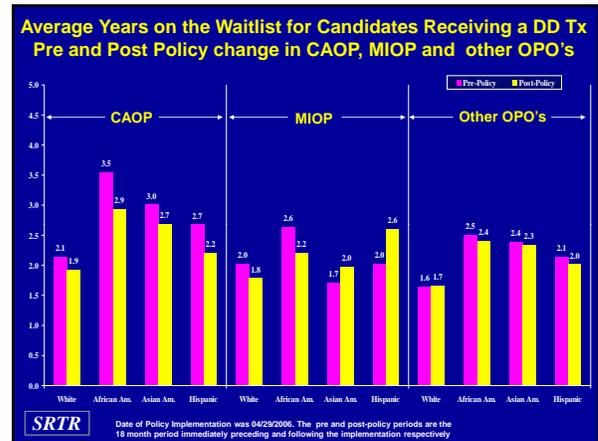
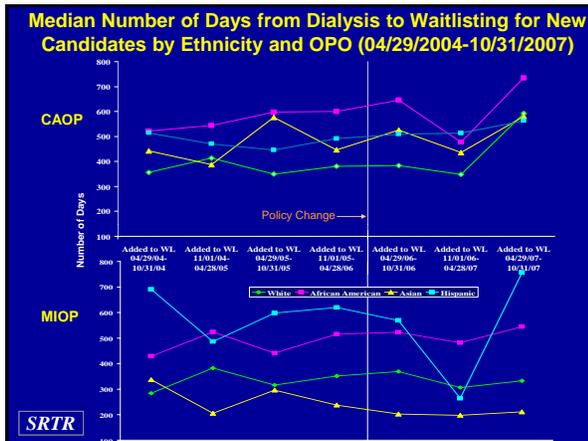
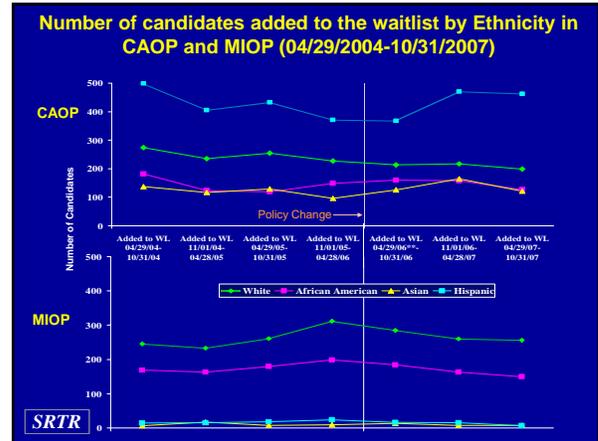
Methods (2)

- The average time from dialysis to waitlisting and average time from waitlisting to transplantation for deceased donor transplant recipients in the 18 month period before and after policy implementation was calculated by ethnicity and OPO

SRTR

Results

SRTR



- ## Summary of Results
- There were no patterns observed in the ethnic distribution of candidates entering the waitlist before and after the policy change.
 - The number of Deceased Donor Transplants did not change significantly in these time periods, but there is some indication that the characteristics of these Deceased Donor Recipients have changed.
 - On average, there was an increase in the average years on Dialysis and decrease in the average years on the waitlist for patients receiving Deceased Donor Transplants in the period following policy implementation across all ethnicities in CAOP and MIOP.
 - This trend was not observed in the OPO's where this allocation policy was not implemented.
- SRTR

**OPTN/UNOS Minority Affairs Committee
Descriptive Data Request**

FINAL REPORT:

***Update on Prior Kidney Living Donors Who Were Subsequently Placed
on the Waiting List and Rate of Being Placed on the Kidney Waiting List within
Five Years of Donation***

Prepared for:
Minority Affairs Committee Meeting
July 18, 2008

By:
Wida Cherikh, Ph.D., Sarah Taranto and Charlotte Carroll, M.S.
Research Department
United Network for Organ Sharing

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Background/Purpose

Over the past years, living donation rates have substantially increased. The MAC expressed an interest in examining data that pertain to safety of living donation, particularly, with respect to individuals who have donated their organ and were subsequently placed on the waiting list due to end stage organ failure.

At the May 12, 2006 meeting the Committee was presented with information on 117 prior living kidney donors and 3 prior living liver donors who were subsequently placed on the kidney and liver waiting lists. At the July 13, 2007 meeting the Committee was presented additional information on 148 prior living kidney donors who were subsequently placed on the kidney waiting list and the 3 liver donors who were placed on the liver waiting list. The Committee is ultimately interested in determining if the rate of being placed on the waiting list within 5-6 years is higher for previous living kidney donors who are Blacks as compared to non-Blacks.

It was noted that CMS data will be useful to determine whether some of the previous living donors are on maintenance dialysis without necessarily being placed on the waiting list.

Committee Request

Provide updated data on individuals who have donated their organ and ended up on the wait list due to end stage organ failure. The data should include demographics (age, gender, ethnicity), cause of end stage organ failure, years after donation, whether they have received a transplant or not, and patient status.

Determine if the rate of being placed on the waiting list within 5-6 years is higher for previous living kidney donors who are Blacks as compared to non-Blacks.

UNOS has recently received the CMS 2728 database and plan to link it with the OPTN living donor database to determine if individuals who have donated their kidney subsequently received maintenance dialysis, and examine the limitations of the CMS data.

Data and Methods

Starting on September 9, 1996, prior living kidney donors who were subsequently placed on the kidney waiting list may request four additional points with the appropriate documentation to the OPTN.

For kidney analysis, we included candidates ever on the OPTN kidney waiting list between 1/1/1996 and 2/28/2008, and who were indicated as a previous donor, or had a prior living donation record in the OPTN living donor database as matched by SSN. Note that living donor SSN was not collected prior to 4/1/1994 by the OPTN, and therefore SSN matching could not be performed for living donors recovered prior to 4/1/1994.

When available, information on age at donation and years between donation and listing is summarized. Basic waiting list demographics and waiting list outcomes of these candidates are also summarized. Relationship between the donors and the recipients and diagnosis of the donors at the time of listing were ascertained on previous living donors who were found through linking the OPTN living donor and wait list databases by SSN.

The Social Security Death Master File (SSDMF) is used to ascertain extra waiting list and post-transplant deaths.

For determining rates of being placed on the kidney waiting list within 5 years of transplant, living donors who donated their kidneys during 1996-2002 in the OPTN living donor database were examined. OPTN kidney WL database was queried to see if these donors were placed on the WL within 5 years of the donation.

Information provided in this report is based on the OPTN data as of May 23, 2008.

Results

There were 172 previous living kidney donors who were on the kidney waiting list (WL), between 1/1/1996 and 2/29/2008. Note that since the majority of these candidates donated prior to the inception of the OPTN in 1987 or prior to 4/1/1994, their demographics and clinical characteristics at the time of donation cannot be ascertained. For those cases we could not link with the OPTN data, some additional data on date of donation was obtained through phone calls to the transplant centers and from documentation provided to the OPTN in support of requests for donation points.

Table 1 summarizes age at donation and years between donation and first listing.

- Of the 148 candidates with known age at donation, 98 (66%) donated their kidney at less than 34 years of age, 41 (28%) donated between the age of 35 and 49, and 9 (6%) donated between the age of 50 and 64. The median and mean age at donation was 31 and 31.8 years, respectively.
- Of the 148 candidates with known time of donation, 61 (41%) were placed on the WL between 16 and 25 years post-donation, 32 (22%) were placed on the WL 26 years or more post-donation, 23 (16%) between 11 and 15 years post-donation, 20 (14%) between 6 and 10 years, and 12 (8%) within 5 years of donation.
- The overall mean and median time from donation to listing were 18.5 years and 19 years, respectively.
- The median time from donation to listing was 21 years for White, 16 years for Black and 19 years for Hispanic.

**Table 1. Age at Donation and Years from Donation to First Listing
Kidney Waiting List Candidates Indicated to be a Previous Living Kidney Donor
Candidates Ever Waiting During 1/1/1996-2/29/2008**

| | N | % |
|---|------|-------|
| Age at Donation (Years) | | |
| ○ Unknown | 24 | - |
| ○ < 35 | 98 | 66 |
| ○ 35-49 | 41 | 28 |
| ○ 50-64 | 9 | 6 |
| Total | 172 | 100.0 |
| - Median Age at Donation | 31 | |
| - Mean Age at Donation | 31.8 | |
| Years from Donation to First Listing | | |
| ○ Unknown | 24 | - |
| ○ 0-5 | 12 | 8 |
| ○ 6-10 | 20 | 14 |
| ○ 11-15 | 23 | 16 |
| ○ 16-25 | 61 | 41 |
| ○ 26+ | 32 | 22 |
| Total | 172 | 100.0 |
| - Overall Mean | 18.5 | |
| - Overall Median | 19 | |
| ○ White (N=64) | 21 | |
| ○ Black (N=63) | 16 | |
| ○ Hispanic (N=12) | 19 | |

Table 2 summarizes basic waiting list demographics and clinical characteristics of these 172 previous living kidney donors at the time of the listing, as well as diagnosis at time of listing:

- One hundred and five (61%) of these candidates were male, and 67 (39%) were female.
- Seventy three (42%) of these previous donors were White, 74 (43%) were Black, 15 (9%) were Hispanic, 5 (3%) were Asian, and 3 (2%) were American Indian/Alaska Natives and 2 (1%) were multiracial.
- Seventy (41%) of these previous donors were between 50 and 64 years old at time of listing, 66 (38%) were between 35 and 49 years old, 16 (10.8%) were 65+, and 13 (8.8%) were between 18 and 34 years.
- The three most common waiting list diagnoses were hypertensive nephrosclerosis – N=53 (31%), glomerular diseases - N=47 (27%), and diabetes – N=18 (10%).
- A total of 142 (83%) of these candidates have received a deceased donor kidney transplant, 7 (4%) received a living donor transplant, 5 (3%) died on the WL, 2 (1%) were too sick to transplant, 1 (1%) were removed for being too well, 1 (1%) refused transplant and 14 (8%) were still waiting for a transplant.
- Of the 149 candidates who had received a transplant, 138 (93%) were still alive and 11 (7%) died post-transplant.

**Table 2. Basic WL Demographics and Clinical Characteristics
Kidney WL Candidates Indicated to be a Previous Living Kidney Donor Candidates Ever Waiting
During 1/1/1996-2/29/2008 (N=172)**

| | N | % |
|------------------------|-----|-------|
| Year Listed | | |
| 1987 | 1 | 0.6 |
| 1988 | 2 | 1.2 |
| 1990 | 1 | 0.6 |
| 1991 | 3 | 1.7 |
| 1992 | 2 | 1.2 |
| 1993 | 1 | 0.6 |
| 1994 | 3 | 1.7 |
| 1995 | 2 | 1.2 |
| 1996 | 4 | 2.3 |
| 1997 | 7 | 4.1 |
| 1998 | 9 | 5.2 |
| 1999 | 10 | 5.8 |
| 2000 | 10 | 5.8 |
| 2001 | 6 | 3.5 |
| 2002 | 18 | 10.5 |
| 2003 | 11 | 6.4 |
| 2004 | 9 | 5.2 |
| 2005 | 20 | 11.6 |
| 2006 | 26 | 15.1 |
| 2007 | 25 | 14.5 |
| 2008 | 2 | 1.2 |
| Total | 172 | 100.0 |
| Donor Gender | | |
| Female | 67 | 39.0 |
| Male | 105 | 61.0 |
| Total | 172 | 100.0 |
| Donor Ethnicity | | |
| White | 73 | 42.4 |
| Black | 74 | 43.0 |

| | N | % |
|---|-----|-------|
| Hispanic | 15 | 8.7 |
| Asian | 5 | 2.9 |
| Amer Ind/Alaska Native | 3 | 1.7 |
| Multiracial | 2 | 1.2 |
| Total | 172 | 100.0 |
| Age at Listing | | |
| < 35 Years | 16 | 9.3 |
| 35-49 | 66 | 38.4 |
| 50-64 | 70 | 40.7 |
| 65+ | 20 | 11.6 |
| Total | 172 | 100.0 |
| Outcome of Waiting List | | |
| Still Waiting | 14 | 8.1 |
| Deceased Donor Transplant | 121 | 70.3 |
| Refused Transplant | 1 | 0.6 |
| Died | 5 | 2.9 |
| Too Well to Transplant | 1 | 0.6 |
| Too Sick To Transplant | 2 | 1.2 |
| Living Donor Transplant | 7 | 4.1 |
| Two Deceased Donor Transplants, Relisted, Still Waiting | 2 | 1.2 |
| Deceased Donor Transplant, Relisted, Died | 3 | 1.7 |
| Two Deceased Donor Transplants | 9 | 5.2 |
| One Deceased, One Living Donor Transplant | 1 | 0.6 |
| Deceased Donor Transplant, Relisted, Still Waiting | 6 | 3.5 |
| Total | 172 | 100.0 |
| Waiting Time | | |
| Less Than Three Months | 58 | 33.7 |
| Three to Six Months | 28 | 16.3 |
| Six Months to One Year | 25 | 14.5 |
| Greater Than One Year Up to Two Years | 33 | 19.2 |
| Greater Than Two Years | 28 | 16.3 |
| Total | 172 | 100.0 |

| | N | % |
|---|-----|-------|
| Region Where Listed | | |
| 1 | 8 | 4.7 |
| 2 | 25 | 14.5 |
| 3 | 25 | 14.5 |
| 4 | 8 | 4.7 |
| 5 | 22 | 12.8 |
| 6 | 9 | 5.2 |
| 7 | 19 | 11.0 |
| 8 | 9 | 5.2 |
| 9 | 10 | 5.8 |
| 10 | 14 | 8.1 |
| 11 | 23 | 13.4 |
| Total | 172 | 100.0 |
| Diagnosis at Listing | | |
| Congenital, Rare Familial, and Metabolic Diseases | 1 | 0.6 |
| Diabetes | 18 | 10.5 |
| Glomerular Diseases | 47 | 27.3 |
| Hemolytic Uremic Syndrome | 1 | 0.6 |
| Hypertensive Nephrosclerosis | 53 | 30.8 |
| Neoplasms | 6 | 3.5 |
| Not Reported | 1 | 0.6 |
| Other | 6 | 3.5 |
| Renovascular and Other Vascular Diseases | 8 | 4.7 |
| Retransplant/Graft Failure | 6 | 3.5 |
| Tubular and Interstitial Diseases | 9 | 5.2 |
| Unknown | 16 | 9.3 |
| Total | 172 | 100.0 |
| Patient Received a Transplant | | |
| No | 23 | - |
| Yes - Alive | 138 | 92.6 |
| - Died | 11 | 7.4 |
| Total | 172 | 100.0 |

Rate of Being Placed on the Kidney Waiting List within 5 Years of Donation:

Table 3 shows that among the living kidney donors recovered during 1996-2002, 7 were placed on the kidney waiting list within 5 years of donation. Two of these donors were White and 5 of these donors were Black. Since the overall median time for previous living donors to be placed on the kidney waiting list is 19 years, the number and the rate of being placed on the WL within 5 years of donation are very small. However, despite small numbers, the rate was substantially higher for Black than White donors (0.11% vs. 0.01%).

Table 3. Rates of Being Placed on Kidney WL within 5 Years of Donation for Living Donors Recovered during 1996-2002

| Donor Ethnicity | No. of Donors | Placed on WL Within 5 Yrs of Donation | |
|-----------------|---------------|---------------------------------------|------|
| | | N | % |
| White | 24,334 | 2 | 0.01 |
| Black | 4,582 | 5 | 0.11 |

Basic demographics and clinical information of these seven donors are summarized in Table 4.

Table 4. Basic WL Demographics and Clinical Characteristics for the Seven Prior Living Donors Subsequently Placed on Kidney WL Within 5 Years of Donation Among Living Donors Recovered during 1996-2002

| | White | Black |
|--|-------|-------|
| | N | N |
| Number of Wait Listed Donors | 2 | 5 |
| Gender | | |
| - Male | 1 | 3 |
| - Female | 1 | 2 |
| Age at Donation | | |
| - < 35 | 1 | 2 |
| - 35-49 | 1 | 3 |
| Recipient and Donor Diagnoses * | | |
| - <i>FGS and Membranous Glomerulonephritis</i> | 0 | 1 |
| - <i>Hemolytic Uremic Syndrome (for both recipient and donor)</i> | 1 | 0 |
| - <i>Hypertensive Nephrosclerosis (for both recipient and donor)</i> | 0 | 1 |
| - Malignant Hypertension and IGS Nephropathy | 1 | 0 |
| - <i>Nephritis (for both recipient and donor)</i> | 0 | 1 |
| - Type II Diabetes and Membranouse Nephropathy | 0 | 1 |
| - Unknown and Chronic Pyelonephritis/ Reflux Nephropathy | 0 | 1 |
| Waiting List Outcome | | |
| - Received a Deceased Donor Transplant | 1 | 3 |
| - Received Two Deceased Donor Transplants | 0 | 1 |
| - Received Deceased Donor Transplant, Relisted and Still Waiting | 0 | 1 |
| - Received Two Living Donor Transplants | 1 | 0 |

Note: * Diagnosis in italics indicates the same diagnosis category between the recipient and the living donor.

Update on Prior Kidney Living Donors Who Were Subsequently Placed on the Waiting List and Rate of Being Placed on the Kidney Waiting List within Five Years of Donation

Minority Affairs Committee
July 18, 2008

by:

Wida Cherikh PhD, Charlotte Carroll MS, and Sarah Taranto

OPTN



Background

- The safety of living donation, particularly with respect to individuals who have donated their organ and were subsequently placed on the waiting list due to end stage organ failure remains to be of great interest and importance.
- The MAC continues to express an interest in examining data that pertain to safety of living donation, particularly, with respect to individuals who have donated their organ and were subsequently placed on the waiting list due to end stage organ failure.

OPTN



Background

- The Committee is ultimately interested in determining if the rate of being placed on the waiting list within 5-6 years is higher for previous living kidney donors who are Blacks as compared to non-Blacks.

OPTN



Committee Request

- Provide updated characteristics of individuals who have donated their kidneys and ended up on the wait list due to end stage organ failure.
- Determine if the rate of being placed on the kidney waiting list within 5-6 years is higher for previous living kidney donors who are Blacks as compared to non-Blacks.

OPTN



Data and Methods

- We included candidates ever on the OPTN kidney WL between 1/1/96 and 2/29/08, and who were indicated as a previous donor, or had a prior living donation record in the OPTN living donor database as matched by SSN.

Notes:

- Living donor SSN was not collected prior to 4/1/94 by the OPTN, and therefore SSN matching could not be performed for living donors recovered prior to 4/1/94.
- Starting on September 9, 1996, prior living donors who were subsequently placed on the kidney WL may request four additional points with the appropriate documentation to the OPTN.

OPTN



Data and Methods

- Demographics and characteristics of the previous living donors (LDs) were summarized, when available.
- Relationship between donors and recipients were ascertained, when reported.
- Rates of being placed on the WL within 5 years of donation were computed for White and Black donors who donated their kidneys during 1996-2002.

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Previous Living Kidney Donors Subsequently Placed on WL during 1/1/96-2/29/08

- There were **172** previous living kidney donors who were on the kidney WL between 1/1/96 and 2/29/08.
- **152** were identified from donation points, **4** through SSN linkage, and **16** through both donation points and SSN linkage.

OPTN



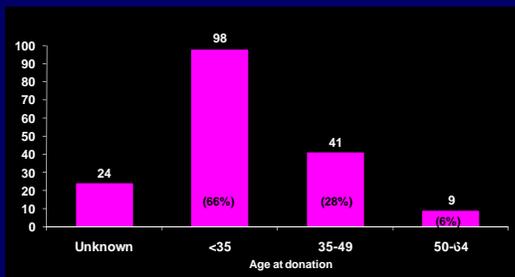
Previous Living Kidney Donors Subsequently Placed on WL during 1/1/96-2/29/08

- Since majority of these candidates donated prior to the inception of the OPTN in 1987 or prior to 4/1/94, their demographics and clinical characteristics at the time of donation can not be ascertained.
- For those cases we could not link with the OPTN data, additional data on date of donation was obtained through phone calls to the transplant centers and from documentation provided to the OPTN in support of requests for donation points.

OPTN



Previous Living Kidney Donors on WL during 1/1/96-2/29/08 (N=172) Age at Donation

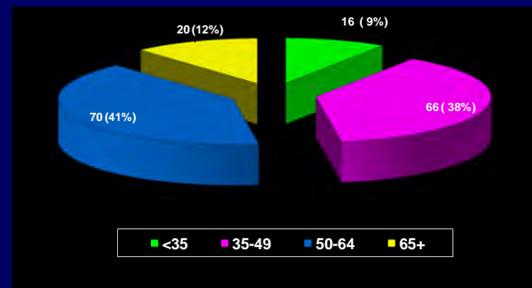


Median: 31 years; Mean: 31.8 years

OPTN



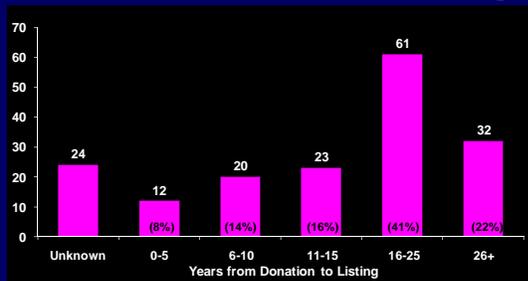
Previous Living Kidney Donors on WL during 1/1/96-2/29/08 (N=172) Age at Listing



OPTN



Previous Living Kidney Donors on WL during 1/1/96-2/29/08 (N=172) Years from Donation to First Listing

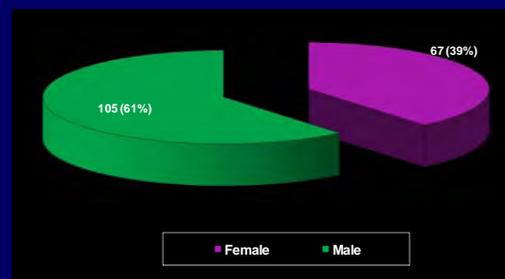


Overall Median: 19 yrs; Mean: 18.5 yrs
 Median for Whites: 21 yrs; Median for Blacks: 16 yrs

OPTN

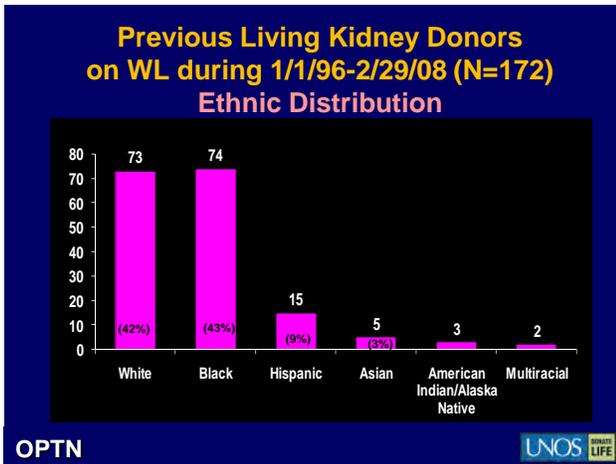


Previous Living Kidney Donors on WL during 1/1/96-2/29/08 (N=172) Gender Distribution



OPTN





Previous Living Kidney Donors on WL during 1/1/96-2/29/08 (N=172) Diagnoses at Listing

| Diagnosis at Listing | N | Percent |
|--|----|---------|
| Diabetes | 18 | 10 |
| Glomerular Diseases | 47 | 27 |
| Hypertensive Nephrosclerosis | 53 | 31 |
| Neoplasms | 6 | 4 |
| Hemolytic Uremic Syndrome | 1 | 1 |
| Renovascular and Other Vascular Diseases | 8 | 5 |
| Retransplant/Graft Failure | 6 | 4 |
| Tubular and Interstitial Diseases | 9 | 5 |
| Other | 6 | 4 |
| Unknown/Not Reported | 16 | 9 |

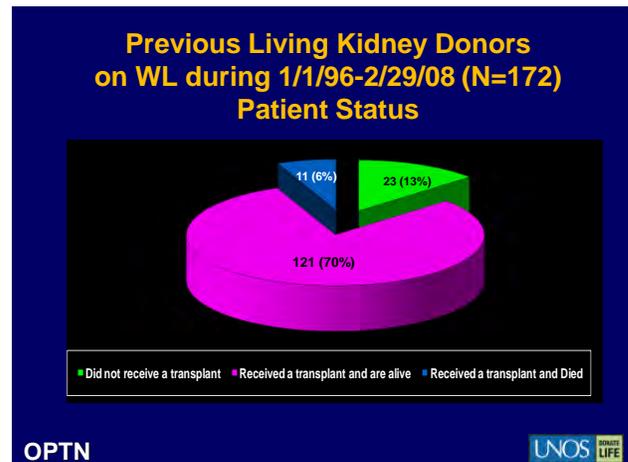
OPTN UNOS DONOR LIFE

Previous Living Kidney Donors on WL during 1/1/96-2/29/08 (N=45) Relationship of Donors to Recipients

| Donor Relationship | N | % |
|----------------------------------|----|-----|
| Biological, blood related Parent | 2 | 4.4 |
| Biological, blood related Child | 8 | 18 |
| Biological, blood related Full | 31 | 69 |
| Biological, blood related Half | 1 | 2.2 |
| Biological, blood related Other | 1 | 2.2 |
| Non-Biological, Other Unrelated | 2 | 4.4 |
| Total | 45 | 100 |

Note: Excluding cases with unknown LD type.

OPTN UNOS DONOR LIFE



Rates of Being Placed on the Kidney WL Within 5 Years of Donation

- Living donors who donated their kidneys during 1996-2002 in the OPTN living donor database were examined.
- OPTN kidney WL database was queried to see if these donors were placed on the WL within 5 years of the donation.

OPTN UNOS DONOR LIFE

Rates of Being Placed on Kidney WL Within 5 Years of Donation for Living Donors Recovered during 1996-2002

| Donor Ethnicity | No. of Donors | Placed on WL within 5 Yrs of Donation | |
|-----------------|---------------|---------------------------------------|------|
| | | N | % |
| White | 24,334 | 2 | 0.01 |
| Black | 4,582 | 5 | 0.11 |

OPTN UNOS DONOR LIFE

**Characteristics of LDs Placed on Kidney WL
Within 5 Years of Donation
for Living Donors Recovered during 1996-2002**

- 2 White living donors -
 - Gender: 1 male and 1 female
 - Donated kidneys in 1998 and 1999
 - Age at donation
 - 1 donated at age 18-34
 - 1 donated at age 35-49
 - Both donated to full siblings
 - Years from donation to listing: 4 - 5 years

OPTN



**Characteristics of LDs Placed on Kidney WL
Within 5 Years of Donation
for Living Donors Recovered during 1996-2002**

- 2 White living donors –
 - Recipient and donor diagnoses:
 - Malignant hypertension and IGS Nephropathy
 - Hemolytic uremic syndrome (HUS) and HUS
 - WL outcome:
 - 1 received deceased donor transplant
 - 1 received 2 living donor transplants

OPTN



**Characteristics of LDs Placed on Kidney WL
Within 5 Years of Donation
for Living Donors Recovered during 1996-2002**

- 5 Black living donors –
 - Gender: 2 female and 3 male
 - Donated in 1997, 1998, 1999, 2001 and 2002
 - Age at donation
 - 2 donated at age 18-34
 - 3 donated at age 35-49
 - 3 donated to full siblings, 1 to parent and 1 to biological relative
 - Years from donation to listing: 2 - 5 years

OPTN



**Characteristics of LDs Placed on Kidney WL
Within 5 Years of Donation
for Living Donors Recovered during 1996-2002**

- 5 Black living donors –
 - Recipient and donor diagnoses:
 - FGS and Membranous Glomerulonephritis
 - Type II Diabetes and Membranous Nephropathy
 - Unknown and Chronic Pyelonephritis/Reflux Nephropathy
 - Nephritis and Nephritis
 - Hypertensive Nephrosclerosis and Hypertensive Nephrosclerosis

OPTN



**Characteristics of LDs Placed on Kidney WL
Within 5 Years of Donation
for Living Donors Recovered during 1996-2002**

- 5 Black living donors –
 - WL outcome:
 - 1 received 2 deceased donor transplants
 - 3 received a deceased donor transplant
 - 1 received a deceased donor transplant, was relisted and is still waiting

OPTN



Summary

- Since the median time for previous living donors to be placed on the KI WL is 19 years, the number and the rate of being placed on the WL within 5 years of donation are very small.
- However, the findings on the relatively shorter time for Black donors to be placed on the WL and the higher rate of being on the WL within 5 years of donation experienced by Black donors are interesting and warrant further investigation.

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Future Analysis

- Link the OPTN living donor database with CMS Form 2728 database to determine how many living kidney donors subsequently received chronic maintenance dialysis.

OPTN

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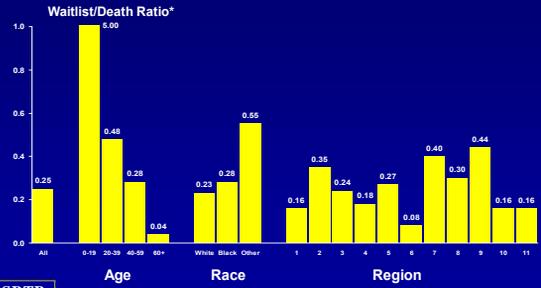
Access to Liver and Heart Transplantation

OPTN Minority Affairs Committee
July 18, 2008

Alan Leichtman, M.D.
Scientific Registry of Transplant Recipients

SRTR

Acute Liver Failure Waitlist/Death Ratio Overall and by Age, Race, and Geography, 1998



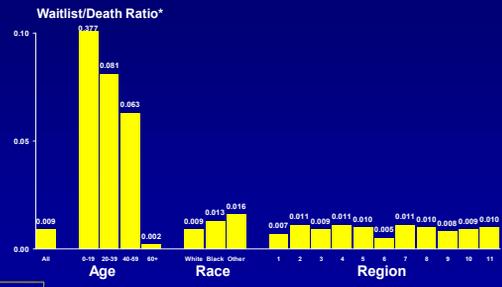
SRTR

Chronic Liver Failure Waitlist/Death Ratio Overall and by Age, Race, and Geography, 1998



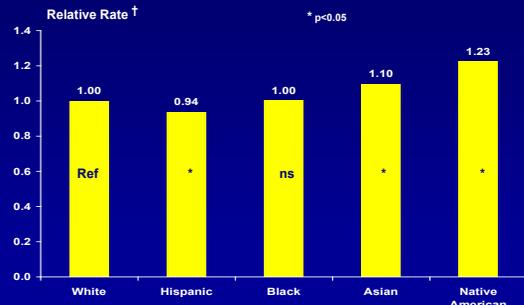
SRTR

Heart Failure Waitlist/Death Ratio Overall and by Age, Race, and Geography, 1998



SRTR

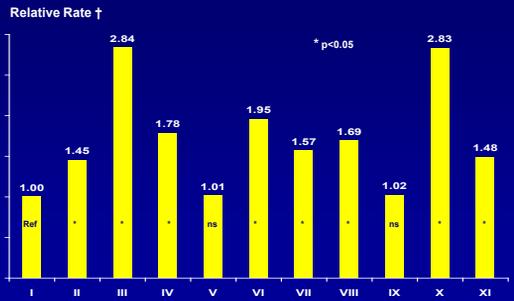
Relative Rate* of Deceased Donor (DD) Transplantation among Liver Waitlist Recipients by Ethnicity, 2002-2005



SRTR

† Adjusted for adjusted for age, gender, BMI, diagnosis group, blood type, year waitlisted, previous transplants, education, insurance, and medical urgency

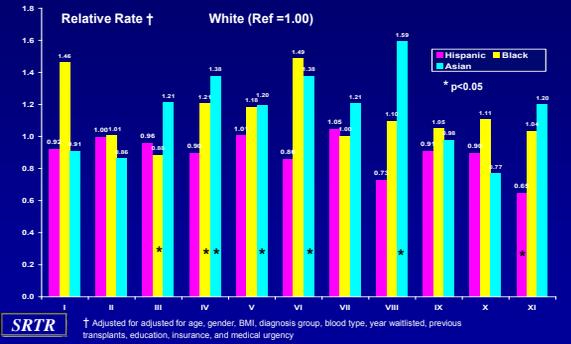
Relative Rate* of Deceased Donor (DD) Transplantation among Liver Waitlist Recipients by OPTN Region, 2002-2005



SRTR

† Adjusted for adjusted for age, gender, BMI, diagnosis group, blood type, year waitlisted, previous transplants, education, insurance, and medical urgency

Relative Rate* of Deceased Donor (DD) Transplantation among Liver Waitlist Recipients by Ethnicity and by OPTN Region, 2002-2005



Importance of Insurance, Race, and Geography on Access

| Characteristic | Chi-square (df) | | | |
|----------------|--|------------|-----------|-----------|
| | Characteristic with larger Chi-square explain more variance. | | | |
| | WL Kidney | Tx Kidney | Tx Liver | Tx Heart |
| Insurance | 5691 (6) | 109 (6) | 70 (6) | 44 (6) |
| Race | 1523 (4) | 344 (4) | 44 (4) | 51 (4) |
| Geography | 3871 (50) | 10878 (47) | 5555 (35) | 1124 (38) |

SRTR