

OPTN/UNOS MINORITY AFFAIRS COMMITTEE REPORT

SUMMARY

I. Organ Availability Issues

Action Items for Board Consideration:

- None.

Other Significant Issues:

- None.

II. Patient Access Issues

Action Items for Board Consideration:

- None.

Other Significant Issues:

- Update on Proposals Presented to the OPTN/UNOS Board of Directors, November 14-15, 2003 (Item 1, Page 1)
- Update on Minority Affairs Subcommittee on Patient Satisfaction/Minority Patient Education Initiative (Item 2, Page 2)
- Overview of HRSA Activities Related to Minority Patient Education (Item 3, Page 2)

III. Other Issues

Action Items for Board Consideration:

- None.

Other Significant Issues:

- Proposals Distributed for Public Comment on March 15, 2004 (Item 4, Page 3)
- Proposal Distributed for Public Comment on March 25, 2004 (Item 5, Page 16)
- Analysis of Access to the Liver Waitlist Among all Patients with Liver Failure for Both Acute and Chronic Failure (Item 6, Page 16)
- Evaluation of the Revised Kidney Allocation Policy After the Elimination of HLA-B Mismatched Points (Item 7, Page 17)
- A₂/A₂B into B Kidney Allocation Alternative System Data Update (Item 8, Page 18)
- CREG Matching Subcommittee (Item 9, Page 20)
- Analysis of MELD Data for HCC Patients (Item 10, Page 20)
- Descriptive Data on Heart Transplantation, including the Number of Minority Patient Deaths on the Waiting List, the Number of Minority Patient Heart Transplants, and the Number of Minority Patients with Assist Devices (Item 11, Page 21)
- Donation Rates For Kidney Transplant in US Minority and Underserved Populations (Item 12, Page 23)
- Minority Access for Diabetes Replacement Therapy (Item 13, Page 24)
- Board Resolution on OPTN Policy Development, Final Rule and OPTN Long Range Planning (Item 14, Page 24)

- Public Comment Process (Item 15, Page 24)
- Review of Ethics Committee White Paper on Living Non-Directed Donation (Item 16, Page 24)
- Application Requirements for Requesting an Alternative Organ Allocation/Distribution System (Item 17, Page 24)
- Request from Midwest Transplant Network Regarding Allocation of A₂/A₂B Expanded Criteria Donor Kidneys (Item 18, Page 25)
- Request from Gift of Hope Organ Tissue Donor Network for Alternative System of Kidney Allocation (Item 19, Page 25)
- Request from Gift of Hope Organ Tissue Donor Network for Alternative System for Allocation of Pancreata (Item 20, Page 25)
- Request from LifeGift Organ Donation Center for Modification to Alternative System for Kidney Allocation (Item 21, Page 25)
- Request from Mid-America Transplant Service/Midwest Transplant Network for a Statewide Alternative Local Unit for Livers (Item 22, Page 25)
- Request from LifeCenter NorthWest for Alternative System for Heart Allocation (Item 23, Page 26)

**REPORT OF THE
OPTN/UNOS MINORITY AFFAIRS COMMITTEE**

**TO THE
BOARD OF DIRECTORS**

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

**Winfred W. Williams, M.D., Chairman
Carlton J. Young, M.D., Vice Chairman**

This report includes items addressed by the OPTN/UNOS Minority Affairs Committee at meetings held on January 27, 2004, and April 27-28, 2004.

1. Update on Proposals Presented to the OPTN/UNOS Board of Directors, November 20-21, 2003. At its meeting on January 27, 2004 (which was truncated due to weather related travel delays), Dr. Williams updated the Committee regarding actions taken by the Board of Directors on November 20-21, 2003, on policy proposals of interest to the Committee.

Proposal for Kidney Waiting Time Accrual from Initiation of Dialysis. The Board declined to approve a standard alternative allocation system that would permit kidney waiting time to begin for primary transplant candidates, from the time of initiation of chronic maintenance dialysis once listed as an active transplant candidate even if this time pre-dated the date of listing, and for repeat transplant candidates, from the date the candidate returned to chronic maintenance dialysis after graft failure once re-listed even if this time pre-dated the date of re-listing. After further review and discussion, the Board approved a modified proposal that would permit the proposed protocol to be tested as a voluntary pilot study.

At its meeting on April 27, 2004, Dr. Leichtman further updated the Committee regarding the status of the voluntary study on waiting time accrual from the initiation of dialysis (**Exhibit A**). A summary of the background of the study was provided to the Committee. The study is designed to minimize disparities in time from dialysis until transplantation among ethnic groups, regardless of when candidates are placed on the waiting list. It is also hypothesized that the study will result in improvements in access to transplantation while not having deleterious effects on referrals to transplantation or transplant outcome. Specifically, the hypotheses are that the system will:

- Increase access for minorities
- Increase access for patients with ESRD whose only insurance is Medicare or Medicaid
- Not delay time to kidney transplant referral for patients with ESRD
- Not adversely effect case mix resulting in poorer post-transplant outcomes

The study will extend for a 3-year period and use time to event models (*e.g.*, Cox Logistic Regression analysis), adjusted for age, gender, cause ESRD, incidence year, ethnicity, comorbidities, dialysis unit type, donor service area, and insurance. It will compare outcomes in participating donor service areas, before and after policy implementation, as well as compare outcomes between participating and nonparticipating donor service areas.

To test the hypothesis that the study protocol will increase access for minorities, the following will be reviewed:

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

These same factors, with associations to Medicare and Medicaid, will be used to test the hypothesis that the study protocol will increase access to kidney transplantation for patients with public insurance only.

The study also will look at trends in the interval between the date of first dialysis and waitlisting date for minority and non-minority populations and trends in preemptive listing (listing prior to initiation of dialysis). Finally, the study will examine pre- and post-transplant survival.

A Subcommittee of the Kidney/Pancreas Transplantation Committee is continuing to develop the methodology for and design of the study. Once this is finalized, it will be presented for further input. Dr. Leichtman reported that a number of OPOs and at least 2 Regions have indicated interest in participating in the study.

Proposal to Restrict Multiple Listing. At its November 20-21, 2003, meeting, the Board declined to approve a resolution presented by the OPTN/UNOS Patient Affairs Committee that would restrict multiple listing to patients who are biologically disadvantaged. The definition of biologic disadvantage as defined by the Patient Affairs Committee would include ABO blood group B and highly sensitized patients. While the Board declined to approve the resolution, it did approve several other resolutions put forth by the Patient Affairs Committee, with the goal of increasing access to multiple listing and improving patient understanding regarding listing practices and options.

2. Update on Minority Affairs Subcommittee on Patient Satisfaction/Minority Patient Education Initiative. At its January 27, 2004, meeting, Dr. Williams provided the Committee with an overview of his presentation of the patient education video to the OPTN/UNOS Board of Directors. Dr. Williams reported that the video garnered some positive feedback from several members of the Board, with limited enthusiasm from others. There was concern that the video imparts a negative tone and that this may overwhelm the audience, preventing real understanding of messages from the video. A next step for the Committee would be to focus on how to address these concerns so that the video can be used to effectuate the type of change envisioned. Several opinions were expressed. It was noted that many of the comments made in the video apply to patients across ethnic groups. A focus on themes with such universal applicability could begin the dialogue. Further, there are two separate issues being addressed in the video. The first is challenges in communication between large transplant programs and their patients listed for kidney transplantation. The second relates to the disparity in transplantation rates among ethnic patient groups and perceptions of minorities. The Subcommittee and then full Committee will continue discussion of the project.
3. Overview of HRSA Activities Related to Minority Patient Education. At its meeting on April 28, 2004, the Committee reviewed a presentation by Renee Dupee, Esq., Program Analyst, Operations and Analysis Branch, Health Resources and Services Administration (HRSA), on government activities related to minority organ donation and transplantation outreach efforts. The Committee requested the information to avoid duplication of minority education efforts already underway or completed by HRSA or other groups in conducting the Committee's own initiatives.

The Education Branch of the Department of Transplantation at HRSA is charged with increasing the awareness of the need for increased donation consent rates, family discussions about intent to donate, and healthy lifestyles that decrease the risk of end stage organ failure. The Committee was informed of various grant programs within HRSA that address these areas. These grants include the Social Indicator Grant program, which awards funds to non-profit organizations for the purpose of increasing donation and transplantation and awareness, the Social and Behavioral Grant Program, and a new program which is a media based grassroots effort specifically geared toward minority outreach to increase minority awareness. Ms. Dupee reported that there were seven grants awarded in 2001, 4 grants awarded in 2002, and 5 grants awarded in 2003, all focused on minority outreach. One of the grant programs funded a campus-wide intervention effort for college students at historically Black universities and colleges. The initiative revealed a high intention to donate, which does not necessarily translate to actual donation. A Member of the Committee commented on a small pilot program in his area, College Campaign for Organ Donation, which canvassed students at two universities and found that across subgroups the most important factor determining a person's willingness to donate was superstitious views and beliefs about death. Level of education or income, ethnicity, nor religion, had an impact on donation. This pilot study concluded that for educational purposes, focusing efforts on developing pamphlets and other educational materials was not necessarily productive; instead, discussion groups about belief systems and death

were more effective. Ms. Dupee concurred, referring the Committee to additional pamphlets and information on their website which address the myths and preconceptions that people have about donation, including, for example, urban legends and issues regarding transplantation of prisoners. The Committee also was informed that information about the minority grant program is available at www.organdonor.gov. A Member of the Committee inquired whether any grants had been awarded to faith-based organizations. It was responded that the Department has issued such awards; however, an organization would need to tailor its application to the award program criteria. The Committee requested that the current Requests for Proposals (RFPs) on minority outreach be included in the next meeting packet.

The Committee also was informed about several public service announcements (PSAs) and films produced by HRSA. The Department developed the television documentary, "No Greater Love," which won an Emmy. However, most of the minorities who appeared in the film were donors and there was feedback from the community that there should be additional images of minority transplant recipients. The Department is beginning work on such a minority outreach film. Dr. Clive Callendar is involved in this effort and has been interviewed for the film. Ms. Dupee is part of a focus group that has viewed the first iteration of the initiative; it was determined that additional work and more minority input is needed. Ms. Dupee suggested that the Committee view the film as it progresses in development.

Ms. Dupee reported that DOT is often invited by organizations to set up exhibits and make presentations for various meetings. In addition to industry related groups, the Department has exhibited and presented at the League of United Latin American Citizens, the NAACP, the National Association of Hispanic Nurses, the National Urban League, the US/Mexico Border Health Meeting, the National Congress of American Indians, the National Organ and tissue Donation Exhibit Consortium, the National Black Nurses Association, the National Council of LaRaza, the Congressional Black Caucus, the National Hispanic Medical Association, and the American Society of Multicultural Health and Transplant Professionals. The Committee was provided with a number of transplant and organ donation related brochures and other educational materials. Feedback regarding the pamphlets was encouraged, including the need for general information and/or information tailored to specific groups. The Department is interested as well in feedback from the Committee regarding additional venues where the materials can be distributed. Black Expos, dialysis centers, churches, hair salons, and barbershops were suggested by Committee members.

Local educational programs targeted toward minority populations were discussed. A Committee Member commented on a Canadian group from the International Transplant Nurses Society that has an educational curriculum on disk for classroom use they are willing to share. Included in the curriculum are complete lesson plans on organ donation, and a mentorship program for students. A Committee Member also remarked that her OPO has an African American and Hispanic Task Force that engages in community events. In addition to OPO staff, the initiative enlists transplant professionals, fire department personnel, family members, donors, and recipients to talk about organ donation.

After discussion, a subcommittee of the full Committee was formed to address donation in minority and underserved populations. It was noted that this group may be best established as a subgroup within the subcommittee working on the Committee's patient satisfaction/minority education initiative. Additionally, care should be taken not to duplicate effort in this area already underway. The Committee was encouraged to communicate with HRSA regarding additional suggested outlets for distribution of the educational materials provided to the Committee.

4. Proposals Distributed for Public Comment on March 15, 2004

1. Proposed Modifications to Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys (Kidney and Pancreas Transplantation Committee). The proposal would clarify a previous Committee proposal approved by the Board to create a generic alternative system that would provide priority in the kidney allocation system for original intended candidates (ICs) for living donor kidneys who are incompatible with their living donors due to crossmatch results or ABO blood type, when the living donors donate to candidates on the list of patients waiting for deceased donor kidneys. Under the proposal, ICs would be ranked, in situations where more than one IC appeared on a match run, in order of date of donation from the living donor. The term "time waiting"

would be eliminated from this portion of the alternative system so as not to be confused with the standard meaning of candidate waiting time. The intent of the alternative system approved by the Board was to facilitate kidney donation by living persons and increase the availability of organs for transplantation overall. The present proposal is intended to assign priority among ICs, when more than one, in a manner that better reflects the alternative system's overall objectives.

The Committee discussed the expected effect of the proposal on minority candidates. The Committee reiterated concerns it had expressed previously regarding the potential adverse impacts of this system on blood group O candidates. The majority of incompatible exchanges would involve blood type O intended candidates with an A, B or AB living donor. When the living donor donates to the deceased donor waiting list, the original intended candidate in turn receives a higher priority on the list for an O kidney. Consequently, although more organs for transplantation into blood type A, B, or AB patients are made available through living organ donation, the blood type O patient waiting list expands, with, perhaps, longer waiting time for blood type O patients who would have been eligible for organ offers but for the new IC priority. A Committee member remarked that Region 1, which currently utilizes a similar system, has monitored the increase in waiting time for unsensitized blood type O candidates who would have been prioritized for organ offers and determined the increase to be substantial but not significant. The Region remains concerned that without additional safeguards for blood type O candidates, problems could develop, particularly if a large volume of patients use the system. One possible safeguard mentioned is a provision limiting the number of times priority for blood type O candidates who would have been prioritized for organ offers but for the IC policy can be reduced.

The overall accessibility of the system was also discussed. A Committee member inquired whether it would be possible to determine who was utilizing the system. It was noted that minority patients might have relatively limited access to the system because of family health concerns or socioeconomic barriers, making it more difficult to locate suitable donors. The Committee member suggested implementing a 1-2 year registry for individuals who express an interest in donating to the deceased donor kidney waiting list when incompatible with their intended candidates. This could include a brief form describing why they did or did not ultimately donate. It was noted, however, that the policy results in increased organ availability through donation of living donor kidneys. It also was reported that the Ethics Committee has expressed concern with the program, but acknowledges the overall benefit to the system of increased organ availability.

Finally, it was noted that minority patients may experience relatively little benefit from the system even when they receive the policy's IC priority because they may be more likely to be incompatible with the living donor kidneys offered through the system just as were the donors' original intended candidates. It was reiterated that it would be important to evaluate which patients, by ethnicity, are using and benefiting from the policy assigning IC priority.

As part of the initial proposal, the Kidney/Pancreas Committee determined that it would monitor impacts upon blood type O candidates and recommend policy revisions if and as appropriate based upon these assessments. The Minority Affairs Committee requests that analyses of the ethnic distribution of patients who utilize and benefit from the system, as well as the impact on waiting time of those unable to utilize the system be performed also.

After noting the additional system analyses requested by the Committee, the Committee voted to approve the policy proposal as written.

Committee vote: 14 For, 0 Against, 0 Abstentions

2. Proposed Modifications to OPTN/UNOS Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) ("Exemption of Kidneys Recovered from Donation after Cardiac Death (DCD) Donors from Sharing Requirements for Zero Antigen Mismatched Kidneys or Payback) (Kidney and Pancreas Transplantation Committee). The proposal would exempt Donation after Cardiac Death (DCD) donor kidneys from the requirements of the zero antigen mismatch kidney sharing policy, except at the local level of organ distribution, as well as, the kidney payback policy. OPOs would retain the option to offer DCD

donor kidneys for payback, but would not be required to do so under the policy. The intent of the proposal is to place DCD donor kidneys as rapidly as possible to avoid adverse impacts from increased cold ischemia time, as well as, increase organ donation by providing an incentive for transplant centers to develop and enhance their DCD donor programs.

Dr. Alan Leichtman, Chair of the Kidney/Pancreas Committee, presented the proposal to the Minority Affairs Committee. In summary, after reviewing the data analyzed several different ways, the Kidney/Pancreas Committee determined that shared (or shipped) zero antigen mismatched DCD kidney transplants do not experience significantly different outcomes from mismatched DCD kidney transplants performed locally. The Minority Affairs Committee discussed various issues regarding shipping organs and the need for rapid placement of DCD kidneys to avoid extended cold and warm ischemia time. One of the issues to be considered, especially with opportunities for broader sharing, is expected impact upon highly sensitized patients. The Kidney/Pancreas Committee examined this matter. Although there were small numbers in the dataset, it does appear that sensitized candidates (defined as PRA > 20%) accept DCD zero antigen mismatch kidney offers at a higher rate than non-sensitized candidates (16.2% versus 11.3%). It was noted, however, that during the 2-year period studied, only 13 DCD kidneys were transplanted into sensitized candidates who had a zero antigen mismatch with the donor. Due to the low volume of patients that would be impacted, the Kidney/Pancreas Committee felt that an exception for sensitized candidates from the proposal was not warranted. Not allowing such an exception also would help to simplify the algorithm and further the intent of placing the DCD donor kidneys more rapidly. In the event that DCD kidney acceptance and transplantation become more prevalent in the future, this is an issue that should be reconsidered. Moreover, it may be of particular importance for minority patients since they tend to be highly sensitized relatively more frequently than white patients. It was noted that outcomes generally for DCD kidney transplants are not as good as they are compared with outcomes for heartbeating donor kidney transplants. For sensitized patients, however, the opportunity for receiving any transplant, even with expectations for poorer outcome, can be of benefit. The Committee recommends, therefore, reassessment of the policy within 1- 3 years of its implementation to evaluate impact upon sensitized patients.

Data provided with the proposal also show that blacks receive a higher proportion of DCD donor kidney transplants (33.5%) than heartbeating donor kidney transplants (28.9%). There was some discussion of whether DCD kidney transplant outcomes are better in low PRA versus high PRA recipients. This was not specifically addressed for the proposal. There was discussion also regarding the necessity of a separate consent process for acceptance of DCD donor kidneys. Currently, this is addressed by transplant hospitals through their processes for obtaining informed consent. This might include specific informed consent for receipt of a DCD kidney transplant or there may be a more general approach to informed consent and donor characteristics regardless of the distinction for DCD or heartbeating. After noting the analysis for impact of the proposal upon sensitized patients (1-3 years following implementation) requested by the Committee, the Committee voted in favor of the policy proposal.

Committee vote: 14 For, 0 Against, 0 Abstentions

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

The Committee discussed this proposal in conjunction with the proposal regarding DCD kidney transplants reviewed above and recommends a similar analysis for impact upon sensitized patients (1-3 years following implementation of the proposal). With this recommendation noted, the Committee voted to support the proposal. It was suggested as well that studies of the ECD kidney allocation policy being performed and evaluated by a Joint Subcommittee of the Kidney/Pancreas and Organ Availability Committees also be presented to the Minority Affairs Committee.

Committee vote: 13 For, 0 Against, 0 Abstentions

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

The Committee expressed an interest in assessing results from the payback system, especially with regard to minority patients. Currently, OPTN/UNOS policy provides that OPOs receiving a kidney shared for zero-antigen mismatched patients, or with an extra renal organ, or for a highly sensitized patient incur an obligation to pay back the kidney (i.e. a debit or debt) to the national system. This debt must be repaid with offers of kidneys from the next suitable donors (six years and older up to and including age 59) of the same ABO blood type as the donor of the shared organ (once the OPO has accumulated two such debts) until accepted by an OPO that is owed a debt. Currently, OPOs are limited to accumulating a total of nine kidney payback debts after which they are in violation of OPTN/UNOS policy. This cap is not being changed under the proposed policy modifications; however, the proposal would allow greater flexibility to OPOs in managing their debt within the threshold (cap) limits.

The Committee discussed the expected impact of the proposal on minority patients. Concern was expressed that permitting increased payback debt accumulation disadvantages minorities. This could be true since zero antigen mismatched kidneys are more frequently allocated for white candidates versus African American candidates based at least in part on commonality of HLA antigens among the population of the donors and potential candidates. Directing (payback) kidneys back to the OPOs that shared the zero antigen kidneys is intended to correct imbalances in the system among patient populations more versus less likely to receive benefit from the zero antigen mismatch sharing policy. Deferring payback kidney offers by allowing more kidneys available for payback to be used with pancreata locally rather than for payback would extend the time the system is in disequilibrium. The proposal also could disadvantage African American patients since African Americans are at least historically less likely to be listed for a combined kidney/pancreas transplant than are white candidates. Data reviewed by the Committee in a subsequent discussion (see item 13 below) suggest that this may be changing now and into the future. Moreover, waiting times for kidney/pancreas candidates already generally are shorter than are waiting times for candidates waiting for isolated kidney transplants. The proposal appears, therefore, to advantage kidney/pancreas candidates, who already benefit in general from relatively shorter waiting times and who presently are less likely to be African American, at the expense of patients listed with OPOs owed kidney payback debts.

The Committee discussed the benefit of receiving a combined kidney/pancreas transplant versus a pancreas-after-kidney transplant. Both are intended to treat diabetes. Recent data show that, in general, simultaneous kidney/pancreas transplants result in better pancreas graft outcomes than pancreas alone or pancreas-after-kidney transplants. It was noted that there is discretion at the local level of organ distribution to assign preference in allocating pancreata alone or with a donor kidney. As a result, differences in these priority assignments exist across the country. The current proposal does not attempt to address these differences. Instead, the proposal would allow OPOs additional flexibility in using the organs together while managing their payback debt.

Finally, the Committee discussed public comment responses received in time for Committee review. The proposal was supported by 86% of the individual comments and opposed by 14% of individual comments. Nine Regions supported the proposal (although one Region approved it by a slim margin). Regions 8 and 9 voted against the proposal. Comments from the Regions were similar to individual comments in expressing concern that the proposal allows too much flexibility for OPOs; instead, OPOs should be held to tighter standards for managing their debt more efficiently. Committee Members suggested as well that increasing the threshold for allowing use of the kidney/pancreas combinations would only defer the time it takes for an OPO to reach the limit and would not resolve underlying concerns regarding utility of the

combined versus isolated pancreas transplant. A Committee Member questioned the activity level of OPOs that are owed kidneys. The Kidney/Pancreas Committee currently reviews quarterly reports of payback debt by OPO and blood group. These reports would help in evaluating patient impacts by area of the country and blood group. The Minority Affairs Committee is interested as well in reviewing overall how well the kidney payback system is working to address imbalances resulting from the zero antigen mismatch sharing policy. The Committee will review the quarterly data reports and other available data for any adverse impacts on minority candidates.

After additional discussion, the Committee determined that the limited increased flexibility for use of kidney/pancreas combinations in lieu of more rapid payback offers permitted by the proposal is appropriate. This allows additional opportunity for use of the organs with the best expected outcomes without increasing the overall payback debt limit of 9. The Committee voted in favor of the proposed policy modifications.

Committee Vote: 11 For, 2 Against, 2 Abstentions

5. Proposed Modifications to OPTN/UNOS Policies 3.5.5 (Payback Requirements) and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Not Transplanted within Time Goals) (Kidney and Pancreas Transplantation Committee). The proposed modifications, originally developed by the OPTN/UNOS Joint Kidney and Pancreas, Pediatric Transplantation, Minority Affairs and Histocompatibility Subcommittee, would elevate the priority at the local level of organ distribution assigned to high scoring high panel reactive antibody (PRA) candidates and pediatric candidates who surpassed their transplant goals ahead of payback debts and credits. This is supported by medical criteria justifying priority in allocation to highly sensitized patients and children versus no similar medical justification for payback offers specific to the patient group receiving the priority. The intent is to provide better opportunities for transplant for pediatric candidates who surpass their transplant goals as well as high PRA candidates who would rank ahead of these children but for the pediatric preference.

The Committee voted unanimously to support the proposed policy modifications.

Committee Vote: 15 For, 0 Against, 0 Abstentions

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

In November 2002, the OPTN/UNOS Board of Directors approved modifications to the national system of standard criteria donor kidney allocation to eliminate points for HLA similarity between potential donor and recipient pairs at the B locus, and modify the number of points assigned for HLA similarity between potential donor and recipient pairs at the DR locus. Current policy assigns two points for a 0 HLA DR mismatch and 1 point for a 1 HLA DR mismatch. During the development of the policy modification, a joint subcommittee of the OPTN/UNOS Kidney and Pancreas Transplantation, Pediatric Transplantation, and Minority Affairs Committees was convened to examine potential impacts of the proposal upon pediatric transplant candidates.

The OPTN/UNOS Pediatric Transplantation Committee has for some time been studying why children are not getting transplanted once they reach their time thresholds even with the additional priority that is assigned for them at this time. The Committee found that less than half of children received transplants

with deceased donor kidneys within their targeted time goals and approximately 91% of pediatric kidney recipients were receiving transplants with three or more HLA mismatches. This raised concerns that children were not receiving well-matched kidney transplants even under the former policy assigning substantially more priority for HLA matching.

One of the solutions proposed was to award a large enough number of points for a 0 DR mismatch to essentially assure an offer for any child when a 0 DR mismatched deceased donor kidney becomes available. The Joint Subcommittee unanimously agreed to recommend a proposal awarding a total of 6 points to pediatric candidates who are a 0 DR mismatch with the kidney donor.

The Committee discussed the benefit of HLA matching for pediatric patients. There was some disagreement expressed regarding its relative importance for these patients. For living donor renal transplantation, for example, effects from ATN, ischemic time, and donor age appear to be more predictive of outcome than are effects from HLA matching. Children's physiology, such as size of blood vessels, and, for older children, compliance issues are important as well. Data presented with the proposal suggest no statistically significant benefit for adolescent (11-17 years old) patients from receipt of DR matched transplants. Such analyses suffer, however, from relatively small data available for study. It was remarked that priority for HLA matching has tended to favor non-minority patient groups over minorities and the Committee member expressed concern that the proposal would extend this disproportionate advantage.

Conversely, it was noted that allocation priority assigned at the HLA DR locus does not appear to disadvantage minorities. Instead, commonality of antigens at the DR locus between potential donors and candidates appears to be more evenly distributed among ethnic groups. Therefore, where there is a benefit to transplant outcomes from receipt of a well-matched kidney at the DR locus, this benefit should apply across patient groups. It also was noted that an additional intent of the proposal is to prevent sensitization in children following a failed kidney transplant through better HLA matching. This may be particularly important for children due to their likelihood of requiring multiple organ transplants throughout their lifetime.

Committee Members acknowledged that presently there is no clear demonstration of advantage for children from receiving DR matched kidney transplants, but there also is no clear demonstration that the advantage does not exist. It seems logical to assume that the benefit from DR matching shown for patients overall would apply also for children and that sample size simply is preventing this conclusion with statistical significance. After additional discussion, the Committee voted in support of the proposed policy modification.

Committee Vote: 14 For, 0 Against, 1 Abstention

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

The Committee voted in favor of the proposal.

Committee Vote: 16 For, 0 Against, 0 Abstentions

8. Proposed Modifications to OPTN/UNOS Policy 3.8.1.6 (Mandatory Sharing of Zero Antigen Mismatch Pancreata) (Kidney and Pancreas Transplantation Committee). The proposed modifications would eliminate requirements for sharing isolated pancreata for zero antigen mismatched patients except for highly sensitized candidates, defined as candidates with panel reactive antibody (PRA) levels of 80% or higher. The proposal arose out of concerns presented to the Committee over the lack of demonstrated survival benefit for isolated whole pancreas transplantation when compared to the demonstrated survival benefit for simultaneous pancreas-kidney transplantation. The Committee based its decision, in part, on data presented to the Committee showing only 50 zero antigen mismatched pancreata were transplanted between 1995 and 2002. The intent is to allow for increased simultaneous pancreas-kidney transplantation by not requiring sharing of zero antigen mismatched pancreata, except for highly sensitized candidates whose opportunities for an isolated pancreas offer are limited.

The Committee discussed the proposal generally, as well as potential minority impacts. It was noted that the proposal addresses what may be a minority issue, preserving sharing requirements for highly sensitized patients who are zero antigen mismatched with the donor. The Committee, therefore, voted in support of the proposal.

Committee Vote: 12 For, 0 Against, 0 Abstentions

9. Proposed Modifications to OPTN/UNOS Policy 3.6.2.1 (Allocation of Blood Type O Donors) (Liver and Intestinal Organ Transplantation Committee). This proposal, which was approved by the OPTN/UNOS Board of Directors for implementation concurrent with public comment, would increase the threshold for allocation of blood type O donors to blood type B candidates from a MELD/PELD score of 20 to a MELD/PELD score of 30. This is intended to better equalize the donor pool for O and B candidates. It was predicted to reduce the number of blood type O livers transplanted into blood type B patients and to increase the number of blood type O livers transplanted into blood type O recipients by the same number, without affecting the death rate in either population.

The Committee discussed the impact of the proposal on blood group B candidates, a relatively large portion of whom tend to be minority candidates. It was noted that there was opposition voiced in public comment concerning the advantage to O patients at the expense of B candidates. It was felt that by raising the MELD threshold for sharing blood type O donor livers to these patients to 30, many of the blood type B patients currently receiving O livers would die before being transplanted. The Committee discussed impacts on waiting list and post transplant deaths for both O and B candidates. The Committee was referred to an LSAM analysis in which deaths were compared using thresholds of 20, 25, and 30 for sharing blood type O donor livers. The number of waiting list and post transplant deaths for O and B candidates were compared under each scenario. The percentage of O livers allocated to B candidates ranged from 5.9% (current policy) to 0.0% (allocation not allowed); the percentage was 1.7 using a threshold of 30. Similarly, under the current policy, 20.8% of B recipients received O livers, which was reduced to 6.9% using a threshold of 30. The data revealed that the total number of deaths for both type B and O patients was relatively unchanged. A Member of the Committee remarked that the simulation examined total deaths rather than separating out waitlist deaths. Therefore, impact of the proposal upon patients who continue to wait for a liver transplant is not reported. It was noted as well that since the size of the blood type B waiting list is smaller than the blood type O waiting list, the fact that total deaths are not changed is not particularly reassuring.

In summary, given that blood group B candidates tend to include a relatively substantial proportion of minority patients, the Committee is concerned that it has insufficient data to render an opinion on minority impacts from the proposal. The Committee requests data on the ethnic composition of the blood group B liver waiting list, MELD scores of candidates receiving liver transplants, and deaths on the waitlist, excluding exception cases, by blood group and ethnicity. Subsequently, the Committee voted against the proposal as written. The Chair also convened a subcommittee of the full Committee to consider these issues further.

Committee Vote: 0 For Approval of the Proposal, 11 Against Approval of the Proposal, 3 Abstentions

10. Proposed Modifications to OPTN/UNOS Policy 3.6.2.1 (Allocation of Blood Type O Donors). (Liver and Intestinal Organ Transplantation Committee). This proposal would allow any remaining blood type compatible candidates to appear on the match run list for blood type O donors after the blood type O and B candidate list has been exhausted at the local, regional and national level. Under current policy, these patients do not appear on the match run and are therefore not eligible for organ offers. This may reduce organ wastage in some instances.

The Committee approved the proposal as written.

Committee Vote: 16 For, 0 Against, 0 Abstentions

11. Proposed Modifications to OPTN/UNOS Policy 3.6.4.4.1 (Adult Patient Reassessment and Recertification Schedule) and 3.6.4.2.1 (Pediatric Patient Reassessment and Recertification Schedule). (Liver and Intestinal Organ Transplantation Committee). This proposal, which was approved by the OPTN/UNOS Board of Directors for implementation concurrent with public comment, specifies that patients whose MELD/PELD scores remain uncertified will be reassigned to a MELD/PELD score of 6. Pediatric patients whose uncertified score is less than 6 would remain at that lower, uncertified PELD score. Under the current policy, some patients who are uncertified are allowed to remain indefinitely at an uncertified MELD/PELD score.

The Committee approved the proposal as written.

Committee Vote: 17 For, 0 Against, 0 Abstentions.

12. Proposed Modifications to OPTN/UNOS Policy 3.6 (Adult Donor Liver Allocation Algorithm) (Liver and Intestinal Organ Transplantation Committee). This proposal would modify the sequence of allocation for adult donor livers such that organs would be allocated to local and regional candidates with MELD/PELD score of 15 or higher prior to candidates with MELD/PELD scores less than 15. The intent of the policy is to direct livers towards those patients who are likely to receive more benefit from liver transplantation.

The Committee discussed whether there are minority issues. It was noted that the proposal should result in allocating more livers to candidates with greater risk of dying on the wait list.

The Committee approved the proposal as written.

Committee Vote: 18 For, 0 Against, 0 Abstentions

13. Proposed Modifications to OPTN/UNOS Policy 3.6.4.1 (Liver Allocation, Adult Patient Status) (Liver and Intestinal Organ Transplantation Committee). This proposal would institute minimum listing criteria of a MELD score of 10 for adult candidates, with the exception of candidates meeting the requirements of Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma) and 3.6.4.5 (Liver Candidates with Exceptional Cases). Patients with Stage T1 HCC could be listed with their laboratory MELD score upon prospective agreement by the Regional Review Board. Patients listed at the time the policy is implemented whose MELD score is less than 10, as well candidates whose MELD scores fall below the threshold of 10 after appropriate listing, would not be removed from the list. Analyses of OPTN data indicate that it is highly unlikely that an adult candidate will benefit with transplantation during the first year post-transplant if their MELD score is 10 or less.

The Committee discussed potential adverse impacts for minority patients. Members of the Committee expressed concern that the proposal would compromise access to care for poor and minority patients. Insurance companies may use the minimum criteria to deny payment for transplant evaluation and other medical care protocols. The Committee does not have data to support these concerns; however, it was strongly asserted that insurance companies, upon learning that a prospective candidate's MELD score is less than 10, could use the information to deny access to the waiting list for transplantation. Members noted that the Transplant Center is the only official source for submitting a MELD score. Conversely, it

was noted that MELD scores can be calculated for informational purposes using the calculator that is publicly available.

Other Committee Members disagreed that the concern is warranted. They questioned how patients could be attributed with MELD scores if they were not already being evaluated by a transplant center. The MELD values must first be obtained after performing appropriate tests and then a score calculated. Scores are submitted through UNetsm.

A Committee Member suggested that, currently, referral to a transplant Center is required to list a patient. If information is available to calculate a MELD score less than 10, then the insurance authorization for transplantation may not be approved. This could limit patient access to transplantation. On the other hand, it was suggested that the patient should remain eligible for ongoing evaluation, just not transplantation.

Committee Members noted that, perhaps, impact of the proposal upon insurance company behaviors is beyond the scope of the Committee's expertise or ability to assess with evidence. Additionally, it may be more of a generic concern regarding financial matters and access to transplantation for all patients rather than a minority issue to be addressed through this proposal. It was noted as well that the proposal allows patients with a calculated MELD score less than 10 to be listed with prior approval of the appropriate Regional Review Board. Again, the patient first needs to be evaluated, a score calculated, and determination made that the patient is expected to benefit from a liver transplant. This opportunity may be sufficient for appeal of any adverse insurance company decisions. It also was suggested that the language be changed from minimum threshold for listing to a minimum threshold for transplant. Under this scenario, a MELD score of less than 10 would not prevent the candidate from being listed; it would prevent only the transplant itself. This is similar to kidney allocation policy, which permits listing candidates regardless of renal function but allows accumulation of waiting time only when the candidate meets renal function criteria. However, unlike kidney transplantation, liver candidate MELD scores must be recertified at particular frequencies. If patients with a MELD score under 10 are listed, there would be additional costs associated with recertifying these patients. Another Committee Member suggested that because minorities tend to be referred later in the progression of their disease, it is possible that minimum listing criteria at a MELD score of 10 would not be a disadvantage for them.

Finally, the Committee was informed that 5 of the 11 Regions voted against supporting the proposal.

The Committee acknowledges the intent of the proposal to address data showing no benefit from liver transplantation with a MELD score less than or equal to 10. The Committee, therefore, voted in favor of the proposal in light of the analyses demonstrating transplant benefit with MELD scores greater than 10. At the same time, however, the Committee remains concerned that the change in policy could limit access to transplantation based upon adjustment of insurance company practice in response to the modified policy.

Committee Vote; 12 For, 3 Against, 2 Abstentions

14. Proposed Modifications to OPTN/UNOS Policies 3.6 (Pediatric Donor Liver Allocation Algorithm & Allocation Sequence for Patients with PELD or MELD scores Less than or Equal to 6 (All Donor Livers)), 3.6.4.2 (Pediatric Patients Status), 3.6.4.2.1 (Pediatric Patient Reassessment and Recertification Schedule), and 3.6.4.3 (Pediatric Liver Transplant Candidates with Metabolic Diseases), 3.6.4.4.1 (Pediatric Liver Candidates with Hepatoblastoma). Under the proposed modifications, adolescent pediatric liver candidates (age 12-17) would be assigned a MELD score rather than a PELD score. For the majority of adolescent liver candidates, a calculated MELD score offers an increase in allocation score and, thus, an increase in opportunity for transplant. Based on the variables included in allocation score calculation in the MELD system, MELD scores may also offer a more accurate picture of mortality risk and disease severity for adolescent candidates. Adolescents will, however, maintain pediatric status in the policy, including assigned priority for children in the allocation of pediatric donor livers.

The Committee voted to approve the proposed policy modifications.

Committee Vote: 17 for, 0 Against, 0 Abstentions

15. Proposed Modifications to the Region 5 Status 1 Sharing Agreement. (Liver and Intestinal Organ Transplantation Committee). The proposed changes to the Region 5 Status 1 sharing agreement would eliminate the provision for payback for Status 1 shares. The definition of Status 1 for both adult and pediatric candidates will be redefined to better identify patients in urgent need of a liver. These changes are recommended by the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, having been charged by the Board of Directors to adjudicate the issue.

After brief discussion regarding the background of the proposal, the Committee determined that there is no minority impact requiring comment by the Committee.

16. Proposed Modifications to OPTN/UNOS Bylaws Appendix B Attachment 1 (Standards for Histocompatibility Testing) Standard H3.100 and Proposed New Policies for Kidney Transplantation - 3.5.17 (Prospective Crossmatching), and for Pancreas Transplantation - 3.8.8 (Prospective Crossmatching), and Proposed Appendix D to Policy 3. (Histocompatibility Committee). The proposed modifications to standard H3.100 of the Bylaws is intended to make the standard pertinent to laboratory practice. Concurrent with this modification, new policies 3.5.17 and 3.8.8 are proposed that are clinical practice policies and set out the conditions when a prospective crossmatch for kidney (3.5.17) and pancreas (3.8.8) organ transplantation is mandatory. Appendix D to Policy 3 sets out guidelines for the development of joint written agreements between Histocompatibility laboratories and transplant programs regarding risk assignment and the timing of crossmatch testing.

After brief discussion, the Committee voted in favor of the proposed modifications with a request that the Histocompatibility Committee evaluate mechanisms for increasing transplant access to minorities who are sensitized. This might include, for example, identification of unacceptable antigens for sensitized candidates. The Committee acknowledges that differences in Histocompatibility laboratory testing techniques and similar issues may make this difficult to develop into policy at this time. The Committee's recommendation is general, therefore, referring to any mechanisms that would increase access for sensitized candidates.

Committee Vote: 16 For, 0 Against, 1 Abstention

17. Proposed New OPTN/UNOS Policy 3.7.17 (Crossmatching for Thoracic Organs). (Histocompatibility Committee). The proposed new policy 3.7.17 (Crossmatching for Thoracic Organs) would require all thoracic organ transplant programs and its Histocompatibility laboratory to have a joint written policy that sets out the circumstances when a crossmatch is necessary.

The Committee voted in support of the proposed policy.

Committee Vote: 15 For, 0 Against, 0 Abstentions

18. Proposed Modifications to OPTN/UNOS Policy 6.4 (Exportation and Importation of Organs - Developmental Status) (Ad Hoc International Relations Committee). The OPTN/UNOS Ad Hoc International Relations Committee proposes modifications to the Policy 6.4 that would help to ensure the accuracy and fairness of organ allocation where organs are offered into the U.S. from foreign countries by requiring higher standards of verification from the foreign exporters. In addition, the proposed policy changes would ensure that imported organs would first be available to the OPO or transplant center that arranged to import them. The proposed changes to policy would require:

1. Foreign donor organizations must provide verification of donor consent, brain death, and donor ABO.
2. Organ importers must obtain verification that foreign entities are medical centers authorized to export organs.
3. Imported organs will be first allocated locally to the OPO or transplant center that arranged the import.

The Committee discussed the proposal generally. Dr. Wida Cherikh provided the Committee with the estimated number of organs imported into the US. From 1988 to 2003, there were 575 donors with at least

one organ imported from outside the country. This represents less than 1% of donated organs in the US. The majority of organs being imported are from Canada and Bermuda. The Committee discussed whether there are any minority concerns with regard to the proposal.

Several Committee Members expressed concern regarding the proposed policy language that appears to allow allocation of the imported organs by other than standard policy. It was noted that language in Policy 6.4.2.1 stating that organs would be allocated according to UNOS policy had been stricken. The new wording in the proposal states that the organ would first be allocated to the OPO or transplant Center that arranged the import. Members of the Committee raised concern regarding the equity of distributing organs to an individual transplant center. It was noted that some of these exporting countries are equal in distance to and border upon states within the US. It was commented that the policy for allocating importing organs should be consistent with standard allocation policy to avoid potential abuse of organ import opportunities and abide by the principles of equitable organ allocation that resulted in the standard policy.

It was noted that this issue has been raised in Regional discussion of the proposal. It appears that the Ad Hoc International Relations Committee did not intend to change references to allocation by standard policies, although this is what the revised language implies.

The Minority Affairs Committee voted against the proposed modifications to Policy 6.4 by a vote of 0 For the Proposal, 17 Against the Proposal, and 0 Abstentions. The Committee subsequently voted to approve the following amended policy language:

RESOLVED, that the next-to-the-last line in Policy 6.4.2.1 of proposal 18 from the Ad Hoc International Relations Committee be modified to read, "All imported organs will be allocated first to the OPO or transplant center that arranged the importation of the organ according to local organ allocation policies."

Committee Vote: 17 For, 0 Against, 0 Abstentions

19&20. Proposed Guidelines for Living Liver and Kidney Donor Evaluation (Ad Hoc Living Donor Committee).

The proposal would establish guidelines for living liver transplant candidate and donor evaluation, including provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiologic, and anesthesia evaluation. While not proposed as OPTN/UNOS policy, the Ad Hoc Living Donor Committee believes that the guidelines could evolve into the standard of practice for living donor evaluation. As the Ad Hoc Living Donor Committee has also issued a similar proposal for living kidney donation guidelines, the Minority Affairs Committee discussed both proposals together.

The Committee debated the merits of the proposal. Several Committee Members agreed with the spirit of the proposal but felt that some of the details would be burdensome on the process of living donor transplantation. There was particular concern regarding requirements for an independent donor evaluation team. These concerns included the intended definition of "independent," and whether this means individuals not involved in transplantation at all, or not involved with both the living donor and potential candidate at the same time. A Committee Member felt that it is possible to appropriately address all of the potential donor's medical and psychosocial factors within the donor team, and that independence of the physician from the donor team to determine the suitability of a potential donor is not necessary. In the Committee Member's transplant center, the team includes all of the recommended evaluation components, and though the transplant physician is not "independent," he or she would not be evaluating a patient under his or her care. The Committee discussed ways in which donor evaluation is handled in other centers. One Committee Member remarked that using independent teams promotes community trust. In his program, family assessment teams are used to handle potential donors, while a transplant physician makes the final determination as to the suitability of the donor.

Another Committee Member felt strongly that an independent nephrologist should evaluate the donor. HRSA's representative to the Committee offered that based on her understanding of a discussion at a recent meeting of the Secretary's Advisory Committee on Transplantation (ACOT), this group was looking for a completely independent advocate. The predominant concern raised within ACOT was coercion of potential donors rather than medical suitability. Individual Committee Members recounted instances of donors

changing their minds and stressed the importance of supporting these individuals and their decisions. Another Committee Member suggested that one way to address the issue would be to change the language from evaluation team to donor advocate team. It was also suggested that the word independent be stricken from the proposal and substituted with language referencing a transplant professional not associated with the transplant team. There was concern that transplant experience is necessary for appropriate donor support.

The Committee also expressed other concerns with the proposal. The need for requiring an anesthesiologist to see every potential living donor before they are accepted as a donor was questioned. Another Committee Member expressed concern with the language contained in the living kidney transplantation guidelines being so closely aligned with the living liver donor evaluation guidelines. Differences between the two organ systems and corresponding needs of donors may not have been thoroughly evaluated. Another Committee Member felt that all donors need to have some type of psychiatric or psychological evaluation as appropriate, and advocated for this wording change in the proposal. The Committee discussed the need for a central living donor registry for follow up of these patients. A Committee Member pointed out that if marginal donors with strong family history of diabetes, hypertension, etc. are going to be accepted as donors, it is essential that risks to these potential donors are explained. The risks cannot be adequately assessed without comprehensive, accurate registries, however. The Committee discussed the importance and responsibility of the Committee to make a strong statement to this effect.

Committee Members expressed concern that the proposal establishes another unfunded mandate. Another Committee Member felt the process should be reviewed to enable assessment of socioeconomic disincentives to donation as well. A specific suggestion was made that educational information be tailored to specific populations and include culturally competent materials. The Committee was reminded that the proposal is not a mandate of care, but proposed guidelines for a process where none currently exist. Another Committee Member felt that guidelines are often very close to standard of care from practical and legal perspectives. A question was asked about living lung donation as this is being performed in several centers. It was reported that the Ad Hoc Living Donor Committee is hoping to address this practice in the future.

The Committee approved the proposed guidelines and notes its strong support for culturally competent advocacy for living donors. There is concern, however, that guidelines, particularly those that are applied without concurrent funding, can be overly detailed resulting in proscription of practices that are very well thought out and safe. The Committee also reiterates the need for a comprehensive, accurate living donor registry to record and report the medical condition of these patients following the transplant event. This is essential to enable appropriate explanation of the risks of living organ donation and meaningful donor advocacy.

Committee Vote: 14 For, 3 Against, 0 Abstentions

21. Proposed Modifications to OPTN/UNOS Policy 3.1.4 (Patient Waiting List). (Ad Hoc Operations Committee). The Ad Hoc Operations Committee is seeking public comment on new and modified policies for listing transplant candidates on the national waiting list. The proposed policies address: processes for ensuring the accuracy of a transplant candidate's ABO type on the waiting list; requiring transplant centers to enter and maintain transplant candidate data electronically using UNetsm; requiring transplant candidate ABO typing on two separate occasions prior to listing; and listing transplant candidates with their actual ABO type.

The Committee briefly discussed the rationale for the proposal. The Committee also discussed a request from the Ad Hoc Operations Committee for input regarding applicability of double verification procedures to living donors and living donor organ recipients.

The Committee determined that there was no discernible minority issue requiring comment from the Committee.

22. Proposed Modifications to OPTN/UNOS Policy 3.2.3 (Match System Access). (Ad Hoc Operations Committee). The Ad Hoc Operations Committee is seeking public comment on modifications to Policy 3.2.3, (Match System Access). The proposed modifications would require two separate determinations of the donor's ABO type prior to initiating the organ recovery incision, and more specific policy language for the process of distributing organs using the match.

The Committee determined that there was no discernible minority issue requiring comment from the Committee.

23. New OPTN/UNOS Policy 3.4.7 (Allocation of Organs During Regional/National Emergency Situations), 3.4.7.1 (Regional/National Transportation Disruption), and 3.4.7.2 (Regional/National Communications Disruption) (OPO Committee). The Health Resources Services Administration (HRSA) has requested the OPTN develop policies for maintaining the organ matching and allocation process during times of regional or national emergencies that compromise telecommunication, transportation, or the function of or access to the OPTN wait list or matching system. OPTN staff drafted the proposed policies for consideration by the OPO Committee. The policy was approved by the Board of Directors and became effective December 22, 2003, concurrent with public comment.

The Committee determined that there was no discernible minority issue requiring comment from the Committee.

24. Proposed Modification to the Criteria for Institutional Membership, OPTN/UNOS By-Laws, Appendix B, Section III (C) (Transplant Programs): Proposed Modifications to Item (15) (Social Support) (Transplant Administrators Committee). The OPTN/UNOS Transplant Administrators Committee proposes a By-law modification that delineates a transplant program's specific responsibilities in providing psychiatric and social support services (psychosocial services) for transplant candidates, recipients, living donors, and family members. Individuals trained in psychiatry, psychology or social work may provide these services. These individuals should be designated members of the transplant team, and work with patients and families in a compassionate and tactful manner in order to facilitate access to and continuity of care.

The Committee reviewed the proposal and determined that while there is no overriding minority concern, it could be very helpful to improve transplant program operations generally. It was suggested that the need for cultural competency in administering psychosocial services should be added. The Committee voted to approve the proposed policy modifications.

Committee Vote: 16 for, 0 Against, 0 Abstentions

25. Proposed Modification to the Criteria for Institutional Membership, OPTN/UNOS By-Laws, Appendix B, Section III (C) (Transplant Programs): Proposed New Item (20) (Clinical Transplant Pharmacist) (Transplant Administrators Committee). The OPTN/UNOS Transplant Administrators Committee proposes a change to the OPTN/UNOS By-laws that delineates the specific responsibilities of a clinical transplant pharmacist in an active transplant program. The goal of the proposal is to provide additional detailed information about the essential care provided by pharmacists and teams led by pharmacists, in an effort to assure that this care remains available to transplant recipients and the transplant team. It is not the committee's goal to create a membership requirement on par with the primary physician or surgeon.

The Committee reviewed the proposal and determined that while there is no overriding minority concern, it could be very helpful to improve transplant program operations generally. It was suggested that the need for cultural competency in administering the duties of clinical transplant pharmacist should be added. The Committee voted to approve the proposed policy modifications.

Committee Vote: 16 For, 0 Against, 0 Abstentions

5. Proposal Distributed for Public Comment on March 25, 2004

1. Proposed Amended OPTN/UNOS Policy 3.7.6 (Status of Patients Awaiting Lung Transplantation) Policy 3.7.9 (Time Waiting for Thoracic Organ Candidates), Policy 3.7.9.2 (Waiting Time Accrual for Lung Candidates with Idiopathic Pulmonary Fibrosis (IPF)), and Policy 3.7.11 (Allocation of Lungs). The OPTN/UNOS Thoracic Organ Transplantation Committee proposes a new system for allocating lungs that uses lung transplant candidates' waitlist medical urgency and transplant benefit to determine priority for lung offers. The proposed system would assign priority to lung candidates who are at higher risk of death if they do not receive a transplant (waitlist urgency) and who are likely to receive a greater benefit of longer lifetime with a transplant as compared to without a transplant (transplant benefit). This proposal would replace the current system that assigns priority to lung transplant candidates based solely on the amount of time they have accrued on the lung waitlist. The Committee predicts that these changes to the lung allocation system would direct lungs to those candidates who are most urgently in need of a lung transplant and who are expected to receive the greatest survival benefit from the transplant. The proposal includes provisions for updating transplant candidates' clinical status, regular periodic review and improvement of the algorithm, and assigned allocation priority for pediatric candidates.

The Committee could not determine a minority effect with regard to the proposal; however, it will review the policy over time to determine if any such impacts develop.

6. Analysis of Access to the Liver Waitlist among all Patients with Liver Failure for both Acute and Chronic Failure. At its meeting on April 28, 2004, the Committee reviewed an analysis (**Exhibit B**) estimating access to the liver waitlist among all patients with liver failure for both acute and chronic failure. Studies of access to the waitlist for liver transplantation are complicated by the fact that there is no registry of patients with liver failure. The current analysis was performed by examining the population who dies of causes related to liver failure. Data from the National Center for Health Statistics for 1998 were used. The study identified ICD-9 codes (primary and secondary) for deaths potentially due to acute and chronic liver failure. Waitlist registrant counts were also obtained for Status 1 liver registrants and Non-Status 1 liver registrants in 1998. The study population included all waitlist registrants age < 65 for acute liver (Status 1) and chronic liver (Non-status 1) disease in 1998, and deaths in 1998 for acute and chronic liver disease for patient's age < 65 years. For acute liver deaths, deaths due to alcoholism or cancer were excluded. Acute liver failure codes included:

270.6 Disorders of urea cycle metabolism
275.1 Disorders of copper metabolism
570 Acute and sub acute necrosis of liver
573.3 Hepatitis unspecified
573.4 Hepatic infarction

For chronic liver failure deaths, non-liver cancer deaths only were excluded. Chronic liver failure codes included:

270.2 Other disturbances of aromatic amino acid metabolism
271.0 Glycogenosis
272.7 Lipidoses
277.4 Disorders of bilirubin excretion
277.6 Other deficiencies of circulating enzymes
571.0 – 571.9 Chronic liver disease and cirrhosis
572.2 Hepatic coma
572.3 Portal hypertension
572.4 Hepatorenal syndrome
573.8 Other specified disorders of liver

The count of waitlist registrants was calculated by adding the number of waitlist registrants on the waitlist on December 31, 1997, and the number of new registrants in 1998. The ratio of waitlist/liver failure pool was calculated as: waitlist registrants/(waitlist registrants + NCHS deaths – waitlist deaths - transplant deaths). The

analysis showed the overall ratio of waitlist/liver failure pool for acute liver failure was 0.47. Similarly, the overall ratio for chronic liver failure was 0.43, while the ratio for chronic liver failure by specific diagnosis was 0.15, 0.31, and 0.68 for liver cancer, alcohol-related, and hepatitis C, respectively. All subgroup analyses showed that patients age 0-19 years old had higher ratios than older patients and whites had higher ratios than blacks. Children appear to have the highest access to the waitlist. Females generally were more likely to be listed than males. Waitlist rates also varied by Region. As with kidney waitlist rates, geography is a very important factor in determining access to the liver waiting list. It was noted that the ratios are believed to be over-estimated since individuals with liver disease and no access to the waitlist who do not die are not captured in the analysis. Still, however, it is expected that the trends are accurate.

A Member of the Committee inquired about insurance coverage and access to the liver waitlist. Data were presented to the Committee previously, indicating that insurance is a factor in listing for liver transplantation, but does not have much impact on who is eventually transplanted once listed. It was suggested that in this regard, there may be more equity in access to liver transplantation than in kidney transplantation, though it was reiterated that it is hard to discern those who are not referred to the wait list if they survive. The Committee then discussed the significance of the results for policy development. Suggestions for future areas of study included a re-examination of issues related to geography and transplantation.

7. **Evaluation of the Revised Kidney Allocation Policy After the Elimination of HLA-B Mismatched Points.** At its meeting on April 28, 2004, the Committee reviewed data summarizing kidney transplant results both before and after implementation of the revised kidney allocation policy that eliminates points for HLA-B mismatches; and modifies points assigned for HLA-DR mismatches (**Exhibit C**). Dr. Wida Cherikh presented the analysis to the Committee.

The Histocompatibility Committee Task Force on Kidney Allocation requested the data to compare the first full 6 months after the points were modified (May 7, 2003-November 7, 2003) with the last full six months of allocation using the previous system (November 6, 2002-May 6, 2003). The purpose of the data request was to monitor performance of the modified HLA point system after 6 months of implementation with regard to minority allocation and local distribution of HLA-DR matched transplants. Because of variations of the standard kidney allocation algorithm, only 18 OPOs that operated the same standard kidney allocation algorithm during the entire study period were included in the analysis. In addition, pediatric recipients and recipients of expanded criteria donor (ECD) kidneys were excluded from the analysis. The study examined all match runs for all donors at these 18 OPOs during the study period. Potential candidates in the top 10% of the local list were included, and the ethnic composition of these candidates was compared between the pre- and post-modified policy periods. All information is based on OPTN data as of January 2, 2004.

There were 1,394 deceased donor kidney transplants included in the analysis (697 in each period). The proportion of zero-antigen mismatched transplants was 15.06% (105/697) in the pre-policy period, and 14.92% (104/697) in the post policy period.

The distribution of non-zero HLA mismatched transplants by period, ethnicity and ABO blood group was presented to the Committee. In summary, the proportion of Whites transplanted decreased (by 7.8% pts), while the proportion of Blacks and Asians increased (by 3.4% and 3.9% pts, respectively) and the proportion of Hispanics and other ethnic group stayed about the same. For ABO blood group, the proportion of A and AB patients transplanted stayed about the same, the proportion of B patients transplanted increased (by 2% pts), and the proportion of O patients transplanted decreased (by 2% pts).

The distribution of non-zero HLA mismatched transplants by HLA-ABDR, BDR, and DR mismatch (MM) levels also was summarized. The proportion of 1-, 2- and 3-ABDR MM went down (by 3.05%, 8.5% and 15.6% pts), while the proportion of 4-, 5- and 6-ABDR MM went up (by 2%, 23.8%, and 1.4% pts). For HLA BDR mismatch level, the proportion of 0-, 1- and 2-BDR MM went down (by 1.52%, 16%, and 16% pts), while the proportion of 3- and 4-BDR MM went up (by 24% and 10% pts). For HLA Dr mismatch level, the proportion of 0- and 1-DR MM went down (by 9.5% and 1.2% pts), while the proportion of 2-DR MM went up (by 10.7% pts).

Recipient waiting time also was summarized. As compared to the pre-policy period, the proportion of transplant recipients who waited less than 24 months appeared to decrease, while the proportion of transplant recipients who waited for more than 24 months increased during the post-policy period.

The distribution of zero-antigen mismatched transplants in the pre-and post-policy periods by ethnicity and ABO blood group was summarized. The proportion of White recipients decreased (by 6% pts) while the proportion of Black recipients and other ethnic group increased (by 4% and 3% pts), and the proportion of Hispanic and Asian recipients stayed about the same. For ABO Blood type, the proportion of A and B recipients increased (by 8% and 2% pts), while the proportion of AB recipients stayed about the same. Further, the proportion of O recipients decreased (by 11% pts).

Finally, the ethnic distribution of potential candidates in the top 10% of the local list for match runs performed in the pre-and post-policy periods was summarized. The proportion of White candidates that appeared in the top 10% of the local list decreased from 42% to 38%, while the proportion of Black and Asian candidates went up from 40% and 3.6% in the pre-policy period to 42% and 4.8% in the post-policy period respectively. The percentage of Hispanic candidates and candidates of other ethnic group went up slightly from 12.1% and 2.4% to 12.4% and 2.8% respectively.

Thus, the data showed that during the post-revised policy period, more minority candidates received a non-zero mismatch kidney, there were more transplants with worse mismatches and more transplants with long waiting times, and there was a similar proportion of overall zero mismatch transplants, but less Whites and more Blacks with zero mismatch. Further, minority candidates seemed to appear more often in the top 10% of the local list.

The Committee discussed possible next steps in evaluating the policy change. The Histocompatibility Committee will continue to monitor the data every 6 months as well as begin to look at post-transplant outcomes. It was commented that post transplant outcomes will be important to study as the early data show higher degrees of mismatching than probably was initially contemplated.

The Committee discussed results of the analysis. The Committee questioned why a higher proportion of blacks would receive 0 antigen mismatch transplants during the post policy period. There was some expectation that the number of 0 antigen mismatched transplants would increase under the modified policy since patients would not be receiving organ offers based on the lesser HLA BDR matches. Committee Members speculated that the surprisingly low levels of matching at the DR locus may be due to too few points assigned for a 0 or 1 DR mismatch. Alternatively, the results may simply reflect relatively long patient waiting times that will need to filter through the system before the system can stabilize.

The SRTR reported a similar analysis that evaluated the policy change both pre and post policy change, which was recently updated to include 8 months pre and post policy change. The analysis assessed the system overall and did not exclude pediatric or ECD kidney transplants. The major findings were an increase in transplantation of pediatric patients, non-whites, and sensitized patients. The analysis also showed that 0 mismatch transplants overall increased, while ODR transplants decreased.

A Member of the Committee commented that the data show that the revised policy has benefited patients who have been waiting the longest, even if they are receiving poorly matched kidneys, by addressing their risk of death on the waiting list. By design, the policy change assigned higher priority for time waiting. However, it was noted that impact of the revised policy on transplant outcomes and the balance between justice and utility factors will be important to understand. The Committee was reminded that the data presented show early results and that it will take additional time for the system to stabilize. In the interim and pending availability of more robust data, the Committee was urged not to form premature opinions.

8. A₂/A₂B into B Kidney Allocation Alternative System Data Update. At its meeting on January 27, 2004, Dr. Wida Cherikh provided the Committee with descriptive data highlights regarding patients transplanted under the standard alternative allocation system to allocate blood type A₂ and A₂B kidneys into blood type B patients, approved by the OPTN/UNOS Board of Directors in June 2001. The alternative system was implemented in September 2002.

At its meeting on April 28, 2004, the Committee was provided with an expanded review of the data, including additional requested information (**Exhibit D**). Dr. Cherikh reported that, at present, there are six OPOs participating in the alternative system. Starting dates for OPO participation range from September 10, 2002 – December 11, 2002.

Data regarding donors and candidates involved in the system were summarized for the Committee. There were 16 A₂ and 2 A₂B donors, 15 of whom were White, 2 who were Hispanic, and 1 who was classified as non-Hispanic multiracial. Six of these donors were female and 12 were male, with a median age of 25 years (ages ranged from 18-66). These 18 donors donated 24 A₂ and 4 A₂B kidneys. The analysis shows that thirteen kidneys were transplanted into blood group B recipients, 12 kidneys were transplanted into A recipients, and 3 kidneys were transplanted into AB recipients.

Allocation category, indicating how the kidney was allocated within the alternative allocation sequence, *e.g.*, whether it was allocated as a zero antigen mismatch kidney, to an eligible B candidate, or to an A or AB candidate, was reported. Allocation of the kidney as a result of the alternative system is shown below as “Common OPO Eligible B Candidate” (A₂/A₂B deceased donors only). For example, of the 28 kidneys in the study, 13 were allocated to eligible B candidates, 5 were allocated to zero antigen mismatched candidates, and 1 was allocated to a blood type A candidate on the common OPO list for high PRA.

Allocation Category	N
Common OPO Eligible B Candidate	13
0 ABDR Mismatch	
- to A candidate	2
- to AB candidate	3
Common OPO, high PRA - to A	1
Common OPO list - to A	5
Statewide list - to A	4
Total	28

Information about blood type B recipients of the A₂ and A₂B kidneys was reported. As of January 9, 2004, there were thirteen transplants performed at two of the participating OPOs from 2 A₂B donors (4 kidneys) and six A₂ donors (9 kidneys) between December 6, 2002 – October 4, 2003. Transplant and post transplant information on three of the 13 recipients is not available at this time, since data collection forms have not been completed yet. Days to transplant for these patients ranged from 180 to 1,817 days, with a median waiting time of 1,101 days. Patient ethnicity included three White, four Black, one Hispanic, two Asian, two Native American/Alaska Native, and one Arab/Middle Eastern. The gender of recipients included six female and seven male candidates. The median age of the recipients was 53 years, with a range of 33-74 years. Eight of the recipients had peak PRA < 10%, 4 had peak PRA 10%-79%, and one had peak PRA ≥ 80%. The level of HLA mismatch ranged from 3 HLA mismatch – 6 HLA mismatch.

Post transplant highlights for the 10 recipients with complete follow-up were summarized. The median serum creatinine at discharge was 3.05 mg /dl (range: 0.9 mg /dl – 9.1 mg/dl). Two patients had their creatinine declined by 25% or more within the first 24 hours of transplant, 8 did not have a decline in creatinine by 25% or more within the first 24 hours of transplant, and 3 were unknown. Seven patients produced >40 ml urine in the first 24 hours, three did not, and three were unknown. Two recipients had dialysis within one week of transplant and none of the recipients were treated for rejection prior to discharge. All ten patients had a functioning graft, with graft survival ranging from 5 to 372 days, and median graft survival of 189 days.

Titer data for the thirteen patients who were transplanted at two OPOs also were summarized. It was reported that all patients had low titer values (<1:8) from all the samples taken within 90±20 days of each other.

Out of 198 patients involved in the system with titer data, 26 (13%) had high titer (≥1:8) at first test, and became ineligible for receiving an A₂/A₂B kidney. The remaining 172 patients (87%) had low titer (<1:8) at first test. Of the 26 patients with high titer value (≥1:8) at first test, five patients continued to have anti-A titer tests done. Three (60%) out of 5 had consistently high titer after two additional tests, and two (40%) had a low

titer (<1:8) at second test. Of the 172 patients with low titer (<1:8) at first test, 19 (11%) had a high titer (\geq 1:8) at second test or beyond, and 153 (89%) had consistently low titer (<1:8) from all tests.

In sum, all 10 patients who received A₂/A₂B kidneys under the system who had complete follow-up data were alive with functioning graft as of January 9, 2004. None of the patients were treated for rejection prior to discharge. All 13 patients who were transplanted had consistently low titer prior to transplant. Of all the blood type B participating candidates on the wait list with more than one titer test done, 89% of them had consistently low titer (<1:8).

The Committee will continue to monitor activities of the alternative system every six months. The following data for pre- and post-system periods, by OPO, will be included in future analyses:

- Percent of B candidates on the wait list
- Percent of B candidates on the wait list who transfer into the system
- Percent of B transplants
- Percent of B High PRA transplants
- Percent of B transplants from A₂/A₂B donors
- Percent of A candidates on the Waitlist
- Recipient Creatinine at 6 months

The Committee discussed expected graft survival under the alternative system. Dr. Cherikh informed the Committee that Dr. Christopher Bryan, of the Midwest Transplant Network, was preparing to submit an article for publication detailing the long-term graft survival of A₂/A₂B donor kidneys allocated under his OPO's version of the alternative system. Dr. Bryan's research shows graft survival up to 9 years after transplantation. Comparing B kidneys transplanted into B recipients and A₂ or A₂B kidneys transplanted into B recipients shows no statistical difference in graft survival. Since long-term outcomes are of particular concern in these studies, these data are encouraging. Outcomes under the standard alternative system will continue to be evaluated as data are available.

9. **CREG Matching Subcommittee.** At its January 27, 2004, meeting, the Committee was updated by Dr. Takemoto regarding the development of a proposal to begin a new CREG standard alternative system. The proposal is in its infancy and Dr. Takemoto is presently looking for 2-3 individuals from the Committee to work with several individuals from other interested Committees to continue the project. The utility and purpose of creating a new CREG alternative system was discussed. The original CREG alternative system study was designed to promote greater equity for minorities. It was developed before implementation of current changes to the standard national algorithm such as eliminating points for matching at the HLA B locus, which also are intended to reduce disparities in transplantation for minorities. It was noted that the OPTN/UNOS Histocompatibility Committee has begun assessing impacts from these policy changes. These analyses would be useful in developing a new CREG study. It also was noted that under the former study, fewer patients received CREG mismatched transplants than was expected. The reasons for this are not yet fully known.

Dr. Williams expressed interest in the Subcommittee reviewing the data reviewed by the Histocompatibility Committee. Drs. Williams, Bow, and Young were invited to serve on the CREG Subcommittee; other volunteers were asked to contact Dr. Takemoto as soon as possible.

10. **Analysis of MELD Data for HCC Patients.** At its meeting on April 28, 2004, the Committee reviewed data on liver registrations, transplants and post-transplant survival for different ethnic groups by diagnosis (HCC vs. other) and MELD score. The Liver and Intestinal Organ Committee had previously recommended a proposal to reduce the MELD score for liver patients with HCC diagnosis with certain tumor size. During discussion of the proposal, the Minority Affairs Committee noted that the incidence of Hepatitis C in minorities is relatively high. Hepatitis C can lead to development of Hepatocellular Carcinoma. The Committee was interested in reviewing data to evaluate impact of the proposal on minority patients (**Exhibit E**). Dr. Wida Cherikh presented the analysis to the Committee.

The study included adult (age ≥18 years) liver candidates added to the wait list between March 1, 2002, and September 30, 2003, for determining the distribution of MELD scores on the waitlist, and adult liver transplant recipients between March 1, 2002, and June 30, 2003, for determining the distribution of MELD scores at time of transplant and calculating the 3-month Kaplan-Meier patient survival.

Overall, candidates with diagnosis of HCC comprised about 10% of liver candidates added to the waitlist. Of these candidates, 63.5% were White, 7.9% were Black, 12.6% were Hispanic, and 13.1% were Asian. Among patients of White, Hispanic, and other ethnic group, the majority had a MELD score between 11 – 18 (49%, 55%, and 47%, respectively). Among Asian candidates with HCC, the majority (59%) had a MELD score of 10 or lower. Overall, liver transplant recipients with diagnosis of HCC comprised 24% of all liver recipients. Of these recipients, 65% were White, 8% were Black, 14% were Hispanic, and 10% were Asian. The majority were transplanted with a MELD score of 25 or greater in all ethnic groups (76% in Whites, 78% in Blacks, 79% in Hispanic, 83% in Asians). Finally, overall, the three-month patient survival for HCC patients appeared higher than that for non-HCC patients. Among HCC recipients with MELD scores of 0-24 or with MELD scores of 25 or greater, three-month patient survival appeared comparable among patient ethnic groups as noted in the table below.

HCC Recipient Three-Month Patient Survival

	Whites	Blacks	Hispanics	Asians
HCC Recipients w/ MELD 0-24	97.9%	95.2%	100%	95.7%
HCC Recipients w/ MELD ≥ 25	95.1%	98.7%	96.0%	97.3%

In summary, the data do not show apparent disparity by ethnicity in listing, transplant, or survival by MELD score or liver diagnosis. As expected, HCC candidates appear to experience at least somewhat higher post-transplant survival than non-HCC recipients. The Committee will continue to review results from the allocation policy.

11. Descriptive Data on Heart Transplantation, including the Number of Minority Patient Deaths on the Waiting List, the Number of Minority Patient Heart Transplants, and the number of Minority Patients with Assist Devices. Historically, the Committee has focused its attention on various aspects of kidney allocation/transplantation. A Committee Member expressed interest in examining data on minority patient heart waitlist and transplantation. At its meeting on April 28, 2004, the Committee reviewed descriptive data regarding heart transplantation in minority patients (**Exhibit F**). Dr. Wida Cherikh presented a summary of the highlights of the analysis to the Committee.

This included heart registrations added to the waiting list for the time period January 1, 1995, to June 30, 2003, by age group, listing year, and ethnicity. During 1995-2003, 63% of 3,918 pediatric registrations were White, 18% were Black, 15% were Hispanic, 3% were Asian, and 2% were of other ethnic group. Among 27,032 adult registrations, 78% were White, 14% were Black, 6% were Hispanic, and 1% was Asian and of other ethnic group. Among pediatric registrations, although the proportion of each ethnic group seemed to fluctuate over the years, there seemed to be a slight decreasing trend in the proportion of White patients, and an increasing proportion of Hispanics and patients of other ethnic group during the more recent years. Among adult registrations, the proportion of Whites seemed to decrease, whereas the proportion of Blacks, Hispanics, Asians, and patients of other ethnic group seemed to increase.

A Summary of Kaplan-Meier median waiting time to transplant for pediatric registrations added between January 1, 1995, through December 31, 2001, by listing year and ethnicity, shows that the median wait time to transplant seemed to fluctuate for White, Black, and Hispanic patients over the years. Median waiting time for patients of other ethnic group was not computed due to number of registrations less than 10. Overall, the median waiting time for pediatrics was the smallest in patients of other ethnic group (36 days), followed by Asians (42 days), Whites (64 days), Hispanics (73 days), and Blacks (74 days). Median waiting time to

transplant for adult registrations added between January 1, 1995, through December 31, 2001, by listing year and ethnicity, shows that the median waiting time to transplant for adults also seemed to fluctuate for Whites, Blacks, and Hispanics. Overall, the median waiting time for adults was the smallest in Asian patients (85 days), followed by Hispanics (152 days), patients of other ethnic group (171 days), Blacks (215 days), and Whites (220 days).

The Committee also reviewed data summarizing mortality rates. Since categories for heart medical urgency status were revised on January 19, 1999, the data pertaining to status were broken out into two eras, *i.e.*, pre January 19, 1999, and post January 19, 1999. Mortality rates are expressed as deaths per 1,000 patient years, for registrants waiting during the relevant time period, by age group, ethnicity, and medical urgency status at listing. The rate is based on the amount of time patients were waiting, therefore, the smaller the death rate, the fewer the number of deaths per 1,000 patient years waiting. As expected, the data showed that the mortality rate per 1,000 patient years was higher for Status 1/1A than Status 2 for both pediatric and adult patients.

The number of heart transplants performed between January 1, 1995, through June 30, 2003, by age group, transplant year, and recipient ethnicity, also was presented. Overall, of 16,579 adult transplants during the study period, 79% were White, 13% were Black, 6% were Hispanic, 1.4% were Asian, and 1.2% were of Other ethnic group. Among adult transplants, the proportion of Whites seemed to decrease, whereas the proportion of ethnic minority patients seemed to increase over the years. This was not true for pediatric patients among whom the ethnic distribution did not seem to change substantially over the years, although there appeared to be an increasing proportion of Hispanics and patients of other ethnic group in the more recent years.

A summary of Kaplan-Meier one-and three year pediatric patient survival rates for transplants performed during the time period January 1, 1995, through December 31, 2001, by transplant year and ethnicity, shows that one-year patient survival was 85% for Whites, 81% for Blacks, 90% for Hispanics, 84.5% for Asians, and 79% for patients of other ethnic group. Three-year patient survival was 80% for Whites, 69% for Blacks, 84% for Hispanics, 72% for Asians, and 65% for patients of other ethnic group.

A summary of Kaplan-Meier one-and three year adult patient survival rates for transplants performed during January 1, 1995, through December 31, 2001, by transplant year and ethnicity, shows that, overall, one year patient survival was 85% for Whites, 82% for Blacks, 84% for Hispanics, 86.5% for Asians, and 88% for patients of other ethnic group. Overall, three year patient survival was 79% for Whites, 72% for Blacks, 77% for Hispanics, 80% for Asians, and 83.5% for patients of other ethnic group.

A summary of ventricular assist device (VAD) usage at time of listing or transplant during January 1, 1995-June 30, 2003, by age group, ethnicity, and medical urgency status, also was provided. Overall, VAD use was reported most often in Status 1 patients as compared to Status 1B or Status 2 and was used most often for adults in Status 1 and Status 1A. Examining VAD usage in Status 1, 1A, and 1B at time of transplant, white and black patients have a similar proportion of VAD use at time of transplant. Among Status 1B patients, White and other ethnicity had the largest proportion of VAD usage at time of transplant.

The Committee discussed the analysis generally. Dr. Wade Fisher addressed questions from the Committee. A Committee Member inquired about the various diagnoses that can lead to heart disease and the level of mortality across diagnoses and ethnic groups. Further analysis of these data may better answer questions regarding possible disparity in access. Dr. Fisher commented that one area of particular concern is access to neonatal care for minority patients. Also, in the adult population, incidence of hypertension and diabetes in black and other minority populations would be expected to be relatively high.

A Committee Member inquired about the use of VADs for Status 1B patients. The usage rates reported probably are explained by policy, which now allows patients with VADs to be upgraded to Status 1A for 30 days once they are determined to be clinically stable. Status 1A Patients with VADs implanted longer than 30 days would be moved to Status 1B absent some significant device-related complication. Dr. Fisher noted as well that the longer the VAD is implanted, the greater the risk of infection or other complication. In his experience, allowing about one month for the patient to recover after initially implanting the VAD and before upgrading the patient to Status 1A is appropriate. The Committee was informed that the SRTR presented a similar heart analysis for the ACOT. The Committee requested this analysis to be presented at its next meeting.

12. Donation Rates For Kidney Transplantation in US Minority and Underserved Populations. Dr. Ross Isaacs presented an analysis to the Committee on donation rates for kidney transplantation in US minority and underserved populations (**Exhibit G**). Chronic kidney disease in the US is widespread, impacting approximately 20 million patients. This is especially problematic for minorities for whom kidney disease is relatively more prevalent. Special challenges exist for the working poor as well, including barriers to insurance coverage and excess burden of disease. Dr. Isaacs reviewed donation rates for living donor (LD) and deceased donor (CAD) kidney transplants in the southeastern US by ethnicity and socioeconomic status using UNOS registry and US Census Data from 2001-2002. Study variables included:

- Ethnicity
- Age
- Gender
- Education level
- Income level
- Employment status

Waitlisting and transplantation rates by ethnicity were summarized for the Committee. In the Southeastern US, Caucasians comprise 64% of general population, 66% of the living donor population, and 61% of the waiting list population. African Americans comprise 19% of the general population, 18% of the living donor population, and 21% of the waiting list population. Dr. Isaacs indicated that according to USRDS data, African Americans currently comprise 35% of the ESRD population. These data were not available for the presentation, however. While there is a common perception that African Americans donate at a low rate, the data show that this is not correct. Instead, African Americans are overrepresented in the ESRD population. This appears to be true for Latinos and Native Americans who also experience relatively high rates of ESRD while their donation rates are proportional to their representation in the general population.

Waitlisting and transplantation rates by income also were reported. The data were stratified by, above the poverty level and below the poverty level. The data showed that 86% of the southeastern US general population is above the poverty level, with the population of deceased donors above the poverty level at 85%, and the population of living donors above the poverty level at 86%. Fifteen percent of the southeastern US general population is below the poverty level, with 15% of the population of deceased donors below the poverty level, and 14% of the population of living donors below the poverty level. Dr. Isaacs suggested that at least in comparison to their representation in the general US population, the poor are donating proportionately. There also is the perception that the poor do not donate, but similar to minorities, they also are overrepresented in the ESRD population. Again, the ESRD data were not available for the presentation.

In summary, Dr. Isaacs concluded that patients donate at rates similar to their representation in the US population but different from ESRD rates by ethnicity and socioeconomic status. Dr. Isaacs noted that more comprehensive data addressing issues for the working poor are currently being evaluated. He believes that more efforts are needed to encourage earlier referral for transplantation and increased living donation for the uninsured chronic kidney disease population.

The Committee discussed the presentation. There was concern that living donation and wait list rates reported for African Americans are not accurate. Dr. Isaacs responded that the analysis is based on data from 11 states in the Southeastern US only versus the entire US. It was suggested that the low rates for wait listing could show that African Americans in the Southeast have less access to the wait list, since it might be assumed that prevalence of chronic kidney disease would be consistent with overall prevalence rates.

There also was concern that deceased donor rates, by ethnicity, are not reported. Committee Members suggested that use of data from only a portion of the country and without presenting complete data showing the magnitude of kidney disease by the various populations being studied, fails to describe the issues clearly and fully. The Committee would be interested in an update of the data once the parameters noted are addressed.

13. Minority Access for Diabetes Replacement Therapy. Dr. Ross Isaacs presented an analysis on minority access for diabetes replacement therapy to the Committee (**Exhibit H**). Diabetes is developing rapidly in minority and underserved populations in the US and abroad. Presently, 177 million people are affected with diabetes, with 300 million expected to have diabetes by 2025. In the US, the relative risk of developing diabetes for African Americans and Hispanics is twice as great as compared to Caucasians. Further, diabetes is increasing in African Americans for all age groups as the population ages. While Native Americans currently comprise a relatively small proportion of the US population, their representation in the ESRD population is greater than 2 to 1. USRDS data show that African Americans account for 22% of patients with Type 1 diabetes. Despite the fact that African Americans make up 22% of the Type 1 population, they constitute 11% of the waitlist population and receive only 5% of all kidney/pancreas transplants.

Pancreas transplantation and islet cell transplantation are procedures which can allow people with diabetes to experience greater quality of life. However, data show that whole pancreas and islet cell transplantation remain underutilized in high-risk minority populations. There is a trend toward increased use in more recent years. Dr. Isaacs concluded that more efforts are urgently needed to promote earlier referral for either combined kidney/pancreas, pancreas-after-kidney, pancreas alone, or pancreatic islet transplantation for high-risk diabetic minority populations. Dr. Isaacs notes as well that organs used for this purpose are donated by individuals of all ethnic and socioeconomic backgrounds.

14. Board Resolution on OPTN Policy Development, Final Rule and OPTN Long Range Planning. The Committee briefly discussed a resolution from the Board of Directors directing that policy proposals made to the Board include recommendations specifically addressing the performance goals set forth in the OPTN Final Rule, including performance indicators to measure the achievement of performance goals and transplant center performance. Committees were also encouraged to take the deliberations of the strategic planning process of the OPTN into consideration. The Committee expressed interest in being updated as to the development of specific language from the organ specific committees.
15. Public Comment Process. Over several meetings, Committee members have raised concerns that the process for obtaining public comment on policy proposals recommended by the various OPTN/UNOS Committees is not collecting input from all OPTN constituencies and/or interested parties. Decisions with respect to these proposals are very important to individual patients and impact public trust in the system of organ procurement and transplantation. Realistic opportunity for comment needs to be available to all persons who may have opinions regarding the system, including, for example broad perspective from the dialysis and ESRD communities. There is effort underway to assess the origins and present operation of the public comment process, as well as how well it is capturing input from the diverse populations with interest in transplantation. Dr. Williams recommended that this effort be continued and reported out to the Committee for further discussion. The matter will be continued on the agenda for future meetings of the Committee.
16. Review of Ethics Committee White Paper on Living Non-Directed Donation. The Ethics Committee requested that the Minority Affairs Committee review a white paper on living non-directed donation, which it has endorsed as being morally commendable and ethically acceptable. The Committee voted unanimously to support the white paper.
17. Application Requirements for an Alternative Organ Allocation/Distribution System. At the Committee's request, the Committee was provided with a brief overview of the requirements for applying for an organ allocation or distribution system that differs from the standard system of organ allocation/distribution. For all such systems, applications must be agreed to by at least 75% of the member OPOs or Transplant Centers that would be participating in the system. Applications then must be submitted to the appropriate organ specific committee and various constituent committees interested in reviewing the proposals. Applications also must be submitted to the applicable Region to obtain their input before being forwarded to the Board of Directors for consideration.

UNOS has developed an application that it requests be used for such requests. The application asks for standard information including contact information for each participating OPO or Center, a statement of agreement that is signed by at least those participants that are agreeing to the system, and a written explanation and justification for the proposed system. Also included in the application are a list of questions the applicant

is expected to address, including, for example, advantages of the proposed system over the standard system; expected impact upon highly sensitized patients, patient and graft survival, as well as pediatric, female, and minority patients; expected impact upon patients by blood type and medical urgency category; and expected impact upon organ availability. The application notes that some of these questions are applicable only to certain organ systems or categories of proposal.

18. Request from Midwest Transplant Network Regarding Allocation of A₂/A₂B Expanded Criteria Donor Kidneys.

The Committee discussed a request from the Midwest Transplant Network to change their alternative system for kidney allocation. The OPO is requesting a change to permit the OPO to allocate blood type A₂/A₂B kidneys procured from expanded criteria donors (ECDs) to blood type B and O patients consistent with the OPO's protocol applicable to standard criteria donor kidneys. The intent is to further broaden access to kidney transplants for blood type B and O candidates. The Committee voted unanimously in favor of the proposal.

19. Request from Gift of Hope Organ and Tissue Donor Network for a Modification to Alternative System for Kidney Allocation.

The Committee considered a request from the Gift of Hope Organ and Tissue Donor Network for a Modification to its alternative system for kidney allocation that would retain the OPO's previous priority awarded to children and adolescents. The proposed system would also eliminate HLA points for DR matching. The Committee was informed that the Kidney Pancreas Committee had reviewed the proposal and expressed concerns with both aspects of the request, due to data demonstrating continued benefit from donor and candidate HLA matching at the DR locus and the importance of balancing waiting for a well-matched kidney for pediatric recipients with the benefit of meeting children's time to transplant goals.

A Member of the Committee expressed interest in suggesting that the OPO be permitted to use its proposed system as a study, alternating donor kidneys allocated by the standard and alternative systems. Several Committee Members raised concerns that the OPO's volume would be too small to yield meaningful data. Others remarked that it was not appropriate for the Committee to suggest such a study versus simply comment on the OPO's proposal. The Committee voted to disapprove the Member's suggestion and table further consideration of the OPO's proposal pending response from the OPO to the Kidney/Pancreas Committee's concerns.

20. Request from Gift of Hope Organ and Tissue Donor Network for Alternative System for Allocation of Pancreata.

The Committee discussed a request from the Gift of Hope Organ and Tissue Donor Network to allocate pancreata using a modified system for prioritizing combined kidney/pancreas versus isolated pancreas candidates as well as whole pancreas and pancreatic islet candidates. The Committee was informed that the Kidney Pancreas Transplantation Committee had reviewed the proposal and expressed concerns regarding impacts upon candidates in need of isolated pancreas transplants. Furthermore, the Kidney/Pancreas Committee believes that it will be important to allow the newly approved standard system for allocating pancreata for whole organ versus islet transplantation time to function before approving variations on this protocol. It was noted that these concerns have been communicated to the OPO. The Minority Affairs Committee voted to table further consideration of the OPO's proposal pending response to the Kidney/Pancreas Committee's concerns.

21. Request from LifeGift Organ Donation Center for Modification to Alternative System for Kidney Allocation.

Due to time constraints, the Committee declined to comment on the OPO's request to eliminate priority assigned for HLA matching between donor and candidate pairs at the DR locus across the entire OPO.

22. Request from Mid-America Transplant Services/Midwest Transplant Network for a Statewide Alternative Local Unit for Livers.

The Committee voted against a request from Mid America Transplant Services for a statewide ALU for livers that would allocate livers, first, within the state of Missouri. The proposal did not explain the effect of the proposed system on minorities. Further, in the spirit of the OPTN Final Rule's emphasis upon medical urgency, the Committee determined that it could not support the ALU. The Committee would endorse a broader sharing agreement that would address patient access in an equitable manner. The Committee vote in favor of not approving the proposal was 9 For; 1 Against; 4 Abstentions.

23. Request from LifeCenter NorthWest for Alternative System for Heart Allocation.

The Committee declined to comment on the OPO's request for guidance regarding thoracic organ offers to patients listed with Canadian transplant centers.

**Attendance at Minority Affairs Committee Meeting
Chicago, Illinois**

January 27, 2004

Committee Members Attending:

Winfred W. Williams, MD	Chairman
Carlton J. Young, MD	Vice-Chairman/Region 3
Pang-Yen Fan, MD	Region 1
Henry B. Randall, MD	Region 4
Steven K. Takemoto, Ph.D	Region 5
Maxine Chan	Region 6
Daren D. Marshall	Region 10
Erskine Gillespie	Region 11
Melissa L. Zinnerman, RN, MSN	At Large
Sheila Nichols Bullock, MSW	At Large
Wade Fischer, MD	At Large
Denise Y. Alveranga, MD	At Large

Members Unable To Attend:

Linda Darrel, MSW, LCSW-C	Region 2
Jackie L. Johnson, LICSW	Region 7
Cynthia Simien	Region 8
Melia Hollar	Region 9
Nasimul Ahsan, MD	At Large
Laurine Bow	At Large
George H. Coates, BS	At Large
Cass Franklin, MD	At Large
Ross Isaacs	At-Large
Renee Dupee, Esq.	Ex-Officio Government Liaison

UNOS Staff Attending:

Cindy M. Sommers, Esq., UNOS Director of Allocation Policy
Deanna L. Parker, MPA, Policy Analyst, UNOS Department of Allocation Policy
Wida Cherikh, Ph.D., Senior Biostatistician, UNOS Department of Research

SRTR Staff Attending:

Alan Leichtman, , MD
Valarie Ashby, MS

Guests Attending:

None

**Attendance at Minority Affairs Committee Meeting
Chicago, Illinois
April 27-28, 2004**

Committee Members Attending:

Winfred W. Williams, MD	Chairman
Carlton J. Young, MD	Vice-Chairman/Region 3
Pang-Yen Fan, MD	Region 1
Linda Darrel, MSW, LCSW-C	Region 2
Henry B. Randall, MD	Region 4
Steven K. Takemoto, Ph.D	Region 5
Maxine Chan	Region 6
Jackie L. Johnson, LICSW	Region 7
Daren D. Marshall	Region 10
Erskine Gillespie	Region 11
Nasimul Ahsan, MD	At Large
Denise Y. Alveranga, MD	At Large
Laurine Bow	At Large
Sheila Nichols Bullock, MSW	At Large
George H. Coates, BS	At Large
Wade Fischer, MD	At Large
Cass Franklin, MD	At Large
Ross Isaacs, MD	At Large
Melissa L. Zimmerman, RN, MSN	At Large
Renee Dupee, Esq.	Ex-Officio Government Liaison

Members Unable To Attend:

Cynthia Simien	Region 8
Melia Hollar	Region 9

UNOS Staff Attending:

Cindy M. Sommers, Esq., UNOS Director of Allocation Policy
Deanna L. Parker, MPA, Policy Analyst, UNOS Department of Allocation Policy
Wida Cherikh, Ph.D., Senior Biostatistician, UNOS Department of Research

SRTR Staff Attending:

Alan Leichtman, MD
Valarie Ashby, MS

Guests Attending:

None

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

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

Hypotheses

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

Kidney Allocation

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

Methodology

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

Methodology

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

Increase Minority Access

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

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

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

Time to referral

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

Survival

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

Scientific Registry of Transplant Recipients

Minority Affairs Committee

April 27-28, 2004
Chicago, Illinois

SRTR

Purpose

Estimate access to the liver transplant waitlist among patients with acute and chronic liver failure. Chronic liver failure will also be analyzed separately for the diagnoses of liver cancer, alcoholism, and hepatitis C.

SRTR

Study Populations

- All waitlist registrants age < 65 for acute liver (Status 1) and chronic liver (Non-Status 1) disease in 1998 (OPTN database)
- Deaths in 1998 for acute and chronic liver for those age < 65 (NCHS)

SRTR

Methods

- For acute liver failure deaths, we excluded those deaths due to alcoholism or cancer. For chronic liver failure deaths, we excluded non-liver cancer deaths only.
- The count of waitlist registrants was calculated by adding the number of waitlist registrants on the waitlist on 12/31/97 and the number of new registrants in 1998.
- The ratio of waitlist/liver failure pool is calculated as
$$\frac{\text{Waitlist registrants}}{\text{Waitlist registrants} + \text{NCHS deaths} - \text{waitlist deaths} - \text{transplant deaths}}$$
- A similar approach has been previously employed to assess access to the kidney waitlist among all patients on chronic dialysis (the sum of number on the waitlist at start of the year plus newly listed during the year divided by all patients on dialysis).

SRTR

Acute and Chronic Liver Failure ICD-9 Codes

Acute Liver Failure Codes

270.6 - disorders of urea cycle metabolism
275.1 - disorders of copper metabolism
570 - acute and subacute necrosis of liver
573.3 - hepatitis unspecified
573.4 - hepatic infarction

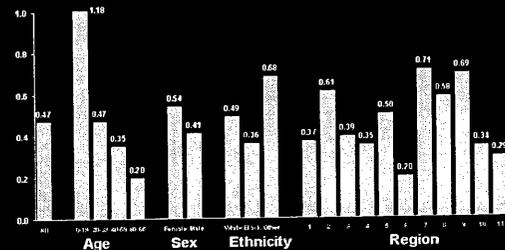
Chronic Liver Failure Codes

270.2 - other disturbances of aromatic amino-acid metabolism
274.0 - glycogenosis
272.7 - lipidoses
277.4 - disorders of bilirubin excretion
277.6 - other deficiencies of circulating enzymes
574.0 - 574.9 - chronic liver disease and cirrhosis
572.2 - hepatic coma
572.3 - portal hypertension
572.4 - hepatorenal syndrome
573.8 - other specified disorders of liver

SRTR

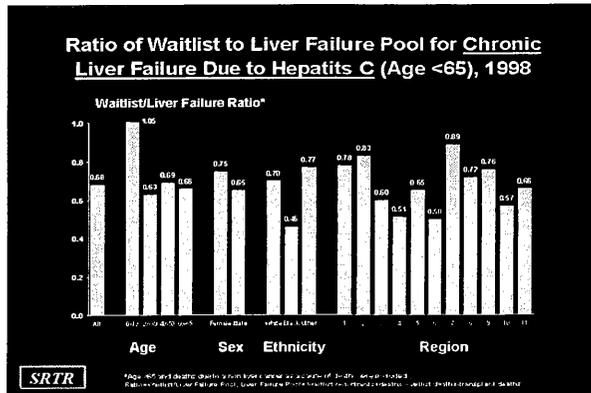
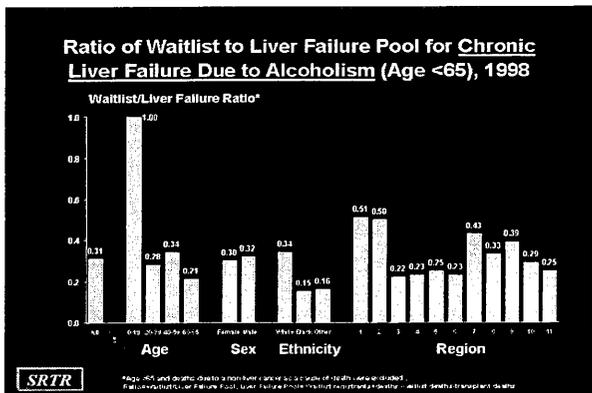
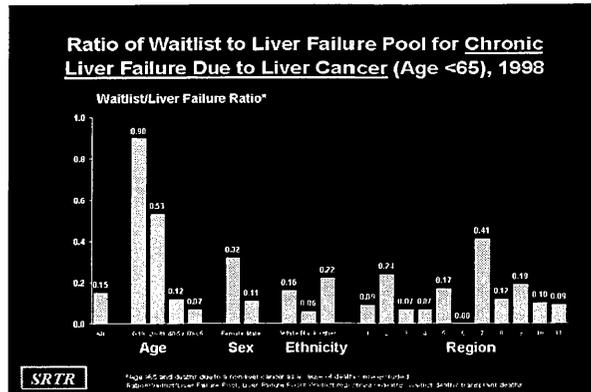
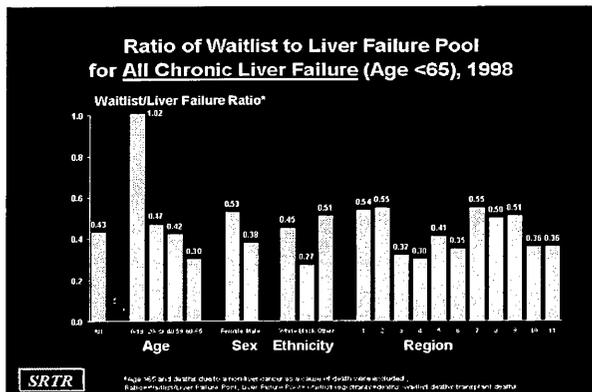
Ratio of Waitlist to Liver Failure Pool for Acute Liver Failure (Age <65), 1998

Waitlist/Liver Failure Ratio*



SRTR

*Age 65 and death due to liver cancer or alcoholism or cirrhosis or death were excluded



Summary

- The ratio of waitlist/liver failure pool for acute liver failure was 0.47.
- Similarly, the ratio for all chronic liver failure was 0.43, while the ratio for chronic liver failure by diagnosis was 0.15, 0.31, and 0.68 for liver cancer, alcoholism, and hepatitis C, respectively.
- All subgroup analyses showed that younger patients had higher ratios than older patients and Whites had higher ratios than Blacks.
- There were also regional differences in waitlist rates.

SRTR

**Final Analysis for Data Requests from the OPTN Minority Affairs Committee
Meeting of October 1, 2003 as Presented to the ACOT Public Concerns Committee
on September 17, 2003**

**Prepared by Alan Leichtman, M.D., Robert Wolfe, Ph.D., Robert Merion, M.D.,
Friedrich K. Port, M.D., M.S., and Valarie Ashby, M.A.,
of the Scientific Registry of Transplant Recipients**

This final analysis is submitted by the Scientific Registry of Transplant Recipients (SRTR) in response to the data request from the Minority Affairs Committee that met on October 1, 2003.

Data Request Routing Information and Analysis Timeline:

OPTN Committee request made: 10/16/2003
Analysis plan submitted: N/A
Draft Analysis submitted: N/A
Final Analysis submitted: 10/31/2003
Next Committee Meeting: 1/27/2004

Analytical/Inferential Request from the OPTN Minority Affairs Committee

Review the analysis that the SRTR prepared for the ACOT meeting in September 2003 regarding access to the liver waitlist among all patients with liver failure for (a) acute and (b) chronic liver failure.

Analytical Notes

The final analysis on the following pages was presented to the ACOT Public Concerns Subcommittee (B) on September 17, 2003.

Purpose: Estimate the access to the liver waitlist among all patients with liver failure for (a) acute and (b) chronic liver failure.

Table of Contents

ANALYTICAL/INFERENTIAL REQUEST #1	2
STUDY POPULATION	2
ANALYTICAL APPROACH.....	2
RESULTS.....	4
<i>Table 1.1: Number of Deaths for Acute Liver Failure, Number of Status 1 Registrants on Liver Waitlist, and Waitlist/Liver Failure Pool, 1998</i>	<i>4</i>
<i>Table 1.2: Number of Deaths for Chronic Liver Failure, Number of Non-Status 1 Registrants on Liver Waitlist, and Ratio of Waitlist/Liver Failure Pool, 1998</i>	<i>4</i>

Analytical/Inferential Request #1

Repeat the analysis of obtaining death counts and waitlist registrations by age group, race, and geographic region using ICD-9 codes for deaths due to acute liver failure and chronic liver failure but analyze separately those with deaths due to (1) liver cancer, (2) alcoholism, and (3) hepatitis C. Also add the subgroup for gender.

STUDY POPULATION

Access to the waitlist cannot be studied for livers, as there is no registry of patients with liver failure. However, we examined the population that dies of causes related to liver failure. These data were available from the National Center for Health Statistics for 1998. We identified ICD-9 codes (primary & secondary) for deaths potentially due to acute liver failure and chronic liver failure. Note that acute with chronic liver failure are listed only by chronic. We also obtained waitlist registrant counts for status 1 liver registrants and non-status 1 liver registrants in 1998.

ANALYTICAL APPROACH

We obtained death counts for people who were 65 or younger by age group, gender, race, and geographic region using the following ICD-9 codes for deaths due to acute liver failure and chronic liver failure.

Acute Liver Failure Codes

270.6 - disorders of urea cycle metabolism
 275.1- disorders of copper metabolism
 570 – acute and subacute necrosis of liver
 573.3 – hepatitis unspecified
 573.4 – hepatic infarction

Chronic Liver Failure Codes

270.2 – other disturbances of aromatic amino-acid metabolism
 271.0 – glycogenosis
 272.7– lipidoses
 277.4 – disorders of bilirubin excretion
 277.6 – other deficiencies of circulating enzymes
 571.0 – 571.9 – chronic liver disease and cirrhosis
 572.2 – hepatic coma
 572.3 – portal hypertension
 572.4 – hepatorenal syndrome
 573.8 – other specified disorders of liver

For acute liver failure deaths, we excluded those deaths due to alcoholism or cancer. For chronic liver failure deaths, we excluded non-liver cancer deaths only. The count of waitlist registrants was calculated by adding the number of waitlist registrants on the waitlist on 12/31/97 and the number of new registrants in 1998.

The ratio of waitlist/liver failure pool is calculated as

$$\text{Waitlist registrants}/(\text{Waitlist registrants}+\text{deaths}-\text{waitlist deaths}-\text{transplant deaths})$$

This approach is similar to the access to the kidney waitlist among all patients on chronic dialysis (the sum of number on the waitlist at start of the year plus newly listed during the year divided by all patients on dialysis).

Results are shown in Table 1.1 overall and by age, gender, race, and geography for acute liver failure deaths and status 1 liver registrants. Table 1.2 reports chronic liver failure deaths and non-status 1 liver registrants. The table displays the results overall and for deaths and diagnoses related to (1) alcohol, (2) liver cancer, and (3) hepatitis C separately.

RESULTS

Table 1.1: Number of Deaths for Acute Liver Failure, Number of Status 1 Registrants on Liver Waitlist, and Waitlist/Liver Failure Pool, 1998

Group	Deaths*	Waitlist	Ratio of WL/Liver Failure Pool
All	1,327	925	0.47
Age 0-19	50	322	1.18
Age 20-39	281	199	0.47
Age 40-59	791	357	0.35
Age 60-65	205	47	0.20
Female	562	482	0.54
Male	765	443	0.41
White	972	715	0.49
Black	308	141	0.36
Other	47	69	0.68
Reg 1	73	36	0.37
Reg 2	163	173	0.61
Reg 3	224	119	0.39
Reg 4	127	58	0.35
Reg 5	194	154	0.50
Reg 6	60	14	0.20
Reg 7	92	127	0.71
Reg 8	72	63	0.58
Reg 9	51	71	0.69
Reg 10	128	56	0.34
Reg 11	143	54	0.29

*Age >65 and deaths due to any cancer or alcoholism as a cause of death were excluded.

Table 1.2: Number of Deaths for Chronic Liver Failure, Number of Non-Status 1 Registrants on Liver Waitlist, and Ratio of Waitlist/Liver Failure Pool, 1998

Group	All			Liver Cancer			Alcohol Related			Hepatitis C		
	Deaths*	WL	Ratio**	Deaths*	WL	Ratio**	Deaths*	WL	Ratio**	Deaths*	WL	Ratio**
All	24,973	17,172	0.43	943	166	0.15	10,647	4,570	0.31	2,631	4,615	0.68
0-19	132	1,567	1.02	6	28	0.90	0	3	1.00	4	40	1.05
20-39	2,748	2,226	0.47	31	31	0.53	1,242	472	0.28	272	403	0.63
40-59	17,013	11,309	0.42	610	84	0.12	7,572	3,617	0.34	2,008	3,650	0.69
60-65	5,080	2,070	0.30	296	23	0.07	1,833	478	0.21	347	522	0.66
Female	7,077	7,057	0.53	144	64	0.32	2,640	1,066	0.30	719	1,680	0.75
Male	17,896	10,115	0.38	799	102	0.11	8,007	3,504	0.32	1,912	2,935	0.65
White	20,200	14,873	0.45	692	130	0.16	8,720	4,237	0.34	2,122	4,047	0.70
Black	3,768	1,334	0.27	148	10	0.06	1,472	247	0.15	411	314	0.46
Other	1,005	965	0.51	103	26	0.22	455	86	0.16	98	254	0.77
Reg 1	1,082	1,125	0.54	39	4	0.09	394	366	0.51	97	270	0.78
Reg 2	2,485	2,676	0.55	83	25	0.24	787	714	0.50	205	722	0.83
Reg 3	3,400	1,473	0.32	101	8	0.07	1,267	352	0.22	351	443	0.60
Reg 4	2,466	1,004	0.30	127	9	0.07	886	252	0.23	337	307	0.51
Reg 5	5,430	3,542	0.41	233	48	0.17	2,890	917	0.25	669	1,040	0.65
Reg 6	1,073	541	0.35	52	0	0.00	652	185	0.23	152	131	0.50
Reg 7	1,751	1,911	0.55	56	36	0.41	760	527	0.43	97	409	0.89
Reg 8	1,168	1,040	0.50	47	6	0.12	567	259	0.33	131	252	0.72
Reg 9	1,572	1,499	0.51	60	14	0.19	645	377	0.39	214	522	0.76
Reg 10	2,260	1,176	0.36	77	9	0.10	867	332	0.29	168	188	0.57
Reg 11	2,286	1,185	0.36	68	7	0.09	932	289	0.25	210	331	0.66

*Age >65 and deaths due to a non-liver cancer as a cause of death were excluded.

**Ratio=Waitlist/Liver Failure Pool; Liver Failure Pool= Waitlist registrants+deaths -waitlist deaths-transplant deaths

Evaluation of New Kidney Allocation Policy after the Elimination of Points for HLA-B Matching

*Prepared for and Presented to
Histocompatibility Committee Meeting
January 20-21, 2004*

*Presented to MAC
April 27-28, 2004*

By: Wida Cherikh, Ph.D.



Background:

- On May 7, 2003, the kidney allocation system has been modified so that points are no longer given for HLA-B mismatches, but 2 points are given for zero HLA-DR mismatches and 1 point for one HLA-DR mismatches.



Purpose:

- Monitor performance of new HLA point system after 6 months of implementation with regard to minority allocation and local distribution of HLA-DR matched transplants.



Committee Request:

- The Histocompatibility Task Force on Kidney Allocation has requested some descriptive data with regard to minority and ABO allocation to compare the first full 6 months after the points are modified with the last full 6 months of allocation using previous system.



Data/Methods:

- To assess the impact of the new HLA point system, the data was stratified to two periods,
 - Pre-policy period: 11/6/02-5/6/03
 - Post-policy period: 5/7/03-11/7/03
- Since there are variations of the standard kidney allocation algorithm, 18 OPOs that ran the same standard kidney allocation algorithm during the entire study period were included.



Data/Methods:

- I. Transplant Data:
 - Deceased donor kidney alone transplants performed at 18 OPOs between 11/6/02 and 11/7/03 were included.
 - Pediatric recipients and recipients of expanded criteria donor (ECD) donor kidneys were excluded from the analysis.



Data/Methods:

II. Match run data:

- Match runs for all donors at these 18 OPOs during 11/6/02-11/7/03 were included. Potential candidates in the top 10% of the local list were used for comparing the ethnic composition of the candidates between the two periods.

All information provided in this report is based on OPTN data as of Jan 2, 2004.



Results:

- There were 1,394 deceased donor kidney transplants included in the analysis (697 transplants in each period).
- The proportion of the zero-antigen mismatched transplants was 15.06% (105/697) in the pre-policy period, and 14.92% (104/697) in the post-policy period.

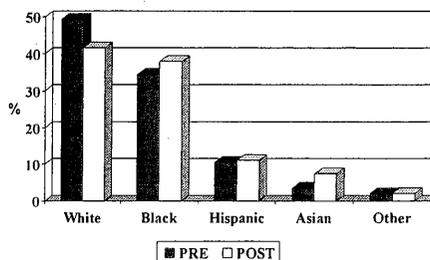


Table 1. Non-Zero HLA MM Transplants, 11/6/02-11/7/03

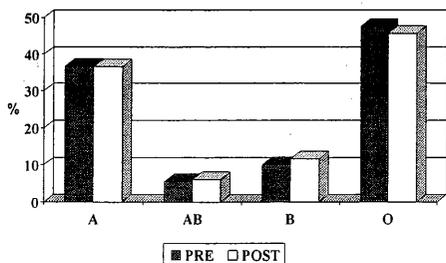
RECIPIENT ETHNICITY	TRANSPLANT PERIOD			
	Pre-Policy (11/6/02-5/6/03) (N=592)		Post-Policy (5/7/03-11/7/03) (N=593)	
	N	%	N	%
White	292	49.3	246	41.5
Black	204	34.5	225	37.9
Hispanic	63	10.6	66	11.1
Asian	21	3.55	44	7.42
Other Ethnic Group	12	2.03	12	2.02
RECIPIENT ABO				
A	218	36.8	217	36.6
AB	33	5.57	36	6.07
B	60	10.1	69	11.6
O	281	47.5	271	45.7



Non-0 MM Transplants, 11/6/02-11/7/03 by Period and Ethnicity



Non-0 MM Transplants, 11/6/02-11/7/03 by Period and Blood Group



Results:

Table 1 - Non-Zero HLA MM Transplants:

- Ethnicity:
 - Proportion of Whites decreased (by 7.8% pts)
 - Proportion of Blacks and Asian increased (by 3.4% and 3.9% pts)
 - Proportion of Hispanics and other ethnic group stayed the same
- ABO Blood Type:
 - Proportion of A and AB stayed the same
 - Proportion of B increased (by 2% pts)
 - Proportion of O decreased (by 2% pts)

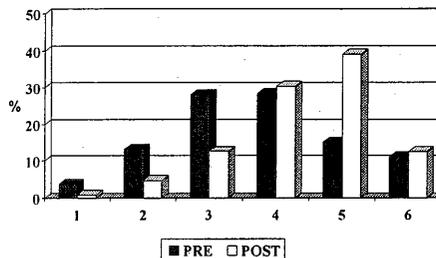


Table 1. Non-Zero HLA MM Transplants, 11/6/02-11/7/03

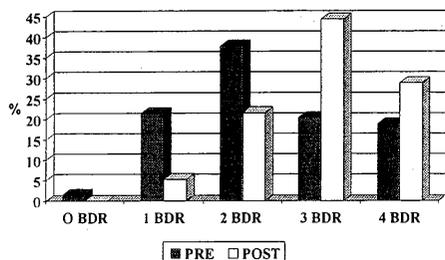
HLA-ABDR MM LEVEL	TRANSPLANT PERIOD			
	Pre-Policy (11/6/02-5/6/03) (N=592)		Post-Policy (5/7/03-11/7/03) (N=593)	
	N	%	N	%
1	23	3.89	5	0.84
2	78	13.2	28	4.72
3	167	28.2	75	12.6
4	168	28.4	180	30.4
5	90	15.2	231	39
6	66	11.1	74	12.5
HLA-BDR MM LEVEL				
0	9	1.52	0	0
1	127	21.6	31	5.23
2	224	37.8	128	21.6
3	121	20.4	263	44.4
4	111	18.8	171	28.8



Non-0 MM Transplants, 11/6/02-11/7/03 by Period and HLA ABDR MM Level



Non-0 MM Transplants, 11/6/02-11/7/03 by Period and HLA BDR MM Level



Results:

Table 1 - Non-Zero HLA MM Transplants:

- HLA-ABDR MM:
 - Proportion of 1-, 2- and 3-ABDR MM went down (by 3.05%, 8.5% and 15.6% pts)
 - Proportion of 4-, 5- and 6-ABDR MM went up (by 2%, 23.8%, and 1.4% pts)
- HLA-BDR MM:
 - Proportion of 0-, 1- and 2-BDR MM went down (by 1.52%, 16%, and 16% pts)
 - Proportion of 3- and 4-BDR MM went up (by 24% and 10% pts)

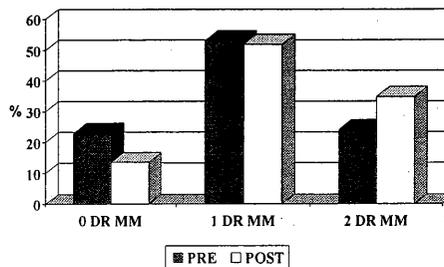


Table 1. Non-Zero HLA MM Transplants, 11/6/02-11/7/03

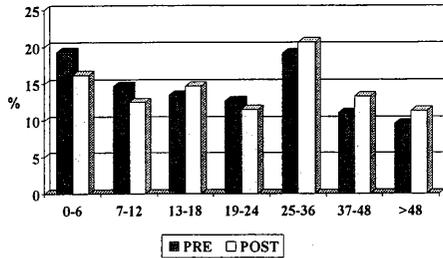
HLA-DR MM LEVEL	TRANSPLANT PERIOD			
	Pre-Policy (11/6/02-5/6/03) (N=592)		Post-Policy (5/7/03-11/7/03) (N=593)	
	N	%	N	%
0	136	23.0	80	13.5
1	314	53.0	307	51.8
2	142	24.0	206	34.7
MONTHS ON WAIT LIST				
0-6	114	19.3	86	16.2
7-12	87	14.7	74	12.5
13-18	80	13.5	87	14.7
19-24	75	12.7	68	11.5
25-36	113	19.1	122	20.6
37-48	66	11.1	79	13.3
>48	57	9.63	67	11.3



Non-0 MM Transplants, 11/6/02-11/7/03 by Period and HLA DR MM Level



Non-0 MM Transplants, 11/6/02-11/7/03 by Period and Days Waiting



Results:

Table 1 - Non-Zero HLA MM Transplants:

- HLA-DR MM:
 - Proportion of 0- and 1-DR MM went down (by 9.5% and 1.2% pts)
 - Proportion of 2-DR MM went up (by 10.7% pts)
- Waiting Time (WT):
 - Proportion with WT <24 mths decreased
 - Proportion with WT >24 mths increased

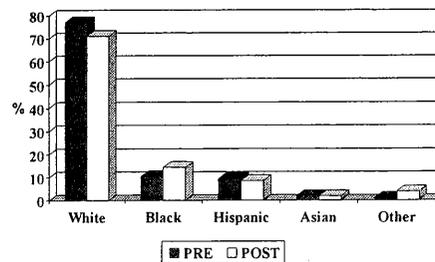


Table 2. Zero HLA MM Transplants, 11/6/02-11/7/03

RECIPIENT ETHNICITY	TRANSPLANT PERIOD			
	Pre-Policy (11/6/02-5/6/03) (N=105)		Post-Policy (5/7/03-11/7/03) (N=104)	
	N	%	N	%
White	81	77.1	74	71.2
Black	11	10.5	15	14.4
Hispanic	10	9.52	9	8.65
Asian	2	1.9	2	1.92
Other Ethnic Group	1	0.95	4	3.85
RECIPIENT ABO				
A	38	36.2	46	44.2
AB	1	0.95	2	1.92
B	12	11.4	14	13.5
O	54	51.4	42	40.4



Zero MM Transplants, 11/6/02-11/7/03 by Period and Ethnicity



Results:

Table 2 - Zero HLA MM Transplants:

- Ethnicity:
 - Proportion of Whites decreased (by 6% pts)
 - Proportion of Blacks and other ethnic group increased (by 4% and 3% pts)
 - Proportion of Hispanics and Asians stayed about the same
- ABO Blood Type:
 - Proportion of A and B increased (by 8% and 2% pts)
 - Proportion of AB stayed about the same
 - Proportion of O decreased (by 11% pts)



Table 3. Distribution of Candidate Ethnic Groups in the Top 10% of Local List Match Runs During 11/6/02-11/7/03

Time Period	Top 10% of Local List Candidate Ethnicity					
	No. Of Donors	White %	Black %	Hispanic %	Asian %	Other %
	Pre-Policy	451	42.07	39.81	12.08	3.64
Post-Policy	470	38.44	41.57	12.37	4.82	2.8



Results:

Table 3 – Distribution of Candidates' Ethnicities
in Top 10% of Local List:

- Proportion of Whites decreased
- Proportion of non-Whites increased

**Summary:**

During post-policy period,

- More minority candidates received a non-zero MM kidney
- More transplants with worse mismatches
- More transplants with long waiting times
- Similar proportion of overall zero MM transplants, but less Whites and more Blacks with zero MM
- Trend for minority candidates to appear more often in the top 10% of the local list

**Next Steps:**

- Continue to monitor the data every 6 months
- Start to look at post-transplant outcomes



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

*Evaluation of the New Kidney Allocation Policy
After the Elimination of Points for HLA-B Mismatch*

Originally Prepared and Presented for:
Histocompatibility Committee Meeting
January 20-21, 2004

Made Available for:
Minority Affairs Committee Meeting
April 27-28, 2004

By:
Wida Cherikh, Ph.D. and Timothy Baker, B.S.
Research Department
United Network for Organ Sharing

Table of Contents

Committee Request.....	2
Background/Purpose.....	2
Data and Methods.....	2
Results.....	3

Committee Request

On May 7, 2003, the kidney allocation system has been modified so that points are no longer given for HLA-B mismatches, but 2 points are given for zero HLA-DR mismatches and 1 point for one HLA-DR mismatched. The Histocompatibility Task Force on Kidney Allocation has requested some descriptive data with regard to minority and ABO allocation to compare the first full 6 months after the points are modified with the last full 6 months of allocation using previous system.

Background/Purpose

Monitor performance of new HLA point system after 6 months of implementation with regard to minority allocation and local distribution of HLA-DR matched transplants.

Data and Methods

To assess the impact of the new HLA point system, the report was broken out into two periods, the pre-policy period, which covered the first full 6 months prior to the implementation of the policy (11/6/02-5/6/03), and the post-policy period, which covered the first full 6 months after the policy was implemented (5/7/02-11/7/03).

Since there are variations of the standard kidney allocation algorithm, we included only 18 OPOs that ran the same standard kidney allocation algorithm during the entire study period. This would ensure a cleaner data comparison between the pre- and post-policy periods.

I. Transplant Data

For reporting the transplant data, we included recipients of deceased donor kidney transplants (excluding multiorgan) performed at these 18 OPOs between 11/6/02 and 11/7/03. Pediatric recipients and recipients of expanded criteria donor (ECD) donor kidneys were excluded from the analysis.

The following data were provided for the first full 6 months (11/6/02-5/6/03) and the last 6 months (5/7/02-11/7/03):

1. Numbers and percentages of non-zero antigen mismatched transplants by ethnicity (White, Black, Asian, Hispanic, Other)
2. Numbers and percentages of non-zero antigen mismatched transplants by blood group
3. Numbers and percentages of non-zero antigen mismatched transplants by HLA-ABDR mismatch level, HLA-BDR mismatch level, HLA-DR mismatch level, and waiting time (0-6, 7-12, 13-18, 19-24, 25-36, 37-48, >48 months)
4. Number and percentages of 0-antigen mismatch mandatory shares stratified by ethnicity and blood group

II. Match Run Data

We looked at all the match runs for all the donors at these 18 OPOs during the study period. Potential candidates in the top 10% of the local list were included, and the ethnic composition of these candidates was compared between the two periods (11/6/02-5/6/03 vs. 5/7/03-11/7/03).

All information provided in this report is based on OPTN data as of January 2, 2004.

Results

There were 1,394 deceased donor kidney transplants included in the analysis (697 transplants in each period). The proportion of the zero-antigen mismatched transplants was 15.06% (105/697) in the pre-policy period, and 14.92% (104/697) in the post-policy period.

Table 1 summarizes the data for non-zero HLA mismatched transplants during the study period (pre- vs. post-policy period) by recipient ethnicity, ABO blood group, HLA-ABDR, BDR and DR mismatch levels, and wait time to transplant (in months) for all 18 OPOs combined.

Some of the data highlights from Table 1 are as follows:

- While the percentage of White recipients went down from 49.3% in the pre-policy period to 41.5% in the post-policy period, the percentage of Black recipients went up by 3.4 percentage points from 34.5% to 37.9%. The percentage of Asian recipients also went up by 3.9 percentage points from 3.55% to 7.42%. The percentage of Hispanic recipients and recipients of other ethnic group during the pre- and post-policy periods remained the same at about 11% and 2%, respectively.
- The percentage of recipients with B blood group went up by 2 percentage points from 10% in the pre-policy period to 12% in the post-policy period, while the percentage of O recipients went down by 2 percentage points from 48% to 46%. The percentage of A and AB recipients during the pre- and post-policy periods remained the same at about 37% and 6%, respectively.
- The percentage of transplants with 2- and 3-ABDR mismatches went down from 13% and 28% in the pre-policy period to 5% and 13% in the post-policy period, respectively. While the percentage of transplants with 4- and 6-ABDR mismatches only went up by about 2 percentage points, the percentage of transplants with 5-ABDR mismatches went up dramatically from 15% in the pre-policy period to 39% in the post-policy period.
- The percentage of transplants with 1- and 2-BDR mismatches went down from 22% and 38% in the pre-policy period to 5% and 22% in the post-policy period, respectively. In contrast, the percentage of transplants with 3- and 4-BDR mismatches went up from 20% and 19% in the pre-policy period to 44% and 29% in the post-policy period, respectively.
- The percentage of transplants with 0-DR mismatch went down from 23% in the pre-policy period to 14% in the post-policy period. In contrast, the percentage of transplants with 2-DR mismatches went up from 24% in the pre-policy period to 35% in the post-policy period. The percentage of transplants with 1-DR mismatch went down only by 1 percentage point from 53% to 52%.

- As compared to the pre-policy period, the percentage of transplant recipients who waited less than 24 months seemed to have gone down, while the percentage of transplant recipients who waited for more than 24 months increased during the post-policy period.

Table 2 summarizes the distribution of the zero-antigen mismatched transplants in the pre- and post-policy periods by recipient ethnicity and ABO blood group. Some of the data highlights from Table 2 include the following:

- While the percentage of White recipients with zero-mismatched transplants went down from 77% in the pre-policy period to 71% in the post-policy period, the proportion of Black recipients went up from 10.5% to 14.4%. The percentage of Hispanic and recipients went down slightly from 10% to 9%. Although there was essentially no change in the percentage of Asian recipients, the proportion of recipients with other ethnic group went up from 1% to 4%.
- The proportion of O recipients went down from 51% in the pre-policy period to 40% in the post-policy period, while the proportion of recipients with A, AB and B blood type went up by 8, 1 and 2 percentage points, respectively.

Table 3 summarizes the ethnic distribution of the potential candidates in the top 10% of the local list for match runs performed in the pre- and post-policy periods at the 18 OPOs. The proportion of White candidates that appeared in the top 10% of the local list went down from 42% to 38%, while the proportion of Black and Asian candidates went up from 39.8% and 3.6% in the pre-policy to 41.6% and 4.8% in the post-policy period, respectively. The percentage of Hispanic candidates and candidates of other ethnic group only went up very slightly from 12.1% and 2.4% to 12.4% and 2.8%, respectively.

In summary,

- More minority recipients (Black and Asian, in particular) received a non-zero mismatched transplants during the post-policy period
- There were more transplants with worse mismatches during the post-policy period
- There were more transplants for patients with longer waiting times during the post-policy period
- Although the proportion of zero-mismatched transplants was similar in the pre- and post-policy periods (about 15%), there were less White and more Black recipients of a zero-mismatched transplant in the post-policy period.
- There was a trend for more minority candidates to appear in the top 10% of the local list for the match runs performed during the post-policy period.

Table 1. Non-Zero HLA Mismatched Transplants During 11/06/02 - 11/07/03

	TRANSPLANT PERIOD			
	Pre-Policy (11/6/02-5/6/03)		Post-Policy (5/7/03-11/7/03)	
	N	%	N	%
RECIPIENT ETHNICITY CATEGORY				
White	292	49.3	246	41.5
Black	204	34.5	225	37.9
Hispanic	63	10.6	66	11.1
Asian	21	3.55	44	7.42
Other Ethnic Group	12	2.03	12	2.02
RECIPIENT ABO BLOOD GROUP				
A	218	36.8	217	36.6
AB	33	5.57	36	6.07
B	60	10.1	69	11.6
O	281	47.5	271	45.7
HLA-ABDR Mismatch Level				
1	23	3.89	5	0.84
2	78	13.2	28	4.72
3	167	28.2	75	12.6
4	168	28.4	180	30.4
5	90	15.2	231	39.0
6	66	11.1	74	12.5
HLA-BDR Mismatch Level				
0	9	1.52	0	0.00
1	127	21.5	31	5.23
2	224	37.8	128	21.6
3	121	20.4	263	44.4
4	111	18.8	171	28.8
HLA-DR Mismatch Level				
0	136	23.0	80	13.5
1	314	53.0	307	51.8
2	142	24.0	206	34.7

	TRANSPLANT PERIOD			
	Pre-Policy (11/6/02-5/6/03)		Post-Policy (5/7/03-11/7/03)	
	N	%	N	%
Months on Waiting List				
0-6	114	19.3	96	16.2
7-12	87	14.7	74	12.5
13-18	80	13.5	87	14.7
19-24	75	12.7	68	11.5
25-36	113	19.1	122	20.6
37-48	66	11.1	79	13.3
> 48	57	9.63	67	11.3
All	592	100	593	100

Table 2. Zero HLA Mismatched Transplants During 11/06/02 - 11/07/03

	TRANSPLANT PERIOD			
	Pre-Policy (11/6/02-5/6/03)		Post-Policy (5/7/03-11/7/03)	
	N	%	N	%
RECIPIENT ETHNICITY CATEGORY				
White	81	77.1	74	71.2
Black	11	10.5	15	14.4
Hispanic	10	9.52	9	8.65
Asian	2	1.90	2	1.92
Other Ethnic Group	1	0.95	4	3.85
RECIPIENT ABO BLOOD GROUP				
A	38	36.2	46	44.2
AB	1	0.95	2	1.92
B	12	11.4	14	13.5
O	54	51.4	42	40.4
All	105	100	104	100

Table 3. Distribution of Candidate Ethnicity in the Top 10% of the Local List Match Runs During 11/6/02-11/7/03

	Top 10% of Local List					
	Donors	Candidate Ethnicity				
		White	Black	Hispanic	Asian	Other Ethnic Group
N	%	%	%	%	%	
Time Period						
Pre-Policy (11/6/02-5/6/03)	451	42.07	39.81	12.08	3.64	2.40
Post-Policy (5/7/03-11/7/03)	470	38.44	41.57	12.37	4.82	2.80

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

**Summary of Data on the National
Voluntary Variance to Allocate the A₂/A₂B
Deceased Donor Kidneys to B Candidates**

by:
Wida S. Cherikh, Ph.D.
UNOS Research Department
April 27-28, 2004



Background:

- The MAC put forth a national voluntary variance to allocate the A₂/A₂B deceased donor kidneys to B candidates.
- This variance was approved by the OPTN/UNOS Board at its meeting on June, 28-29, 2002, to be in place for at least 3 years.
- It was implemented in September 2002.



Data Request:

- An update of the variance including:
 - Titer data
 - Donor and recipient demographics/ characteristics
 - Outcomes (early graft function, delayed graft function, early acute rejection)
 - Match runs data (including what happened to the A₂/A₂B kidney that did not end up in the B candidates)



**Allocation Sequence
of A₂ Kidneys:**

- Zero antigen mismatched patients
- UNOS payback
- A and AB candidates, PRA_≥80%
- Surpassed pediatric goals
- Eligible B candidates
- A and AB candidates, PRA<80%
- Regional
- National



**Allocation Sequence
of A₂B Kidneys:**

- Zero antigen mismatched patients
- UNOS payback
- AB candidates, PRA_≥80%
- Surpassed pediatric goals
- Eligible B candidates
- AB candidates, PRA<80%
- Regional
- National



Criteria for Participation:

- Written consent must be obtained from each patient entered into the study if it is the requirement of the transplant center.
- Patients will not be eligible to receive a kidney through this allocation variance until they have had at least two consecutive quarterly anti-A titers performed and all test results are low (IgG anti-A titer < 1:8).



Exclusion Criteria:

- Potential candidates who have one or more test result, at any time, with a high titer (IgG anti-A titer 1:8 or higher) will be excluded from the study.



Anti-A Titer Test:

- Anti-A titers must be performed at least every 90 days \pm 20 days, on each patient before transplantation.
- A minimum of two anti-A titers must be available, but a longer history of up to one year of anti-A titer testing is recommended to assure the patient's titer is consistently low.



Data:

- Match runs for A₂ or A₂B kidney donors submitted by the participating OPOs, where at least one organ was accepted were included → Table 1
- Information on the B recipients of the A₂ or A₂B deceased donor kidney transplants performed at the participating OPOs are compiled → Tables 2A and 2B



Data:

- Titer data for B patients who already received a transplant and for all B patients at the participating OPOs have been listed → Tables 3 and 4
- All information is based on OPTN data as of January 9, 2004



Results:

- To date, 6 OPOs have participated in the variance. The implementation dates at each of the OPOs are as follows:
 - 1) OPO 1056: 09/10/02
 - 2) OPO 1506: 10/02/02
 - 3) OPO 1511: 11/06/02
 - 4) OPO 1632: 11/06/02
 - 5) OPO 1467: 12/11/02
 - 6) OPO 1756: 12/11/02



Results:

- Table 1 - Match runs for the A₂ or A₂B kidney donors submitted by three OPOs with the following information:
 - Donor blood type and ethnicity
 - Number of eligible B candidates at time of match
 - Recipient blood type
 - Allocation category: how kidney was allocated in the allocation sequence, whether it was allocated as a zero-antigen mismatch, to an eligible B candidate, or to an A or AB candidate



Results – Table 1:

- There were 16 A₂ and 2 A₂B donors
- 15 were White, 2 Hispanic, and 1 non-Hispanic multiracial
- 6 were female and 12 were male
- Age – median: 25 yrs, range: 18-66 yrs



Results – Table 1:

- These 18 donors donated 24 A₂ and 4 A₂B kidneys
- Number of eligible B candidates ranged from 0 to 22
- 13 kidneys were transplanted into B, 12 into A, and 3 into AB recipients



Results – Table 1:

Allocation Category	N
Common OPO Eligible B Candidate	13
0 ABDR Mismatch	
- to A candidate	2
- to AB candidate	3
Common OPO, high PRA - to A	1
Common OPO list - to A	5
Statewide list - to A	4
Total	28



Results – Tables 2A and 2B:

Donor ABO	# Donors	# B TXs
A ₂ B	2	4
A ₂	6	9
Total	8	13

Note: Discharge and post-transplant data were not available on 3 of the 13 recipients



Results – Table 2A (N=13):

- Days to transplant ranged from 180 to 1,817 days, median: 1,101 days
- Ethnicity: 3 White, 4 Black, 1 Hispanic, 2 Asian, 2 Native American/Alaska Native, and 1 Arab/Middle Eastern
- Gender: 6 female and 7 male
- Age – median: 53 yrs, range: 33-74 yrs



Results – Table 2A (N=13):

- Peak PRA level: <10% - 8
10%-79% - 4
≥80% - 1
- HLA mismatch level:
3 MM – 2 4 MM – 6
5 MM – 3 6 MM – 2
- 12 were reported with pre-transplant dialysis, and 1 with unknown dialysis status



Results – Table 2A:

- Serum creatinine at transplant:
Median: 7.85 mg/dl
Range: 5.6 – 11.2 mg/dl
- Creatinine at transplant decline by 25% within 24 hrs of transplant:
Yes: 2; No: 8; Unk: 3
- Produced >40 ml urine in first 24 hrs:
Yes: 7; No: 3; Unk: 3

**Results – Table 2B (N=10):**

- Two patients had dialysis within one week of transplant
- None of the patients were treated for rejection prior to discharge
- Median serum creatinine at discharge was 3.05 mg/dl (range: 0.9- 9.1 mg/dl)

**Results – Table 2B (N=10):**

- All 10 patients had a functioning graft, with graft survival ranging from 5 to 372 days, and median graft survival of 189 days
- All 10 patients were alive, with patient survival ranging from 5 to 372 days, and median patient survival of 189 days

**Results – Table 3:**

- Lists titer data for the 13 patients who were transplanted at two OPOs
- All patients had low titer values (<1:8) from all the samples taken within 90±20 days of each other

**Results – Table 4:**

- Lists titer data submitted by the participating OPOs, including the titer data on the 13 patients who have been transplanted
- When a sample was taken too early from the previous one, or the value was $\geq 1:8$, an asterisk (*) has been placed after the corresponding sample date

**Results – Table 4:**

- Summary of all titer data for the variance:
 - Out of 198 patients with titer data, 26 (13%) had high titer ($\geq 1:8$) at first test, and became ineligible for receiving an A₂/A₂B kidney.
 - The remaining 172 patients (87%) had low titer (<1:8) at first test.



Results – Table 4:

- All titer data (continued):
 - Of the 26 patients with high titer value ($\geq 1:8$) at first test, five patients continued to have anti-A titer tests done.
 - Three (60%) out of 5 had consistently high titer after two additional tests, and two (40%) had a low titer ($< 1:8$) at second test.



Results – Table 4:

- All titer data (continued):
 - Of the 172 patients with low titer ($< 1:8$) at first test, 19 (11%) had a high titer ($> 1:8$) at second test or beyond, and 153 (89%) had consistently low titer ($< 1:8$) from all tests.



Summary

- Of all the B candidates on the wait list with more than one titer test done, 89% of them had consistently low titer ($< 1:8$)
- All 13 patients who were transplanted had consistently low titer prior to transplant
- All 10 patients who received A_2/A_2B kidneys who had follow-up data were alive with functioning graft as of Jan 9, 2004. None of the patients had acute rejection at discharge

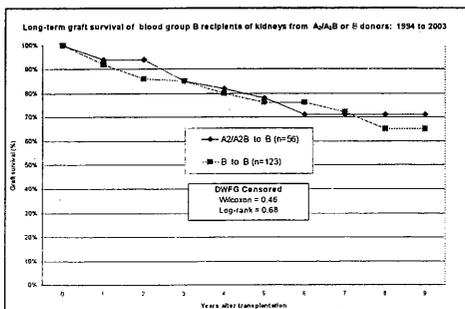


Next Steps:

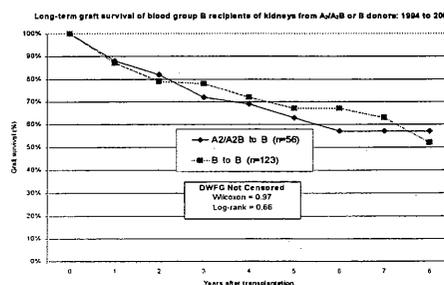
- Continue to monitor activities of the variance (every 6 months)
- Add the following data items for pre- and post-variance periods by OPO:
 - % B on the wait list (WL)
 - % B on the WL who transferred in
 - % B transplants
 - % B high PRA transplants
 - % B transplants from A_2/A_2B
 - % A on the WL



Graft Survival for Recipients at Midwest Transplant Network Censoring Deaths with Functioning Grafts



Graft Survival for Recipients at Midwest Transplant Network Not Censoring Deaths with Functioning Grafts



The End ... For Now ..



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

*Summary of Data on the National Voluntary Variance
To Allocate the A₂/A₂B Deceased Donor Kidneys to B Candidates*

Prepared for:
*Minority Affairs Committee
April 27-28, 2004
Chicago, IL*

By:
*Wida Cherikh, Ph.D. and Yulin Cheng, B.S.
Research Department
United Network for Organ Sharing*

Table of Contents

Committee Request.....	2
Background/Purpose.....	2
Data and Methods.....	2
Results.....	3



Committee Request

Data update of the variance including: titer data, donor and recipient demographics/ characteristics, outcomes (early graft function, delayed graft function, early acute rejection), match runs (including what happened to the A₂/A₂B kidney that did not end up in the B candidates).

Background/Purpose

The MAC put forth a national voluntary variance to allocate the A₂/A₂B deceased donor kidneys to B candidates. This variance was approved by the OPTN/UNOS Board at its meeting on June, 28-29, 2002, and was implemented in September 2002.

This variance uses the following allocation sequence that does not supercede the allocation algorithm (UNOS algorithm or local variance) used by the participating OPO, but is superimposed on to their allocation algorithm. The following table summarizes the allocation sequence of A₂ and A₂B deceased donor kidneys:

<i>Allocation Sequence of A₂ kidneys:</i>	<i>Allocation of A₂B kidneys:</i>
<ul style="list-style-type: none"> • Zero antigen mismatched recipients • UNOS payback • A and AB waiting list candidates, PRA ≥ 80% • Surpassed pediatric goals • Eligible B waiting list candidates • A and AB waiting list candidates, PRA < 80% • Regional • National 	<ul style="list-style-type: none"> • Zero antigen mismatched recipients • UNOS payback • AB waiting list candidates, PRA ≥ 80% • Surpassed pediatric goals • Eligible B waiting list candidates • AB waiting list candidates, PRA < 80% • Regional • National

Criteria for patient participation (i.e., eligible B waiting list candidates)

1. Written consent must be obtained from each patient entered into the study if it is the requirement of the transplant center.
2. Patients will not be eligible to receive a kidney through this allocation variance until they have had at least two consecutive quarterly anti-A titers performed and all test results are low (IgG anti-A titer < 1:8).
3. Potential candidates who have one or more test result, at any time, with a high titer (IgG anti-A titer 1:8 or higher) will be excluded from the study.

The MAC has planned to monitor the activity of the variance periodically.

Data and Methods

Match runs for A₂ or A₂B kidney donors submitted by the participating OPOs, where at least one organ was accepted were included and summarized in Table 1. Information on the B recipients of the A₂ or A₂B deceased donor kidney transplants performed at the participating OPOs are listed in Tables 2A and 2B. The titer data for B patients who already received a transplant and for all B patients at the participating OPOs have been listed in Tables 3 and 4.

All information provided in this report is based on OPTN data as of January 9, 2004.

Results

As of January 9, 2004, 6 OPOs have participated in the variance. The implementation dates at each of the OPOs are as follows:

1. OPO 1056: 09/10/02
2. OPO 1506: 10/02/02
3. OPO 1511: 11/06/02
4. OPO 1632: 11/06/02
5. OPO 1467: 12/11/02
6. OPO 1756: 12/11/02

Table 1 summarizes the match run data for the A₂ or A₂B kidney donors submitted by four of the participating OPOs as of January 9, 2004. For each donor, the following information is provided: donor ABO blood type, gender, age, ethnicity, number of eligible B candidates at the time of the match, recipient blood type, and the allocation category. As of January 9, 2004, there were 18 donors from 4 OPOs (16 A₂ and 2 A₂B donors), of which 12 were male and 6 were female. Majority (15) of the donors were White, 2 were Hispanic, and 1 was non-Hispanic multiracial. The median donor age was 25 years (range: 18-66 years).

The allocation category column indicates how the kidney was actually allocated in the allocation sequence, i.e., whether it was allocated as a zero-antigen mismatch kidney, to an eligible B candidate, or to an A or AB candidate. When the kidney was allocated as a result of the variance, the allocation category would fall under “Common OPO Eligible B Candidates(A₂/A₂B Cadaver Donors Only)” category. These 18 donors donated 24 A₂ and 4 A₂B kidneys, of which 13 were transplanted into blood type B recipients, 12 into blood type A recipients, and 3 into blood type AB recipient.

Tables 2A and 2B list information on the B recipients of the A₂ or A₂B kidneys at time of transplant, immediately after and at the latest follow-up. As of January 9, 2004, there have been 13 transplants performed at two of the participating OPOs from 2 A₂B donors (4 kidneys) and 6 A₂ donors (9 kidneys) between 12/6/02 and 10/4/03. Transplant and post-transplant information on three of the 13 recipients is not available at this time, since the data collection forms have not been completed yet.

The following are some of the data highlights of the B recipients at time of transplant and immediately after transplant (**Table 2A**):

- Median waiting time to transplant was 1,101 days (range: 180 days-1,817 days).
- Ethnic distribution of these recipients was as follows: 3 White, 4 Black, 1 Hispanic, 2 Asian, 2 Native American/ Alaska Native, and 1 Arab/Middle Eastern.
- There were 6 female and 7 male.
- Median recipient age was 53 years (range: 33-74 years).
- 8 had peak PRA <10%, 4 had peak PRA 10%-79%, and 1 had peak PRA ≥80%

Table 1. Data from Match Runs on A₂ or A₂B Donors Submitted by Participating OPOs, Where at least One Kidney was Accepted

OPO	Donor ID	Recip. ID	Donor ABO	Donor Gender	Donor Age	Donor Ethnicity	No. of Eligible B Candidates	Recip. ABO	Allocation Category
1467	1	1	A2	M	35	White	21	B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
	2	1	A2	F	30	White	12	B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
		2						A1	Common OPO List
	3	1	A2	M	28	White	4	A1	Common OPO List
		2						A2	Common OPO List
	4	1	A2	M	46	Hispanic	19	B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
		2						B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
1506	5	1	A2B	M	14	Non-Hispanic Multiracial	14	B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
		2						B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
	6	1	A2	F	22	White	12	B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
	7	1	A2	M	14	White	20	B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
		2						B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
	8	1	A2	M	55	White	22	B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
		2						B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
	9	1	A2B	M	17	White	17	B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
		2						B	Common OPO Eligible B Candidates(A2/A2B Cadaver Donors Only)
	10	1	A2	F	55	White	0	A	Common OPO List
		2						A	Common OPO List
	11	1	A2	M	18	White	14	A	0 ABDR Mismatch: ABO Ident Payback, 0%-20% PRA
	12	1	A2	M	22	White	16	A	0 ABDR Mismatch: ABO Ident Local

OPO	Donor ID	Recip. ID	Donor ABO	Donor Gender	Donor Age	Donor Ethnicity	No. of Eligible B Candidates	Recip. ABO	Allocation Category
	13	1	A2	F	20	White	19	AB	0 ABDR Mismatch: ABO Compat Local
1632	14	1	A2	M	8	White	5	AB	0 ABDR Mismatch: ABO Compat National, 0%-20% PRA
	15	1	A2	F	20	White	4	AB	0 ABDR Mismatch: ABO Compat Payback, 21%-79% PRA
	16	1	A2	M	49	White	3	A	Common OPO List, Highest Scoring High PRA Candidates
1756	17	1	A2	F	42	Hispanic	1	A	Statewide List
		2						A	Statewide List
	18	1	A2	M	66	White	0	A1	Statewide List
		2						A2	Statewide List

**Table 2A. Blood Type B Recipients of A₁ or A₂B Deceased Donor Kidney Transplants
Data at Time of Transplant and Immediately After Transplant**

OPO	Donor ID	Recip. ID	Donor ABO	TX Date	Days Waiting On WL	Ethnicity	Gender	Age	Peak PRA (%)	HLA Mismatch Level	Pre-TX Dialysis	Serum Creat. At TX (mg/dl)	Creat. Decline by 25% or More in First 24hr	KI Produced > 40ml of Urine in First 24hrs
1467	1	1	A2	12/21/02	684	White	M	74	0	4	Y	10.1	Y	Y
	2	1	A2	06/18/03	756	Black	M	60	0	4	Y	11.2	N	Y
	4	1	A2	10/04/03	774	Hispanic	F	33	0	5	Y	7.3	N	Y
		2		10/04/03	1054	Black	F	44	0	4	Y	5.6	N	Y
1506	5	1	A2B	12/06/02	1473	NativeAmerican	F	65	35	5	Y	6.0	N	N
		2		12/06/02	1353	Black	M	63	0	6	Y	7.2	N	N
	6	1	A2	12/07/02	1101	Arab/MidEast	M	53	4	6	Y	8.4	N	Y
	7	1	A2	03/29/03	1591	White	F	46	72	4	Y	.		
		2		03/29/03	1367	Black	M	52	0	5	Y	6.4	N	N
	8	1	A2	03/18/03	180	NativeAmerican	M	71	38	3	Y	.		
		2		03/17/03	1817	Asian	F	45	12	4	Y	11.1	N	Y
	9	1	A2B	07/29/03	1369	Asian	M	51	97	3		.		
		2		07/29/03	1076	White	F	62	0	4	Y	10.2	Y	Y

*Table 2B. Blood Type B Recipients of A₂ or A₂B Deceased Donor Kidney Transplants
Post-Transplant Information*

OPO	Donor ID	Recip. ID	Donor ABO	TX Date	Dialysis within 1st Week	Treated for Rejection Before Discharge	Serum Creat. At Discharge (mg/dl)	Current Graft Status	Graft Survival Time (Days)	Current Patient Status	Patient Survival Time (Days)
1467	1	1	A2	12/21/2002	N	N	1.0	Functioning	346	Alive	346
	2	1	A2	06/18/2003	N	N	2.3	Functioning	134	Alive	134
	4	1	A2	10/04/2003	N	N	1.6	Functioning	9	Alive	9
		2		10/04/2003	N	N	2.7	Functioning	19	Alive	19
1506	5	1	A2B	12/06/2002	N	N	3.5	Functioning	206	Alive	206
		2		12/06/2002	Y	N	7.9	Functioning	330	Alive	330
	6	1	A2	12/07/2002	N	N	3.4	Functioning	372	Alive	372
	7	1	A2	03/29/2003			.		.		.
		2		03/29/2003	Y	N	5.7	Functioning	230	Alive	230
	8	1	A2	03/18/2003			.		.		.
		2		03/17/2003	N	N	9.1	Functioning	172	Alive	172
	9	1	A2B	07/29/2003			.		.		.
		2		07/29/2003	N	N	0.9	Functioning	5	Alive	5

Table 3. Titer Data for B Patients Who Already Received a Transplant

OPO	Donor ID	Recip. ID	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5	
			Titer Value	Sample Date	Titer Value	No. of Days from Sample 1	Titer Value	No. of Days from Sample 2	Titer Value	No. of Days from Sample 3	Titer Value	No. of Days from Sample 4
1467	1	1	1:2	08/10/2002	1:2	91						
	2	1	1:1	08/08/2002	1:1	98	1:1	83	1:1	82		
	4	1	1:2	08/14/2002	1:2	93	1:4	96	1:4	84	1:2	98
		2	1:2	08/14/2002	1:1	91	1:2	98	1:1	77	1:1	98
1506	5	1	1:4	07/29/2002	1:2	86						
		2	1:1	07/02/2002	1:2	88						
	6	1	1:2	06/26/2002	1:4	93						
	7	1	1:4	06/23/2002	1:2	77	1:1	79	1:2	96		
		2	1:1	08/02/2002	1:1	87	1:1	93				
	8	1	1:2	09/09/2002	1:2	85	1:4	76				
		2	1:2	07/31/2002	1:2	82	1:4	79				
	9	1	1:1	07/29/2002	1:1	86	1:2	98	1:1	86		
		2	1:2	06/23/2002	1:2	70	1:2	93	1:4	96	1:1	74

Table 4. Titer Data Submitted by Participating OPOs
Note: An asterisk () after number of days indicates that sample was not qualified for titer eligible evaluation, i.e., a sample date that was too early (less than 70 days of the previous sample date), or titer values that were consistently high ($\geq 1:8$)*

OPO	ID	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6		Sample 7	
		Titer Value	Sample Date	Titer Value	No. of Days from Sample 1	Titer Value	No. of Days from Sample 2	Titer Value	No. of Days from Sample 3	Titer Value	No. of Days from Sample 4	Titer Value	No. of Days from Sample 5	Titer Value	No. of Days from Sample 6
1467	1	1:1	10/03/2001	1:1	364	1:1	96								
	2	1:4	11/11/2002	1:4	58*	1:2	91	1:4	91	1:4	100				
	3	1:1	08/09/2002	1:1	91	1:1	96	1:1	91	1:1	96	1:1	86		
	4	1:1	08/12/2002	1:1	93	1:4	96	1:1	79	1:1	100	1:1	87		
	5	1:8	03/05/2002												
	6	1:1	08/14/2002	1:2	91	1:1	91	1:1	98	1:1	90	1:1	91		
	7	1:2	08/20/2002	1:4	93	1:1	82	1:1	58*	1:2	35	1:2	96	1:1	86
	8	1:2	08/07/2002	1:1	97	1:1	83	1:2	100	1:2	97	1:1	93		
	9	1:2	08/12/2002	1:1	98	1:1	91	1:2	79	1:1	107	1:1	80		
	10	1:1	08/15/2002	1:1	97										
	11	1:4	07/19/2002	1:4	54*	1:4	61	1:2	93	1:1	84	1:2	98	1:4	91
	12	1:1	08/12/2002	1:1	98										
	13	1:1	07/18/2002	1:1	172	1:1	70	1:1	56*	1:1	165				
	14	1:2	07/03/2002	1:2	91										
	15	1:1	08/07/2002	1:1	89										
	16	1:2	12/13/2002	1:1	89	1:1	96	1:1	98						
	17	1:1	09/02/2002	1:1	70	1:1	98	1:1	79	1:1	103	1:4	91		
	18	1:2	08/14/2002	1:1	91	1:2	98	1:1	77	1:1	98				

OPO ID	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6		Sample 7	
	Titer Value	Sample Date	Titer Value	No. of Days from Sample 1	Titer Value	No. of Days from Sample 2	Titer Value	No. of Days from Sample 3	Titer Value	No. of Days from Sample 4	Titer Value	No. of Days from Sample 5	Titer Value	No. of Days from Sample 6
19	1:1	08/14/2002	1:1	91	1:1	91	1:1	98	1:1	85	1:1	97		
20	1:1	08/19/2002	1:2	92										
21	1:2	08/21/2002	1:1	98	1:2	140	1:1	71	1:1	90				
22	1:2	08/10/2002	1:2	91										
23	1:4	08/08/2002	1:2	90										
24	1:1	08/13/2002	1:1	56*										
25	1:4	11/08/2002	1:2	103	1:4	82	1:4	92	1:4	91				
26	1:4	08/10/2002	1:4	101										
27	1:1	08/08/2002	1:1	98	1:1	83	1:1	82						
28	1:2	08/26/2002	1:2	70	1:1	93	1:1	89						
29	1:2	08/14/2002	1:2	93	1:4	96	1:4	84	1:2	98				
30	1:8	03/01/2002												
31	1:1	08/15/2002	1:1	90	1:2	91	1:2	91						
32	1:1	08/14/2002	1:1	98	1:1	49*	1:1	133						
33	1:1	08/20/2002	1:4	93	1:1	84	1:2	91	1:2	96	1:8	86		
34	1:8	10/30/2001												
35	1:2	08/15/2002	1:1	92	1:1	90								
36	1:4	08/14/2002	1:4	98	1:4	91	1:4	91	1:4	175				
37	1:1	08/12/2002	1:1	119	1:1	65*	1:1	33	1:1	84	1:2	91		
38	1:8	02/14/2001												

OPO	ID	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6		Sample 7	
		Titer Value	Sample Date	Titer Value	No. of Days from Sample 1	Titer Value	No. of Days from Sample 2	Titer Value	No. of Days from Sample 3	Titer Value	No. of Days from Sample 4	Titer Value	No. of Days from Sample 5	Titer Value	No. of Days from Sample 6
	39	1:4	08/14/2002	1:2	93	1:2	96	1:2	84	1:1	98	1:1	76		
	40	1:2	08/09/2002	1:1	89	1:1	65*	1:1	148	1:1	103				
	41	1:1	08/08/2002	1:2	91	1:1	96	1:1	84						
	42	1:1	08/20/2002	1:1	28*	1:1	63	1:1	93	1:1	84	1:1	98	1:1	91
	43	1:2	07/15/2002	1:1	25*	1:2	61								
	44	1:2	08/08/2002	1:4	88	1:2	106								
	45	1:2	09/02/2002	1:1	70	1:1	98	1:1	79	1:4	103	1:1	91		
	46	1:1	08/22/2002	1:1	116	1:1	70	1:1	25*	1:1	108	1:1	77		
	47	1:1	09/16/2002	1:1	63*										
	48	1:1	08/13/2002	1:1	93	1:1	89	1:1	84	1:2	98	1:1	91		
	49	1:1	03/03/2002	1:1	78	1:1	168								
	50	1:2	08/16/2002	1:1	89	1:2	61*	1:1	63	1:2	86	1:2	107		
	51	1:1	08/06/2002	1:1	90	1:1	108	1:1	81	1:1	91	1:1	94		
	52	1:8	11/11/2002												
	53	1:1	09/18/2002	1:4	84	1:2	84	1:2	96	1:4	91				
	54	1:1	09/17/2002	1:1	91	1:1	89	1:1	86	1:1	88	1:1	70		
	55	1:1	02/21/2003	1:1	73	1:1	102	1:1	87						
	56	1:1	03/03/2003	1:1	98	1:1	88	1:1	87						
	57	1:1	03/03/2003	1:4	81	1:4	89	1:1	92						
	58	1:1	02/13/2003	1:8	90										

OPO	ID	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6		Sample 7	
		Titer Value	Sample Date	Titer Value	No. of Days from Sample 1	Titer Value	No. of Days from Sample 2	Titer Value	No. of Days from Sample 3	Titer Value	No. of Days from Sample 4	Titer Value	No. of Days from Sample 5	Titer Value	No. of Days from Sample 6
	59	1:1	10/10/2002	1:1	154	1:1	99	1:2	88						
	60	1:1	09/10/2002	1:1	83	1:1	77	1:1	86	1:2	103		84		
	61	1:1	01/30/2003	1:1	82	1:1	108	1:1	96						
	62	1:1	05/15/2003	1:1	97	1:1	86								
	63	1:2	12/17/2002	1:1	205	1:2	97								
	64	1:8	09/11/2002												
	65	1:4	06/11/2003	1:4	97										
	66	1:1	09/11/2002	1:1	91	1:1	91	1:1	91	1:1	93				
	67	1:1	11/07/2002	1:1	214	1:1	88								
	68	1:1	06/11/2003	1:1	92										
	69	1:1	07/08/2003	1:2	64*										
	70	1:1	07/02/2003	1:1	84										
	71	1:1	05/07/2003	1:1	98										
	72	1:1	06/18/2003	1:2	89										
	73	1:1	04/03/2003	1:2	95	1:1	100								
	74	1:1	09/13/2002	1:1	88	1:1	59*	1:1	87	1:1	105	1:1	91		
	75	1:1	08/13/2003	1:2	91										
	76	1:2	08/14/2003	1:1	91										
1506	1	1:8	09/17/2002												
	2	1:16	04/09/2003												



OPO	ID	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6		Sample 7	
		Titer Value	Sample Date	Titer Value	No. of Days from Sample 1	Titer Value	No. of Days from Sample 2	Titer Value	No. of Days from Sample 3	Titer Value	No. of Days from Sample 4	Titer Value	No. of Days from Sample 5	Titer Value	No. of Days from Sample 6
	3	1:2	08/28/2002												
	4	1:2	07/31/2002	1:2	82	1:4	79								
	5	1:1	06/26/2002	1:4	98	1:2	95								
	6	1:4	06/21/2002	1:4	96	1:4	100	1:32	82						
	7	1:4	06/23/2002	1:2	77	1:1	79	1:2	96						
	8	1:4	07/29/2002	1:2	86										
	9	1:1	07/02/2002	1:2	88										
	10	1:1	06/28/2002	1:4	94	1:1	91	1:8	81						
	11	1:4	06/27/2002	1:2	91	1:1	95								
	12	1:1	08/02/2002	1:1	87	1:1	93								
	13	1:16	07/03/2002	1:2	93*										
	14	1:2	07/09/2002	1:2	85	1:4	89								
	15	1:2	08/01/2002	1:1	82										
	16	1:1	07/29/2002	1:1	86	1:2	98	1:1	86						
	17	1:2	06/26/2002	1:4	93										
	18	1:4	08/02/2002	1:1	70	1:8	123								
	19	1:2	05/24/2002	1:2	123	1:4	76								
	20	1:4	06/24/2002	1:2	95	1:1	94	1:16	81						
	21	1:2	07/03/2002	1:2	91	1:4	96								
	22	1:2	06/23/2002	1:2	70	1:2	93	1:4	96	1:1	74				

OPO	ID	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6		Sample 7	
		Titer Value	Sample Date	Titer Value	No. of Days from Sample 1	Titer Value	No. of Days from Sample 2	Titer Value	No. of Days from Sample 3	Titer Value	No. of Days from Sample 4	Titer Value	No. of Days from Sample 5	Titer Value	No. of Days from Sample 6
	23	1:1	06/28/2002	1:2	94	1:4	91	1:4	84	1:1	126	1:16	123		
	24	1:2	06/26/2002	1:4	98										
	25	1:1	07/09/2002	1:1	91	1:2	92	1:1	80	1:2	222				
	26	1:1	06/17/2002	1:2	84	1:2	84	1:1	77	1:2	56*				
	27	1:1	08/08/2002	1:1	89	1:1	102	1:4	45*	1:1	99	1:2	84		
	28	1:2	06/04/2002	1:2	107	1:4	169	1:1	83						
	29	1:1	09/02/2002	1:4	86	1:2	96	1:2	84	1:2	98				
	30	1:4	07/08/2002	1:8	93	1:4	86*								
	31	1:1	06/10/2002	1:1	86	1:2	273	1:1	90	1:8	91				
	32	1:1	06/27/2002	1:1	96	1:1	91	1:4	81	1:1	164				
	33	1:1	07/02/2002	1:1	93	1:2	89	1:2	121	1:1	91	1:1	86		
	34	1:4	11/28/2002	1:4	96	1:2	79	1:4	158						
	35	1:8	09/26/2002												
	36	1:8	07/18/2002	1:2	75*										
	37	1:1	06/24/2002	1:2	98	1:2	89	1:4	85	1:2	92	1:8	102		
	38	1:1	07/29/2002	1:1	86	1:1	96	1:1	92	1:1	91	1:4	91		
	39	1:1	06/22/2002	1:1	98	1:2	96	1:1	82						
	40	1:8	05/25/2002												
	41	1:1	05/24/2002	1:1	104	1:2	90								
	42	1:2	07/04/2002	1:2	91	1:2	93	1:32	89						

OPO ID	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6		Sample 7	
	Titer Value	Sample Date	Titer Value	No. of Days from Sample 1	Titer Value	No. of Days from Sample 2	Titer Value	No. of Days from Sample 3	Titer Value	No. of Days from Sample 4	Titer Value	No. of Days from Sample 5	Titer Value	No. of Days from Sample 6
43	1:4	02/28/2003	1:4	84	1:4	103	1:4	81						
44	1:1	12/03/2002	1:2	88	1:4	87	1:4	98	1:16	83				
45	1:2	08/28/2002	1:4	90	1:16	93								
46	1:2	09/28/2002	1:4	96	1:4	79	1:2	66*						
47	1:1	08/26/2002	1:1	98	1:4	100	1:2	72	1:1	98	1:4		87	
48	1:4	07/17/2002	1:2	103	1:4	87	1:4	89	1:4	98	1:8	97		
49	1:1	08/09/2002	1:1	75	1:1	96	1:4	91	1:1	91	1:1	91		
50	1:1	10/02/2002	1:2	88	1:16	84								
51	1:2	09/09/2002	1:2	85	1:4	76								
52	1:1	10/24/2002	1:1	91	1:2	98								
53	1:4	08/26/2002	1:16	99										
54	1:1	10/25/2002												
55	1:2	12/30/2002	1:1	116	1:1	101	1:4	88						
56	1:2	12/30/2002	1:16	84										
57	1:4	04/29/2003	1:4	72	1:2	91								
58	1:4	11/15/2002	1:2	110	1:8	79								
59	1:4	03/13/2003	1:1	103	1:2	107								
60	1:16	01/06/2003												
61	1:2	01/24/2003	1:2	94	1:1	100	1:4	79						
62	1:1	06/26/2002	1:4	98	1:2	95	1:4	87	1:2	84	1:4	109		

OPO	ID	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6		Sample 7	
		Titer Value	Sample Date	Titer Value	No. of Days from Sample 1	Titer Value	No. of Days from Sample 2	Titer Value	No. of Days from Sample 3	Titer Value	No. of Days from Sample 4	Titer Value	No. of Days from Sample 5	Titer Value	No. of Days from Sample 6
	63	1:32	03/01/2003												
	64	1:2	02/28/2003												
	65	1:2	02/28/2003	1:4	84	1:4	101	1:8	85						
	66	1:8	02/19/2003												
	67	1:2	02/03/2003	1:2	80	1:4	98	1:4	86						
	68	1:8	06/04/2003												
	69	1:8	04/28/2003												
	70	1:4	06/02/2003	1:2	95	1:4	89								
	71	1:2	04/07/2003	1:4	75	1:4	73	1:4	85						
	72	1:4	06/03/2003												
	73	1:2	06/26/2003												
	74	1:8	05/15/2003												
	75	1:4	04/23/2003	1:4	99	1:16	123								
	76	1:4	05/20/2003	1:1	77	1:2	93								
	77	1:8	07/24/2003												
	78	1:4	05/14/2003	1:2	106	1:4	103								
	79	1:2	06/19/2003	1:4	71	1:4	89								
	80	1:16	10/01/2003												
	81	1:16	09/24/2003												
	82	1:4	08/06/2003	1:8	80										



OPO ID	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6		Sample 7	
	Titer Value	Sample Date	Titer Value	No. of Days from Sample 1	Titer Value	No. of Days from Sample 2	Titer Value	No. of Days from Sample 3	Titer Value	No. of Days from Sample 4	Titer Value	No. of Days from Sample 5	Titer Value	No. of Days from Sample 6
83	1:4	09/02/2003	1:2	98										
84	1:4	08/12/2003	1:2	93										
85	1:4	09/03/2003	1:4	83										
86	1:16	09/03/2003												
87	1:4	10/09/2003												
88	1:4	09/25/2003												
89	1:8	12/02/2003												
1632	1:8	10/01/2001	1:8	93*	1:8	362*								
2	1:2	10/02/2001	1:2	93	1:2	369								
3	1:2	12/04/2001	1:4	329	1:4	63*								
4	1:2	10/02/2001	1:2	97	1:4	301	1:2	28*	1:2	226	1:2	82	1:2	91
5	1:2	12/10/2001	1:2	330	1:1	27*								
6	1:8	09/26/2001	1:8	99*	1:8	333*								
7	1:2	10/01/2001	1:2	98	1:2	331	1:2	68*	1:2	98	1:2	86	1:2	84
8	1:4	09/05/2001	1:4	119	1:4	306	1:2	28*						
9	1:4	11/06/2001	1:4	92	1:2	273	1:2	26*						
10	1:4	11/06/2001	1:4	92	1:4	271	1:2	63*						
11	1:4	06/10/2002	1:4	119										
12	1:2	07/02/2002	1:2	91	1:2	35*	1:1	63						
13	1:2	07/02/2002	1:2	97	1:2	91	1:2	91	1:2	91				

OPO	ID	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6		Sample 7	
		Titer Value	Sample Date	Titer Value	No. of Days from Sample 1	Titer Value	No. of Days from Sample 2	Titer Value	No. of Days from Sample 3	Titer Value	No. of Days from Sample 4	Titer Value	No. of Days from Sample 5	Titer Value	No. of Days from Sample 6
	14	1:2	08/05/2002	1:2	84	1:2	98	1:2	91	1:2	101	1:2	109		
	15	1:8	10/01/2001	1:8	93*	1:8	362*								
	16	1:4	10/07/2002	1:2	91	1:2	91								
	17	1:4	07/17/2002	1:4	82	1:2	91	1:2	84	1:2	98	1:4	92	1:4	90
	18	1:2	12/11/2002	1:2	54*	1:2	28								
	19	1:4	04/09/2003	1:4	89	1:4	91	1:4	93						
	20	1:4	06/18/2003	1:4	104										
	21	1:2	06/25/2003	1:2	105	1:2	89								
	22	1:2	06/11/2003												
	23	1:2	05/07/2003	1:2	70										
	24	1:4	06/03/2003	1:4	92										
	25	1:2	07/30/2003	1:2	104										
	26	1:4	08/27/2003	1:2	103										
1756	1	1:1	12/16/2002	1:1	77	1:1	91	1:1	91	1:1	75				
	2	1:1	11/06/2002	1:1	62*	1:1	70								
	3	1:1	11/11/2002	1:1	70	1:1	105	1:2	197						
	4	1:1	12/17/2002	1:1	77										
	5	1:1	12/03/2002	1:1	98										
	6	1:1	01/08/2003	1:1	89	1:1	91	1:1	91						
	7	1:2	03/25/2003	1:2	104	1:1	91								

**OPTN/UNOS
Minority Affairs Committee**

**MELD Data on Liver Patients with
Hepatocellular Carcinoma Cancer
(HCC) Diagnosis**

by:
Wida S. Cherikh, Ph.D.
UNOS Research Department
April 27-28, 2004



Background/Purpose:

- Liver and Intestine Committee put forth a proposal for public comment to reduce the MELD score for liver patients with HCC diagnosis with certain tumor size.
- MAC was concerned if this proposal may have a negative impact on minority patients, especially Black patients.



Data Request:

- Liver registrations, transplants and post-transplant survival for different ethnic groups by diagnosis (HCC vs. other) and MELD score



Data/Methods:

- Waiting List: Adult (age \geq 18) liver candidates added to the wait list during 3/1/02-9/30/03 for determining the distribution of MELD scores on the wait list.



Data/Methods:

- Transplant data: Adult (age \geq 18) liver tx recipients during 3/1/02-6/30/03 for determining the distribution of MELD scores at time of transplant and calculating the 3-month Kaplan-Meier patient survival.



Results:



Figure 1A. Adult Liver Patients at Listing (3/1/02-9/30/03) and Transplant (3/1/02-6/30/02) By Ethnicity and Diagnosis

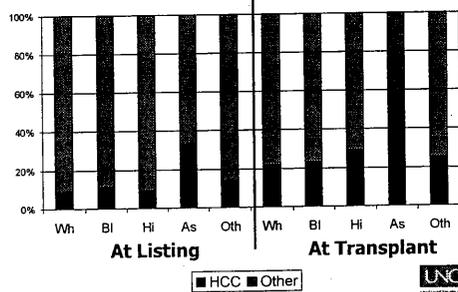


Figure 1B. MELD Scores by Ethnicity At Listing (3/02-9/03) and Transplant (3/02-6/03)

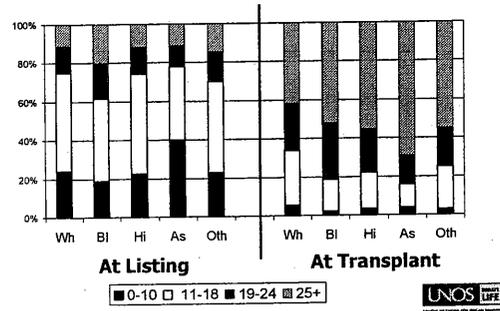


Figure 2. Adult Liver Registrations During 3/1/02-9/30/03 By Ethnicity and MELD score

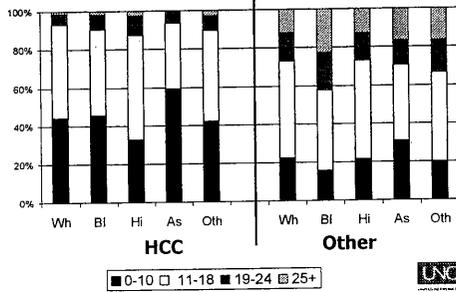


Figure 3. Adult Liver Transplants During 3/1/02-6/30/03 By Ethnicity and MELD Score

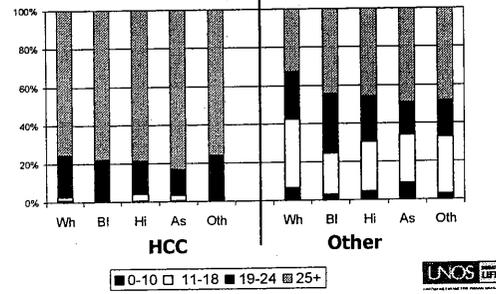
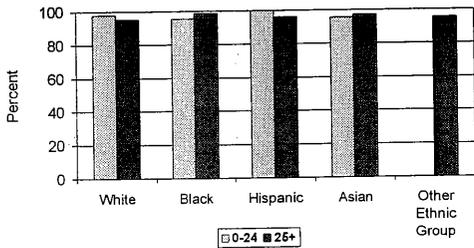
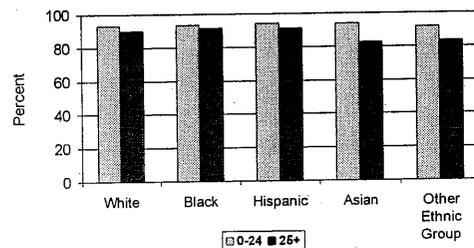


Figure 4. 3-Month Kaplan-Meier Patient Survival for Adult Liver Recipients with HCC by Ethnicity and MELD Score, 3/1/02-6/30/03



*Survival was not computed for patients of other ethnic group with 0-24 MELD due to small number alive

Figure 5. Kaplan-Meier 3-Month Patient Survival for Adult Liver Recipients with non-HCC by Ethnicity and MELD Score, 3/1/02-6/30/03



UNOS LIFE

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

*MELD Data on Liver Patients with
Hepatocellular Carcinoma Cancer (HCC) Diagnosis*

Prepared for:
*Minority Affairs Committee Meeting
April 27-28, 2004
Chicago, IL*

By:
Wida Cherikh, Ph.D. and Yulin Cheng, B.S.
Research Department
United Network for Organ Sharing

Table of Contents

Committee Request.....	2
Background/Purpose.....	2
Data and Methods	2
Results.....	2

Committee Request

In the last Committee meeting on October 1, 2003, the Committee expressed an interest in looking at the MELD data for liver patients with hepatocellular cancer (HCC) diagnosis, by ethnicity. The two data items the MAC was interested were the proportion of minority patients with HCC diagnosis by MELD score, and the post-transplant survival for different ethnic recipients by MELD score.

Background/Purpose

The Liver and Intestine Committee put forth a proposal for public comment to reduce the MELD score for liver patients with HCC diagnosis with certain tumor size. The MAC was concerned if this proposal may have a negative impact on minority patients, especially Black patients.

Data and Methods

Adult (age ≥ 18 years) liver candidates added to the wait list between March 1, 2002 and September 30, 2003 were included in the analysis for determining the distribution of MELD scores on the wait list.

Adult liver transplant recipients between 3/1/2002 and 6/30/2003 were included in the analysis for determining the distribution of MELD scores at time of transplant and calculating the 3-month Kaplan-Meier patient survival.

All information provided in this report is based on OPTN data as of January 9, 2004.

Results

Table 1 - MELD scores at time of listing by ethnicity and liver diagnosis (HCC vs. other):

- Overall, of the 12,961 liver patients added to the wait list between March 1, 2002 and September 30, 2003, 1,333 (10%) had a diagnosis of HCC.
- Of the 1,333 liver registrations with HCC, 847 (63.5%) were White, 105 (7.9%) were Black, 168 (12.6%) were Hispanic, 175 (13.1%) were Asian, and 2.8 (3%) were of other ethnic group.
- Overall, 45% (599) of HCC patients had a MELD score between 0 and 10, 47.3% (631) between 11 and 18, 6% (81) between 19 and 24, and only 1.7% (22) had a MELD score of 25 or higher.
- Among patients of White, Hispanic, and other ethnic group, the majority had a MELD score between 11 and 18 (49%, 55%, and 47%, respectively), whereas among Asian patients with HCC, majority (59%) had a MELD score of 10 or lower.
- Among Black patients with HCC, the percentages with a MELD score of 0-10 and 11-18 were comparable (45.7% and 44.8%, respectively).

Table 2 - MELD scores at transplant by ethnicity and liver diagnosis (HCC vs. other):

- Overall, of the 5,720 liver transplant recipients during 3/1/02-6/30/03, 1,338 (24%) had a primary diagnosis of HCC.

- Among transplant recipients with HCC, 903 (65%) were White, 113 (8%) were Black, 202 (14%) were Hispanic, 143 (10%) were Asian, and 33 (2%) were of other ethnic group.
- The majority of HCC patients were transplanted with a MELD score of 25 or greater in all ethnic groups (i.e. 76% in Whites, 78% in Blacks, 79% in Hispanic, 83% in Asians, and 76% in other ethnic group).

Table 3 - Kaplan-Meier patient survival at 3 months post-transplant by ethnicity, diagnosis (HCC vs. other) and MELD score:

- Overall, the three-month patient survival for HCC patients seemed higher than that for non-HCC patients (i.e., 97.9% for HCC with 0-24 MELD, and 95.8% for HCC with 25+ MELD as compared to 93.3% for non-HCC with 0-24 MELD, and 89.9% for non-HCC with 25+ MELD).
- Among HCC recipients with a MELD score of 0-24, the three-month patient survival seemed comparable among different ethnic groups (i.e., 97.9% for Whites, 95.2% for Blacks, 100.0% for Hispanics, and 95.7% for Asians). Due to small number of HCC recipients of other ethnic group who were alive at 3 months, survival was not computed for this group.
- Among HCC recipients with a MELD score of 25+, the three-month patient survival also seemed comparable among different ethnic groups (i.e., 95.1% for Whites, 98.7% for Blacks, 96.0% for Hispanics, 97.3% for Asians, and 95.5% for recipients of other ethnic group).

Table 1. Distribution of MELD Score at Listing by Ethnicity and Primary Diagnosis for Adult Candidates Added to the Waiting List During 03/01/2002 - 09/30/2003 (Excluding Candidates with Status 1 or Inactive Status at Listing)

Ethnicity, Diagnosis		MELD Score at Listing								Total	
		0-10		11-18		19-24		25+			
		# of TXs	% of TXs	# of TXs	% of TXs	# of TXs	% of TXs	# of TXs	% of TXs	# of TXs	% of TXs
White	HCC	376	44.4	414	48.9	43	5.1	14	1.7	847	100.0
	Other	1,904	22.3	4,357	50.9	1,243	14.5	1,048	12.3	8,552	100.0
	Total	2,280	24.3	4,771	50.8	1,286	13.7	1,062	11.3	9,399	100.0
Black	HCC	48	45.7	47	44.8	8	7.6	2	1.9	105	100.0
	Other	128	15.7	345	42.2	159	19.5	185	22.6	817	100.0
	Total	176	19.1	392	42.5	167	18.1	187	20.3	922	100.0
Hispanic	HCC	55	32.7	92	54.8	17	10.1	4	2.4	168	100.0
	Other	356	21.5	854	51.5	237	14.3	211	12.7	1,658	100.0
	Total	411	22.5	946	51.8	254	13.9	215	11.8	1,826	100.0
Asian	HCC	104	59.4	60	34.3	10	5.7	1	0.6	175	100.0
	Other	111	30.8	143	39.7	47	13.1	59	16.4	360	100.0
	Total	215	40.2	203	37.9	57	10.7	60	11.2	535	100.0
Other	HCC	16	42.1	18	47.4	3	7.9	1	2.6	38	100.0
	Other	48	19.9	113	46.9	40	16.6	40	16.6	241	100.0
	Total	64	22.9	131	47.0	43	15.4	41	14.7	279	100.0
Total	HCC	599	44.9	631	47.3	81	6.1	22	1.7	1,333	100.0
	Other	2,547	21.9	5,812	50.0	1,726	14.8	1,543	13.3	11,628	100.0
	Total	3,146	24.3	6,443	49.7	1,807	13.9	1,565	12.1	12,961	100.0

Table 2. Distribution of MELD Score at Transplant by Recipient Ethnicity and Primary Diagnosis for Adult Recipients of Deceased Donor Transplants Performed During 03/01/2002 - 06/30/2003 (Excluding Recipients with Status 1, 2A or Inactive Status at Transplant)

Ethnicity, Diagnosis		MELD Score at Time of TX								Total	
		0-10		11-18		19-24		25+			
		# of TXs	% of TXs	# of TXs	% of TXs	# of TXs	% of TXs	# of TXs	% of TXs	# of TXs	% of TXs
White	HCC	9	1.0	17	1.9	195	21.6	682	75.5	903	100.0
	Other	219	6.7	1,166	35.7	818	25.0	1,065	32.6	3,268	100.0
	Total	228	5.5	1,183	28.4	1,013	24.3	1,747	41.9	4,171	100.0
Black	HCC	0	0	0	0	25	22.1	88	77.9	113	100.0
	Other	11	2.9	80	21.4	118	31.6	164	44.0	373	100.0
	Total	11	2.3	80	16.5	143	29.4	252	51.9	486	100.0
Hispanic	HCC	1	0.5	7	3.5	35	17.3	159	78.7	202	100.0
	Other	22	4.5	125	25.6	118	24.2	223	45.7	488	100.0
	Total	23	3.3	132	19.1	153	22.2	382	55.4	690	100.0
Asian	HCC	1	0.7	4	2.8	19	13.3	119	83.2	143	100.0
	Other	9	9.0	25	25.0	17	17.0	49	49.0	100	100.0
	Total	10	4.1	29	11.9	36	14.8	168	69.1	243	100.0
Other	HCC	1	3.0	0	0	7	21.2	25	75.8	33	100.0
	Other	3	3.1	29	29.6	19	19.4	47	48.0	98	100.0
	Total	4	3.1	29	22.1	26	19.8	72	55.0	131	100.0
Total	HCC	12	0.9	28	2.0	281	20.2	1,073	77.0	1,394	100.0
	Other	264	6.1	1,425	32.9	1,090	25.2	1,548	35.8	4,327	100.0
	Total	276	4.8	1,453	25.4	1,371	24.0	2,621	45.8	5,721	100.0

Table 3.
Three-Month Kaplan-Meier Patient Survival by Recipient Ethnicity, Primary Diagnosis and MELD Score at Transplant for Adult Recipients of Deceased Donor Transplants Performed During 03/01/2002 - 06/30/2003 (Excluding Recipients with Status 1, 2A or Inactive Status at Transplant)

Ethnicity	Diagnosis	MELD Score at Time of TX	No. of Transplants	No of Alive Recipients	Survival Rate (%)	95% Confidence Limit
White	HCC	0-24	221	177	97.9	[95.90,99.94]
		25+	682	590	95.1	[93.46,96.77]
	Other	0-24	2203	1809	93.2	[92.13,94.31]
		25+	1065	817	90.1	[88.21,92.00]
Black	HCC	0-24	25	20	95.2	[86.13,100.0]
		25+	88	76	98.7	[96.17,100.0]
	Other	0-24	209	165	93.4	[89.90,96.87]
		25+	164	127	91.4	[86.94,95.90]
Hispanic	HCC	0-24	43	32	100.0	[100.0,100.0]
		25+	159	143	96.0	[92.86,99.14]
	Other	0-24	265	219	94.3	[91.44,97.22]
		25+	223	174	91.1	[87.10,95.01]
Asian	HCC	0-24	24	19	95.7	[87.32,100.0]
		25+	119	102	97.3	[94.23,100.0]
	Other	0-24	51	42	93.8	[86.92,100.0]
		25+	49	36	82.3	[71.22,93.47]
Other	HCC	0-24	8	7	.	
		25+	25	21	95.5	[86.75,100.0]
	Other	0-24	51	41	91.7	[83.87,99.50]
		25+	47	33	83.3	[71.97,94.64]
Overall	HCC	0-24	321	255	97.9	[96.19,99.56]
		25+	1073	932	95.8	[94.54,97.01]
	Other	0-24	2779	2276	93.3	[92.36,94.28]
		25+	1548	1187	89.9	[88.35,91.51]

Note: "." indicates that survival rates were not computed due to number of alive recipients less than 10

**OPTN/UNOS
Minority Affairs Committee**

**Descriptive Data Surrounding
Heart Transplantation**

by:
Wida S. Cherikh, Ph.D.
UNOS Research Department
April 27-28, 2004



Background/Purpose:

- Historically, the MAC has been interested in various aspects of kidney allocation/transplantation.
- A Committee member has expressed an interest in examining data on heart wait list and transplantation in minority patients.



Table 1:

- Heart registrations added to the waiting list between 1/1/95 through 6/30/03, stratified by candidate age group, listing year and ethnicity.

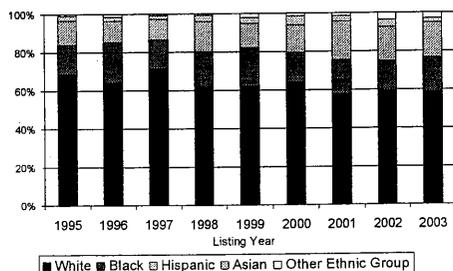


Table 1:

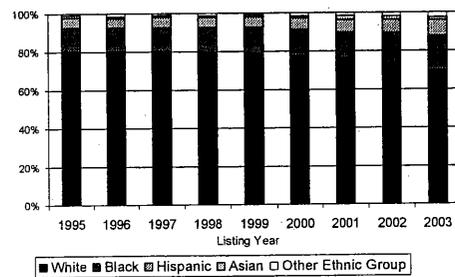
- During 1995-2003, 63% of pediatric registrations were White, 18% were Black, 15% were Hispanic, 3% were Asian, and 2% were of other ethnic group.
- 78% of adult registrations were White, 14% were Black, 6% were Hispanic, 1% were Asian and 1% were of other ethnic group.



**Figure 1A. Pediatric Registrations
During 1/1/95-6/30/03**



**Figure 1B. Adult Registrations
During 1/1/95-6/30/03**



Tables 2A and 2B:

- Summary of Kaplan-Meier median waiting time (MWT) to transplant for registrations added between 1/1/95 through 12/31/01, stratified by listing year and ethnicity, for pediatric and adult candidates.



Figure 2A. Kaplan-Meier MWT (in Days) for Pediatric Registrations, 1/1/95-12/31/01

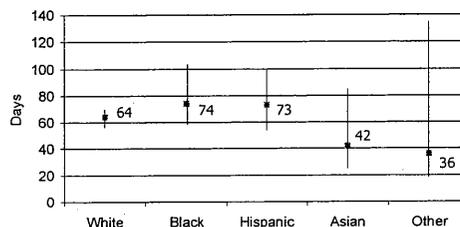
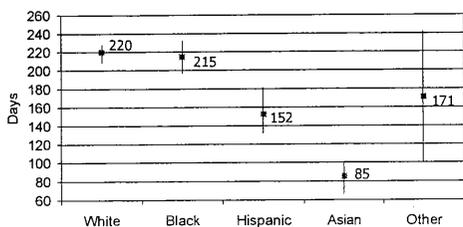


Figure 2B. Kaplan-Meier MWT (in Days) for Adult Registrations, 1/1/95-12/31/01



Tables 3A and 3B:

- Mortality rate, expressed as deaths per 1,000 patient years, for registrations waiting during 1/1/95-12/31/02, stratified by age group, ethnicity, and medical urgency status at listing.
- Since categories for heart medical urgency status were revised on 1/19/99, the data pertaining to status were broken out into two eras, i.e., pre 1/19/99 and post 1/19/99.



Tables 3A and 3B:

- Mortality rate as expressed by deaths per 1,000 patient years was calculated by dividing number of deaths during the study period with sum of the years that patients spent waiting, and then multiplying by 1,000.
- Since the rate was based on the amount of time patients were waiting, the smaller the death rate, the fewer the number of deaths per 1,000 patient years waiting.



Figure 3A. Deaths per 1000 Patient-Years for Adult Registrations, 1/1/95-1/19/99

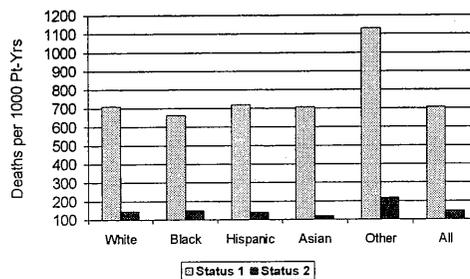


Figure 3B. Deaths per 1000 Patient-Years for Adult Registrations, 1/20/99-12/31/02

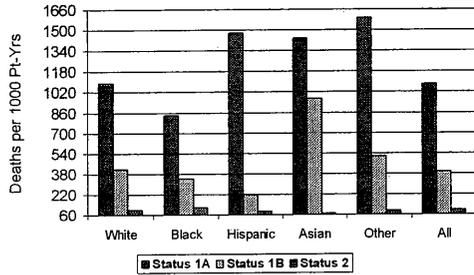


Figure 4A. Pediatric Transplants During 1/1/95-6/30/03

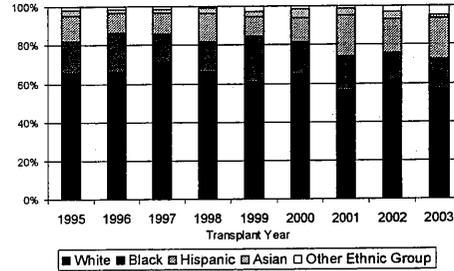


Figure 4B. Adult Transplants During 1/1/95-6/30/03

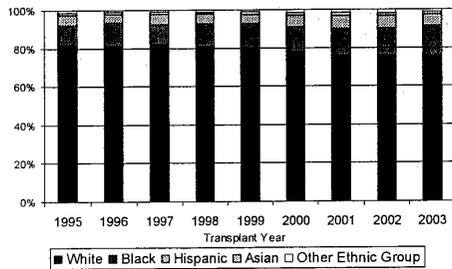


Figure 5A. Kaplan-Meier Patient Survival for Pediatric Recipients During 1/1/95-12/31/01

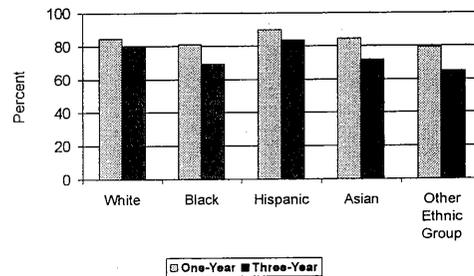
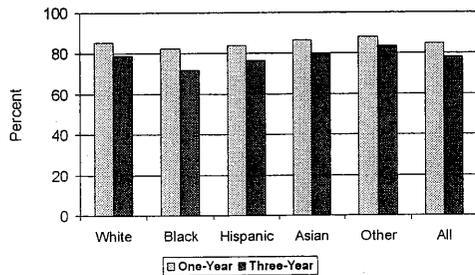


Figure 5B. Kaplan-Meier Patient Survival for Adult Recipients During 1/1/95-12/31/01



Tables 6 and 7:

- Number with ventricular assist device (VAD) at time of listing or transplant during 1/1/95-6/30/03, by age group, ethnicity, and medical urgency status at listing or transplant.
- Since categories for heart medical urgency status were revised on 1/19/99, the data were broken out into two periods, i.e., pre 1/19/99 and post 1/19/99.

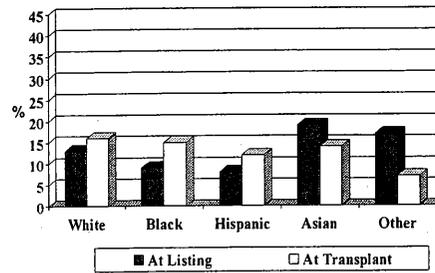


Tables 6 and 7:
VAD Use at Listing and TX

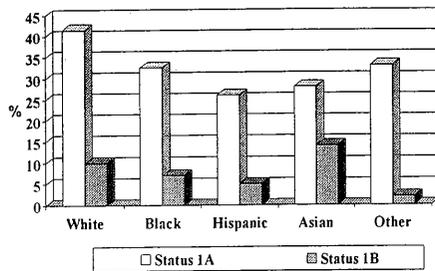
	1/1/95 - 1/19/99			
	Adult		Pediatric	
	Listing	TX	Listing	TX
Status 1	12.5%	15.4%	3.3%	7.4%
Status 2	0.5%	0.3%	0.2%	0.7%
	1/20/99 - 6/30/03			
	Adult		Pediatric	
Status 1A	31.0%	35.5%	5.0%	9.5%
Status 1B	9.0%	16.0%	1.1%	2.6%
Status 2	1.4%	0.1%	0.4%	0.4%



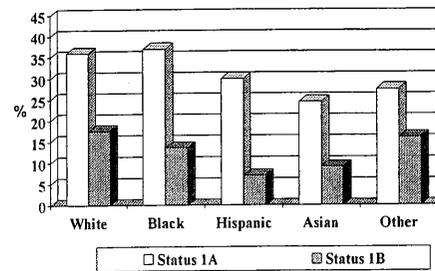
VAD Use in Status 1 Registrations and Transplants During 1/1/95-1/19/99



VAD Use in Status 1A and 1B Registrations During 1/20/99-6/30/03



VAD Use in Status 1A and 1B Transplants During 1/20/99-6/30/03



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

Descriptive Data Surrounding Heart Transplantation

Prepared for:
*Minority Affairs Committee Meeting
April 27-28, 2004*

By:
Wida Cherikh, Ph.D. and Yulin Cheng, B.S.
Research Department
United Network for Organ Sharing

Table of Contents

Committee Request.....	2
Background/Purpose.....	2
Data and Methods	2
Results.....	3

Committee Request

Descriptive data surrounding heart transplantation, including the number of deaths on the waiting list in minority patients, the number of heart transplants in minority patients, and the number with assist devices.

Background/Purpose

Historically, the MAC has been interested in various aspects of kidney allocation/transplantation. A Committee member has expressed an interest in examining data on heart wait list and transplantation in minority patients.

Data and Methods

The following data are provided in this report:

1. Number of heart registrations added to the waiting list between 1/1/95 through 6/30/03, stratified by candidate age group, listing year and ethnicity.
2. Kaplan-Meier median waiting time to transplant for registrations added between 1/1/95 through 12/31/01, stratified by age group, listing year and ethnicity.
3. Mortality rate, expressed as deaths per 1,000 patient years, for registrations waiting during 1/1/95-12/31/02, stratified by age group, ethnicity, and medical urgency status at listing. Since categories for heart medical urgency status were revised on 1/19/99, the data pertaining to status were broken out into two eras, i.e., pre 1/19/99 and post 1/19/99.

The mortality rate as expressed by deaths per 1000 patient years, was calculated by dividing the number of deaths during the study period by the sum of the years that patients spent waiting, and then multiplying by 1000. Since the rate was based on the amount of time patients were waiting, the smaller the death rate, the fewer the number of deaths per 1,000 patient years waiting.

4. Number of deceased donor heart transplants between 1/1/95 through 6/30/03, stratified by age group, transplant year and ethnicity.
5. Kaplan-Meier one- and three-year patient survival rates for deceased donor heart transplants between 1/1/95 through 12/31/01, stratified by age group, transplant year, and ethnicity.
6. Number of candidates with ventricular assist device (VAD) at time of listing for candidates waiting during 1/1/95-6/30/03, stratified by age group, ethnicity, and medical urgency status at listing. Since categories for heart medical urgency status were revised on 1/19/99, the data were broken out into two waiting list (WL) periods, i.e., pre 1/19/99 and post 1/19/99.

7. Number of recipients with ventricular assist device (VAD) at time of transplant, for recipients transplanted during 1/1/95-6/30/03, stratified by age group, ethnicity, and medical urgency status at transplant. Since categories for heart medical urgency status were revised on 1/19/99, the data were broken out into two transplant periods, i.e., pre 1/19/99 and post 1/19/99.

All information provided in this report is based on OPTN data as of December 12, 2003.

Results

Table 1 - Heart registrations added to the waiting list between 1/1/95 through 6/30/03, stratified by candidate age group, listing year and ethnicity:

- Pediatric patients (age<18) constituted 13% of heart registrations added during the study period.
- Overall, 63% of 3,918 pediatric registrations were White, 18% were Black, 15% were Hispanic, 3% were Asian, and 2% were of other ethnic group.
- Among 27,032 adult registrations, 78% were White, 14% were Black, 6% were Hispanic, and 1% was Asian and of other ethnic group.
- Among pediatric registrations, although the proportion of each ethnic group seemed to fluctuate over the years, there seemed to be a slight decreasing trend in the proportion of White patients, and an increasing proportion of Hispanics and patients of other ethnic group during the more recent years.
- Among adult registrations, the proportion of Whites seemed to decrease, whereas the proportion of Blacks, Hispanics, Asians and patients of other ethnic group seemed to increase.

Table 2A - Kaplan-Meier median waiting time (MWT) to transplant for registrations added between 1/1/95 through 12/31/01, stratified by listing year and ethnicity for pediatric candidates:

- The MWT to transplant seemed to fluctuate for White, Black, and Hispanic patients over the years. MWT for patients of other ethnic group was not computed due to number of registrations less than 10.
- Overall, the MWT for pediatrics was the smallest in patients of other ethnic group (36 days), followed by Asians (42 days), Whites (64 days), Hispanics (73 days), and Blacks (74 days).

Table 2B - Kaplan-Meier median waiting time (MWT) to transplant for registrations added between 1/1/95 through 12/31/01, stratified by listing year and ethnicity for adult candidates:

- The MWT to transplant for adults also seemed to fluctuate for Whites, Blacks, and Hispanics.
- Overall, the MWT for adults was the smallest in Asian patients (85 days), followed by Hispanics (152 days), patients of other ethnic group (171 days), Blacks (215 days), and Whites (220 days).

F-7

Table 3A - Mortality rate, expressed as deaths per 1,000 patient years, for registrations waiting during 1/1/95-1/19/99, stratified by age group, ethnicity and medical urgency status at listing:

- Mortality rate per 1,000 patient years was much higher for Status 1 than Status 2 for both pediatric and adult patients.
- Among pediatric patients, overall mortality rate per 1,000 patient years was 958.3 for Status 1 and 153.2 for Status 2.
- Among pediatric Status 1 patients, mortality rate per 1,000 patient years was the highest for Whites (1088.1) and smallest for patients of other ethnic group (221.5).
- Among adult patients, overall mortality rate per 1,000 patient years was 707.1 for Status 1, and 144.3 for Status 2.
- Among adult Status 1 patients, mortality rate was the highest for patients of other ethnic group (1129), and smallest for Blacks (661.5).
- Among adult Status 2 patients, mortality rate was the highest for patients of other ethnic group (214.7), and smallest for Asians (118.6).

Table 3B - Mortality rate, expressed as deaths per 1,000 patient years, for registrations waiting during 1/20/99-12/31/02, stratified by age group, ethnicity, and medical urgency status at listing:

- Mortality rate per 1,000 patient years was the highest for Status 1A and smallest for Status 2 for both pediatric and adult patients.
- Among pediatric patients, overall mortality rate for was 1191.3 for Status 1A, 330.9 for Status 1B, and 105.7 for Status 2.
- Among pediatric Status 1A patients, mortality rate was the smallest for Whites (1030.5) and highest for patients of other ethnic group (4262.8).
- Among pediatric Status 1B patients, mortality rate was the smallest for Hispanics (166.1) and highest for Blacks (591.8).
- Among pediatric Status 2 patients, mortality rate was the smallest for Asians (67.9) and highest for patients of other ethnic group (291.3).
- Among adult patients, overall mortality rate was 1084.8 for Status 1A, 390.8 for Status 1B, and 98.3 for Status 2.
- Among adult Status 1A patients, mortality rate was the smallest for Blacks (838.7) and highest for patients of other ethnic group (1593.0).
- Among adult Status 1B patients, mortality rate was the smallest for Hispanics (221.1) and highest for Asians (971.5).
- Among adult Status 2 patients, mortality rate was the smallest for Asians (68.5) and highest for Blacks (116.9).

Table 4 - Number of heart transplants performed between 1/1/95 through 6/30/03, stratified by age group, transplant year and recipient ethnicity:

- Overall, of 2,288 pediatric transplants during the study period, 64% were White, 17% were Black, 14% were Hispanic, 3% were Asian, and 2% were of other ethnic group.
- Among pediatric transplants, the ethnic distribution did not seem to change significantly over the years, although there seemed to be an increasing proportion of Hispanics and patients of other ethnic group in the more recent years.
- Overall, of 16,579 adult transplants during the study period, 79% were White, 13% were Black, 6% were Hispanic, 1.4% were Asian, and 1.2% were of other ethnic group.

- Among adult transplants, the proportion of Whites seemed to decrease, whereas the proportion of ethnic minority patients seemed to increase over the years.

Table 5A - Kaplan-Meier one- and three-year patient survival rates for transplants performed between 1/1/95 through 12/31/01, stratified by transplant year and ethnicity for pediatric recipients:

- Overall, one-year patient survival was 85% for Whites, 81% for Blacks, 90% for Hispanics, 84.5% for Asians, and 79% for patients of other ethnic group.
- Overall, three-year patient survival was 80% for Whites, 69% for Blacks, 84% for Hispanics, 72% for Asians, and 65% for patients of other ethnic group.

Table 5B - Kaplan-Meier one- and three-year patient survival rates for transplants performed between 1/1/95 through 12/31/01, stratified by transplant year and ethnicity for adult recipients:

- Overall, one-year patient survival was 85% for Whites, 82% for Blacks, 84% for Hispanics, 86.5% for Asians, and 88% for patients of other ethnic group.
- Overall, three-year patient survival was 79% for Whites, 72% for Blacks, 77% for Hispanics, 80% for Asians, and 83.5% for patients of other ethnic group.

Table 6 - Ventricular assist device (VAD) use at time of listing for candidates waiting during 1/1/95-6/30/03, stratified by age group, ethnicity, waiting list (WL) period, and medical urgency status at listing:

Registrations during 1/1/95-1/19/99:

- Overall, VAD use was reported in 3.3% of pediatric Status 1 patients, and only in 0.2% of pediatric Status 2 patients.
- Overall, VAD use was reported in 12.5% of adult Status 1 patients, and only in 0.5% of adult Status 2 patients.
- Among adult Status 1 patients, VAD was used in 13% of Whites, 9% of Blacks, 8% of Hispanics, 19% of Asians, and 17% of patients with other ethnic group.

Registrations during 1/20/99-6/30/03:

- Overall, VAD use was reported in 5% of pediatric Status 1A patients, 1.1% of pediatric Status 1B patients, and only in 0.4% of pediatric Status 2 patients.
- Overall, VAD use was reported in 31% of adult Status 1A patients, 9% of adult Status 1B patients, and only in 1.4% of adult Status 2 patients.
- Among adult Status 1A patients, VAD was used in 32.5% of Whites, 26% of Blacks and Hispanics, 28% of Asians, and 33% of patients with other ethnic group.
- Among adult Status 1B patients, VAD was used in 10% of Whites, 7% of Blacks, 5% of Hispanics, 14% of Asians, and 2% of patients with other ethnic group.

Table 7 - Ventricular assist device (VAD) use at time of transplant, for recipients transplanted during 1/1/95-6/30/03, stratified by age group, ethnicity, transplant period, and medical urgency status at transplant:

F-9

Transplants during 1/1/95-1/19/99:

- Overall, VAD use was reported in 7.4% of pediatric Status 1 patients, and only in 0.7% of pediatric Status 2 patients.
- Overall, VAD use was reported in 15.4% of adult Status 1 patients, and only in 0.3% of adult Status 2 patients.
- Among adult Status 1 patients, VAD was used in 16% of Whites, 15% of Blacks, 12% of Hispanics, 14% of Asians, and 7% of patients with other ethnic group.

Transplants during 1/20/99-6/30/03:

- Overall, VAD use was reported in 9.5% of pediatric Status 1A patients, 2.6% of pediatric Status 1B patients, and only in 0.4% of pediatric Status 2 patients.
- Overall, VAD use was reported in 35.5% of adult Status 1A patients, 16% of adult Status 1B patients, and only in 0.1% of adult Status 2 patients.
- Among adult Status 1A patients, VAD was used in 36% of Whites, 37% of Blacks, 30% of Hispanics, 24.5% of Asians, and 27.5% of patients with other ethnic group.
- Among adult Status 1B patients, VAD was used in 17.5% of Whites, 13.5% of Blacks, 7% of Hispanics, 9% of Asians, and 16% of patients with other ethnic group.

Table 1. Registrations (REGs) Added to Waiting List During 01/01/1995-06/30/2003
By Candidate Age Group, Listing Year and Ethnicity

Age Group, Listing Year		Candidate Ethnicity										Total	
		White		Black		Hispanic		Asian		Other			
		# of REGs	% of REGs	# of REGs	% of REGs	# of REGs	% of REGs	# of REGs	% of REGs	# of REGs	% of REGs	# of REGs	% of REGs
Pediatric	1995	337	68.4	78	15.8	62	12.6	11	2.2	5	1.0	493	100.0
	1996	272	64.0	91	21.4	46	10.8	9	2.1	7	1.6	425	100.0
	1997	329	71.4	70	15.2	50	10.8	8	1.7	4	0.9	461	100.0
	1998	288	61.5	88	18.8	74	15.8	14	3.0	4	0.9	468	100.0
	1999	268	62.2	87	20.2	54	12.5	13	3.0	9	2.1	431	100.0
	2000	265	63.5	67	16.1	59	14.1	20	4.8	6	1.4	417	100.0
	2001	278	57.6	87	18.0	97	20.1	14	2.9	7	1.4	483	100.0
	2002	304	59.4	80	15.6	90	17.6	19	3.7	19	3.7	512	100.0
	2003	133	58.3	42	18.4	41	18.0	5	2.2	7	3.1	228	100.0
	Total	2,474	63.1	690	17.6	573	14.6	113	2.9	68	1.7	3,918	100.0
Adult	1995	3,013	80.3	471	12.5	185	4.9	46	1.2	39	1.0	3,754	100.0
	1996	2,782	80.6	413	12.0	173	5.0	35	1.0	50	1.4	3,453	100.0
	1997	2,638	80.1	410	12.5	180	5.5	37	1.1	27	0.8	3,292	100.0
	1998	2,762	79.6	453	13.1	179	5.2	38	1.1	39	1.1	3,471	100.0
	1999	2,460	79.1	418	13.4	176	5.7	35	1.1	21	0.7	3,110	100.0
	2000	2,368	78.1	408	13.5	176	5.8	37	1.2	42	1.4	3,031	100.0
	2001	2,221	76.1	401	13.7	189	6.5	59	2.0	48	1.6	2,918	100.0
	2002	1,990	73.4	436	16.1	190	7.0	50	1.8	46	1.7	2,712	100.0
	2003	906	70.2	228	17.7	105	8.1	21	1.6	31	2.4	1,291	100.0
	Total	21,140	78.2	3,638	13.5	1,553	5.7	358	1.3	343	1.3	27,032	100.0
Total	1995	3,350	78.9	549	12.9	247	5.8	57	1.3	44	1.0	4,247	100.0
	1996	3,054	78.8	504	13.0	219	5.6	44	1.1	57	1.5	3,878	100.0
	1997	2,967	79.1	480	12.8	230	6.1	45	1.2	31	0.8	3,753	100.0
	1998	3,050	77.4	541	13.7	253	6.4	52	1.3	43	1.1	3,939	100.0
	1999	2,728	77.0	505	14.3	230	6.5	48	1.4	30	0.8	3,541	100.0
	2000	2,633	76.4	475	13.8	235	6.8	57	1.7	48	1.4	3,448	100.0
	2001	2,499	73.5	488	14.3	286	8.4	73	2.1	55	1.6	3,401	100.0
	2002	2,294	71.2	516	16.0	280	8.7	69	2.1	65	2.0	3,224	100.0
	2003	1,039	68.4	270	17.8	146	9.6	26	1.7	38	2.5	1,519	100.0
	Total	23,614	76.3	4,328	14.0	2,126	6.9	471	1.5	411	1.3	30,950	100.0

Table 2A. Kaplan-Meier Median Waiting Time (MWT, In Days) to Transplant For Pediatric Registrations (REGs) Added to Waiting List during 01/01/1995 - 12/31/2001

Listing Year	White		Black		Hispanic		Asian		Other		Overall	
	No. of REGs	MWT [95% CI]	No. of REGs	MWT [95% CI]	No. of REGs	MWT [95% CI]	No. of REGs	MWT [95% CI]	No. of REGs	MWT [95% CI]	No. of REGs	MWT [95% CI]
1995	337	66.0 [51.0, 88.0]	78	43.0 [26.0, 95.0]	62	49.0 [32.0, 75.0]	11	22.0 [9.0, 52.0]	5		493	54.0 [43.0, 70.0]
1996	272	70.0 [55.0, 87.0]	91	87.0 [56.0, 126.0]	46	79.0 [54.0, 131.0]	9		7		425	75.0 [63.0, 87.0]
1997	328	58.0 [50.0, 70.0]	70	59.0 [39.0, 91.0]	50	85.0 [57.0, 328.0]	8		4		460	60.0 [52.0, 70.0]
1998	288	60.0 [49.0, 69.0]	88	94.0 [59.0, 177.0]	74	65.0 [38.0, 154.0]	14	16.0 [11.0, 53.0]	4		468	64.0 [53.0, 72.0]
1999	268	77.0 [61.0, 103.0]	87	104.0 [46.0, 144.0]	54	156.0 [49.0, 312.0]	13	44.0 [29.0, 604.0]	9		431	80.0 [64.0, 104.0]
2000	265	63.0 [45.0, 80.0]	66	85.0 [51.0, 147.0]	59	61.0 [49.0, 172.0]	20	77.0 [8.0, 115.0]	6		416	67.0 [54.0, 80.0]
2001	277	62.0 [45.0, 76.0]	87	48.0 [31.0, 95.0]	97	66.0 [44.0, 104.0]	13	71.0 [19.0, 151.0]	6		480	62.0 [47.0, 71.0]
Overall	2035	64.0 [59.0, 69.0]	567	74.0 [59.0, 91.0]	442	73.0 [54.0, 90.0]	88	42.0 [25.0, 69.0]	41		3173	65.0 [60.0, 70.0]

Table 2B. Kaplan-Meier Median Waiting Time (MWT, In Days) to Transplant For Adult Registrations (REGs) Added to Waiting List during 01/01/1995 - 12/31/2001

Listing Year	White		Black		Hispanic		Asian		Other		Overall	
	No. of REGs	MWT [95% CI]	No. of REGs	MWT [95% CI]	No. of REGs	MWT [95% CI]	No. of REGs	MWT [95% CI]	No. of REGs	MWT [95% CI]	No. of REGs	MWT [95% CI]
1995	3012	220.0 [200.0, 244.0]	471	261.0 [176.0, 331.0]	185	126.0 [84.0, 191.0]	46	79.0 [50.0, 205.0]	39	154.0 [32.0, 300.0]	3753	213.0 [196.0, 237.0]
1996	2781	228.0 [206.0, 256.0]	413	230.0 [163.0, 298.0]	173	161.0 [102.0, 220.0]	35	67.0 [32.0, 444.0]	50	245.0 [51.0, 1201.0]	3452	223.0 [202.0, 243.0]
1997	2636	205.0 [189.0, 220.0]	410	218.0 [184.0, 269.0]	180	180.0 [116.0, 357.0]	36	81.0 [46.0, 96.0]	27	219.0 [28.0, 256.0]	3289	205.0 [190.0, 218.0]
1998	2762	244.0 [223.0, 265.0]	452	193.0 [159.0, 262.0]	179	173.0 [107.0, 257.0]	38	354.0 [69.0, 522.0]	39	130.0 [71.0, 275.0]	3470	233.0 [215.0, 252.0]
1999	2459	237.0 [217.0, 263.0]	418	204.0 [154.0, 254.0]	176	224.0 [151.0, 336.0]	35	87.0 [53.0, 118.0]	21	298.0 [76.0, 329.0]	3109	226.0 [209.0, 251.0]
2000	2367	237.0 [210.0, 264.0]	407	222.0 [161.0, 281.0]	176	116.0 [91.0, 200.0]	37	56.0 [31.0, 211.0]	42	171.0 [50.0, 342.0]	3029	221.0 [199.0, 243.0]
2001	2217	179.0 [160.0, 198.0]	401	177.0 [149.0, 241.0]	189	126.0 [101.0, 199.0]	59	146.0 [65.0, 285.0]	48	172.0 [83.0, 477.0]	2914	174.0 [158.0, 190.0]
Overall	18234	220.0 [213.0, 229.0]	2972	215.0 [194.0, 234.0]	1258	152.0 [134.0, 182.0]	286	85.0 [67.0, 109.0]	266	171.0 [106.0, 245.0]	23016	214.0 [207.0, 220.0]

Note: '-' denotes that MWT could not be determined because less than half of the REGs have been transplanted, or was not computed due to No. of REGs less than 10.

Table 34. Deaths Per 1000 Patient-Yrs for Registrations ever Waiting during 01/01/1995 - 01/19/1999 by Candidate Age Group, Ethnicity and Medical Urgency Status at Listing

		WL Period: 01/01/1995 - 01/19/1999					
		Status 1			Status 2		
Age Group at Listing	Candidate Ethnicity	No. of Patients	No. of Deaths	Deaths per 1000 Pt-Yrs	No. of Patients	No. of Deaths	Deaths per 1000 Pt-Yrs
Pediatric	White	816	227	1088.1	443	42	131.8
	Black	218	59	795.5	116	13	224.3
	Hispanic	164	42	804.4	77	11	206.1
	Asian	31	5	901.7	12	1	271.6
	Other	14	2	221.5	8	0	0.0
	Overall	1243	335	958.3	656	67	153.2
Adult	White	3779	799	708.1	9094	1363	143.9
	Black	679	139	661.5	1334	226	146.8
	Hispanic	269	53	719.3	540	79	139.2
	Asian	64	12	707.0	111	11	118.6
	Other	71	20	1129.0	91	17	214.7
	Overall	4862	1023	707.1	11170	1696	144.3
Overall	White	4595	1026	767.4	9537	1405	143.5
	Black	897	198	696.5	1450	239	149.6
	Hispanic	433	95	754.6	617	90	144.9
	Asian	95	17	755.0	123	12	124.4
	Other	85	22	822.7	99	17	205.2
	Overall	6105	1358	756.0	11826	1763	144.6

Table 3B. Deaths Per 1000 Patient-Yrs for Registrations ever Waiting during 01/20/1999 - 12/31/2002 by Candidate Age Group, Ethnicity and Medical Urgency Status at Listing

WL Period: 1/20/99 - 12/31/02											
Age Group at Listing	Candidate Ethnicity	No. of Patients	Status 1A			Status 1B			Status 2		
			No. of Deaths	Deaths per 1000 Pt-Yrs	No. of Patients	No. of Deaths	Deaths per 1000 Pt-Yrs	No. of Patients	No. of Deaths	Deaths per 1000 Pt-Yrs	
Pediatric	White	592	127	1030.5	127	13	349.2	403	30	84.0	
	Black	168	51	1223.6	39	7	591.8	117	11	110.4	
	Hispanic	161	42	1224.1	52	4	166.1	94	16	192.2	
	Asian	35	16	4310.0	14	1	495.3	16	1	67.9	
	Other	28	8	4262.8	4	0	0.0	7	1	291.3	
	Overall	984	244	1191.3	236	25	330.9	637	59	105.7	
	Adult	White	1731	450	1093.9	1800	262	414.7	7395	927	96.8
		Black	296	59	838.7	487	71	343.6	1191	178	116.9
		Hispanic	153	35	1478.4	179	14	221.1	525	61	85.9
		Asian	41	7	1434.6	45	7	971.5	115	9	68.5
Other		32	8	1593.0	36	5	513.8	104	9	93.9	
Overall		2253	559	1084.8	2547	359	390.8	9330	1184	98.3	
Overall		White	2323	577	1079.2	1927	275	411.1	7798	957	96.3
		Black	464	110	981.9	526	78	357.1	1308	189	116.5
		Hispanic	314	77	1328.0	231	18	205.9	619	77	97.0
		Asian	76	23	2677.0	59	8	867.2	131	10	68.5
	Other	60	16	2319.3	40	5	493.8	111	10	100.7	
Overall	3237	803	1115.1	2783	384	386.2	9967	1243	98.7		

Table 4. Deceased Donor Transplants Performed during 01/01/1995 - 06/30/2003
By Recipient, Age Group, Year of Transplant and Ethnicity

Age Group, TX Year	Recipient Ethnicity														Total	
	White		Black		Hispanic		Asian		Other		Total		# of TXs	% of TXs		
Pediatric	1995	175	65.3	45	16.8	36	13.4	7	2.6	5	1.9	268	100.0			
	1996	174	66.4	52	19.8	27	10.3	5	1.9	4	1.5	262	100.0			
	1997	195	71.2	40	14.6	30	10.9	5	1.8	4	1.5	274	100.0			
	1998	174	66.4	40	15.3	38	14.5	8	3.1	2	0.8	262	100.0			
	1999	153	61.2	58	23.2	25	10.0	7	2.8	7	2.8	250	100.0			
	2000	177	65.1	44	16.2	34	12.5	13	4.8	4	1.5	272	100.0			
	2001	154	56.6	47	17.3	58	21.3	10	3.7	3	1.1	272	100.0			
	2002	177	61.9	39	13.6	50	17.5	11	3.8	9	3.1	286	100.0			
	2003	81	57.0	22	15.5	30	21.1	2	1.4	7	4.9	142	100.0			
	Total	1,460	63.8	387	16.9	328	14.3	68	3.0	45	2.0	2,288	100.0			
	Adult	1995	1,696	81.7	215	10.4	114	5.5	27	1.3	23	1.1	2,075	100.0		
		1996	1,669	81.2	252	12.3	88	4.3	28	1.4	19	0.9	2,056	100.0		
		1997	1,631	81.9	211	10.6	105	5.3	26	1.3	18	0.9	1,991	100.0		
1998		1,654	80.9	242	11.8	104	5.1	21	1.0	23	1.1	2,044	100.0			
1999		1,519	79.7	250	13.1	90	4.7	32	1.7	15	0.8	1,906	100.0			
2000		1,479	78.0	241	12.7	119	6.3	27	1.4	30	1.6	1,896	100.0			
2001		1,449	76.3	259	13.6	130	6.8	33	1.7	28	1.5	1,899	100.0			
2002		1,390	76.1	256	14.0	119	6.5	29	1.6	33	1.8	1,827	100.0			
2003		668	75.5	142	16.0	52	5.9	11	1.2	12	1.4	885	100.0			
Total		13,155	79.3	2,068	12.5	921	5.6	234	1.4	201	1.2	16,579	100.0			



Age Group, TX Year	Recipient Ethnicity												Total	
	White		Black		Hispanic		Asian		Other					
	# of TXs	% of TXs	# of TXs	% of TXs	# of TXs	% of TXs	# of TXs	% of TXs	# of TXs	% of TXs	# of TXs	% of TXs	# of TXs	% of TXs
Total	1,871	79.9	260	11.1	150	6.4	34	1.5	28	1.2	2,343	100.0		
1995	1,843	79.5	304	13.1	115	5.0	33	1.4	23	1.0	2,318	100.0		
1996	1,826	80.6	251	11.1	135	6.0	31	1.4	22	1.0	2,265	100.0		
1997	1,828	79.3	282	12.2	142	6.2	29	1.3	25	1.1	2,306	100.0		
1998	1,672	77.6	308	14.3	115	5.3	39	1.8	22	1.0	2,156	100.0		
1999	1,656	76.4	285	13.1	153	7.1	40	1.8	34	1.6	2,168	100.0		
2000	1,603	73.8	306	14.1	188	8.7	43	2.0	31	1.4	2,171	100.0		
2001	1,567	74.2	295	14.0	169	8.0	40	1.9	42	2.0	2,113	100.0		
2002	749	72.9	164	16.0	82	8.0	13	1.3	19	1.9	1,027	100.0		
2003	14,615	77.5	2,455	13.0	1,249	6.6	302	1.6	246	1.3	18,867	100.0		



Table 5A. Kaplan-Meier Patient Survival Rates by Transplant Year and Recipient Ethnicity for Pediatric Deceased Donor Transplants Performed during 01/01/1995 - 12/31/2001

Year of TX	White			Black			Hispanic		
	No. of TXs	1yr Surv [95% CL]	3yr Surv [95% CL]	No. of TXs	1yr Surv [95% CL]	3yr Surv [95% CL]	No. of TXs	1yr Surv [95% CL]	3yr Surv [95% CL]
1995	175	77.9 [71.7, 84.1]	74.3 [67.7, 80.8]	45	70.6 [57.2, 84.0]	59.2 [44.7, 73.7]	36	94.4 [87.0, 100.0]	88.6 [78.1, 99.1]
1996	174	86.5 [81.4, 91.7]	82.9 [77.2, 88.5]	52	80.2 [69.2, 91.2]	64.2 [50.9, 77.4]	27	81.2 [66.3, 96.1]	77.1 [61.0, 93.2]
1997	195	86.4 [81.6, 91.3]	80.7 [75.0, 86.4]	40	77.0 [63.7, 90.2]	65.6 [50.3, 80.8]	30	83.0 [69.3, 96.6]	72.4 [56.1, 88.7]
1998	174	86.7 [81.6, 91.7]	81.8 [76.0, 87.6]	40	82.1 [70.1, 94.1]	74.0 [60.1, 87.9]	38	89.3 [79.3, 99.2]	80.9 [68.1, 93.6]
1999	153	80.8 [74.5, 87.1]	76.0 [69.1, 82.8]	58	89.5 [81.6, 97.5]	78.2 [67.3, 89.2]	25	88.0 [75.3, 100.0]	83.8 [69.3, 98.3]
2000	177	88.5 [83.8, 93.3]	83.4 [77.5, 89.3]	44	86.4 [76.2, 96.5]	76.5 [63.6, 89.3]	34	100.0 [100.0, 100.0]	96.0 [88.3, 100.0]
2001	154	85.4 [79.8, 91.1]		47	79.8 [67.9, 91.6]		58	89.7 [81.8, 97.5]	
Overall	1202	84.7 [82.7, 86.8]	80.0 [77.7, 82.4]	326	81.1 [76.8, 85.4]	69.0 [63.8, 74.3]	248	89.8 [86.0, 93.6]	83.6 [78.7, 88.5]

Year of TX	Asian			Other			Overall		
	No. of TXs	1yr Surv [95% CL]	3yr Surv [95% CL]	No. of TXs	1yr Surv [95% CL]	3yr Surv [95% CL]	No. of TXs	1yr Surv [95% CL]	3yr Surv [95% CL]
1995	7			5			268	79.6 [74.7, 84.4]	74.0 [68.7, 79.3]
1996	5			4			262	84.0 [79.5, 88.5]	77.1 [71.9, 82.3]
1997	5			4			274	84.0 [79.6, 88.4]	76.7 [71.6, 81.9]
1998	8			2			262	86.4 [82.3, 90.6]	79.9 [75.0, 84.9]
1999	7			7			250	83.0 [78.3, 87.7]	77.0 [71.7, 82.3]
2000	13			4			272	89.9 [86.3, 93.5]	83.6 [78.9, 88.4]
2001	10			3			272	85.7 [81.5, 89.9]	
Overall	55	84.5 [74.5, 94.5]	71.7 [57.2, 86.2]	29	79.2 [64.3, 94.0]	64.7 [45.3, 84.1]	1860	84.7 [83.0, 86.3]	78.2 [76.2, 80.1]

Note: "-" indicates that survival rates were not computed due to number of alive recipients less than 10

Table 5B. Kaplan-Meier Patient Survival Rates by Transplant Year and Recipient Ethnicity for Adult Deceased Donor Transplants Performed during 01/01/1995 - 12/31/2001

Year of TX	No. of TXs	White			Black			Hispanic		
		Yr Surv [95% CL]	3Yr Surv [95% CL]	No. of TXs	Yr Surv [95% CL]	3Yr Surv [95% CL]	No. of TXs	Yr Surv [95% CL]	3Yr Surv [95% CL]	
1995	1696	84.6 [82.8, 86.3]	77.7 [75.7, 79.7]	215	85.5 [80.7, 90.2]	74.6 [68.8, 80.5]	114	90.4 [84.9, 95.8]	83.3 [76.5, 90.2]	
1996	1669	86.9 [85.3, 88.5]	79.7 [77.8, 81.6]	232	76.6 [71.3, 81.8]	62.6 [56.5, 68.6]	88	77.3 [68.5, 86.0]	70.2 [60.6, 79.8]	
1997	1631	85.9 [84.2, 87.6]	78.8 [76.8, 80.8]	211	78.0 [72.3, 83.6]	71.1 [64.9, 77.3]	105	84.5 [77.6, 91.5]	76.6 [68.3, 84.8]	
1998	1654	85.1 [83.4, 86.9]	78.7 [76.8, 80.7]	242	85.9 [81.5, 90.3]	73.7 [68.1, 79.2]	104	84.4 [77.4, 91.4]	76.3 [68.0, 84.6]	
1999	1519	84.5 [82.7, 86.3]	78.4 [76.3, 80.5]	250	82.7 [78.0, 87.4]	73.9 [68.4, 79.4]	90	78.7 [70.2, 87.2]	74.1 [64.9, 83.2]	
2000	1479	84.6 [82.7, 86.4]	78.5 [76.3, 80.7]	241	85.3 [80.8, 89.8]	74.9 [69.3, 80.5]	119	87.0 [80.9, 93.2]	80.4 [72.7, 88.1]	
2001	1449	86.5 [84.7, 88.2]		259	83.7 [79.2, 88.2]		130	82.6 [75.9, 89.2]		
Overall	11097	85.4 [84.8, 86.1]	78.8 [78.0, 79.6]	1670	82.5 [80.7, 84.4]	71.7 [69.4, 73.9]	750	83.9 [81.2, 86.5]	76.6 [73.5, 79.8]	

Year of TX	No. of TXs	Asian			Other			Overall		
		Yr Surv [95% CL]	3Yr Surv [95% CL]	No. of TXs	Yr Surv [95% CL]	3Yr Surv [95% CL]	No. of TXs	Yr Surv [95% CL]	3Yr Surv [95% CL]	
1995	27	88.1 [75.4, 100.0]	83.9 [69.4, 98.4]	23	82.6 [67.1, 98.1]	73.1 [54.7, 91.6]	2075	85.0 [83.5, 86.5]	77.7 [75.9, 79.5]	
1996	28	92.3 [82.1, 100.0]	84.1 [69.8, 98.4]	19	94.7 [84.7, 100.0]	83.6 [66.6, 100.0]	2056	85.4 [83.8, 86.9]	77.3 [75.5, 79.1]	
1997	26	95.8 [87.8, 100.0]	83.3 [68.4, 98.2]	18	83.3 [66.1, 100.0]	83.3 [66.1, 100.0]	1991	85.1 [83.5, 86.6]	78.0 [76.1, 79.8]	
1998	21	71.4 [52.1, 90.8]	71.4 [52.1, 90.8]	23	95.2 [86.1, 100.0]	95.2 [86.1, 100.0]	2044	85.2 [83.6, 86.7]	78.1 [76.3, 79.9]	
1999	32	81.3 [67.7, 94.8]	74.9 [59.8, 90.0]	15	80.0 [59.8, 100.0]	80.0 [59.8, 100.0]	1906	83.9 [82.2, 85.5]	77.6 [75.7, 79.4]	
2000	27	83.9 [69.3, 98.4]		30	92.7 [83.0, 100.0]		1896	84.9 [83.3, 86.6]	78.3 [76.3, 80.2]	
2001	33	90.3 [79.9, 100.0]		28	85.4 [72.2, 98.6]		1899	85.9 [84.3, 87.4]		
Overall	194	86.5 [81.5, 91.4]	79.6 [73.6, 85.6]	156	88.2 [83.1, 93.3]	83.5 [77.4, 89.6]	13867	85.0 [84.4, 85.6]	77.9 [77.2, 78.6]	

Note: "-" indicates that survival rates were not computed due to number of alive recipients less than 10

Table 6. VAD Use at Listing for Registrations Added to Waiting List during 01/01/1995 - 06/30/2003

Age Group, Ethnicity	WL Period: 01/01/1995 - 01/19/1999						WL Period: 01/20/1999 - 06/30/2003											
	Status 1		Status 2		Status 1A		Status 1B		Status 2		Total							
	# of REGs	% of REGs	Total	# of REGs	% of REGs	Total	# of REGs	% of REGs	Total	# of REGs								
Pediatric	White	23	2.7%	837	1	0.3%	400	1,237	33	4.6%	720	1	0.7%	151	2	0.6%	349	1,220
	Black	10	4.6%	217	0	0.0%	114	331	10	4.9%	204	0	0.0%	45	0	0.0%	104	353
	Hispanic	8	5.0%	160	0	0.0%	70	230	9	4.8%	189	1	1.7%	59	0	0.0%	86	334
	Asian	1	3.2%	31	0	0.0%	11	42	2	5.0%	40	1	6.3%	16	0	0.0%	15	71
	Other	0	0.0%	12	0	0.0%	7	19	2	5.7%	35	0	0.0%	4	0	0.0%	9	48
	Total	42	3.3%	1,257	1	0.2%	602	1,859	56	4.7%	1,188	3	1.1%	275	2	0.4%	563	2,026
Adult	White	504	13.3%	3,791	41	0.6%	7,423	11,214	658	32.5%	2,025	212	9.9%	2,143	83	1.5%	5,506	9,674
	Black	64	9.2%	694	3	0.3%	1,063	1,757	95	26.0%	366	39	6.8%	573	5	0.6%	904	1,843
	Hispanic	20	7.5%	268	1	0.2%	453	721	48	26.1%	184	12	5.4%	222	1	0.2%	406	812
	Asian	12	18.5%	65	0	0.0%	90	155	13	27.7%	47	7	14.3%	49	3	2.9%	105	201
	Other	13	17.1%	76	0	0.0%	80	156	14	33.3%	42	1	2.3%	44	4	4.2%	95	181
	Total	613	12.5%	4,894	45	0.5%	9,109	14,003	828	31.1%	2,664	271	8.9%	3,031	96	1.4%	7,016	12,711
Total	White	527	11.4%	4,628	42	0.5%	7,823	12,451	691	25.2%	2,745	213	9.3%	2,294	85	1.5%	5,855	10,894
	Black	74	8.1%	911	3	0.3%	1,177	2,088	105	18.4%	570	39	6.3%	618	5	0.5%	1,008	2,196
	Hispanic	28	6.5%	428	1	0.2%	523	951	57	15.3%	373	13	4.6%	281	1	0.2%	492	1,146
	Asian	13	13.5%	96	0	0.0%	101	197	15	17.2%	87	8	12.3%	65	3	2.5%	120	272
	Other	13	14.8%	88	0	0.0%	87	175	16	20.8%	77	1	2.1%	48	4	3.8%	104	229
Total	655	10.6%	6,151	46	0.5%	9,711	15,862	884	22.9%	3,852	274	8.3%	3,306	98	1.3%	7,579	14,737	

Table 7. VAD Use at Time of Transplant for Deceased Donor Transplants Performed during 01/01/1995 - 06/30/2003 by Recipient Age Group, Ethnicity, Transplant Period and Medical Urgency Status at Transplant

Age Group, Ethnicity	TX Period: 01/01/1995 - 01/19/1999						TX Period: 01/20/1999 - 06/30/2003											
	Status 1			Status 2			Status 1A			Status 1B			Status 2					
	On VAD	% of TXs	Total	On VAD	% of TXs	Total	On VAD	% of TXs	Total	On VAD	% of TXs	Total	On VAD	% of TXs	Total			
Pediatric	White	37	7.2%	513	0	0.0%	207	720	44	9.2%	480	4	3.4%	116	1	0.7%	141	737
	Black	15	11.4%	132	0	0.0%	49	181	18	12.9%	139	0	0.0%	26	0	0.0%	38	203
	Hispanic	2	2.2%	92	1	2.5%	40	132	9	7.1%	126	1	2.8%	36	0	0.0%	34	196
	Asian	2	11.8%	17	1	14.3%	7	24	2	8.3%	24	0	0.0%	11	0	0.0%	8	43
	Other	1	8.3%	12	0	0.0%	3	15	2	8.7%	23	0	0.0%	4	0	0.0%	3	30
Total	57	7.4%	766	2	0.7%	306	1,072	75	9.5%	792	5	2.6%	193	1	0.4%	224	1,209	
Adult	White	719	15.8%	4,553	7	0.3%	2,164	6,717	787	36.1%	2,178	430	17.5%	2,463	2	0.1%	1,780	6,421
	Black	108	15.4%	701	1	0.4%	226	927	157	36.6%	429	66	13.5%	488	0	0.0%	217	1,134
	Hispanic	34	12.0%	283	0	0.0%	135	418	53	30.3%	175	14	6.8%	206	0	0.0%	120	501
	Asian	10	13.7%	73	0	0.0%	31	104	13	24.5%	53	4	8.9%	45	0	0.0%	31	129
	Other	5	7.4%	68	0	0.0%	18	86	11	27.5%	40	7	15.9%	44	0	0.0%	31	115
Total	876	15.4%	5,678	8	0.3%	2,574	8,252	1,021	35.5%	2,875	521	16.1%	3,246	2	0.1%	2,179	8,300	
Total	White	756	14.9%	5,066	7	0.3%	2,371	7,437	831	31.3%	2,658	434	16.8%	2,579	3	0.2%	1,921	7,158
	Black	123	14.8%	833	1	0.4%	275	1,108	175	30.8%	568	66	12.8%	514	0	0.0%	255	1,337
	Hispanic	36	9.6%	375	1	0.6%	175	550	62	20.6%	301	15	6.2%	242	0	0.0%	154	697
	Asian	12	13.3%	90	1	2.6%	38	128	15	19.5%	77	4	7.1%	56	0	0.0%	39	172
	Other	6	7.5%	80	0	0.0%	21	101	13	20.6%	63	7	14.6%	48	0	0.0%	34	145
Total	933	14.5%	6,444	10	0.3%	2,880	9,324	1,096	29.9%	3,667	526	15.3%	3,439	3	0.1%	2,403	9,509	

Donation Rates For Kidney Transplant in US
Minority and Underserved Populations



Ross B. Isaacs, MD
Center for Improvement of Minority Health
University of Virginia

INTRODUCTION

Diabetes and HTN have become modern pandemics of the new millennium and are increasing rapidly in many of the underserved populations throughout the world leading to excess CAD, CVD, & CKD and premature death.

Introduction

CKD has become an epidemic especially in minority and underserved populations in the US

Introduction

- 20 million CKD patients
- Minorities have 2-3x rates of CKD as Caucasians
- ↓ rate CKD in working poor and uninsured secondary to barriers to access to care, excess burden of diseases and ↑ rate of progression.

Prevalence of Diabetes
United States 2003

<u>Ethnicity</u>	<u>% Ethnic Group</u>	<u>Relative Risk</u>
Caucasian	7.8%	1.0
African American	13%	2.0
Hispanic	10.2%	1.9
Native American	15.1%	2.6
Native Hawaiians	14%	2.5

ADA, 2003



Introduction

Purpose: To assess donor rates for LD and CAD kidney transplants in the southeastern US by race, ethnicity and socioeconomic status using UNOS registry and US Census Data from 200-2002

Methods

- Assessed STE status by counting US Census data with donor, zip code data; n = 80,648,083
- Variables assessed
 - Ethnicity
 - Age
 - Gender
 - Education level
 - Income level
 - Employment status

Results USRDS Ethnicity

	SE US	Living Donor	Wait List	Tx Pts
Cauc.	64.0	66	60.9	62.8
AA	18.6	17.8	20.8	19.7
Hisp	13.5	12.2	14.4	13.7
Other	0.9	0.9	0.8	0.8
Asian	1.7	1.7	1.7	1.6

* = Weight %

Results Income

	All SE US	USRDS	CAD	LD	WC	Tx
Above Poverty	85.5		85.4	86.4	84.8	85.3
Below Poverty	14.5		14.5	13.5	15.1	14.7

Conclusions

- Patients donate at rates similar to representation in US population but different from ESRD rates by ethnicity and socioeconomic status
- Data from the working poor currently being evaluated.

Conclusions

- Patients donate at rates similar to representation in US population but different from ESRD rates by ethnicity and socioeconomic status
- Data from the working poor currently being evaluated.

Conclusions

More efforts are needed to encourage earlier referral for transplantation and ↑ LD for the uninsured CKD population.



Universal Coverage

"There are now almost 45 million uninsured – about the same as the entire population of Canada plus Australia. . . Major change will be required. Any viable plan for the future needs to be based on universal coverage"

Garson, A.
JACC, 2000

"I find the greatest thing in this world not so much where we stand, as in what direction we are moving. To reach the port ... we must sail sometimes with the wind, and sometimes against it, but we sail, and not drift, nor live at anchor."



- O. W. Holmes -



Minority Access for Diabetes Replacement Therapy



Ross Isaacs, MD
 Center for Improvement of Minority Health
 Department of Medicine
 University of Virginia

INTRODUCTION

Diabetes has become a pandemic of the new millennium and is increasing rapidly in many of the underserved populations throughout the world.

Global Perspective - 2003



- 44 million people infected with HIV
- 177 million people affected by DM
- 300 million people expected to have DM by 2025

Diabetes Atlas , IDF

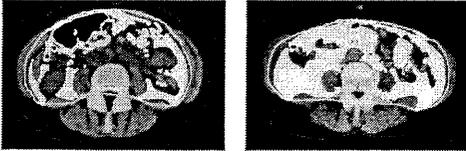
Global Perspective -1995-2025



- 170% Increase developing world
- 47% Increase developed world

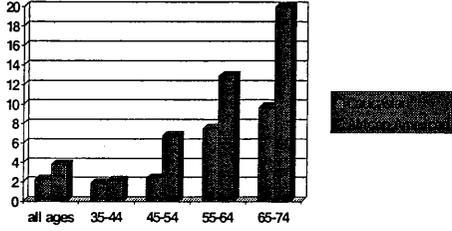
Diabetes Atlas, 2000, IDF

Visceral Fat Distribution: Normal vs Type 2 Diabetes



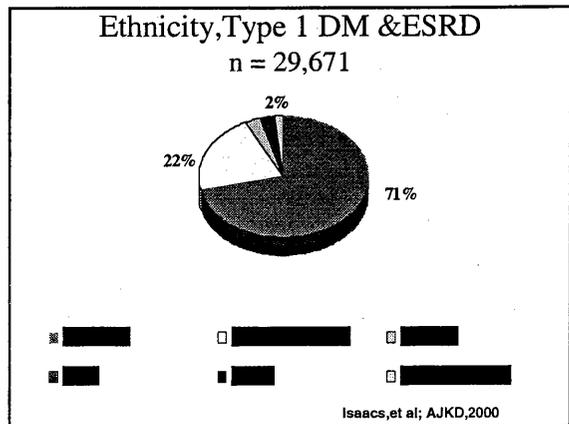
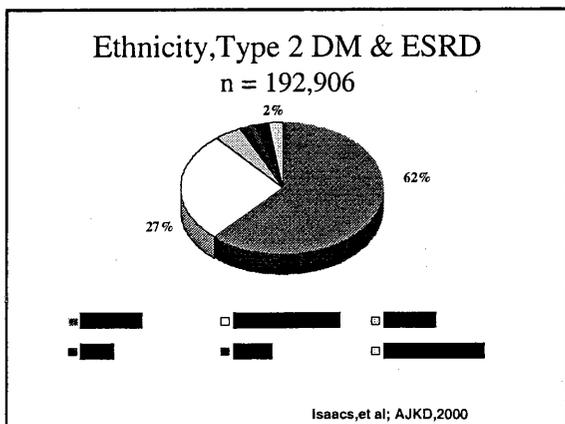
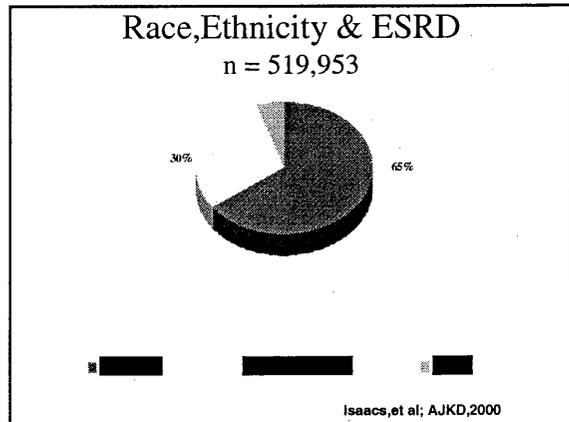
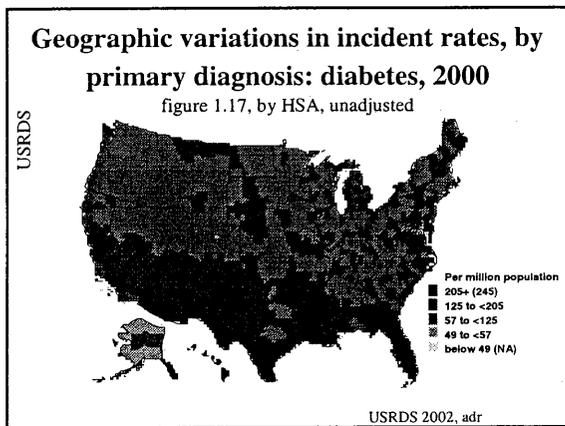
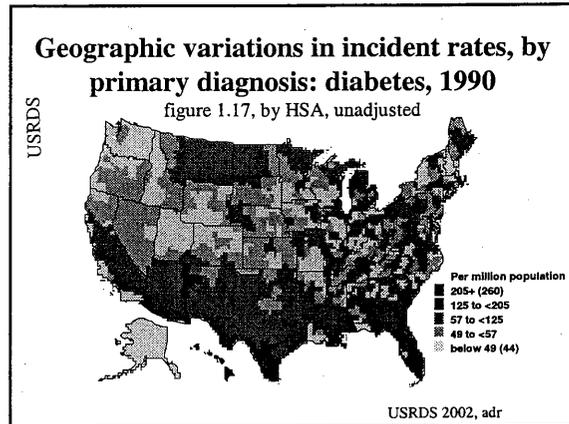
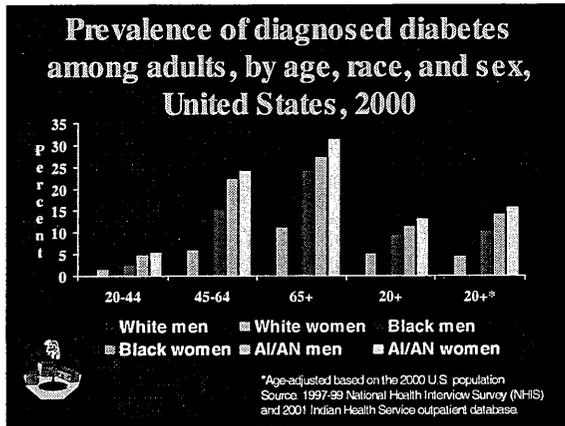
Normal
Type 2 Diabetes

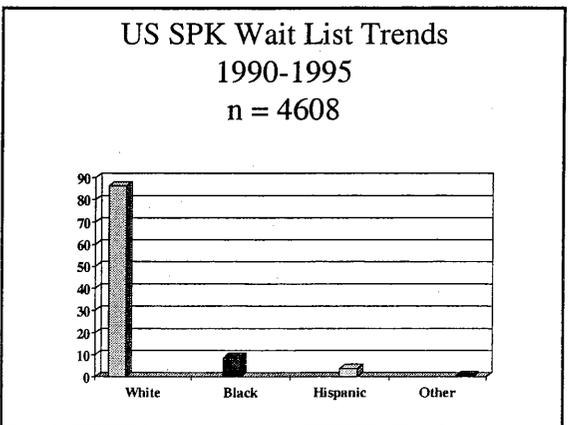
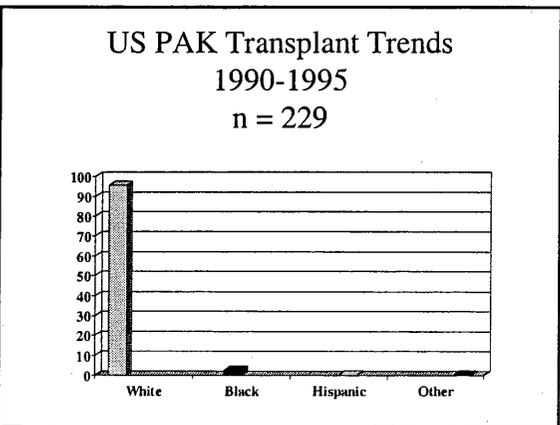
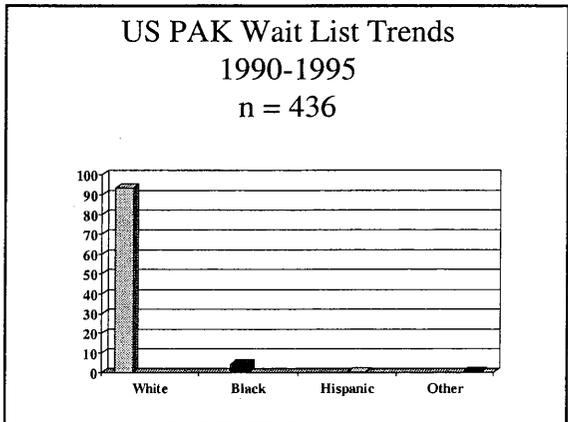
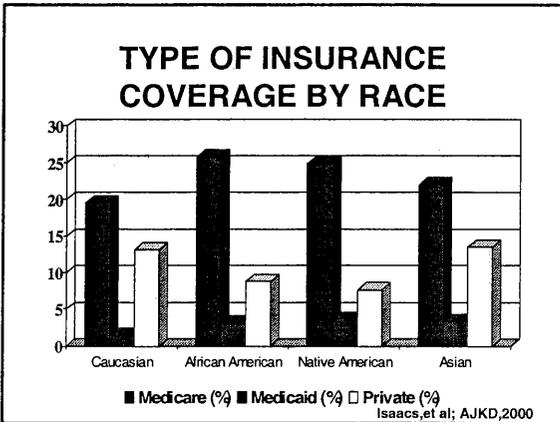
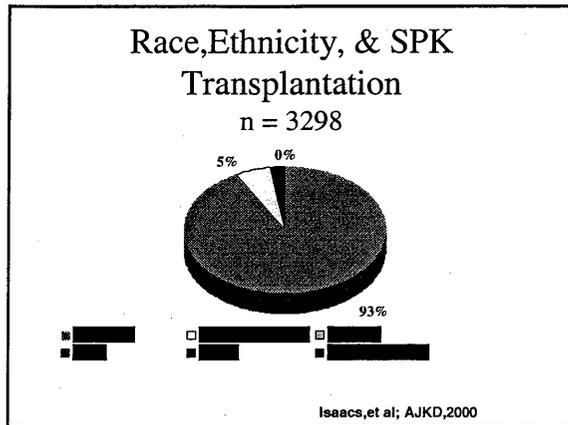
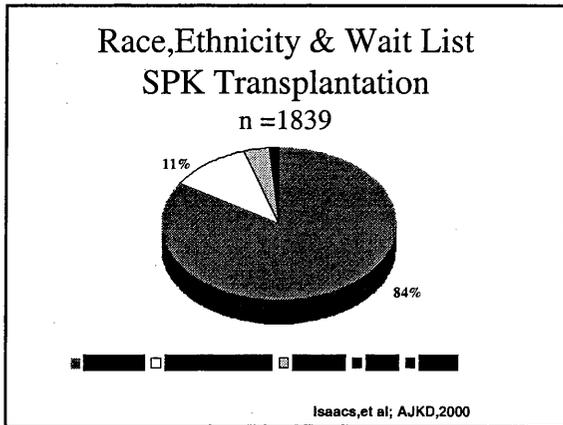
Percent of Caucasians and African Americans with Diabetes by Age

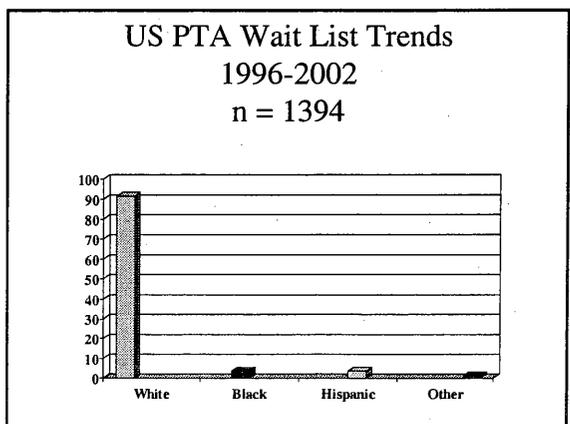
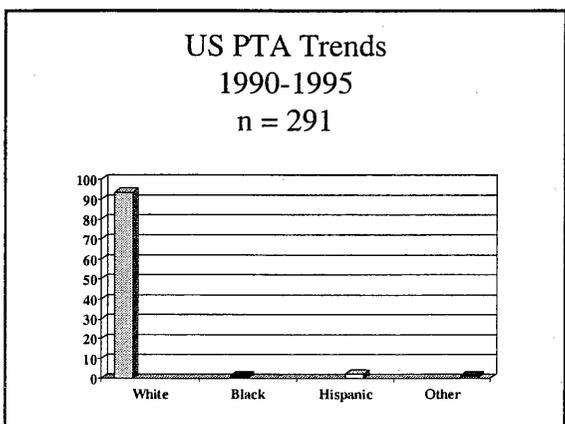
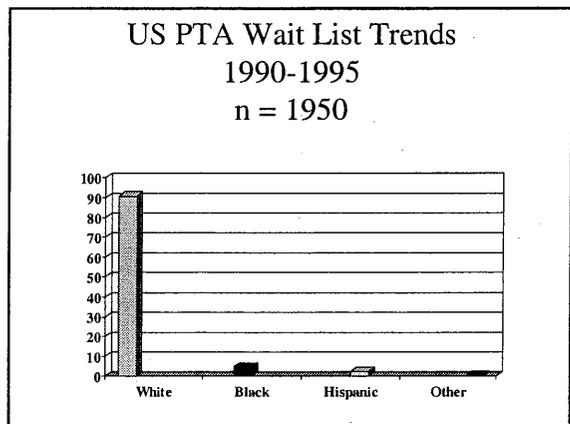
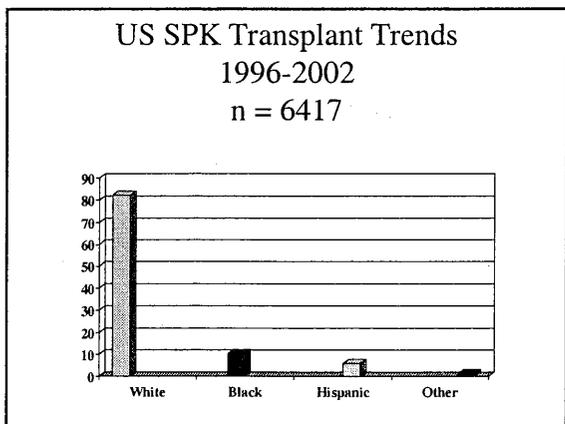
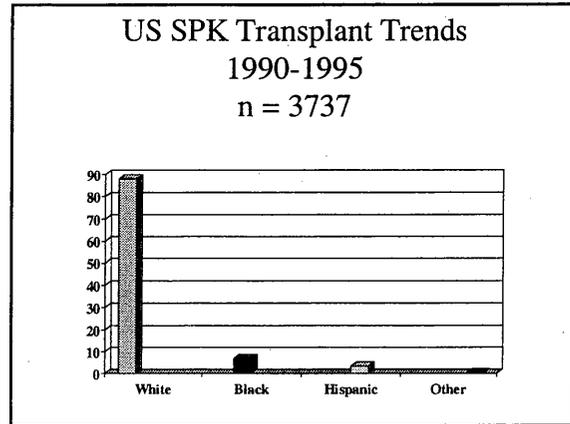
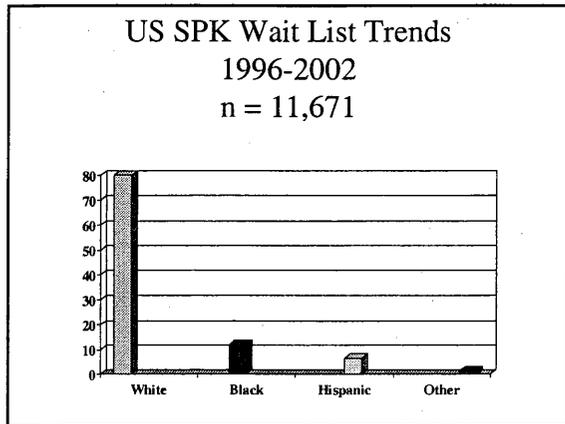


Age Group	Caucasians (%)	African Americans (%)
all ages	~3	~4
35-44	~2	~3
45-54	~4	~7
55-64	~8	~13
65-74	~10	~20

Source: Data from National Vital Statistics System, Health, United States, 1996-97







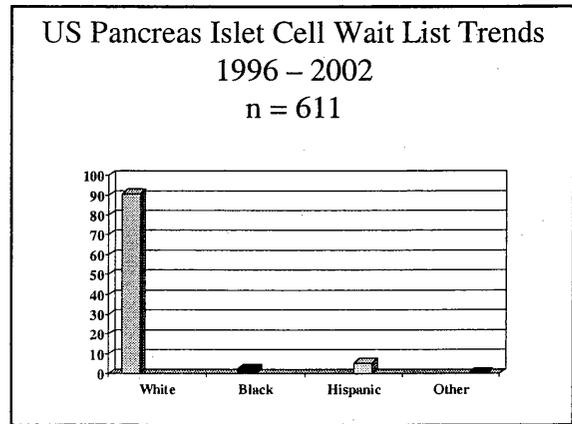
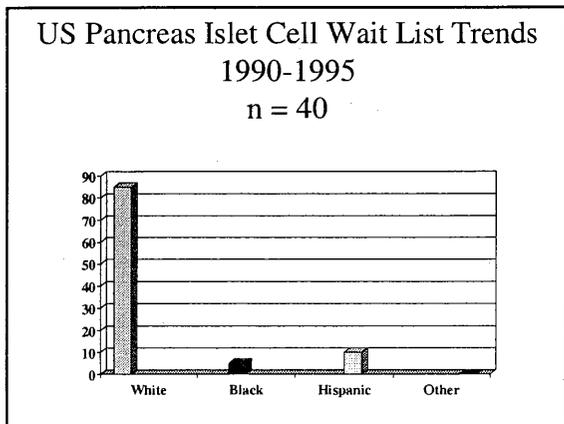
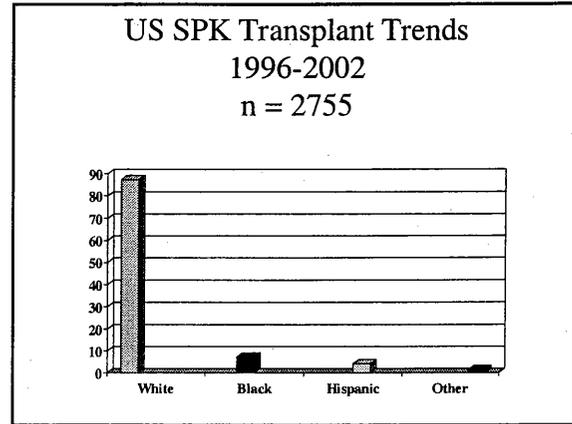
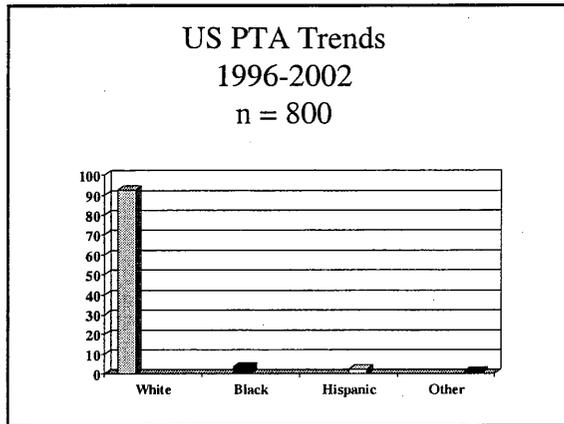


Table 2: SPK 5 yr. Outcomes

	1990 - 1995	1996-2000
Caucasian	65%	70%
African American	66%	63%
Hispanic	68%	73%

CONCLUSIONS

Diabetes has become a major public health crisis in minority and underserved populations both in the US and abroad.

CONCLUSIONS

PTA and islet cell wait listing and transplantation remain under utilized in high risk minority populations.

CONCLUSIONS

Conversely, SPK and PAK wait list and transplant trends are slowly improving for minority populations although disparities in diabetic and renal healthcare persist.

CONCLUSIONS

More efforts are urgently needed to promote earlier referral for either SPK,PAK,PTA, or PITx for high risk diabetic minority populations, especially when the organs used to save such lives come for individuals of all racial, ethnic and socioeconomic backgrounds.

"I find the greatest thing in this world not so much where we stand, as in what direction we are moving. To reach the port ... we must sail sometimes with the wind, and sometimes against it, but we sail, and not drift, nor live at anchor."



- O. W. Holmes -

