

OPTN/UNOS Minority Affairs Committee
Report to the Board of Directors
November 16-17, 2009
Orlando, FL

Summary

Action Items for Board Consideration

- None

Other Significant Items

- The Committee will present the Final Report of the Dialysis Facility Public Comment Opinion Survey to the Board. (Item 4, Page 5)
- The Committee is pursuing publication of an article summarizing all of the data and issues it has examined over the last decade. (Item 3, Page 3)
- The Committee is pursuing publication of an article examining transplant outcomes in minority patients. (Item 3, Page 3)
- The Committee has distributed a Survey on Referral to the Kidney Waitlist to review specific activities being undertaken by centers to improve referral and waitlisting rates. (Item 6, Page 12)
- The Committee is developing a Survey on Referral to the Liver Waitlist to explore barriers to liver referral and waitlisting for different ethnic groups. (Item 8, Page 13)

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**Report of the OPTN/UNOS Minority Affairs Committee to the Board of Directors
November 16-17, 2009
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**Henry Randall, MD, Chairman
Silas Norman, MD, Vice-Chairman**

This report includes items addressed by the Minority Affairs Committee at its meetings held on March 27 and July 14, 2009.

1. Executive Summary of the Meeting of the Board of Directors.

During its meetings on March 27, 2009, and July 14, 2009, the Committee was provided with brief updates and a summary of relevant actions from the March 2-3, 2009, and June 22-23, 2009, meetings of the Board of Directors in Houston, TX and Richmond, VA.

2. 2009-2010 Committee Goals

During the July meeting, the Committee was referred to the finalized goals for the 2009-2010 year. The Committee was informed that the goals were developed by the incoming OPTN President and Senior Staff with input from Committee Liaisons and Committee Chairs. It was noted that the final goals incorporate Board and strategic priorities as well as ongoing Committee activities. The Committee goals are as follows:

- Publish papers reviewing work and accomplishments of the Committee over the years and analyzing transplant outcomes in minority patients.
- Complete surveying component of the Dialysis Facility Public Comment Opinion Survey; issue findings and publish as appropriate; propose future actions as appropriate.
- Monitor progress of ongoing kidney allocation policy development and provide input as efforts and a potential proposal evolve.
- Monitor progress of ongoing development and implementation of OPTN Kidney Paired Donation Program, to ensure that potential implications of the program for minority populations are addressed. Participate in the development of educational resources related to the Kidney Paired Donation program.

Provide minority population perspectives to other Committees as they develop policies aimed at reducing geographic/regional variation in access to transplantation.

3. MAC Review Articles

To support the Committee objective to build upon the body of evidence to improve minority access to transplantation, the Committee began preparing a comprehensive review of its work over the last decade. The article would encompass many issues related to minority transplantation through various dedicated subject areas. The Committee hopes to distribute the information in the public arena so as to initiate a dialogue with a broader community than the OPTN membership. The article would add to the body of literature, encourage discussion, and attempt to substantiate or refute concerns commonly raised.

The initial Subcommittee met and prepared a draft outline of the topics to be covered in the paper. The paper would focus on the following three major areas: 1.) Minority access to transplantation; 2.) Minority organ donation trends; and, 3.) Minority transplant outcomes. The SRTR offered to submit the article to the American Journal of Transplantation (AJT) for inclusion in the Annual State of Transplantation series as a special interest piece. In a subsequent meeting, the format of the article was revised to comprise one paper with three topic areas to accommodate the space available in the AJT publication.

During discussion at the March Committee meeting, a member expressed concern that the broad focus areas would present inadequate coverage of the topics and may not provide enough information to be useful. It was responded that though the article would be more general in nature, information that is well-known in one community, may not have penetrated in another. For this reason the article could still provide important information to those outside of the transplant community. Another Committee member commented on the fact that changes in allocation policy would not address the underlying problem of the organ shortage, particularly for minorities who are overrepresented on the ESRD waiting list. It was responded that there is a need to continue to dispel the myths of organ donation and better inform the public about the strides that have been made in minority donation. It is not well known by the public that the rate of minority donation actually exceeds the ratio in which minorities are represented in the population. Though the prevalence of ESRD in the minority community is much greater than in other populations, the burden should not be placed upon that population to match their representation on the waiting list. However, the message should be conveyed that the community's efforts are having an impact and that though there have been significant advances made, minority donation efforts should continue. Recognition of the successes made in minority donation should complement policy efforts aimed at improving access to transplantation.

A member remarked that the Health Resources and Services Administration (HRSA) continues to invest money in projects aimed at improving donation rates. There will also be a forum at the National Medical Association (NMA) addressing front line physicians on issues related to minority organ donation and transplantation to encourage them to become advocates. It was suggested that Ms. Parker forward the information about this meeting to the group when it is made available.

During the July meeting, Dr. Fan updated the Committee on the status of the paper. The Committee was informed that a decision was made to change the focus of the article from a review manuscript with three sections, to a paper on minority transplant outcomes only. It was also noted that there is a substantial amount of information in the published literature on minority transplantation and donation. However, there is not as much in the literature examining minority transplant outcomes. Because the article is proposed to be included in the American Journal of Transplantation as part of the SRTR contract deliverable, it has the benefit of additional SRTR financial resources. Additionally, articles utilizing original research, data, and analysis are preferred by the SRTR Technical Advisory Committee and HRSA, and would be more likely to be accepted for publication. The original authors are also contributing to the outcomes article, and two additional authors representing the Committee and the SRTR have also been included.

The outcomes article will review transplant trends for minorities as well as outcomes. The SRTR is currently developing models to analyze the differences in transplant outcomes by ethnicity and racial group, as currently African Americans experience poorer graft and patient survival and the reasons for this are unclear. The modeling approach will examine patient specific factors and compare these to characteristics that are more removed from the patient to determine possible reasons for the differences. The article will also contain much of the information that the Committee has viewed over the years. The Committee will continue to pursue efforts to publish the original article as part of

its annual goals; however, that project would not necessarily require SRTR resources. The Review Article Subcommittee will be reconvened to review the original topic areas considered for the paper to determine if changes need to be made.

A Committee member inquired whether compliance would be considered as a factor in the paper. It was responded that the article will only consider factors for which there is data. Compliance is not well defined and can be multi-factorial. It is also not necessarily a patient factor and could represent financial issues, lack of access to support or care, lack of access to medication, etc. It was suggested that this global issue could be redefined as medical non-adherence of which non-compliance is a subset but could also include other components (financial, educational, etc.) Another member suggested that the Committee define areas where data is not available and direct the appropriate institutions to either define the data or change the dataset so that in the future the questions asked are able to be answered. Another member commented that it would also be helpful for the Committee to define the parameters of what it intends to examine to assist policymaking in these areas.

4. Dialysis Facility Public Comment Opinion Survey

For the past several years, the Committee has expressed concern with regard to the inclusiveness of public comment and the possibility that important allocation policy decisions were being made without the input of specific affected patient populations. In 2004, the Board of Directors approved a survey of dialysis patients to 1.) Collect baseline information on public perception of organ allocation policy and 2.) Assess public knowledge of the ability to provide input into the development of these policies through public comment. It was intended that results of the survey would provide some insight into public awareness of transplant policies and potentially identify demographic differences. It was also hoped that the survey results would facilitate refinement of the public comment process and support the development of public education and outreach initiatives.

During the March meeting, Dr. Fan presented preliminary results from the dialysis survey to the Committee. The responses appear to document limited understanding of organ allocation policies and very limited participation in public comment among dialysis patients. During discussion, Committee members noted that most patients appeared to have been approached about receiving a transplant; however, there were differences in the level of patient education and understanding about transplantation and awareness of public comment. The Committee discussed whether or not this was a result of inadequate information and education provided to patients. It was commented that lack of patient referral is only one barrier to transplantation; how the information on transplantation is presented to the patient is equally important. Culturally competent patient education about transplantation could increase the likelihood that the patients who are referred attend their meetings, evaluations, etc. The survey results could present an opportunity for additional education in this area.

Members also briefly discussed where the responsibility for appropriate patient education should reside. The debate centered upon whether this should be the responsibility of the dialysis unit or the transplant nephrologist. One Committee member remarked that in her unit, patients may be delayed waiting on the sign off from the nephrologist before being listed. It was suggested that the Committee could engage the American Society of Nephrology (ASN) and the National Kidney Foundation (NKF) for assistance in addressing patient education and referral. There could be a study of practice patterns or an educational forum or session at upcoming meetings, etc. It was further suggested that the community should refocus its thought processes on transplantation as the standard of care therapy with dialysis serving primarily as the bridge therapy.

The Committee also discussed the possibility of additional governmental controls. One member suggested that the government could decrease the amount of dialysis funding once the patient has been evaluated and has been on dialysis for a year, as incentive for centers to broach transplantation as an option for patients. This way, all patients would be referred, and it would be the responsibility of the transplant center to decide who is an appropriate candidate. It was responded that there is no End State Renal Disease (ESRD) mandate or definition as to how transplant options should be presented to the patient. This area is not within the OPTN purview and so ultimately, additional government regulation may be required. It was further commented that HRSA does not have jurisdiction in this area and that the Centers for Medicare Services (CMS) has authority over reimbursement issues. It was suggested that this issue could be added to the list of ongoing OPTN issues regarding CMS.

The Committee also discussed the appropriate role of public comment, given the knowledge about limited patient involvement. It was suggested that the public comment process should be used only as a forum for the dissemination of ideas and as a way to distribute points useful in a policy debate. Members expressed strongly that the system should not be viewed as an election or a public opinion poll and that responses should not be considered to be representative of the transplant community or patient population as a whole. The appropriate role of public comment in the policy development process should be defined or clarified.

In July, the Committee viewed the final results from the Minority Affairs Committee Dialysis Facility Survey Final Report, presented by the project consultant, Cleve Corlett, Ph.D, principal of BrandPlanning, Inc. (**Exhibit A**).

The survey methods consisted of a self-administered, anonymous written survey of 154 patients in seven dialysis facilities in Alabama (AL) and Massachusetts (MA). There were 100 completed questionnaires returned in MA and 54 received from AL. The questionnaires were developed in both English and Spanish versions. Survey administration and data entry was provided by UNOS staff or designee with data analysis conducted by BrandPlanning, Inc.

Highlights of the final results include the following:

Patient Characteristics

- 80% of African Americans in this study reside in Alabama
- 97% of Caucasians in this study reside in Massachusetts
- The Massachusetts participants are older than the Alabama participants

Age 65 or Older

<u>African American</u>	<u>Caucasian</u>
11%	46% (Significant difference)

<u>Alabama</u>	<u>Massachusetts</u>
12%	39% (Significant difference)

- Large percentage retired or unemployed
 - 77% receive Medicare benefits
 - 57% have household incomes below \$25,000
 - 57% do not have Internet access
 - 14% do not have access to a phone

- Access to Internet and telephone does not vary by ethnicity for participants in this study
- One of the Alabama locations for data collection has an active social worker
 - When comparing differences between ethnicity, some patterns may reveal the positive effects of this social worker

Awareness & Interest

- 99% of all of the dialysis patients in this study are aware of kidney transplantation
 - This is true for both African Americans and Caucasians
- 84% have not received a kidney transplant
 - Does not vary significantly by ethnicity
- 77% are interested in having a kidney transplant
 - African Americans more interested than Caucasians (88% vs. 67%)

Evaluation & Waiting List

- 73% have had a discussion with a medical professional about kidney transplantation
 - Does not vary significantly by ethnicity
- 57% have been evaluated for a kidney transplant
 - Does not vary significantly by ethnicity
- Among patients who have not been evaluated
 - 42% believe they are too old
 - 33% believe they are not medically well enough
 - Virtually all of the patients who believe they are too old are age 65 or older.
- Among those who have been evaluated, 70% are on a waiting list
 - African Americans who have been evaluated are more likely to be on a waiting list than Caucasians (76% vs. 55%, at the at the 90% confidence level)

Patient Interest in Having a Kidney Transplant

<u>African American</u>	<u>Caucasian</u>
88%	67% (Significant difference)
<u>Alabama</u>	<u>Massachusetts</u>
86%	2% (Significant difference)

Patients on the Waiting List (of those evaluated)

<u>African American</u>	<u>Caucasian</u>
76%	55% (Significant at 90% confidence)
<u>Alabama</u>	<u>Massachusetts</u>
89%	59% (Significant difference)

Organ Allocation

- 74% believe they have a “good” or “fair” understanding of the policies for kidney allocation
- 19% have no understanding of these policies
 - This finding does not vary significantly by ethnicity
- 59% believe the policies for kidney allocation are “very” or “somewhat” fair
- 33% do not know if these policies are fair or not

- These findings do not vary significantly by ethnicity
- 60% of patients believe kidney allocation practices are fair
- 37% do not know if kidney allocation practices are fair or not
 - These findings do not vary significantly by ethnicity

Public Comment

- 85% are unaware of the public comment process
- African Americans are significantly more likely to be aware of this public comment process than Caucasians (22% vs. 5%)
 - Effect of active social worker in AL?
- Only 2% of these dialysis patients have ever used the public comment process
 - This finding is consistent across all the demographic groups examined in this study

Public Comment Barriers

- Among those who have not used the public comment process, 79% are unaware of its existence
- Other common barriers:
 - Not knowing how to get a copy of the proposed policy (23%)
 - Belief that doctors are more qualified to make policy decisions (22%)
 - Unawareness of the public comment process and not knowing how to get a copy of the proposed policy is consistent across all demographic groups
 - Belief that doctors are more qualified than patients to make policy decisions is significantly higher among Caucasians than African Americans (29% vs. 13%)

Public Comment Interest

- 76% of these patients are “very” or “somewhat” interested in expressing their opinions on proposed kidney allocation policies
 - African Americans are more interested than Caucasians in expressing their opinions (85% vs. 63%)
- Among patients who are not interested in expressing their opinions:
 - 77% believe doctors are more qualified than they are for making policy decisions
 - 23% do not believe their opinions would be taken seriously
 - African Americans are more likely to believe that their opinions won’t be taken seriously (33% vs. 7% among Caucasians)
 - Caucasians are more likely to believe that doctors are more qualified than they are to make these policy decisions (96% vs. 64% among African Americans)

Awareness of Public Comment Period

<u>African American</u>	<u>Caucasian</u>
22%	5% (Significant difference)
<u>Alabama</u>	<u>Massachusetts</u>
20%	13% (Higher, but not statistically significant)

Interest in Public Comment Period

<u>African American</u>	<u>Caucasian</u>
85%	63% (Significant difference)

Alabama
86%

Massachusetts
70% (Significant difference)

Public Comment Modes

- 54% would like to express their opinions during the public comment process through postal mail
- 33% would like to express their opinions via telephone
- 26% would like to express their opinions via email
 - 57% do not have Internet access and 63% do not have email
 - Caucasians are more likely to prefer email than African Americans (34% vs. 20%, at the 90% confidence level)

The Committee discussed some of the highlights of the survey results. One member questioned whether the differences shown could be explained by age and inquired about the possibility of extracting information from the dataset to show comparisons within subgroups by age. It was responded that the sample sizes were too small for comparison, and the reliability of the results would be low. Another member commented that the survey results seem to demonstrate the importance of patients being informed about their transplant option. Further, the results corroborate with data on preemptive transplantation, as these patients are more likely to be informed about options by physicians. The member also noted that of those evaluated, the waiting list frequency for African Americans was better than for Caucasians. He reported that some older published data showed that African Americans had only about a 50% likelihood of completing their evaluations and moving on to becoming waitlisted, as compared to their Caucasians counterparts. He remarked that this suggests that previously published study results were probably not intrinsic to the minority population but probably more due to external factors.

The Committee reiterated concerns about the role of public comment. Members commented on the disparate views of the various publics represented in public comment as well as their possible individual agendas. Because the study revealed only scattered minority participation in public comment, it should not be assumed that the views expressed correlate with the general views of the population. Members reflected upon a past proposal whereby the Board of Directors seemed to oppose a proposal primarily based upon negative sentiment expressed during public comment. Members commented on the need to solicit feedback from the mainstream public as well as from the transplant community.

The Committee was informed that an abstract of the dialysis survey project was submitted for verbal report to the American Society of Multicultural Health and Transplant Professionals (ASMHTP) and will also be submitted for publication by Dr. Young and Dr. Fan. The feedback from external publics will be helpful in assisting the Committee in developing appropriate initiatives.

5. Update on Development of a Kidney Allocation System (KAS)

During the March meeting, Silas Norman, MD, Minority Affairs Committee liaison to the Kidney Transplantation Committee, provided the MAC with an update on developments following the KAS public forum held January 26, 2009 in St. Louis, MO. The Committee was informed that 93 responses to the RFI were received and 9 organizations representing transplant professionals, patients, and histocompatibility experts weighed in at the forum.

Although support for various elements of the proposal was expressed, particularly the use of the Donor Profile Index (DPI) in place of standard criteria donor/expanded criteria donor (SCD/ECD) designations, as well as the use of dialysis time in place of waiting time; the public expressed very

limited support for Life Years from Transplant (LYFT) overall. At this time, the Kidney Committee plans to investigate data elements to determine what data need to be collected to estimate survival and convene an expert panel to discuss cardiovascular disease risk assessment. The Committee plans to convene a focus group to discuss allocation and revamp existing communication materials. There are also plans to discuss modeling proposed alternatives, including donor/recipient age matching as well as an examination of different combinations of DPI/donor age/LYFT/candidate age.

The Committee briefly reviewed data showing the index of concordance model or c-statistic. The c-statistic is a measure of how well a clinical prediction rule can correctly rank order patients by risk. The purpose of the presentation was to demonstrate that despite the perceptions, the criticisms of the model made by the public are not data based.

The Committee discussed the need to refocus the patient education and communication message. It was expressed that the primary barrier to acceptance of the concepts presented is that the overall patient population has not been convinced that the change is worthwhile and that they should make a personal sacrifice for the benefit of the majority. Until the conversations begin to address this area, the proposal and its related concepts will not be supported. The Committee discussed the possibility of losing the modest gains in minority transplantation that may have been realized under the proposed concepts should the proposal be significantly delayed. The Committee also noted and discussed the public support for specific parts of the proposal. Following the discussion, the Committee voted unanimously to approve and forward the following resolution to the Kidney Committee:

Resolved, the Minority Affairs Committee supports implementation of the various elements of the KAS concepts, specifically dialysis time and the donor profile index, if the current proposal for KAS will be significantly delayed. The MAC recognizes that the use of LYFT is in question and would like the minority patient population to be able to receive the benefits of implementation of elements such as dialysis time and/or DPI, while the community continues to debate the merit of the concept of LYFT in a revised kidney allocation system.

Committee vote: 11, 0, 0

In July, Dr. Norman provided an update on the KAS proposal following the June Board meeting (**Exhibit B**). Feedback from the public forum regarding proposed concepts incorporating LYFT indicated that there was support for the use of ESRD/dialysis time, and the donor profile index; however, there was not as much support for the use of LYFT in general. Concerns noted by participants during the Kidney Allocation Forum were difficulty predicting patient survival with or without a transplant as well as graft survival for average candidates, limited use of data to calculate LYFT, complexity of a system incorporating LYFT, DPI, and DT; difficulty in predicting waiting time; and concerns regarding the ability to transition existing candidates to a new system. Due to these concerns, the Board recommended that the Kidney Committee not embark upon a pilot study using KAS, but focus on incremental changes to the proposed formula. They were directed to incorporate renal failure time and DPI into the new proposed system, focusing on the benefit portion. As a starting point, they were also advised to address the problem of donor kidneys projected to survive the longest being allocated to relatively short-lived recipients.

Dr. Norman reported that following the May 12, 2009, meeting of the Kidney Committee, the group determined:

- DT would be installed as the backbone of the new system;
- Allow time to accrue from GFR<20;
- Utilize recipient post transplant survival as an outcomes measure;

- Allocate the top 20% DPI kidneys to candidates with top 20% projected post-transplant survival;
- Use survival projections for patient education; and
- Remove priority for HLA matching.

The presentation was followed by Committee discussion. A member of the Committee inquired about the integrity of the remaining kidneys after the 20% highest DPI kidneys were removed from the donor pool and allocated according to the proposed concepts, especially considering the fact that pediatric candidates already receive priority and would receive additional priority because they are expected to live longer. The SRTR responded that the KAS proposal will only impact adult recipients and available kidneys, so the 20% of kidneys allocated to the top ranked DPI candidates would come from the remaining population of 70% or so of organs not allocated to pediatric candidates and multi organ transplant candidates. It was noted that DPI would be based upon recovered organs. Further, the majority of mandatory sharing has already been eliminated so the intent is that the system would not include paybacks.

The Committee discussed the outlook for candidates with lower LYFT scores. A member of the Committee inquired whether there was going to be any consideration given to creating a list of candidates at the lowest 20% threshold ranking in terms of extra survival expectations. The member expressed concern that these lower ranked patients will probably not be eligible to receive a transplant. The member further commented that it would be an error on the part of the Kidney Committee to focus on the best outcome for candidates but ignore utilization of organs with DPI's that are not considered acceptable according to the KAS formula. This will probably result in additional organ discards. It was responded that the Committee was primarily focused upon providing for the top 20% of kidneys to be allocated to recipients with the highest expected survival and not the shortest expected survival. It was also remarked that there would probably be a high discard rate but these organs are already being discarded presently.

The SRTR explained that the fundamental difference between this new direction and the old is that a candidate's relative place on the spectrum of LYFT would become more obvious. The previous LYFT calculations did not distinguish between patients with similar characteristics, as it was intended that these patients would have similar LYFT scores. However, in this new approach, there would be distinct boundaries between patients. Patients with less projected post transplant survival will not receive extra LYFT and because they do not receive as many extra years of life under the new KAS, they may not be included in the pool to receive organs. For example, a candidate falling within the 19.9% access group for organs would be eligible to receive a kidney; however, a candidate falling within the 21.1% access group will now be excluded from receiving these kidneys. A question was also asked whether Type I diabetics would be negatively impacted under the new system. It was responded that Type I diabetics had high LYFT scores due to their disease, although their absolute survival benefit was not as great. The model; however, would need to separate out SPK candidates and determine where Type 1 pancreas candidates would fit.

Another member commented that consent in this area will be challenging since DPI is much less transparent than ECD/SCD designations, though it is a much more practical application of the concept. The Kidney Committee will need to give additional thought as to how this would be explained. This new direction could be a useful tool to help in determining organ quality for decision making purposes and for resource utilization. It was suggested that this feedback should be given to the Kidney Committee. A member of the Committee inquired as to whether the HHS Office of Civil rights has made a determination with regard to whether LYFT concepts constitute age discrimination. It was reported that there has been no feedback as of yet.

The Committee reflected on the fact that there has been a considerable change in the attitude of the transplant community over the years. It was 2003 when the MAC and Kidney Committees distributed the proposal to award priority for waiting time beginning at the initiation of chronic dialysis or GFR greater than 20. At the time, the transplant community was strongly against this proposal. However, with the introduction of the LYFT concepts, the community seems to be more receptive and supportive of establishing dialysis time as a legitimate factor to be included in the kidney allocation system and an improvement to current allocation rules. It was remarked that the Committee may have lost the battle but won the war. If approved, this direction could become one of the more important OPTN policy changes addressing equity and fairness of the system.

6. Subcommittee on Referral to Kidney Transplantation

The Committee has been exploring ways to examine the factors related to referral rates and delays for patients getting onto the kidney waitlist. Subsequently, the Committee formed a Subcommittee on Referral to Transplantation that is currently reviewing evidence and other activities being undertaken by centers geared toward increasing referral and wait listing rates.

During its March meeting, the Committee discussed a very preliminary draft list of questions to submit to transplant centers to inquire about any activities they may be performing to ensure that suitable patients are referred and evaluated for transplantation. The purpose of the questionnaire would be to identify best practices occurring in this area. After Committee discussion, several additional questions/issues were added to the list and will be refined when the Subcommittee reconvenes.

Additional issues/questions added include:

- Centers who are delaying referrals based on financial eligibility;
- Centers where referrals are delayed based on ability to see the transplant surgeon.

One Committee member shared that her center is currently conducting a pilot program examining referral to listing time. The program emphasizes a specialized transplant education process. She reported that the program has received positive feedback from patients and that referral rates in the center are rising. There was interest from the Committee in examining this program further, as well as programs operated in other localities.

Following the March meeting, the draft survey was reviewed by a staff member in the UNOS Research department with expertise in Key Survey, a customized survey software program. The purpose of the review was to determine how the questions might be converted into an electronic format supported by the survey software. A subgroup of the Committee met on May 15, 2009 to respond to specific questions from the staff specialist based on her review.

During the July meeting, the full Committee was provided with a demonstration of the online survey instrument. The Committee was informed that the final survey should be distributed within the next month.

Pilot: Pre-Transplant Referral to Waitlisting Process – North Carolina Baptist Hospital

The Committee was provided with an update on the pilot project initiated by a former Committee member, examining improving referral to listing time for kidney transplantation. The project has also been submitted to ASMHTP as an abstract. The Committee expressed interest in following this project as it directly addresses some of the issues the referral survey hopes to capture.

7. Kidney Paired Donation (KPD)

In November 2008, the Committee viewed a detailed presentation outlining the background, history and concepts incorporated in the Board approved KPD pilot program. During the discussion, members of the Committee expressed concern regarding the proposed inclusion of factors in the KPD program that are known to disadvantage minority candidates, specifically awarding points for HLA and zero antigen mismatches. These factors were deemphasized in the proposed new kidney allocation system and members questioned why they were being included in the KPD program. As a result, the Committee requested to view the results of KPD computer simulations showing the percentage of minorities matched in the system that were eventually transplanted through KPD.

During the March meeting, Dr. Cherikh presented the Committee with data from the KPD simulations which showed that the additional points awarded for zero mismatches in the KPD system did not affect the number of minorities matched through the KPD system (**Exhibit C**). Dorry Segev, MD and Sommer Gentry, Ph.D, were both available via teleconference to respond to questions about the simulations. Though the simulations do not show a negative impact on minorities matched through KPD, it was remarked that minorities do not have the same access to the system due to their difficulty in locating a suitable living donor. It was suggested that the program would need to be monitored for accessibility due to its potential to increase transplantation rates for candidates enrolled in the system.

In July, the Committee viewed a brief overview of the background, history and concepts incorporated in the Board approved KPD pilot program for the benefit of the new Committee members. Dr. Norman, outgoing KPD liaison to the Committee, presented the summary to the Committee.

The Committee reiterated the need for KPD monitoring to be able to determine who is enrolling in the program. It was recommended that the program have UNOS oversight and review at regular intervals. Members expressed interest in viewing a demographic breakout of the number of minorities currently enrolled. It was suggested that the MAC request to view the reports the Kidney Committee receives on KPD. The Committee will request access to this data for review and monitoring.

8. Examination of Issues Regarding Geographic Variation in Organ Allocation

Share 29 Review

The “Share 29” liver policy was implemented in Region 8 on 5/9/07. Under this allocation sequence, livers from adult donors would be shared regionally for adult and pediatric candidates, except for candidates with exceptions. At the March 27 meeting, the Committee was presented waiting list death rates, number of transplants and graft survival by status or MELD/PELD category and ethnicity in Region 8 before and after the implementation of the Share 29 policy (**Exhibit D**). The data showed that after the implementation of the “Share 29” policy in Region 8:

- Death rates went down (27 vs. 24) for the overall black population.
- Death rates for Status 1A/1B decreased for all ethnicities.
- Death rates increased for all ethnicities in the MELD/PELD 15-28 group.
- Death rates decreased for the Black and Hispanic populations in the MELD/PELD 29+ group but increased for White candidates.
- Median MELD/ PELD score at transplant seemed to increase slightly in the Hispanic population after the implementation of “Share 29” policy in Region 8.
- Seven-day graft survival rate seemed to decrease in the Black and Hispanic populations but remained comparable in the White population after “Share 29” policy implementation.

The Committee discussed the results. A member of the Committee remarked that once regional sharing was instituted, it appeared that the sicker African American patients began receiving livers as a result. However, another member responded that the geographic areas studied in Region 8 did not have large minority populations and so even small changes in the numbers would show a large impact graphically. Further, the policy illustrated that the Share 29 experiment was not based on data showing the significance of MELD score 29 as a cut point, except for the predicted mortality at those scores in those centers studied. It was noted that this observation might not translate nationally. The member commented that the center effect should be studied to determine what happened to the centers in those regions in terms of volume.

The Committee also discussed the case mix before and after the policy change. Waitlist characteristics both pre- and post-transplant may have changed with different patients listed. The Committee previously viewed MELD at time of initial waitlisting by ethnicity to determine if African Americans are sicker upon entering the waitlist. Following the discussion, the Committee requested to continue to be updated on characteristics of candidates and recipients, waiting list death rates, number of transplants and post-transplant survival, stratified by MELD/PELD scores and ethnicity, before and after Share 29 implementation.

MELD/PELD Scores by Region and Ethnicity

In July, the Committee was presented with liver waiting list death rates, the number of additions, and the number of transplants in different regions by MELD/ PELD (M/P) score and ethnicity. Death rates in various MELD/PELD categories were computed for all single organ liver candidates ever listed on the liver waiting list between 1/1/2006 and 12/31/2008, by region at listing and candidate ethnicity. Charlotte Carroll, MS, presented the information to the Committee (**Exhibit E**). The data showed the following:

Data highlights presented include the following:

- Across regions, the percent of new registrations of African American candidates ranged from 5% to 13%.
- Within status 1A, the percent of new African American registrations ranged from 4%-28% across regions.
- New registrations for Caucasians ranged from 54% to 84% across regions while, new registrations for Caucasians in Status IA ranged from 45% to 78% across regions.
- New registrations for Hispanics ranged from 3% to 29% across regions, while new registrations for Hispanics in Status IA ranged from 4% to 29%.
- Median MELD/PELD scores at listing across regions and ethnicity ranged from 14-18 and African Americans seem to have the higher MELD/PELD scores as compared to Caucasians and Hispanics.
- Median MELD/PELD scores at transplant across regions and ethnicity ranged from 21-30.