OPTN/UNOS Kidney Transplantation Committee
Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- Development of a Revised National Kidney Allocation System
  On December 3, 2007, the Kidney Transplantation Committee voted to circulate for public comment a new approach for kidney allocation. This approach incorporates time on dialysis, life years following transplant (LYFT), and donor factors into a kidney allocation score (KAS). (Item 1, Page 3)

- Update on Kidney Paired Donation
  The Committee reviewed progress on the efforts to develop a national kidney paired donation system. Current work includes the circulation of a request for information to all existing kidney paired donation to assess whether advances have been made since the proposal was circulated in June 2006. (Item 2, Page 13)

- Proposed Revisions to Pediatric Policy
  The Committee reviewed data following the implementation of the policy to direct kidneys from donors under the age of 35 preferentially to pediatric candidates. The Committee voted to circulate for public comment a proposal to provide additional priority for sensitized pediatric candidates. (Item 3, Page 13)

- Proposals Currently Circulating for Public Comment
  The Committee reviewed two proposals for public comment and provided feedback to the Living Donor Committee and the Membership and Professional Standards Committee regarding the Proposed Resource Document for the Medical Evaluation of Living Kidney Donors and proposal to document informal discussions in the bylaws. (Item 4, Page 14)

- Long Term Kidney Payback Debt Request
  The Committee reviewed a request from the Living Legacy Foundation of Maryland to review its long term kidney payback debt and to eliminate the current kidney payback system. (Item 5, Page 15)

- Clarification: California Transplant Donor Network (CADN) Alternative Allocation System
  The Committee reviewed supplemental documentation from the California Transplant Donor Network regarding its alternative allocation system. The Committee determined that CADN's practice of allocating kidneys (when only 1 kidney is available from a donor for local allocation) was acceptable. (Item 6, Page 15)

This page is intentionally left blank.

Report of the OPTN/UNOS Kidney Transplantation Committee
to the Board of Directors

February 20-21, 2008
Orlando, Florida

Peter G. Stock, MD, PhD, Chair
Kenneth A. Andreoni, MD, Vice Chair

1. Development of a Revised National Kidney Allocation System

During the December 3, 2007, Kidney Transplantation Committee meeting, the Committee continued its work to develop a proposal for a new, national kidney allocation system. Members focused on the results from the latest round of simulation modeling and worked through a series of proposal elements that had not yet been addressed. At the conclusion of this meeting, the Committee voted to circulate a proposal for public comment during the first quarter of 2008.

This report contains a number of acronyms. For the convenience of the reader, Table 1 contains those acronyms that are most widely used. Please refer to **Exhibit A** which contains all of the data considered by the Committee when reviewing the contents of this report.

DPI	Donor Profile Index
LYFT	Life Years From Transplantation
DY	Dialysis Years
KAS	Kidney Allocation Score

Table 1: Frequently used acronyms

Feedback from Other Committees and Organizations

As part of the ongoing efforts to communicate about the policy under development, members of the Committee shared feedback that they had received from other OPTN Committees and outside organizations regarding the development of a new kidney allocation system. The feedback from each of the groups is summarized in the Table 2 below.

Committee or Organization	Specific Recommendations
Patient Affairs Committee	• Need for transition planning, communication and education • Request for ways to significantly improve LYFT score by improving overall health (such as through weight loss)
Minority Affairs Committee	• Develop a plan for addressing geographic disparities in the foreseeable future • Develop a timeline for assessing the proposal and to correct for any unintended consequences
Ethics Committee	• Allocation system must not discriminate on the basis of age, race, or disease • Consider the unintended consequence of a decrease in living donor transplants for those with higher LYFT scores.
American Diabetes Association	• Concerns over data quality, especially regarding cardiovascular and diabetes data • Concerns over a decrease in transplants for Type II diabetics
American Society of	• A new allocation system:

Transplantation	o Needs to improve efficiency without overt discrimination against any group of patients. o Cannot be based on complex algorithms o Has to provide predictable timeline to transplant o More appropriate matching of donors and candidates o Prior to adoption, full public vetting of any policy proposal.

Table 2: Feedback from OPTN/UNOS Committees and Other Organizations

The Committee discussed further the American Diabetes Association (ADA) comments regarding data quality. While the Committee is working with the best available data on transplant recipients, candidates and organ donors, it also realizes that the data available for diabetic candidates and recipients are limited. For instance, in the LYFT calculation, a 50 year old type II diabetic patient without coronary artery disease has the same LYFT score as 50 year old type II diabetic who has advanced coronary artery disease (all else being equal). Robert Wolfe, PhD of the Scientific Registry for Transplant Recipients (SRTR) explained that the ADA recommended that additional data on coronary artery disease should be collected for the purposes of future policy development.

Possibilities for Improving Transplantation Rates

Finally, Dr. Stock shared with the Committee data on the percent of highest DPI kidneys transplanted within each donor service area (DSA) (Figure 1). These data indicate that there is a substantial variability in transplantation of kidneys from donors in the highest DPI category (from <5% to over 35%). One Committee member remarked that the focus should not be on the transplant rate of kidneys in this category, but on the number of kidneys that are procured and then transplanted in each DSA. In response, Committee member and Collaborative faculty member, Kevin O'Connor, shared some data from the Collaborative that indicated nationally, 82% of kidneys recovered during the first half of 2007 were transplanted. This rate varied by DSA from 95% procurement followed by transplantation to 61%. Dr. Stock asked the Committee to consider policies that would encourage OPOs to procure and transplant kidneys in the highest DPI category to increase the number of kidneys available for transplantation.

To provide further context, Dr. Leichtman of the SRTR explained that the kidney transplant waiting list increases by roughly 3,500 registrations each year and has done so over the past 10 years. However, the number of *active* candidates on the kidney transplant waiting list has not changed much over the past five years. There are only about 600 more active candidates on the list currently than in 2002. Dr. Leichtman explained that if there were only 600 more kidneys available per year, then the increase in the number of candidates on the active list would cease. In response to these data, the Collaborative has embraced the 7,000 kidney challenge, which states that if each DSA procures only 10 more kidneys per month, then it would eliminate the active waitlist within 10 years.

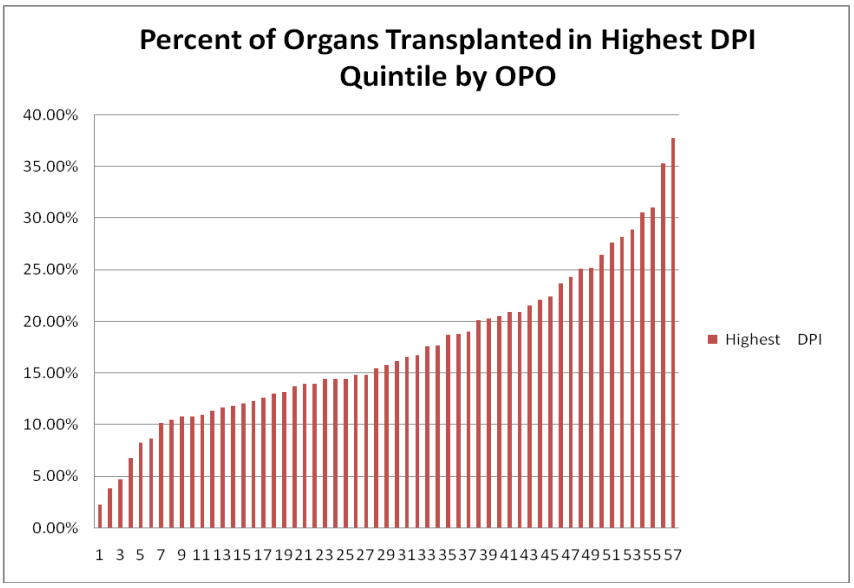

Figure 1

Review of Simulation Results

The Committee reviewed the most recent results from the Kidney-Pancreas Simulated Allocation System (KPSAM) (Exhibit A). Keith McCullough, MS, of the Scientific Registry for Transplant Recipients reviewed some of the decisions previously made by the Committee for the remaining category of simulation runs still under consideration:

1. <u>LYFT balanced with Dialysis Years</u> (Consensus choice from prior meeting):
    a. Incorporates all LYFT for SCD changes except instead of using LYFT for SCD, allocates all kidneys by the following formula:

    $$LYFT * (1-DPI) + DY * DPI + 4*PRA$$

    b. Kidney-pancreas (KP) candidates receive priority over all kidney-alone candidates

2. <u>LYFT alone for Standard Criteria Donor (SCD)</u> (for comparison):
    a. Eliminates paybacks
    b. Eliminates zero HLA mismatch priority and sharing
    c. Nationalizes the Committee sponsored alternative system to allow allocation of A_2 and A_2B kidneys to B candidates.
    d. Incorporates zero HLA MM sharing (but not priority) for PRA 80+
    e. Uses LYFT instead of waiting points for allocating SCD kidneys

3. <u>Current System</u> (for comparison):
    a. Current national kidney allocation system without any alternative systems or variances

Mr. McCullough explained that a few corrections have been made to the KPSAM runs regarding PRA since the last Committee review. Previous simulation results incorrectly used a factor of PRA * 1, instead of PRA * 4 in runs 18c-e. This has been corrected. Additionally, prior reports of KPSAM results for run 18c allocated ECD kidneys by dialysis years alone, rather than by the blended weighting of dialysis years and LYFT. This has been corrected in the current results.

The Committee reviewed results from new simulation runs (referred to as run numbers 25-28). Simulation run numbers in Table 3 correspond to the simulation run numbers provided in Exhibit A.

Table 3: Brief descriptions of new simulation runs reviewed by the Committee

Run Number	Brief Description
Run 25	• LYFT/DY+PRA*8: – Same as LYFT/DY except with PRA*8 instead of PRA*4 – Formula is: LYFT * (1-DPI) + DY * DPI + PRA*8
Run 26	• LYFT/DY + Reg PRA 80: – Same as LYFT/DY except candidates with PRA 80+ are put on all local lists in their region
Run 27	• LYFT/DY no HLA: – Same as LYFT/DY except LYFT is calculated without any HLA for PRA < 80 and with the only HLA factor being zero HLA MM for PRA 80+
Run 28	• 80%LYFT/DY: – Same as LYFT/DY except the maximum contribution of LYFT is 80% for the lowest DPI instead of 100% – Formula is: LYFT*0.8*(1-DPI) + DY*(0.8*DPI + 0.2) + PRA * 4

Table 4: Years of Life Expected with Modeled Allocation of Kidneys

	Current System	16a LYFT For SCD	18f LYFT/ DY	25 LYFT/ DY +PRA* 8	26 LYFT/ DY+Reg P80	27 LYFT/ DY noHLA	28 80% LYFT /DY
Number of candidates	80,549	80,549	80,549	80,549	80,549	80,549	80,549
Number of transplant recipients	9,124		9,111	8,899	7,448	9,031	9,035
Years after tx	107,865	143,505	122,140	116,013	100,109	120,820	118,133
Total graft yrs	72,814	86,614	75,600	72,555	61,082	74,691	73,772
Total extra life yrs	48,187	59,691	52,947	50,784	43,746	52,467	51,589
Δ years after tx		35,640	14,275	8,148	-7,757	12,955	10,268
Δ graft yrs		13,800	2,786	-259	-11,732	1,877	958
Δ extra life yrs		11,504	4,760	2,597	-4,441	4,280	3,402

Some Committee members questioned the decrease in number of transplants for runs 18f, 25-28 and how these decreases may affect the values for total lifespan, total graft years of life, and total extra years of life in Table 4. Mr. McCullough explained that when a kidney was turned down due to a positive crossmatch, that kidney was then offered to the next candidate on the list, even if the next candidate was not in the same OPO. After 200 turn downs, the kidney was discarded in the KPSAM run. Dr. Leffell remarked that this decline may be due to a bolus effect since highly sensitized candidates have lots of time on dialysis and therefore lots of priority in the new system. This effect should level out over time. Dr. Wolfe agreed that the decline in number of transplants appeared to be dramatic between the current system and runs 18f, 25-28, but that the candidate level data did not show a significant decline in LYFT as shown in Table 5.

Table 5: Extra Years of Life Due to Transplant by KPSAM Run

Years	Average Post-Tx Lifetime	Average Graft Lifetime	Average Extra Years of Life	Total Extra Years	KI + KP Tx
Run 1: Current nat. allocation system	11.8	8.0	5.3	48,187	9124
Run 16a: LYFT for SCD	15.0	9.1	6.2	59,691	9569
Run 18f: LYFT/DY	13.4	8.3	5.8	52,947	9111
Run 25: LYFT/DY+PRA*8	13.0	8.2	5.7	50,784	8899
Run 26: LYFT/DY+Reg P80	13.4	8.2	5.9	43,746	7448
Run 27: LYFT/DY no HLA	13.4	8.3	5.8	52,467	9031
Run 28: 80%LYFT/DY	13.1	8.2	5.7	51,589	9035

One member remarked that Run 27 (LYFT/DY no HLA) had no effect on the average extra years of life and that at the candidate level, retaining HLA in the LYFT calculation had no effect on patient survival. A member of the Committee remarked that while there may be no statistical impact on survival, HLA matching affects the type and level of immunosuppressive medication prescribed to recipients. Patient representatives on the Committee shared that the increased immunosuppression required for lesser matched kidneys has a diminishing effect on post-transplant quality of life. Therefore, the decision to maintain HLA matching in the system should be made based on both statistical results and clinical effect.

The results from KPSAM (Table 4) indicate that allocating all SCD kidneys by LYFT (Run 16a) adds about 11,500 years to the extra years of life obtained from a year's worth of kidneys. By balancing LYFT with dialysis years (Run 18f) this benefit is reduced to about 4,800 years and each modification simulated further reduces this benefit. Balancing LYFT with dialysis years (Run 18f) achieves or exceeds current kidney allocation outcomes to both moderately and highly sensitized candidates. LYFT balanced with dialysis years and regional sharing for sensitized candidates (Run 26) results in the greatest access for highly sensitized candidates, but reduces the number of kidney transplants (7,448 v. 9,111) as currently modeled with the acceptance models. When PRA is weighted by a factor of 8 (Run 25) the result is the next greatest access levels among moderately and highly sensitized candidates, but a reduction in the extra years of life from 4,800 to 2,600 . Removing HLA from the LYFT equation (Run 27) results in a distribution of recipient characteristics very similar to that of LYFT (with HLA) balanced by dialysis years(Run 18f), but results in reducing the extra years of life from 4,800 to 3,400. Finally, maximizing the LYFT contribution to the KAS at 80% (Run 28) results in increased transplants among candidates over the age of 50 (39% v. 36% of kidneys to 50+ in LYFT/DY) but also results in reduced extra years of life (3,400 v. 4,800). Figure 3 through Figure 6 provide distribution of kidney recipients by race, blood type, PRA, diagnosis and age by simulation run.

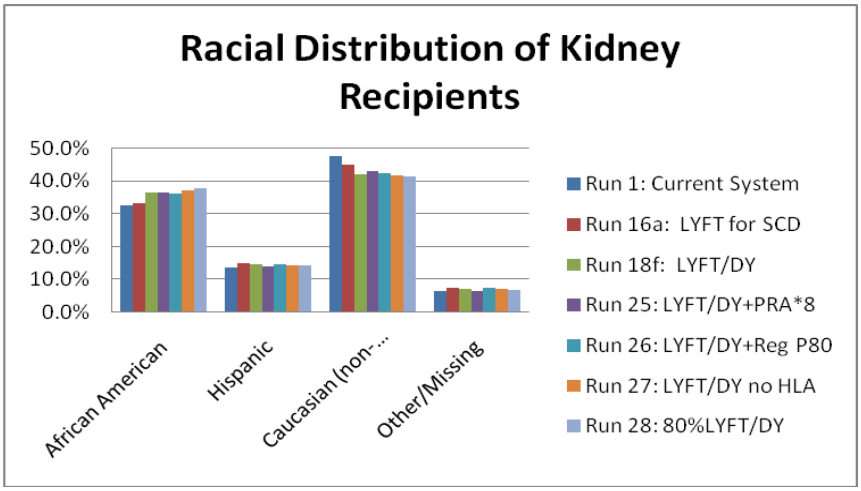

Figure 2

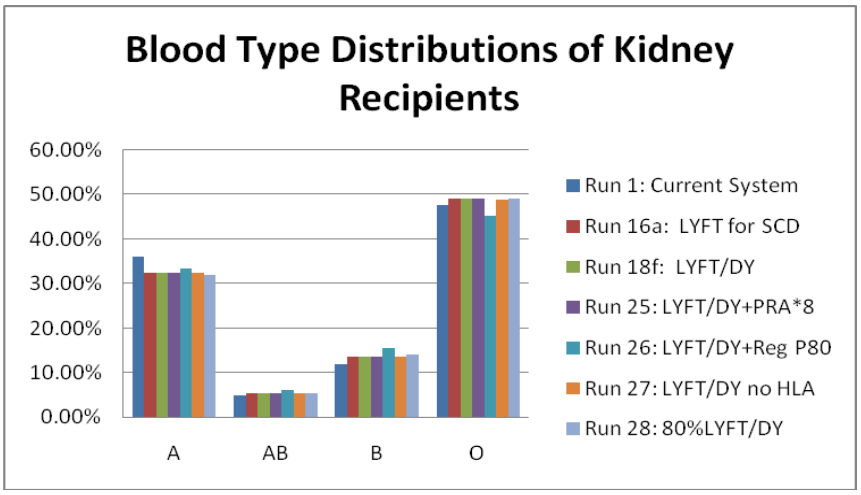

Figure 3

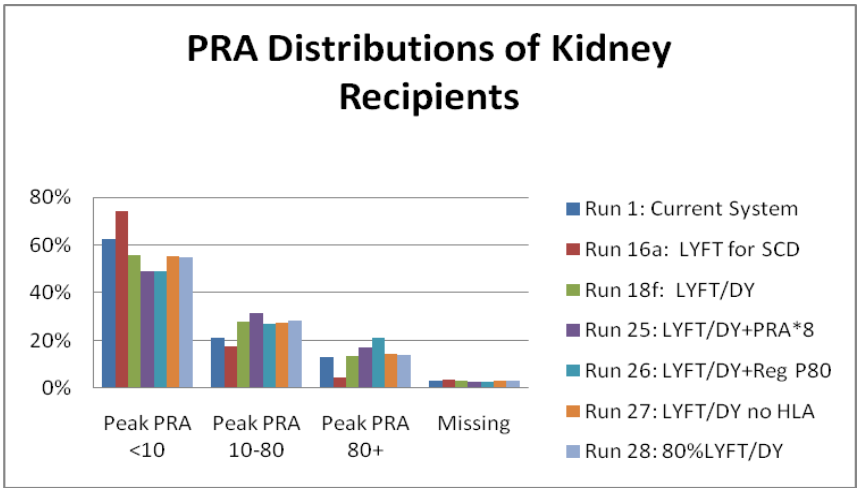

Figure 4

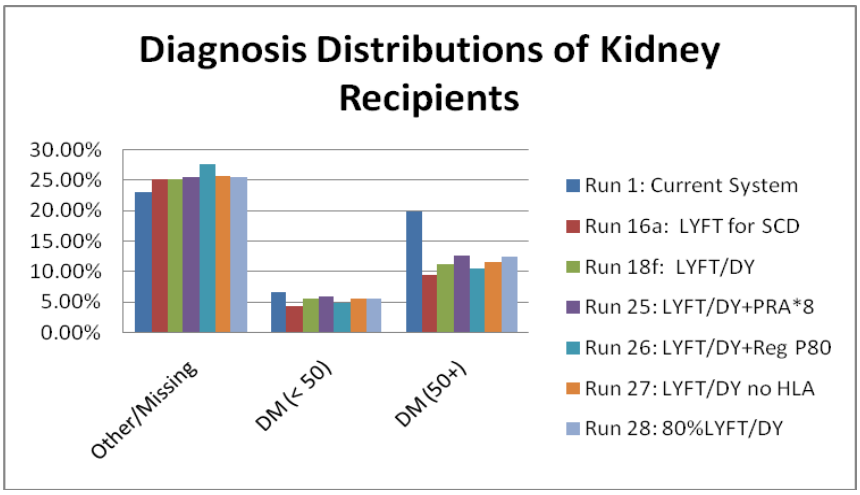

Figure 5

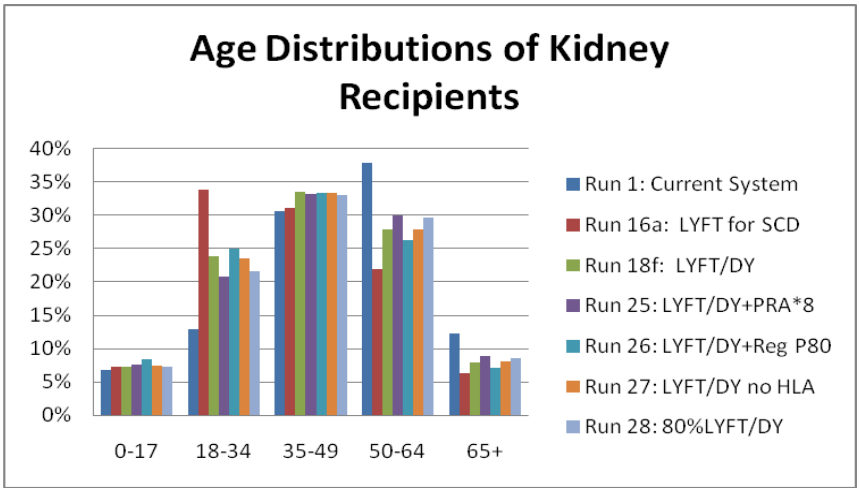

Figure 6

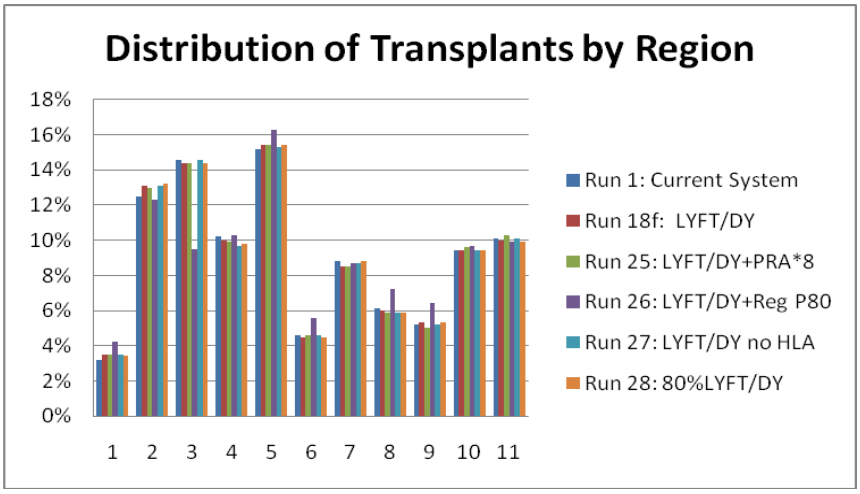

Figure 7

For future simulation modeling, Mr. McCullough explained that KPSAM will be able to produce results up to three years. These results will not be as accurate, as the assumptions about unchanging acceptance patterns and practice will be less valid over 3 years than 1 year, but they will be useful in evaluating size and duration of bolus effects.

The Committee focused its discussion on LYFT/DY (Run 18f), LYFT/DY without HLA (Run 27), and maximizing the LYFT contribution to the KAS at 80% (Run 28). Approximately half of the Committee members expressed that removing HLA-DR from the LYFT calculation (as in Run 27) would make kidney allocation more efficient, without a substantial reduction in life years. Others members expressed that HLA-DR matching may have increased importance for sensitized and pediatric candidates and that eliminating HLA-DR from the LYFT calculation may disproportionately affect these candidate groups. One member reminded the Committee that one of its criteria for including variables in the LYFT calculation was that the variable was significant both statistically and clinically. HLA-DR met this criterion and should therefore be retained in the LYFT calculation. Following discussion, the Committee voted on the following resolution:

*RESOLVED that HLA-DR be retained in the LYFT calculation, 23 in favor, 9 opposed, 0 abstentions.

The Committee discussed whether or not to hold the LYFT score constant at the time of listing. During past meetings, some Committee members expressed that the incremental decline in LYFT scores (due to increasing age and time on dialysis) would lead to conditions of hopelessness in some candidates. One Committee member remarked that LYFT is a predictor of survival and that by "fixing" the score, the measure will not accurately predict pre- or post-transplant survival. Another Committee member added that fixed LYFT scores would create access problems as candidates who are referred earlier in their course of treatment will have higher scores than those who are referred later, even if their biological characteristics are similar at a future point in time. Finally, several Committee members expressed any diminishment to a candidate's LYFT score will be more than compensated for by the inclusion of a candidate's time on dialysis as a separate allocation factor. Transition to a new system with LYFT scores fixed at listing would also be nearly impossible because of the nearly 70,000 candidates currently listed who may not have all the data necessary to calculate their LYFT scores at their times of listing. Following discussion, the Committee voted on the following resolution:

*RESOLVED, that the life years from transplantation (LYFT) score be held constant from each candidate's date of listing, 0 in favor, 30 opposed, 0 abstentions.

Figure 9 graphically depicts the interplay between LYFT and Dialysis Years (DY) based on donor profile index (DPI) in Run 18f. As shown on this graph, each candidate would receive an allocation weight comprised of his LYFT calculation (the red line) and his time spent on dialysis (the blue line). As a donor

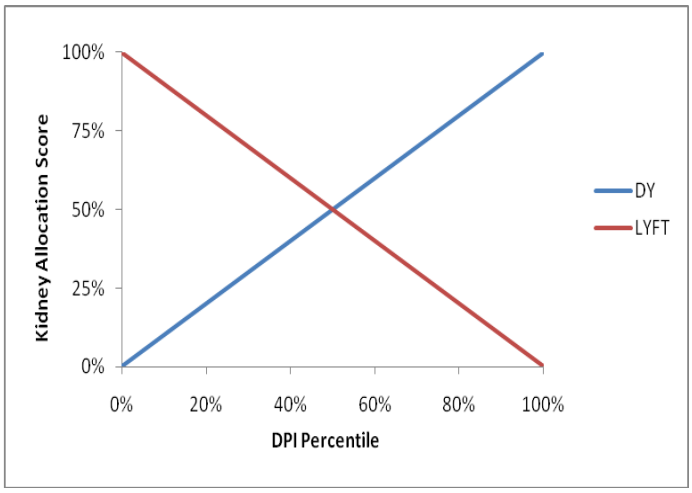

Figure 9: Interplay of LYFT and Dialysis Years (DY) based on Donor Profile Index (DPI) Percentile in Run 18f

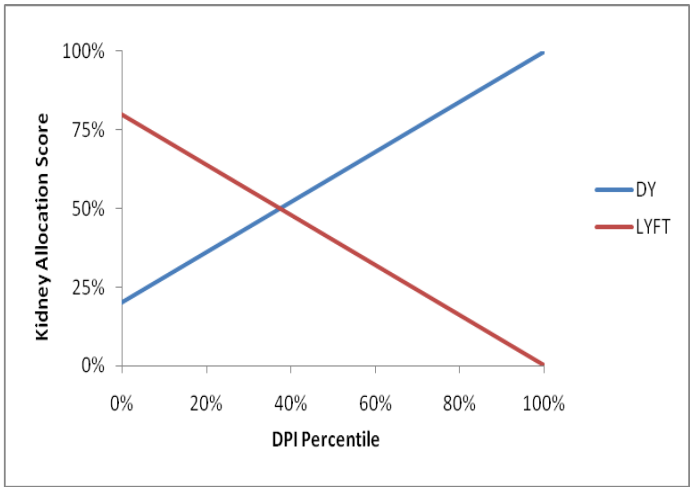

Figure 8: Interplay of LYFT and Dialysis Years (DY) based on Donor Profile Index (DPI) Percentile in Run 28

kidney becomes available, it would receive a donor profile index (DPI) score. Each candidate would then receive an allocation weight based on his or her LYFT score and dialysis years. For example, when a donor kidney from the 50th DPI percentile became available, each candidate would receive an allocation weight comprised of 50% of his LYFT score, and 50% of his dialysis years. For a donor kidney from the 20% percentile, each candidate would receive an allocation weight of 15% of his dialysis years and 85% of his LYFT. The lowest DPI percentile kidneys are allocated almost entirely by LYFT.

Figure 8 depicts the interplay of LYFT and DY and based on DPI that is employed in Run 28. In this run, the maximum amount of weight that LYFT is given in the kidney allocation score (KAS) is 80% (Run 28). Many members expressed an interest in incorporating this approach to address the concerns raised by the OPTN Ethics Committee, 2007 public forum participants, and others over impact of a new system on living donation. The Committee has observed, through implementation and subsequent evaluation of the policy to give additional priority to pediatric candidates for donors <35 years of age that living donation rates can be affected by diminished time to transplant. The concern that higher LYFT candidates will not pursue a living donor (despite improved graft and overall survival) in favor of an expeditious transplant from a deceased donor would be addressed by only weighting LYFT to a maximum of 80% in the KAS. Following discussion, the Committee voted on the following resolution:

*RESOLVED, that the life years from transplant (LYFT) contribution to the kidney allocation score (KAS) be capped at a maximum of 80%, 19 in favor, 11 opposed, 1 abstention.

Based on the Committee's deliberations and decisions, the policy proposal that will be circulated for public comment will include the following elements:

- Formula for kidney allocation score: (KAS) = LYFT * 0.8 * (1-DPI) + DY * (0.8*DPI + 0.2) + PRA*4
- Separation of pediatric and adult candidates (pediatric rules remain same as current system: priority for donors < 35, no offers from donors > 35 to pediatric candidates)
- No paybacks
- No 0 mismatch HLA priority
- No 0 mismatch HLA sharing, except for highly sensitized adult candidates and pediatric candidates regardless of sensitization level
- Inclusion of A2 and A2B kidneys into B candidates
- HLA-A and HLA-B are not included in the LYFT calculation
- Dialysis years (not waiting time) since most recent initiation of dialysis
- Kidney-pancreas candidate priority (allocated by pancreas allocation rules)
- Diagnosis categories in LYFT calculation reduced to polycystic kidney disease, diabetes mellitus, and other
- LYFT score updates daily (due to age, dialysis years, PRA)
- A sliding scale for sensitization (4*PRA/100) added to kidney allocation score
- LYFT contribution capped at 80%, blended with dialysis years
- Use of a donor profile index (DPI) instead of the expanded criteria donor (ECD)/ standard criteria donor (SCD) distinction (patient preference to not accept ECD kidneys were kept in simulation)

Discussion of Timeline and Deliverables

Tim Pruett, OPTN President, requested that the Committee focus on preparing a concept proposal for a revised kidney allocation system for public comment circulation in the first quarter of 2008. Due to the complexities associated with obtaining stakeholder and shareholder feedback during the policy development process, Ms. Gould, UNOS staff liaison to the Committee, shared the optimal timeline for accomplishing this request.

Some Committee members expressed that this timeline seemed too lengthy since final approval for a new system would not be sought for at least eleven months. Ms. Gould reminded the Committee that it had publicly committed to hosting a second public forum during the public comment period. The Committee also publicly committed to circulating any proposal for two rounds of public comment. The goal with two rounds of public comment is to obtain as much meaningful feedback as possible. The first round will focus on vetting the concepts that will be used in a new kidney allocation system. The second round of public comment will focus on obtaining feedback on the operational details and policies associated with the proposed system.

Task	Estimated Timeframe
Circulate concept proposal for public comment	Late February 2008-April 2008
Present at regional meetings, committee meetings, and to patient/professional organizations	Early March 2008-April 2008
Host a public forum	March 2008/April 2008 (date is TBD)
Revise proposal based on feedback	April 2008/May 2008
Circulate proposal with relevant policy language for public comment	June 2008-August 2008
Present to OPTN Board of Directors for consideration	November 2008

The Committee agreed that it needs to fulfill its commitments to hosting a public forum and also to circulate any proposal for two rounds of public comment. The above timeline is subject to pending decisions from the Department of Health and Human Services Office of Civil Rights and OPTN leadership.

Pending Decisions from the Office of Civil Rights

Gregory Fant, PhD, Scientific Registry for Transplant Recipients Project Officer at HRSA, briefed the Committee on recent discussions with the HHS Office of Civil Rights (OCR). Department of Transplantation (DOT) staff met with OCR counsel on November 28, 2007 to discuss the work of the Kidney Transplantation Committee including the LYFT calculation. Dr. Fant explained to the Committee that OCR requested additional information and that HRSA is working with the OPTN and SRTR Contractors to fulfill the requests. The OCR has posed the following questions:

1) What happens in the simulations models to all patients over the age of 40 (since this is the bottom threshold for protected class)
2) Why were the examined variables included excluded from the LYFT models?
3) What are the differences between allocation and acceptance?
4) Are the activities of the Kidney Transplantation Committee and resulting allocation policies "federally conducted" or "federally assisted"?
5) What is the entire kidney allocation score comprised of and what is the proper terminology for this score?
6) How is net benefit used in other organ allocation systems?

Dr. Fant explained that answers to these questions are being formulated by the contractors and will be shared with the OCR before the end of 2007. Tentatively, OCR expects to make a determination about the use of age in the LYFT calculation by the end of the first quarter in 2008.

Dialysis Wait Time Study

Wida Cherikh, PhD, presented initial findings from the Committee Sponsored Study to Permit Kidney Waiting Time Accrual to Commence from the Initiation of Chronic Maintenance Dialysis. Since the Committee intends to propose using time on dialysis instead of time since listing, this analysis provided some initial indications as to how time on dialysis may affect transplants by ethnicity, blood group

Three organ procurement organizations (OPOs) currently participate in this Committee Sponsored Alternative System. Since IAOP only recently joined the system, the data analysis only included CAOP and MIOP.

	OPO Name and Location	Implementation Date
CAOP	One Legacy, Los Angeles, CA	April 29, 2006
MIOP	Gift of Life Michigan, Ann Arbor, MI	April 29, 2006
IAOP	Iowa Donor Network, North Liberty, IA	January 24, 2007

Results from the analysis indicated that there was no change in probability of transplant within 12 months for waiting list additions at participating DSAs after the policy implementation. Some of the patient characteristics of waiting list additions at participating DSAs were different than those in rest of US, i.e., higher proportion of patients aged 0-17 and 18-49, and minority patients. The median days between dialysis and waiting list dates was higher for Medicare/Medicaid and non-White patients. The proportion of preemptive listing seems to be lower at participating DSAs than the US. Finally, some of the characteristics of transplant recipients at participating DSAs were different than those in rest of US, i.e., higher proportion of minority transplants and Medicare/Medicaid transplants. As more follow-up becomes available, transplant rates and survival rates need to be re-examined.

Alan Leichtman, MD, from the SRTR, shared additional findings from a separate analysis. In this analysis, the two OPOs were analyzed separately, which may have reduced a masking effect on improvements in minority transplant rates.

2. **Update on Kidney Paired Donation**

Ken Andreoni, MD, Vice Chair of the Committee and Chair of the Kidney Paired Donation Working Group explained the recent progress that the working group has made to develop a national KPD system. From October 15, 2007 through November 15, 2007, UNOS circulated a request for information (RFI) (Exhibit B) requesting information on existing KPD systems. The intent with this RFI was to identify groups that are currently engaged in KPD and to learn from their expertise to further refine a national system. A number of organizations responded to the request. All of these organizations have agreed to share their software with UNOS at no cost and will be invited to present their KPD system to a group of unaffiliated computer experts. From these presentations, Dr. Andreoni explained that the technical details of a new system including data system requirements and matching algorithm details will be compared and the best approach(es) will be selected for the national system.

Separately, work is ongoing to develop patient and professional education materials about kidney paired donation. Several organizations that are currently engaged in kidney paired donation have volunteered to share their educational materials at no cost, to be adapted and used by the OPTN in the running of a national KPD system.

3. **Proposed Revisions to Pediatric Policy**

Committee member, Ruth McDonald, MD, asked the Committee to consider a policy change to address situations in which a sensitized adult candidate (PRA> 80%) is offered a kidney ahead of a sensitized pediatric candidate (PRA>80%). Prior to the implementation of the "Share 35" policy (OPTN/UNOS Policy 3.5.11.5), sensitized pediatric candidates who reached their time limits were prioritized over sensitized adult candidates. Additionally, sensitized pediatric candidates received points for being sensitized and also for being pediatric. By removing time limits with the implementation of Share 35, sensitized pediatric candidates are now intermingled with sensitized adult candidates on the match run. Dr. McDonald explained that there are currently 9,500 sensitized adults on the kidney waiting list and only 94 sensitized pediatric candidates.

Some members expressed concern that the Share 35 policy may have been implemented incorrectly or that this issue had not been considered in its development. One member of the Committee who participated in the development of Share 35 explained that the Committee had considered whether or not to provide additional priority to highly sensitized pediatric candidates and decided that such additional

priority would not be necessary in light of the expanded donor pool to which pediatric candidates would have access.

Wida Cherikh, PhD, of the UNOS Research Department presented the following data which suggest that transplantation rates for sensitized pediatric candidates have increased during the six month time frame following implementation of Share 35 with minimal effect on transplantation rates for sensitized adult candidates (Exhibit C). One member of the Committee remarked that altering the policy to provide additional priority for sensitized pediatric candidates may disadvantage sensitized adult candidates, many who wait for years for a single acceptable offer. Dr. Stock remarked that the situation is a relatively rare occurrence, one that occurs approximately two to three times per year and that developing and implementing a policy to address it will take time.

Following the discussion, the Committee voted to develop a policy to give sensitized children additional priority over sensitized adults for kidneys from all donors (regardless of age) at the local regional and national levels. This proposal will go through the policy development process, including review by the Policy Oversight Committee (POC) prior to public comment.

**RESOLVED that a proposal be developed to prioritize highly sensitized children (PRA>80%) over highly sensitized adults (PRA>80%) in the kidney allocation algorithm for all deceased kidney donors, regardless of donor age. This proposal will affect the allocation of all kidneys (regardless of level of mismatch) at the local, regional, and national levels. 22 in favor, 0 opposed, 0 abstentions.

4. Proposals Currently Circulating for Public Comment

OPTN/UNOS Proposed Resource Document for the Medical Evaluation of Living Kidney Donors (Living Donor Committee)

The OPTN/UNOS Living Donor Committee developed a resource document to help transplant professionals medically evaluate potential living donors. This resource document will also inform and educate potential living donors about their own medical evaluations. This document was originally released for public comment in July 2007 as *Guidelines for the Medical Evaluation of Living Kidney Donors*. Based on the input from the community, the document is being resubmitted after extensive revision. The Living Donor Committee is now seeking public comment on this revised resource document. This resource document is not policy and does not carry the same monitoring implications as policy. The Living Donor Committee hopes to improve the care and follow-up of living donors by providing this information for voluntary adoption by transplant centers.

The Kidney Committee reviewed the Proposed Resource Document for the Medical Evaluation of Living Kidney Donors. One member asked a question about the legal implications of the proposed resource document. Ms. Gould explained that the document is intended only to serve as guidelines for the medical and psychosocial evaluation of potential donors. Similar to other guidelines, such as the findings from the Amsterdam Conference, the resource document would not carry the monitoring implications of OPTN policy. Another member expressed that UNOS should take more of an educational role with regard to living donation and that this resource document fulfilled that role.

Members of the Committee were especially appreciative of Appendix A to the proposal which contained a reference list for all of the living donor medical protocols that the Living Donor Committee reviewed. One member remarked that centers should review this list to measure the strength of their protocols against others in the field.

After the discussion, the Committee voted to approve the proposal with a vote of 19 in favor, 2 opposed, 0 abstentions.

Proposed Modification to the OPTN Bylaws, Appendix B, Transplant Hospitals; Section B. Survival Rates; and Section C "Inactive Membership Status"; and Attachment I, Section II, "Inactive Program Status"; and to the UNOS Bylaws, Attachment I, Section II "Inactive Program Status" and Attachment II, Section XIII, C, (10) "Survival Rates."

The Committee reviewed this proposal to change the Bylaws which would document the Membership and Professional Standards Committee's (MPSC) current practice of holding informal discussions with the Members during its review of survival rates and activity at transplant programs and supported it with a vote of 18 in favor, 0 opposed, 0 abstentions.

5. Long Term Kidney Payback Debt Request

The Committee reviewed a request from the Living Legacy Foundation of Maryland to review its long term kidney payback debt. The Foundation continues to have three long term debts in the AB blood group, despite its efforts to repay these debts. While the Committee was sympathetic about the situation, it decided to table the issue until UNOS staff could produce evidence on the number of kidneys offered for payback and resulting refusals.

The Foundation also requested that the kidney debt system be discontinued upon the adoption of a new, national kidney allocation system. The Committee has already discussed this recommendation and plans to propose it for the new system. Additionally, the Committee will be circulating a proposal for public comment in February 2008 that would significantly reduce the number of payback debts incurred with the current system. This proposal will recommend that mandatory sharing for 0-ABDR kidneys be limited to pediatric candidates (regardless of sensitization level) and adult candidates with CPRA>20%. If implemented, this policy proposal is expected to result in a 68% reduction in regional/national shares for 0-ABDR kidneys. Fewer mandatory shares will result in lower payback debt levels.

6. Clarification: California Transplant Donor Network (CADN) Alternative Allocation System

At the request of UNOS Department of Evaluation and Quality Staff, the Kidney Committee reviewed a clarification to California Transplant Donor Network's (CADN) alternative allocation system (AAS). Since 1993, CADN has allocated kidneys under an OPTN/UNOS Board approved alternative allocation system. Under this alternative allocation system existed two allocation schema: (1) when two kidneys are available for local isolated allocation and (2) when one kidney is allocated for a k/p and one for isolated kidney. CADN utilizes the second allocation schema for scenarios that were not included in their original approved application.

In an effort to more effectively monitor allocation, UNOS Staff recently requested that CADN submit an update to their previously approved variance that documents these practices. As described by CADN, current CADN match runs reflect two candidate classifications: unsensitized candidates and combined (sensitized and unsensitized) candidates. Within each classification, candidates are ranked by waiting time. When both kidneys are available for isolated local allocation, kidney #1 is offered to the unsensitized candidate list and kidney #2 is offered to the combined candidate list. The current request is to have a second allocation schema for scenarios where only one kidney is available for local isolated transplantation. These scenarios include when kidney #1 has been allocated to: extra-renal, exported, directed donation, or when the donor only has one viable kidney. In these instances, kidney #2 is be offered to the combined candidate list.

UNOS Staff requested an opinion from the Kidney Committee regarding this clarification to CADN's alternative allocation system (i.e., the bypassing of the unsensitized pool in all instances where only one kidney is available for placement). Ken Andreoni, MD facilitated the review of this clarification and the Committee determined that CADN's practice of allocating to the sensitized/unsensitized candidate pool when only one kidney is available is acceptable.

KIDNEY COMMITTEE	MONTH	AUGUST	DECEMBER
	DAY	14	3
		Chicago, IL	Chicago, IL
NAME	**POSITION**		
Peter Stock MD, PhD	Chair	x	x
Kenneth Andreoni MD	Vice Chair	x	x
Dicken Ko MD	Regional Rep.	x	
David Klassen MD	Regional Rep.	x	x
Denise Alveranga MD	Regional Rep.	x	x
Charles Van Buren MD	Regional Rep.	x	x
H. Albin Gritsch MD	Regional Rep.	x	x
Stephen Rayhill MD	Regional Rep.	x	x
John Friedewald MD	Regional Rep.	x	x
Christie Thomas MD	Regional Rep.	x	x
Stuart Greenstein MD	Regional Rep.	x	x
Todd Pesavento MD	Regional Rep.	x	x
Oscar Grandas MD	Regional Rep.	x	x
Eileen Brewer MD	At Large	x	x
Dale Distant MD	At Large		x
Mark Fox MD, PhD	At Large	x	x
Daniel Hayes MD	At Large		x
Randall Heyn-Lamb RN, BSN, CPTC	At Large	x	x
Marjorie Hunter, JD	At Large	x	x
Mary Leffell PhD	At Large	x	x
Ruth McDonald MD	At Large		
Silas Norman MD	At Large	x	x
Kevin O'Connor MS, PA	At Large	x	x
Janis Orlowski MD	At Large		x
Tammie Peterson RN, BSN	At Large		
Marla Rodgers MBA	At Large		x
Mark Schnitzler PhD	At Large		
Dorry Segev M.D.	At Large	x	x
Michael Shapiro MD	At Large		
Trent Tipple M.D.	At Large	x	x
Winfred Williams MD	At Large	x	x
Francis Wright Jr, MD	At Large	x	x
James Wynn MD	At Large	x	x
Marla Jill McMaster M A	BOD - Liaison	x	x

Deborah Surlas RN, AEE	BOD - Liaison	x	x
Gregory Fant PhD	Ex Officio	x	x
Mark Stegall MD	Ex Officio	x	x
Elizabeth Ortiz-Rios MD, MPH	Ex Officio	x	x
Chris McLaughlin	Ex Officio	x	
Jack Kalbfleisch Ph.D.	SRTR Liaison	x	
Keith McCullough	SRTR Liaison	x	x
Robert Wolfe Ph.D.	SRTR Liaison		x
Kathryn Meyer	SRTR Liaison		
Ciara Gould MSPH	Committee Liaison	x	x
Maureen McBride Ph.D.	Support Staff	x	x
Dielita McKnight	Support Staff	x	x
Mary D. Ellison, PhD	Support Staff	x	
Karl J. McCleary, PhD	Support Staff	x	x
Anne Paschke	Support Staff	x	x
Elizabeth Sleeman, MHA	Support Staff	x	
Wida Cherikh, PhD	Support Staff	x	x