

OPTN/UNOS Kidney Transplantation Committee
Report to the Board of Directors
June 22-23, 2009
Richmond, Virginia

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- *Progress to Develop a New National Kidney Allocation System.* The committee reviewed stakeholder feedback from a request for information, public forum, and independent assessment conducted by an expert in public policy controversy. The committee then designed a path forward to address stakeholder concerns, realign goals with stakeholder preferences and regulatory requirements. (Item 1, Page 3)
- *Progress to Develop a National Kidney Paired Donation System.* The Committee voted to allow for an interim step in the implementation of the national kidney paired donation system. The purpose of this interim step is to allow for testing of business practices ahead of full scale implementation. The Committee also voted to approve bylaw language that would allow for modification of the Operational Guidelines by the Kidney Committee and oversight by the Membership and Professional Standards Committee. (Item 2, Page 20)

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OPTN/UNOS Kidney Transplantation Committee

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Peter G. Stock, MD, PhD, Chair

Ken Andreoni, MD, Vice Chair

The following report details the discussions and decisions made by the Kidney Transplantation Committee during its January 27, 2009, meeting in Saint Louis, Missouri and its May 12, 2009 meeting in Chicago, Illinois. For the benefit of the reader, the following acronyms are used frequently in this report. Each acronym is defined at its first use and abbreviated thereafter.

- DPI: Donor profile index
- DT: Dialysis time *or* time on dialysis
- HRSA: Health Resources and Services Administration
- KAS: Kidney allocation score
- KPD: Kidney paired donation
- LYFT: Life years from transplant
- SRTR: Scientific Registry of Transplant Recipients

1. Progress on developing a new national kidney allocation system.

In September 2008, the Committee issued a request for information (RFI) that described each of the concepts and gave background on the work to improve deceased donor kidney allocation. On January 26, 2009, the OPTN/UNOS Kidney Transplantation Committee hosted a public forum to discuss possible new concepts for kidney allocation. Briefly, these concepts were: Life Years from Transplant (LYFT), Donor Profile Index (DPI), and Time spent on dialysis (DT). Nearly 100 individual comments were submitted in response to the RFI. Approximately 200 individuals participated in the forum by either attending in person or through the phone and internet. Additionally, the following organizations sent representatives to present formal feedback on the concepts:

- American Association of Kidney Patients,
- American Society of Histocompatibility and Immunogenetics,
- American Society of Transplant Surgeons,

- American Society of Transplantation,
- NATCO,
- National Kidney Foundation, and
- Renal Support Network

The following is a summary of the Committee’s discussion about the feedback obtained from the RFI and forum. For ease in reviewing, the deliberations are divided by concept (LYFT, DT, and DPI).

Life Years from Transplant (LYFT)

The concept of LYFT was the most vigorously discussed during the forum. By far, the bulk of comments related to the use of life years from transplant (LYFT) in an allocation system. There was strong feedback about the limitations of LYFT, namely that LYFT is too complex and that the data used to calculate LYFT is not sufficient. Comments indicated that additional data should be used to calculate post-transplant survival. Many comments specifically mentioned measures of cardiovascular disease. Additional data about duration and severity of other conditions such as hypertension and diabetes were also recommended.

Some comments indicated that the predictive ability of LYFT was not adequate for an allocation system. Robert Wolfe, PhD, of the Scientific Registry of Transplant Recipients (SRTR) gave a presentation during the forum in which he described the index of concordance, or a measure of predictive ability. The index of concordance measures how often the LYFT model can accurately predict which of two candidates will have longer survival. The following table shows the index of concordance for the three separate models used to estimate LYFT.

Index of Concordance for:	0-4 years	4-15 years	0-15 years
Patient survival without transplant	0.66	0.60	0.68
Patient survival with transplant	0.67	0.68	0.68
Graft survival	0.59	0.57	0.62

Some forum participants indicated that the primary problem that needed to be solved in kidney allocation was the mismatch between donor organ and recipient life expectancies. Specifically, they described the problem as very young organs being allocated to candidates with very short life-expectancies. Some participants advocated for a system based on age-matching of donors and recipients. Others advocated allocation systems that would allocate organs from donors younger than 35 to candidates younger than 35. Organs from donors over the age of 35 would then be allocated to candidates over the age of 35 based on dialysis time.

To address some of the data limitations, the Committee will engage in a review of the current data elements collected for kidney transplant candidates and recipients. This effort is a part of the formal review process required by the Office of Management and Budget (OMB). The Committee will pay particular attention to adding or modifying factors related to cardiovascular disease during this review and may involve members of the Thoracic Organ Transplantation Committee in a joint working group.

The Committee also discussed the concerns about the complexity of LYFT. Many comments centered on the concern that transplant professionals and patients are not able to understand the LYFT calculation. Some members expressed that the problem is not that the calculation is complex, but that the explanation has been muddled. One member explained that he does not need to understand the intricacies of how a cell phone works, but that he can rely on it to deliver calls reliably. Likewise, some members of the Committee expressed an interest in improving the way that LYFT is explained so that transplant professionals and patients can understand how the LYFT calculation may affect when they may receive an offer and the types of kidney offers that they receive. This would be similar to the way in which the liver and lung allocation systems are discussed. Many transplant surgeons on the Committee explained that they do not describe the model for end stage liver disease (MELD) equation in great detail to patients. Rather, they explain that MELD is based on clinical information and is designed to minimize death on the waiting list. Similar simpler explanations need to be used to describe LYFT.

Dialysis Time (DT)

The majority of forum participants and RFI comments supported the use of time on dialysis as a concept for kidney allocation. Overall comments with the use of dialysis time as opposed to waiting time included:

- Concern that use of dialysis time would eliminate the option for pre-emptive transplantation (defined as a kidney transplant that takes place prior to a candidate's need for dialysis).
- Concern that use of dialysis time would create a disincentive for timely referral of dialysis patients to a transplant center.
- Comments from those in OPOs that currently use dialysis time (instead of waiting time) that this approach is working and should be incorporated into national policy.

The Committee discussed these comments and concerns and will investigate some additional metrics such as glomerular filtration rate (GFR) ≤ 20 mL/min. By incorporating GFR, candidates could begin to accumulate time when they reach a certain clinical state, even if they do not yet require dialysis. The National Kidney Foundation (NKF) defines stage 5 chronic kidney disease (CKD) as $GFR < 15$ mL/min or the need for dialysis. However, the OPTN database only collects the date at which candidates reach $GFR \leq 20$ mL/min so the Committee agreed to evaluate that threshold in addition to dialysis start date.

Donor Profile Index (DPI)

Donor Profile Index (DPI) as a replacement for the current allocation categories of expanded criteria donor (ECD) and standard criteria donor (SCD) was strongly supported by forum participants and in the RFI comments. Many forum participants expressed that the current ECD/SCD designations led to organ wastage. Some comments indicated that additional experience with DPI is necessary (e.g., through peer-reviewed publications and a DPI calculator). In response to this feedback, the Committee will evaluate options for providing additional experience with DPI.

The Committee discussed some strategies for addressing the feedback that it received from the RFI and forum. It recognized a need to communicate effectively with shareholders/stakeholders about the policy

development process. A subcommittee was formed to work on redesigning the OPTN/UNOS kidney allocation web pages to be more user-friendly, developing one-page descriptions or slide shows for each concept, and developing a chronological reference with all of the committee's deliberations on KAS. The Committee also discussed more direct ways to involve organizations (such as those that presented at the forum) in the policy development process. Possible approaches include surveys, discussion/focus groups, and conference calls. A strategy for involving other organizations was under discussion with HRSA. Following the January meeting, HRSA made arrangements for an independent consultant to assess stakeholder views on kidney allocation.

Findings from Independent Assessment

In May 2009, Suzanne Orenstein, a specialist in collaboration and consensus building in public policy, presented findings from her assessment of the views concerning the proposed kidney allocation concepts (Exhibit A). This assessment was conducted at the request of HRSA and in consultation with UNOS. Ms. Orenstein reported that she was impressed by the commitment of those she interviewed to finding a way through the controversy of designing a new policy for the allocation of deceased donor kidneys. Overall, Ms. Orenstein observed, there is a lot of agreement.

Ms. Orenstein found that there was general agreement with the proposal to calculate waiting time from the initiation of chronic maintenance dialysis. Almost all of the interviewees thought that this policy change would create a more equitable allocation system. There are some situations where individuals are in urgent need of a kidney but have not gone on dialysis, and so many people suggested using the onset for end stage renal disease or the provision of $GFR \leq 20$ mL/min. There was some discussion of whether or not $GFR \leq 15$ mL/min would be more appropriate.

Donor profile index (DPI) was also favorably viewed in most of the interviews as an improvement over the current system. Ms. Orenstein reported that only a couple of interviewees had concerns about the data used for the DPI model but overall, there was general agreement that DPI should be used.

Aside from the concepts of DPI and Dialysis Time, there were concerns expressed about other possible aspects of a new system. For instance, related to the concept of zero-antigen mismatch and compatibility matching, there were some concerns about existing payback debts and whether or not OPOs can pay down current debts in advance of a new system. There were several suggestions that local centers should have the flexibility to decide when to use HLA matching based on individual candidate characteristics. Ms. Orenstein reported that some interviewees were concerned about the multiorgan allocation policies, specifically that the increase in multiorgan transplant will disadvantage kidney-only candidates. Ms. Orenstein also reported that some interviewees from transplant centers were concerned about how the transition to a new system would affect existing candidates. At least one interviewee suggested the use of waiting time and dialysis time weighted equally at the outset to minimize disruption.

Without question, the use of LYFT calculation was the area where there was the most concern for interview participants. Lack of confidence in the survival predictions due to the model and the complexity of the system (specifically that the system is difficult to explain to patients and professionals), and the potential for fewer transplants for older candidates were three primary concerns. Among those interviewed, Ms. Orenstein asked if moving forward with LYFT was a possibility and found that only 11

thought that LYFT was viable, while 21 disagreed, and 17 were unsure. None of the eight stakeholder groups interviewed thought that LYFT should move forward as a national policy. A member of the committee asked Ms. Orenstein to elaborate on the responses received on LYFT, specifically on the large group that remarked that it was unsure of whether to move forward. The member wanted to know if there were multiple reasons for the uncertainty. Ms. Orenstein clarified that that 10 of the 17 respondents were HRSA or UNOS personnel who were not taking a position on the whether to use LYFT.

Ms. Orenstein summarized her findings by stating that there were many agreements among the interviewees (using dialysis time and DPI being the primary points of agreement) and a large disagreement (using LYFT). Almost all interviewees agreed that it is time to move beyond the limitations of the current system and to improve the match between life years for recipients and donors. While everyone agreed with this goal, the methods for achieving it were disparate. How to allocate the organs once they are characterized by DPI is the largest area of disagreement. Ms. Orenstein shared a list of suggestions from the interviewees (Exhibit B). The characteristics of the different approaches were to use LYFT for all allocations (this approach was not widely supported), use LYFT for some allocations (e.g., the top 20% of candidates), or not use LYFT at all. There were several suggestions for age matching since age is the criteria that matters most in the survival predictions. Some recommendations were for definitive lines (e.g., the recommendation to allocate organs from donors younger than 35 to candidates younger than 35). Some interviewees just recommended finding ways to correlate donor and recipient age (e.g., require that the donor and recipient be within 10 years of age of one another). Finally, some interviewees recommended that recipients should chose which types of kidneys they will accept.

Interestingly, many interviewees suggested better matching of donors and recipients without using LYFT as the primary tool. Several suggested pilot testing a new system and enhancing data collection to improve the predictability. Other comments addressed geographic disparity which many interviewees thought would be important to study and address directly. Others wanted to know the impacts on disadvantaged populations and how to preserve benefits for these groups. Quite a few interviewees mentioned the calculator developed by the SRTR and several remarked that the tool should be made available for patient education purposes.

Ms. Orenstein spoke briefly about methods for involving stakeholders and the benefits of including stakeholders early and often in the policy development process. Consensus building is reliant on the trust of those who will be affected by the policy changes. In the case of kidney allocation policy development, the stakeholders are looking for more opportunities for dialogue and periodic updates. Stakeholders want more information sharing. However, in the field of organ transplantation, time is limited for stakeholder engagement because of the volunteer nature of the Committee. Additionally, staff time to support communication efforts is also limited. These constraints can create less than ideal interaction with stakeholders. Ms. Orenstein recommended that the Committee utilize public information tools that reach all of the affected interests (e.g., articles, web sites, and webinars).

Ms. Orenstein also discussed the finding that HRSA's role in the process is not clearly defined. She clarified that HRSA's role is to ensure that the policy complies with the law and the OPTN contract. Because of this role, HRSA has significant weight just as any public agency that is assisting with public policy would. Ms. Orenstein also discussed some comments about how the Committee operates,

specifically about how decisions are made. Several interviewees made comments that some Committee member concerns are overridden by other Committee members who are not open to listening. Ms. Orenstein encouraged UNOS to clarify when it is appropriate for Committee members to represent their constituencies as several committee members supported the concepts in the RFI but their organizations did not support the concepts (e.g., ASTS).

Since allocation of a scarce resource is always a no-win for some groups, Ms. Orenstein encouraged the Committee to be proactive about handling controversy. Articulating a clear rationale for a change is essential. For example, the rationale could be getting more life years from transplanted kidneys. This is a rationale that the public could understand. The Committee should think about public messages in advance.

Finally, Ms. Orenstein reassured the Committee that it is well on the way to achieving the improvements that it seeks. The Committee has done a lot of work already, and a significant number of people are ready to move forward. Ms. Orenstein shared that the Committee is close to reaching consensus on a policy but it's at the hardest point which is dealing with serious disagreement. The Committee needs to narrow its discussion to a couple of realistic options. Ms. Orenstein stated that it is normal for people to be frustrated at this stage of policy development. As the Committee moves forward on a narrow set of realistic options, it needs to focus on what is most essential to achieve. She closed by stating that the Committee has the capacity to get to the end of the road.

Dr. Stock thanked Ms. Orenstein for her presentation and for her work to assess views of so many stakeholders. Dr. Stock then asked the Committee to focus on forming a consensus about a way to move forward on developing a new allocation system (Exhibit C). The need for a new allocation system is demonstrated by the fact that 67% of OPOs are not running the current national allocation system. These OPOs are using variances in an attempt to alleviate some of the shortcomings of the national allocation system. Dr. Stock also reiterated that the current national system does not provide an adequate algorithm for allocating an increasingly limited and diverse donor pool of kidneys to an growing and more diverse group of candidates.

Dr. Stock emphasized that a new system must: be transparent, be understandable by health care workers and transplant candidates, provide a reasonable estimation of waiting times, permit a smooth transition for those already waiting, and provide for better matching of graft and patient survival. In addition, any new allocation system must meet the requirements of the National Organ Transplant Act (NOTA), the OPTN Final Rule, and the Health and Human Services Program Goals.

The OPTN Final Rule states that allocation systems must:

- Be based on sound medical judgment,
- Seek to achieve the best use of donated organs,
- Be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement, and
- Set priority rankings...through objective and measurable medical criteria

NOTA states that allocation systems must recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children. Additionally, NOTA requires that allocation policies should attempt to increase transplantation among populations with special needs, including children and individuals who are members of racial or ethnic minority groups, and among populations with limited access to transplantation.

Finally, as a consideration, the Department of Health and Human Services (HHS) Program Goals state that the OPTN should increase the average number of life-years gained in the first 5 years after transplantation for deceased kidney/kidney-pancreas transplants by 0.003 life-years until the goal of 0.436 life-years gained per transplant is achieved in 2013.

For the past five years, the Committee has been working on a system that incorporates three concepts to meet the multiple requirements stated above. These three concepts are Donor Profile Index (DPI), Life Years from Transplant (LYFT), and Dialysis Time (DT). These three concepts interact to form a Kidney Allocation Score (KAS). The Committee presented these concepts during a public forum in January 2009 and found that the public supported the use of DT and DPI but not LYFT in kidney allocation. Some stakeholders have expressed concerns about LYFT including that it has a low index of concordance for predicting patient survival with/without a transplant and graft survival for average candidates. Others expressed concern that the data used to calculate LYFT is missing key elements necessary for estimating survival (e.g., cardiovascular disease and diabetes type/longevity).

Dr. Stock reviewed the stakeholder feedback received to date. Overall, some stakeholders are concerned about the complexity of a system based on LYFT, DPI, and DT. They believe that the system is too difficult for patients and providers to understand and make informed decisions. Others are concerned that the system will not allow for predictable waiting times. Predictability could be a problem for candidates who want to know how long their wait will be and for transplant programs that need to maintain current workups on candidates. Finally, the transition to a new system was of concern to some stakeholders who feared that existing candidates on the waiting list would be harmed under a new system.

Overall, there was broad support for better matching of the longevity of the donor kidney with recipient post transplant survival. This approach was easier to understand and explain and the Committee found that the primary goal of kidney allocation should not just be to maximize life years gained but to provide access for as many candidates as possible. The Board of Directors, during its March 2009 meeting in Houston, Texas, advised the Committee to focus on the extreme case of allocating longest lived kidneys to shortest lived recipients. In this way, the Committee would not have to solve the entire problem of maximizing survival for all recipients. Instead, it could correct the largest perceived problem with the current system in a way that could be easily expanded over time. The Board also recommended, reviewing existing variances and determining if there is a way to consolidate similar systems, and eliminate non-performers. The Board requested that the Committee revisit data collection to determine if there are ways to improve the predictability of an outcome metric.

Dr. Stock talked about how LYFT was initially considered as a metric because it improved access for candidates with poor waitlist survival and longer post transplant survival. For example, candidates with type 1 diabetes have the highest survival following transplant and poor survival on the waitlist (highest

LYFT). Using an outcome metric like post-transplant survival would not account for the urgency that these candidates face when listed for transplant (waitlist mortality for candidates with type 1 diabetes is quite high). Dr. Stock urged the Committee to consider this patient population as it worked on selecting an outcome metric. One possible approach would be to put candidates with type 1 diabetes into a separate category for allocation. Another approach would be to treat simultaneous kidney-pancreas allocation just like kidney-liver or kidney-heart allocation. Dr. Stock stated that the Pancreas Transplantation Committee will need to develop listing criteria for candidates with type 1 diabetes to facilitate these types of policy changes.

Finally, Dr. Stock discussed the key points that the Committee would need to consider as it designed a system that was responsive to the comments and concerns of the various stakeholder groups. These key points included:

- Implementing dialysis time as the key driver of a new system while allowing time to accrue from a glomerular filtration rate (GFR) of less than 15 mL/min or 20 mL/min,
- Basing outcomes measure on objective and measurable medical criteria,
- Determining whether to utilize post-transplant survival instead of LYFT,
- Determining whether to allocate the top 20% DPI kidneys to candidates with top 20% post-transplant survival,
- Using survival projections for patient education in the form of a calculator, and
- Granting center/patient autonomy for HLA priority.

To start the discussion, Dr. Stock presented the benefits of allowing waiting time to start from the initiation of chronic maintenance dialysis. One benefit is that initiation of dialysis represents a time point at which candidates are in similar states of disease. The National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines state that stage 5 chronic kidney disease (CKD) or kidney failure is defined as a glomerular filtration rate (GFR) of <15 mL/min or dialysis. Currently, candidates listed for kidney transplant can accrue time from the start of dialysis (if listed) or when their GFR is less than 20 mL/min. The Committee discussed whether to change the GFR threshold to <15 mL/min in order to correspond with the NKF KDOQI guidelines. Members who are also nephrologists agreed that the threshold should be changed and that this change would improve understanding of disease states. Other members were concerned that lowering the GFR threshold would disadvantage patients who are proactive in pursuing transplantation. Fourteen members indicated that the GFR time should remain at <20 mL/min and seven indicated that the GFR time should be redefined to start at <15 mL/min. The committee discussed whether to retroactively grant time for candidates who are not on dialysis but who had a GFR <20 mL/min prior to listing. Some members were concerned that backdating time to GFR would be logistically problematic. For instance, patients may not have records of these tests. Dialysis time, on the other hand, is readily verifiable through CMS data sources. At this time, the Committee decided not to allow for backdating of time based on GFR. Some Committee members worried that this action would incentivize candidates to start dialysis earlier for the sole purpose of accruing time. The

Committee plans to monitor listing activity to determine if this unintended consequence occurs in a new system.

A member asked if the dialysis time would be calculated from the candidate's most recent start of dialysis or their original start of dialysis. Dr. Wolfe clarified that the simulation modeling uses the most recent start of dialysis which can be verified against the dialysis claims from the ESRD network. The Committee discussed whether candidates should also be able to backdate their waiting time to the point where their GFR dropped below the threshold. The committee sponsored system currently uses dialysis start time or if the candidate currently has a GFR less than the threshold but it does not allow for backdating to the date that the GFR crossed the threshold. A nephrologist on the Committee remarked that the purpose of allowing for backdating of dialysis time is an access/fairness issue. There are individuals who do not have an ability to be listed for transplant in a timely manner. Candidates who are listed before dialysis tend to be highly educated and from a higher socioeconomic and they do it to accrue time and to workup living donors. The reason to allow for backdating to dialysis only is to address the problem of untimely referral.

Dr. Stock remarked that after reviewing the feedback from the public forum and from the Board of Directors, that the accepted goal of kidney allocation appears to be matching longevity of donor kidneys with candidate projected post-transplant survival. However, there does not appear to be support for allocating every kidney in this way because of the data limitations. For instance, most people agree that the kidneys with the longest potential survival should not be allocated to candidates with the shortest potential survival. So, at the extremes, there is agreement. However, for candidates with average estimated survival and kidneys with average estimated survival, this method of allocation is not supported because of data limitations. The Committee discussed how to define which kidneys should be allocated through matching and which should be allocated solely by time on dialysis.

The Committee also discussed how to handle sensitization in an allocation system. Currently, points are awarded for sensitization when a candidate has enough unacceptable antigens identified to reach a calculated panel reactive antibody (CPRA) score of $\geq 80\%$. Some members of the Committee believe that a new allocation system needs to permit some degree of flexibility for HLA matching without developing variances. For instance, centers could enter information only for patients who are at highest risk of requiring a second transplant to minimize sensitization. Fifteen members agreed that this flexibility should be incorporated into a national system and one member disagreed.

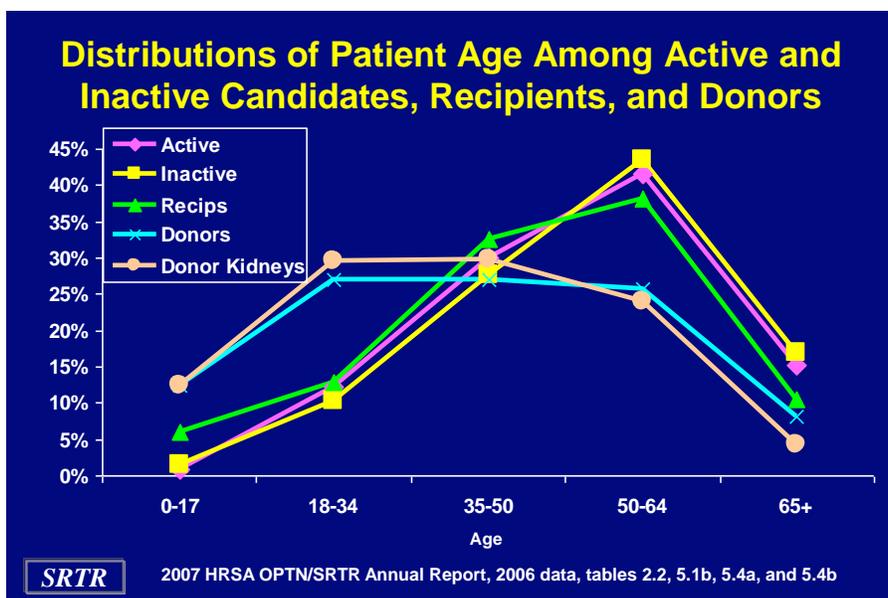
Dr. Stock presented ways to improve access for sensitized patients. The Committee had previously discussed providing additional points on a sliding scale based on number of relevant anti-HLA antibodies listed (calculated PRA). The relevance of these antibodies would be determined by each center, just as is done now. However, Dr. Stock recommended that points should only be awarded once the sensitized patient has waited the necessary dialysis time to move to the top of the list. The goal of this policy approach would be to provide equitable access for sensitized candidates by allowing candidates with varying levels of CPRA to get a transplant at approximately the same length of waiting time as an unsensitized candidate.

Finally, Dr. Stock presented an idea to utilize the Committee's work to date to promote patient education through a calculator. This calculator would provide information regarding post-transplant survival based

on DPI. The information provided could help candidates make decisions about which types of DPI kidneys to accept. Better information could facilitate efficient placement and decrease donor discards.

Dr. Wolfe discussed whether to use percentage or hard cutoffs based on age to assign candidates to categories (such as organs from donors <35 years old allocated to candidates <35 years old). One fact that any allocation system will have to deal with is that 40% of donors are younger than 35. Only 15% of candidates are under age 35. By prioritizing based on donor age as proposed by the ASTS, you're allocating a very large fraction of donors to a smaller fraction of candidates. This may be a useful goal, but to the extent that people were concerned with access for older candidates, this type of matching would have more severe disparity.

The goal being discussed by the committee is matching survival of the organs and the recipients. The models that predict lifetimes of organs are superior to just using age alone for donor longevity. So a lifetime calculation would be more useful than just using age.



Christopher McLaughlin and James Bowman, MD, then presented HRSA's viewpoints on the policy development process (Exhibit D). Overall, HRSA continues to be supportive of the Committee's efforts to create an allocation policy consistent with the OPTN Final Rule. HRSA does think that inclusion of benefit is necessary and needs to be part of any allocation policy. From HRSA's standpoint, the following criticisms of the current allocation policy are valid:

- There are system-wide inequities in access for race, ethnicity, socioeconomic status as well as geographic location of candidates.
- The current system is time consuming, leads to inefficient allocation and prolonged cold ischemic injury.
- The current system does not (with the exception of ECD) account for differences in potential survival of recipients and donors.

- The current system does not account for medical needs of candidates (except for pediatric and SPK candidates).

Mr. McLaughlin explained that HRSA understands that there are not enough donors for all candidates and so allocation policies determine who receives organs and who does not. In an effort to better understand how a system based on KAS would affect candidates, HRSA asked the SRTR to model the current and proposed systems and then compared various outputs. Overall, the simulation modeling results showed that candidates in the older age brackets would receive fewer transplants in a proposed KAS system while younger candidates would receive more transplants. The results showed that about 21% of kidneys currently available to candidates older than 50 would be allocated to candidates under the age of 50 under the proposed system.

Recipient Age	Counts				Percentages		
	Current	KAS	Dif	% change	Current	KAS	Dif
0-17	497	527	30	6%	5%	5%	0%
18-34	1,323	2,015	692	52%	13%	20%	7%
35-49	3,152	3,500	348	11%	32%	35%	4%
50-64	3,708	3,057	-651	-18%	37%	31%	-6%
65+	1,313	884	-428	-33%	13%	9%	-4%
All	9,992	9,983	-9	0%	100%	100%	0%

Additionally, the *types* of kidneys allocated to each group would change as well. In the proposed KAS system, the 65+ candidate category would receive more kidneys from the 65+ donor group. Dr. Bowman expressed concern that geriatric groups would be opposed to the drop in transplants as well as the quality of donor organs offered to this candidate group. Though, this does meet the goal of shifting longer lived kidneys to longer lived recipients.

Kidney Transplants by DPI Current vs KAS

<u>Current system</u>	Recipient age				
<i>DPI Tertile of donor</i>	<u>0-17</u>	<u>18-34</u>	<u>35-49</u>	<u>50-64</u>	<u>65+</u>
0-33% longer-lived kidneys	325	498	1,100	1,079	329
33-67% medium lifespan	135	472	1,120	1,208	395
67-100% shorter-lived	36	353	932	1,421	588
 <u>KAS</u>					
<i>DPI Tertile of donor</i>					
0-33% longer-lived kidneys	402	958	1,252	613	102
33-67% medium lifespan	112	706	1,286	1,004	220
67-100% shorter-lived	13	352	962	1,440	562

HRSA also modeled the life years after transplant for the current system compared to a future proposed KAS system broken out by recipient ages. Dr. Bowman noted that there are only very small impacts on life years after transplant by KAS. In the age group of 18-34 year olds, the median life years per recipient is 0.4 (7.9 under the current system versus 8.3 under the proposed system). Dr. Bowman remarked that the Committee will have to explain why this complex system is necessary, especially with such small gains in overall life years. In the 50-64 age group, the life years after transplant change is also small (4.4 to 4.2). Dr. Wolfe explained that there are two shifts that have occurred under the proposed system. The first shift is the number of recipients in each age category and the second shift is in life years gained per transplant. KAS was designed to shift organs to people with higher LYFT. It turns out that, in addition to shifting organs away from candidates with lower LYFT, there was a secondary benefit of allocating longer-lived kidneys to individuals with higher LYFT. More kidneys are allocated to these higher LYFT candidates *and* longer lived kidneys are allocated to higher LYFT candidates. Dr. Wolfe explained that the allocation was intended to allocate more organs to candidates with better survival; the allocation of longer-lived kidneys to longer-lived recipients was an unexpected benefit. In the graph below, the real benefit was to change from 1323 organs to 2015 organs for candidates in the 18-34 age category. So the real columns to consider are one and two. KAS moves kidneys from recipients with a LYFT score of 3 to recipients with a LYFT score of 9. The people who get these organs have pretty good LYFT anyway, so the LYFT per individual does not change much, but the number of individuals increases.

Life Years after Transplant by Age Current vs KAS

Recipient Age	Number of Kidney Transplants		Median LYFT per Recipient		Total LYFT		
	Current	KAS	Current	KAS	Current	KAS	Diff
0-17	497	527	9.6	9.9	4,633	5,068	435
18-34	1,323	2,015	7.9	8.3	10,442	16,463	6,021
35-49	3,152	3,500	6.0	6.1	19,308	21,668	2,361
50-64	3,708	3,057	4.4	4.2	16,714	12,999	-3,715
65+	1,313	884	3.4	3.0	4,567	2,756	-1,812
All	9,992	9,983	5.1	5.5	55,663	58,953	3,290

Mr. McLaughlin explained that there are two ethical goals in kidney allocation required under the OPTN Final Rule; one goal is to maximize the benefit of the resource the other is to distribute the resource fairly. Since older and younger candidates benefit from transplant, this KAS system may not achieve the goal of fair distribution. Dr. Bowman presented a compromise that would direct longer lived kidneys to longer lived candidates without reducing the number of transplants available for older candidates. The proposal would prioritize transplant of high DPI organs in younger recipients (N=1,285) and low DPI organs in older recipients (N=1,408). This approach is based on an article written in 2005¹ which matched donors and recipients by age alone.

Current system	Recipient age				
DPI Tertile of donor	0-17	18-34	35-49	50-64	65+
0-33% longer-lived kidneys	325	498	1,100	1,079	329
33-67% medium lifespan	135	472	1,120	1,208	395
67-100% shorter-lived	36	353	932	1,421	588

¹ Herwig-Ulf Meier-Kriesche, Jesse Schold, Robert Gaston, Jonas Wadstrom and Bruce Kaplan, "Kidneys from Deceased Donors: Maximizing the Value of a Scarce Resource", American Journal of Transplantation, 2005, 5:1725-1730

In response, Dr. Stock remarked that the Committee had investigated a very similar system that used five categories instead of three. When the simulation modeling was done, it was found that there were no additional life years gained through this system. At that meeting, the HRSA representative stated that HRSA would not support a system that did not add life years gained and so the Committee eliminated that system from consideration. Mr. McLaughlin said that the goal of this system would be to prioritize the longer lived kidneys to younger candidates without reducing the number of transplants for older candidates.

Mr. McLaughlin also shared that the Office of Civil Rights (OCR) will not be able to deliver a pronouncement on the use of age in an allocation system. The OCR is responsible for adjudicating claims and so it would not put itself into the position of approving a policy. The OCR has advised HRSA on how to reduce possible legal risk of using age as a factor in allocation. HRSA believes that the ideal solution would be to improve the data to a point where age is no longer necessary in the survival equations. However, this improvement will take time, though it is being addressed through efforts to improve data collection. If the Committee decides to move forward with the use of age, HRSA could issue a federal register notice that clarifies the components of the Final Rule that discuss organ wastage and best use. In this notice, age would be declared as an appropriate factor to achieve these stated goals. The language of the Final Rule would not necessarily be changed, but the Federal Register notice would create a public record of a statutorily approved use of age. Mr. McLaughlin also said that HRSA could make kidney allocation a federal regulation if the Committee feels strongly about using age in allocation.

Dr. Stock observed that there has been a change in the goals that HRSA would support for a kidney allocation system. Instead of survival benefit, with its presentation, HRSA seemed to imply that the driving force for allocation should be access. Mr. McLaughlin clarified that both goals need to be achieved: survival benefit and access and that the Committee should focus on survival benefit without reducing the number of transplants for older candidates through better matching of organs. Dr. Bowman clarified that the current age distribution of recipients is not necessarily something that must remain static. Dr. Bowman said that HRSA understands that the current distribution is flawed but that any change in distribution has to be clearly explained.

One member asked Dr. Bowman and Mr. McLaughlin about situations in which the candidates could not utilize the longevity of the kidneys. In these situations, allocation of the organ to the candidate would be medically inappropriate. Furthermore, the member remarked that no other intervention in medicine (e.g., cancer care), can deliver the additional 3000 years of life for one year of therapy that a KAS based system could achieve. Mr. McLaughlin asked the Committee to keep in mind that the policy change will affect many people and will be publicly discussed. Mr. McLaughlin urged the Committee to develop a policy that balances equity and utility and is clearly communicated. Dr. Stock thanked Dr. Bowman and Mr. McLaughlin for providing the Committee with the viewpoints of HRSA.

Review of Data Analysis

Keith McCullough, MS, of the Scientific Registry of Transplant Recipients reviewed the findings from the most recent data request (Exhibit E). A copy of the presentation is included as Exhibit F. Mr.

McCullough explained that the simulation runs were conducted over a three year period (2003-2005) instead of the 1 year period (2003) that the Committee had previously seen. The numbers of the runs correspond to the results reported in Exhibit E.

Number	Short Name	Description
Run 29	Old current	Historical reference
Run 30	New Current (2009 reference)	Based on Run 20, eliminates zero antigen mismatch sharing for candidates with PRA <20%
Run 31:	ESRD time	Based on Run 30, but uses ESRD time (defined as maximum of most recent dialysis date on the CMS Form 2728 or date of GFR \leq 20) in place of wait time points.
Run 28	KAS	For reference

Under the Run 31 which used dialysis time instead of waiting time, there was a substantial drop in the number of SPK transplants. One reason for this decline is that SPK candidates have much shorter times on dialysis.

Average per Iteration, 2003-2005 run	Run 29: current rules pre 8/29/08	Run 30: current rules post 8/29/08	Run 31: 30 w/DT instead of wait time	Run 28: KAS
Kidney Alone	28,220	28,209	29,014	28,172
Simultaneous Kidney-Pancreas	2,528	2,650	1,675	2,423
Total	30,748	30,859	30,689	30,595

Mr. McCullough explained the reasons for declines in life years across the simulation runs. One reason is that the changes in zero-antigen mismatch sharing policies resulted in fewer 0-ABDR transplants. While graft lifespan overall was reduced by only 0.14 years (7.91 to 7.77) per transplant, graft lifespan among the 3,017 (402 + 2,615) transplants most affected by the policy changes was reduced by 1.43 years. Graft lifespan among the remaining 27,467 (26,104+1,363) recipients changed by less than 0.01 years. Dr. Stock asked if some of the loss was due to transplanting patients who have a lot of dialysis time as these candidates have poorer survival due to their increased time on dialysis.

Among the three runs, there was not much of a shift in the ages of the recipients. The shifts are mostly due to the decline in SPK transplants as SPK recipients tend to be younger than kidney recipients.

Removing the zero-antigen mismatch sharing improves access among African Americans as does including dialysis time. Transplants for blood group A declined slightly, again most likely due to the removal of 0-ABDR sharing.

Mr. McCullough shared that the kidney pancreas simulated allocation model's (KPSAM) next upgrade will include acceptance/placement models that account for unacceptable antigens. Additionally, donor/recipient age correlation has been increasing, and this increase is now reflected in KPSAM. Due to the changes in zero antigen mismatch sharing, the number of 0-ABDR transplants has been reduced overall, graft survival is decreased by more than one year among the recipients most affected by the rule. These policy changes likely also resulted in increased allocation to African American and blood type O recipients. The change to dialysis time reduced SPK transplants, increased allocation to African American and blood type O recipients by an additional percentage point, and may have reduced PRA 80+ access, but this aspect of the results should be re-evaluated after the KPSAM upgrade.

Due to the decline in SPK transplants caused by using dialysis time instead of waiting time, Dr. Stock asked that the Committee discuss whether to prioritize candidates listed for simultaneous pancreas kidney (SPK) transplantation. Many members agreed that the Committee needs to spend some time talking about criteria for allocation of multiple organs (i.e., kidney/liver, kidney/pancreas, kidney/heart). The criteria for SPK listing would have to be determined in consultation with the Pancreas Transplantation Committee. One member reminded the Committee that SPKs account for about 900 transplants per year, or about 10% of the available deceased donor kidneys. One member expressed concern that this policy would prioritize SPK candidates of all ages and that he wasn't sure that there was benefit of SPK transplantation in recipients over the age of 35. Eleven members agreed that there should be priority for all SPK candidates in the allocation algorithm and seven members believed that only candidates <35 years of age should have priority for SPK.

The Committee then considered whether to use post-transplant survival as the benefit measure in an allocation system instead of LYFT. Members of the committee remarked that post-transplant survival is simpler than LYFT, but it disregards waitlist urgency and quality of life. One member remarked that post-transplant survival relies more heavily on age than LYFT and so the public may see this move as disingenuous. Another member remarked that the medical urgency component is "thrown away" by using post-transplant survival instead of LYFT because post-transplant survival does not take into account death on the waiting list. This member remarked that the arguments about the c-statistic are disingenuous and that recent publications in the peer-reviewed literature show that in ideal situations, with almost perfect data, the c-statistic only reaches 0.83 (instead of its current value of 0.68). The member remarked that the c-statistic is being used as a sort of Trojan horse and that the real concern may be over incorporating a measure of benefit into allocation.

Dr. Wolfe clarified that goal of the current discussion was to use matching of organ and candidate survival as the goal to be achieved. LYFT used post-transplant survival as the outcome, but as compared to survival on dialysis. Dr. Stock remarked that a system that matches post-transplant survival to longevity of the organ makes the most sense to stakeholders. The concept of LYFT was important from a medical urgency standpoint, but from a statistical point of view, it was not being accepted. By removing

the medically urgent candidates (e.g., the candidates with Type 1 diabetes), the same goal is achieved but with a simpler benefit measure.

The Committee also discussed whether to limit the number of variables used to calculate the benefit measure as a way of addressing the complexity issue. Mr. McCullough shared the impact of each factor on predicting post transplant survival. Candidate age, diabetes status, ESRD years, and prior transplant would be the main candidate factors that account for the majority of the predictive ability of the post-transplant model.

The Committee agreed that the path forward needs to provide a response to the criticisms that have been delivered. The Committee described the overall goal of a system based on post-transplant survival, dialysis time and DPI as: avoiding the shortest lived 20% of kidneys (as defined by DPI) from going to the longest lived 20% of candidates (as defined by post-transplant survival). Stakeholders currently understand that kidneys from donors <35 are already preferentially allocated for SPKs and pediatrics and this approach falls in line with the intent of those two policies. Another way to describe the approach would be to say that candidates with shortest estimated survival would not have access to the 20% longest lived kidneys and vice-versa. Another member observed that, compared to KAS, a system that directs the longest lived candidates to the longest lived recipients is not very different. However, the KAS system did not use arbitrary cut points or categories.

One member remarked that the use of 20% needs to be investigated. There needs to be a rationale for choosing this threshold. When a threshold is used (as opposed to a continuous system) candidates can just miss the mark and be disadvantaged. Also, as the list grows, candidates could start in the top 20% and fall out of the category as a function of the list rather than due to changes in their own medical criteria. One member asked when the list would be recalibrated, whether this would happen annually or biannually. Finally, a member cautioned that listing behavior will change once the rules change and so the Committee needs to set goals and then evaluate and recalibrate the system based on the stated goals.

The Committee concluded its discussion about simulation modeling with a discussion on whether to require HLA matching. Dr. Stock remarked that there should be center level autonomy so that centers can identify candidates for whom HLA matching is important (e.g., candidates who are at higher risk of requiring repeat transplant). The histocompatibility member remarked that at the local level, this would result in almost no zero-antigen mismatched kidneys. A member reported on his center's experience by stating that the degree of matching for children is already pretty low because they do not have to wait very long for kidneys. For children that had HLA-DR matches, there was no statistical difference in graft survival at 10 years from children with HLA-DR mismatches. Another member remarked that survival is only part of the story and that causing recipient sensitization is the primary concern in transplanting HLA-DR mismatched kidneys. Fifteen members agreed that centers should have autonomy in deciding whether to list HLA for each patient, one member, the representative from the Histocompatibility Committee, disagreed.

The Committee elected a subcommittee to formulate a data request based on the discussion. The subcommittee includes: John Friedewald, Ken Andreoni, Peter Stock, Sean Van Slyck, Mike Cecka, Dorry Segev, and Devon John.

2. Kidney Paired Donation

Dr. Andreoni, chair of the Kidney Paired Donation(KPD) Work Group, presented recent developments from the Work Group (Exhibit G). In Summer 2009, work will begin to launch a KPD Pilot Program which is designed to help staff gain experience with KPD before rolling out a full system in 2010. The interim implementation will allow for testing of the KPD business processes before they are programmed in the full system. The interim implementation will be open to two to four groups initially and as experience with the pilot grows, UNOS staff and the KPD Work Group will assess whether other groups can be accommodated in the system before full implementation. Full Implementation of the KPD Program is expected in December 2010. The full system will be open to all OPTN/UNOS approved kidney transplant programs and will be fully automated and interfaced with UNetSM.

For the interim solution, participants will enter information needed for matching into a custom Access database provided by UNOS . Participants will post the Access database to a secure SharePoint site and UNOS will pull data from Access databases, compile it, and feed the data into the KPD module. UNOS will develop match reports for each participating group from the match results and post the reports to the secure SharePoint site. Participants will enter acceptance or refusal of the match in a form on the SharePoint site.

In order to select the participating groups, UNOS will issue a request for proposal (RFP). The RFP will include both minimum requirements for participating groups and the evaluation criteria that will be used to select the groups. Initially, the number of participating groups will be limited to two to four groups due to resource limitations.

In order to participate in the pilot test, the applicant must be an OPTN/UNOS member institution (or in the application process) and have OPTN/UNOS member as a sponsor (existing KPD groups may apply to be a public organization member). The applicant must have 2 years experience with kidney paired donation and must have participated in at least four separate KPD exchanges. Finally, the applicant must be willing to designate a primary and secondary KPD contact. The KPD Contact will be responsible for all communications with UNOS and for all match related planning after match results are available. The KPD contact must also participate in regular conference calls to discuss the effectiveness of the business processes and ways to improve the program before the full implementation. All applicants must agree to abide by the KPD Pilot Program Operational Guidelines and must have the necessary software to run the database and submit the database to UNOS (most likely Microsoft Access and a zip program). Members will be encouraged to work together with one member acting as a coordinating center in order to increase the number of pairs that can be entered in the interim implementation.

The selection criteria for participants in the pilot are still being finalized. Consideration will be given to the applicant's willingness to act as a coordinating center, the number of pairs the group will be able to enter in the system, the amount of experience the applicant has with kidney paired donation, and

geographic location. Members of the Kidney Transplantation Committee and the KPD Work Group will use a standard scorecard to assess each applicant.

The Committee voted to approve the following resolution for consideration by the Executive Committee:

****Resolved that, the Executive Committee hereby approves the change in the implementation plan of the KPD Pilot Program to allow for an interim implementation with limited participation to run until a system interfaced with UNetsm is available, effective pending implementation (18 in favor, 0 opposed, 0 abstentions).**

Dr. Andreoni then asked the Committee to consider a process for modifying the KPD pilot program operational guidelines. He recommended that modifications could be made by KPD Work Group through the Kidney Transplantation Committee. All changes would then have to be reported to the Kidney Transplantation Committee and the Board. Additionally, Dr. Andreoni asked that the Committee consider allowing the KPD pilot program to be monitored by the Membership and Professional Standards Committee through an addition to the bylaws. The goal of the proposed language is to explicitly allow the Membership and Professional Standards Committee (MPSC) to monitor the Kidney Paired Donation Pilot Program through its existing due process and confidential medical peer review functions.

Following the discussion, the Committee voted to approve the following resolution for consideration by the Executive Committee.

****Resolved that, the language below is approved for inclusion in the OPTN/UNOS Bylaws and will be effective immediately (17 in favor, 1 opposed, 0 abstaining).**

Appendix B, Attachment 1, Section XIII, D(2)c (Kidney Paired Donation Pilot Program)

c. Kidney Paired Donation- Members that choose to participate in any OPTN kidney paired donation must agree to abide by the kidney paired donation program rules. Potential violations may be forwarded by the Kidney Transplantation Committee to the Membership and Professional Standards Committee for review.

Finally, Dr. Andreoni asked that the Committee consider a proposal to incorporate donor chains into the KPD program. Currently, the KPD Pilot Program only allows living donors with incompatible potential recipients to participate. Non-directed (or altruistic) living donors (those who are not linked to an incompatible potential recipient) have no way to enter the program. Also, candidate/ donor pairs can only be matched in groups of two or three, and all donor nephrectomies in the group must occur simultaneously. A proposal that is under development by the KPD Work Group would allow non-directed living donors (NDDs) to participate in the KPD Pilot Program and add donor chains as an option in the system. Donor chains have the potential to increase the number of transplants in a KPD system.

Dr. Andreoni explained that closed chains start with a NDD and end with a donation to a recipient on the deceased donor waiting list while open chains start with a NDD and end with a bridge donor who will start another segment in the open chain. In open chains, the bridge donor nephrectomy does not occur at

the same time as the other living donor nephrectomies. Closed chains start with a NDD and end with a donation to a list recipient. For closed chains, the chain size will be limited to three. A chain size of three would mean that three transplants take place. A closed chain with a size of three would include a NDD, two donor/candidate pairs, and a list recipient. Closed chains can involve multiple hospitals.

For closed chains, all donor surgeries must occur at the same time and the list recipient should be offered to the center that entered the NDD. Open chains start with a NDD and end with a bridge donor who will start another segment in the open chain. The term "segment" will be used for parts of open chains that occur at different times (rather than clusters or any other term). For open chains, the segment size will be limited to three. An open chain with a size of three would include a NDD and three donor/candidate pairs. One of the donors from the donor/candidate pairs would be the bridge donor and not donate until a later time (the next segment). Three transplants would take place simultaneously in this case. For open chains, all donor surgeries for each segment must take place at the same time, except for the bridge donor. Subsequent segments initiated by that bridge donor will occur at a different time. Open chains can involve multiple hospitals.

Dr. Andreoni discussed donor choices regarding donor chains. A donor choice will be added regarding whether the donor is willing to be a bridge donor. A center choice will be added regarding whether the center that introduced the NDD is willing to take part in an open chain (where they are not guaranteed that any of their patients will "benefit" from the NDD) or whether the center requires a closed chain (where the last living donor will donate to a patient on the waiting list of the center that introduced the NDD). Only the center that introduced the NDD needs to make this decision; the centers with the "middle" pairs in the chain are not affected by whether the chain is open or closed. If approved, the donor chains would be included in the implementation of the full system in December 2010.

3. Minimum Listing Criteria for Simultaneous Liver Kidney Candidates

Dr. Pesavento presented the public comments received on a proposal to standardize listing criteria for liver candidates who require a kidney transplant. This proposal would set minimum criteria for candidates listed for simultaneous liver-kidney (SLK) transplantation. The intent of this proposal is first to identify candidates who are unlikely to regain renal function following liver transplantation. Once identified, these proposed policy changes would provide priority for these candidates to receive a SLK transplant. The goal of this proposal is to improve patient and renal graft survival following SLK transplant.

There were 26 comments received, about half of which did not pertain to the proposal (Exhibit H). Of the six or seven comments pertaining to the proposal, one comment stated that kidney biopsy should be the gold standard, however the Committee did not believe that requiring a kidney biopsy was feasible. Another comment stated that the MDRD formula was not validated in candidates with cirrhosis. The Committee did not know of a formula that would be 100% correct for all patients. Some comments recommended changing the MELD formula to decrease the contribution of renal failure to the MELD score. The Committee will refer this comment to the proposal's co-sponsor, the Liver and Intestinal Organ Transplantation Committee. The National Kidney Foundation (NKF) comments focused on the

CKD classifications and the priority given to candidates in the safety net. Specifically, the NKF was concerned that the terminology used in the proposal for kidney failure and end stage renal disease did not correspond to the NKF guidelines and may lead to confusion in the Community. The Committee agreed to revise the terminology to better correspond with the NKF guidelines, perhaps renal insufficiency instead of kidney failure. The ASTS disagreed with the proposal and instead proposed that the surgeons should have broad discretion over which candidates should receive SLK. They primarily believed that the time requirements would disadvantage centers with very short liver waiting times. A member of the Committee remarked that the ASTS did not formally survey its membership before providing its comments. One member remarked that the Pancreas Transplantation Committee's opposition to the proposal did not make much sense in that the proposal would improve access for kidney-pancreas candidates. Elizabeth Sleeman, liaison to the Pancreas Transplantation Committee added that the Committee was concerned that the liver candidates in the safety net would receive higher quality kidneys than they would have received initially with an SLK transplant.

The Committee understood that it needs to do additional work to discuss how to implement this proposal and will form a joint subcommittee with the Liver and Intestinal Organ Transplantation Committee. However, it unanimously voted (17-0-0) to endorse the proposal to show its support for the concepts and to ensure that it moves forward after the implementation issues are addressed.

4. Policy Options to Increase Access for Sensitized Adolescent Candidates

Eileen Brewer presented some findings from the Kidney Pancreas working group of the Pediatric Transplantation Committee on issues of disadvantaged adolescent groups (Exhibit I). The working group believes that highly sensitized adolescents are disadvantaged by the current share-35 policy. The working group requested simulation modeling to investigate if policy modifications would improve access for these candidates. Run 1 prioritized pediatric candidates over highly sensitized adults, Run 2 added regional sharing for highly sensitized pediatric candidates, and Run 3 added regional sharing for highly sensitized adults.

Expected Number of KI Alone Transplants Mean and Standard Deviation of 3 runs

Transplant	Current Rules	1. OMM PRA ≥ 80% pediatric patients over PRA ≥ 80% adults	2. Add Regional sharing for pediatric PRA ≥ 80%	3. Regional sharing for adults PRA ≥ 80%
Total Pediatric KI:	584 (26)	603 (9)	641 (9)	581 (3)
Pediatric PRA ≥ 80%	39 (5)	42 (6)	67 (3)	74 (7)
OMM Pediatric PRA ≥ 80%	4 (2)	6 (3)	6 (2)	4 (1)
Total Adult KI:	7670 (43)	7692 (53)	7625 (34)	6482 (95)
Adult PRA ≥ 80%	988 (8)	1040 (19)	998 (46)	1649 (29)
OMM Adult PRA ≥ 80%	142 (9)	150 (16)	137 (2)	147 (1)
Total KI:	8254(68)	8295(54)	8266(43)	7063(93)

SRTR

The working group asked for a comment from the Kidney Transplantation Committee about its support for a policy proposal at this time. Dr. Stock remarked that the Committee would support the concept, but the implementation of this change may not be possible at this time. Mr. McCullough remarked that there is an odd allocation rule that sensitized non-zero mismatched adults rank above pediatric candidates when the adult has more points than all of the kids. A member asked if the SRTR assumed a false positive cross match rate for the regional sharing. Mr. McCullough explained that among the sensitized pediatrics, there is not a separate model for positive crossmatch and it does not take into account unacceptable antigens. So the actual effect could be much less than the simulated effect because it does not take into account unacceptable antigens that lead to positive crossmatches. Another member remarked that a better policy approach would be to characterize how allo-antibodies are characterized. Part of pediatric allocation should be to allocate true negative crossmatched kidneys.

Dr. Brewer offered to return to the working group and to report that the Kidney Transplantation Committee is in favor of helping sensitized pediatric candidates gain better access. However, they are concerned with the methods used in the simulation modeling and the implementation of regional sharing which could lead to poor crossmatches, poor graft survival, and increased discards.