

December 18, 2008

Peter G. Stock, MD, PhD
Chair, Kidney Transplantation Committee
Organ and Procurement Transplantation Network (OPTN)
United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23219

Dear Dr. Stock,

The ASTS is pleased to provide this response to the UNOS/OPTN request for information (RFI) regarding the draft proposal for a new kidney allocation plan. The ASTS recognizes the tremendous amount of work, resources, and analytic effort that have been focused on this project. This enormous effort by the UNOS/OPTN and the Scientific Registry for Transplant Recipients (SRTR) is a testimony to the commitment of its volunteer members, diligence of its staff, and the wealth of data available. We support several of the concepts introduced in this proposal, but have major concerns about proceeding toward implementation at this time. In our response, we first outline the concepts we support and then discuss our numerous concerns. An over-riding concern is that the system as now proposed is going to be very difficult to explain to the lay public including the patients.

In general, we think the use of dialysis time (DT) instead of waiting time as a justice measure is appropriate because it is a more patient-specific measure of transplant need. We agree that incorporating this into future kidney allocation policy will likely reduce some patients' disadvantage on the list because of late referral. However, given the benefit of preemptive transplantation, we are not convinced that candidates who seek early referral should be held back.

National Office
2461 South Clark Street
Suite 640, Arlington, VA 22202
Phone: 703 414-7870
Fax: 703 414-7874
Email: asts@asts.org
www.asts.org

President
John P. Roberts, MD
University of California San Francisco
Division of Transplantation
505 Parnassus Ave
Box 0780, Room M896
San Francisco, CA 94143-0780
Phone: 415 353-1888
Fax: 415 353-8709
Email: robertsj@surgery.ucsf.edu

President-Elect
Robert M. Merion, MD
University of Michigan
315 West Huron, Suite 240
Ann Arbor, MI 48103-4262
Phone: 734 936-7336
Fax: 734 998-6620
Email: merionb@med.umich.edu

Secretary
Kim M. Olthoff, MD
University of Pennsylvania
Department of Surgery
3400 Spruce St - 2 Dulles
Philadelphia, PA 19104
Phone: 215 662-6136
Fax: 215 662-2244
Email: kim.olthoff@uphs.upenn.edu

Treasurer
Michael M. Abecassis, MD, MBA
Northwestern University
Division of Transplantation
675 N. St. Clair Street, #17-200
Chicago, IL 60611
Phone: 312 695-0359
Fax: 312 695-9194
Email: mabecass@nmh.org

Immediate Past President
Goran B. Klintmalm, MD, PhD

Past President
Arthur J. Matas, MD

Councilors-at-Large
Mitchell L. Henry, MD
Robert L. Kormos, MD
Alan N. Langnas, DO
Richard B. Freeman, Jr., MD
Dixon B. Kaufman, MD, PhD
Timothy L. Pruett, MD
James D. Eason, MD
Charles M. Miller, MD
Peter G. Stock, MD, PhD

Executive Director
Katrina Crist, MBA
Email: katrinacrist@earthlink.net

We also support the development of a more continuous measure of donor risk as embodied in the Donor Profile Index (DPI). We agree that this will more accurately inform transplant professionals and patients about the risks of individual kidney grafts. This will also improve decision-making at the organ procurement organization, transplant center, and patient levels. There are, however, many concerns that we believe must be addressed to satisfy patients and the public that this proposal represents the fairest system, and that it will improve results. In addition, we think that explaining the DPI to candidates may be much more difficult than explaining a more stratified system (5 categories of risk). This needs to be studied further before moving forward.

GENERAL CONCERNS

We strongly believe that the request to direct comments on the specific aspects of the proposal (LYFT, DPI, DT, and limitations) is very premature. The RFI summarizes the Kidney Committee's (KC) deliberations, but there are numerous areas where it is clear that fundamental assumptions about the kidney allocation system were made. No background was provided for how these assumptions were reached or indicating the wider public input that was used to arrive at them. Our membership remains extremely concerned because many of these underlying assumptions have not been discussed widely enough for a general consensus to be reached. Indeed, our membership is not convinced that this plan offers a significant improvement from the patients' or transplant centers' point of view. *Therefore, although the request was to focus only on the specific aspects of this proposal, we feel compelled to comment on some of the fundamental assumptions for which we believe there is no good consensus, but seem to be forgone conclusions already,* before we discuss areas where requested. We feel there is a clear need for repeated, much wider, discussion of these underlying principles to be sure that this type of system is acceptable to the majority of the transplant community. Moreover, even if with additional discussion and consensus building, all of the assumptions prove acceptable, the accuracy of the models, logistics, and potential implications of operationalizing this plan have not been considered.

We believe the proposal regarding life years from transplant (LYFT) is the weakest and most poorly supported part of the proposal. Numerous ethical and statistical assumptions are made. There are no data showing that other possibilities were considered and why LYFT might be the best one. In addition, there has been no response to the requests for data and alternative approaches that were made at the last public forum.

We think it is important to note that the development of Model of Endstage Liver Disease (MELD) for liver allocation and the Lung Allocation Score (LAS) for lung allocation utilized data that were not included in the UNOS/OPTN database at the time. Policy-makers were not deterred in pursuing these data since they were deemed crucial for constructing accurate predictive models and verification of the statistical principles. This was done *before* any policy proposals were formulated. Therefore, in the following detailed response to the RFI, we indicate where additional data and outside analyses could be obtained to improve the accuracy and better clarify the implications

of this proposal. *Our membership believes that this essential step must be completed before formally proposing any new policy that utilizes risk models for allocation.*

The RFI document outlines what the committee sees as the limitations of the current system that a new system needs to address. These include (page 10 of the RFI):

- a) the general inefficiency of placing kidneys from Extended Criteria Donors, leading to a high discard rate;
- b) lack of predictability of kidney allocation, making maintenance of the list difficult;
- c) great variability in access to transplantation by blood group and geographic location;
- d) inefficiency of current methods of identifying and allocating kidneys to sensitized candidates;
- e) mismatch between expected graft and patient survival;
- f) variation in access to the donor pool by geographic location.

In fact, the proposal outlined in the RFI only addresses one of the above issues ("e"), and does nothing to solve the other problems.

SPECIFIC CONCERNS

1) The introductory paragraphs of the RFI document indicate that many aspects of kidney allocation have been considered and that the KC is now considering LYFT as a major component for a new system. No rationale is provided for why this model has been chosen and why other methods were discarded. Furthermore, although the document indicates that the KC believes the concepts in the document will most effectively improve kidney allocation there is no mention of how the KC defined "effectively". There is an implication that the current system produces a rate of recipient death with a functioning graft that is unacceptably high. The current rate of death with a functioning graft is much more a result of the age distribution on the waiting list, and the fact that expected deceased donor kidney graft function times for most grafts exceed the expected life spans of most patients on the waiting list. While the ASTS agrees with the principle of not using kidneys from the youngest donors in the oldest patients, our view is that applying this concept on a continuous scale does not provide for the best allocation system.

2) The KC has decided that adding 0.43 additional years of transplant benefit on average, compared with the current system, represents "the most effective system". There is no discussion of why this result has been deemed "most effective". Moreover, no data have been presented to indicate how this benefit will be stratified across subgroups. For example, under the proposed system, younger patients are likely to get more survival benefit since they will more frequently receive grafts with longer function times. But older patients will be less likely to receive low-risk grafts and the data provided by the committee clearly show that survival for older recipients will decrease. This result has not been accepted by the community as more equitable, more just, or more effective than the current system.

3) Another potential problem is that the predictable redirection of longer functioning grafts to younger patients will likely decrease the incentive to pursue living donor transplantation (as has been documented with changes in pediatric organ allocation). The KC apparently decided that an arbitrary reduction of the LYFT contribution to the Kidney Allocation System (KAS) from 100% to 80% would be sufficient to reduce this loss of living donor incentive, but there is no justification for why this 20% reduction is the best choice to solve this problem. Did the committee look at other values or other alternatives?

4) The RFI document does not provide any sound rationale for why kidney allocation must have a central goal or, more importantly, why the goal of increasing life years gained is the most acceptable goal (especially given the committee's outline of the problems with the current system described above). It is relatively straight forward to agree on mortality risk goals for the life-saving transplants (e.g., liver or heart) since there is no other treatment option. Kidney transplantation is different because quality of life (QOL) also enters into decision-making much more pervasively, and dialysis offers an alternative treatment option. The KC recognized that these fundamental differences between kidney and other organ allocation exist, but did little to address them. In fact, the inclusion of the global adjustment for reduced QOL on dialysis does not take into account individual patient differences or preferences, and the proposed system offers less patient choice than the current one (see below). In addition, the data used to justify the QOL adjustment were published more than 10 years ago and are likely not reflective of patients' current preferences. Assuming that all patients' QOL decisions are uniform, both while on dialysis and after transplantation, is a paternalistic approach which is again difficult to justify given the extremely small gain in life-years. Furthermore, the committee was asked to look at other models where QOL years early after transplant were given more weight than late after transplant. This information has not been provided.

5) The proposed goal of maximizing LYFT is a graft-based goal since the proposed system ranks patients first according to the DPI in order to determine how much of a role LYFT and DT will play in the final KAS. Many patients have already argued that kidney allocation should be patient-based, rather than driven by the type of graft that is offered. One could easily argue that patient autonomy should be the central goal, or minimizing dialysis years, or even minimizing waiting list deaths. *Without a very comprehensive, open, and diverse debate to establish what this kidney allocation goal should be, in which there is a thorough discussion of alternatives, we believe that it is very premature to assume that maximizing LYFT is the agreed central goal for kidney allocation.* Moreover, while maximizing LYFT may be consistent with the Final Rule, there is no requirement in the Final Rule that LYFT *must* be part of a kidney allocation system as implied in the RFI. This is especially problematic when considering some of value judgment trade-offs in the proposal actually deviate from this central goal (see below).

6) The RFI document suggests that allocation policy changes for other organs have improved patient and graft survival, implying that this should be a justification for changing the kidney allocation system also. We are aware of no data that any allocation system is responsible for improving patient and graft survival. The modeling for the proposed system here suggests that, at best, only marginal improvements are likely.

7) We agree that the current system has limitations, but note that the proposed plan does not address most of them. For example, the RFI suggests that efficiency of placement for kidneys with higher graft failure risks will be improved, but no data are provided to support this contention. Higher risk kidneys are now offered to candidates under the current ECD system.

8) Under this proposed system, centers and patients will be forced to accept the higher- risk graft offers because refusing such offers to wait for a better offer will be futile, since waiting longer results in reduced LYFT for individual patients. The accumulation of additional DT will not result in a higher likelihood of receiving an offer of a lower DPI graft. Therefore, the first offer that older patients with little DT receive will likely be the best one they will ever get.

9) The proposed system will not improve the predictability of allograft offers at all since centers and patients will have to be prepared for a wide range of donor DPI offers. Presumably, each donor will generate a different match run because the DPI will dictate the ranking of all of the possible candidates. Thus, the sequence of waiting candidates for a 60-year-old DCD donor will look dramatically different than that for a 25-year-old brain-dead trauma victim. Furthermore, the sequence would be expected to vary for a 55-year-old donor as compared to a 60-year-old donor. Not only will donor age affect the sequence, it will affect the other components of the DPI as well. Combined with the variability introduced by age, HLA-DR matching, and other components of the LYFT score, it will be difficult for centers and their patients to have a predictable time to transplantation. This uncertainty would generate large costs as centers struggle to keep patients ready for transplantation, and patients are required to undergo invasive testing such as cardiac catheterization to be ready for transplantation. The current system provides predictability at least up to the last two years, at which time HLA-DR points muddle the predictability. Given the small effect that the addition of HLA-DR matching has on the total LYFT score, consideration should be given to eliminating DR matching in LYFT to improve the predictability of transplantation. Under the proposed system, centers will not be able to give much information to patients regarding their likelihood of receiving an offer over a given time frame since this will depend mostly on the type of donor at hand, which cannot be predicted ahead of time. This difficulty will be compounded by the fact that all patients' LYFT will decrease with time, since as they age everyone has less life that could be potentially gained.

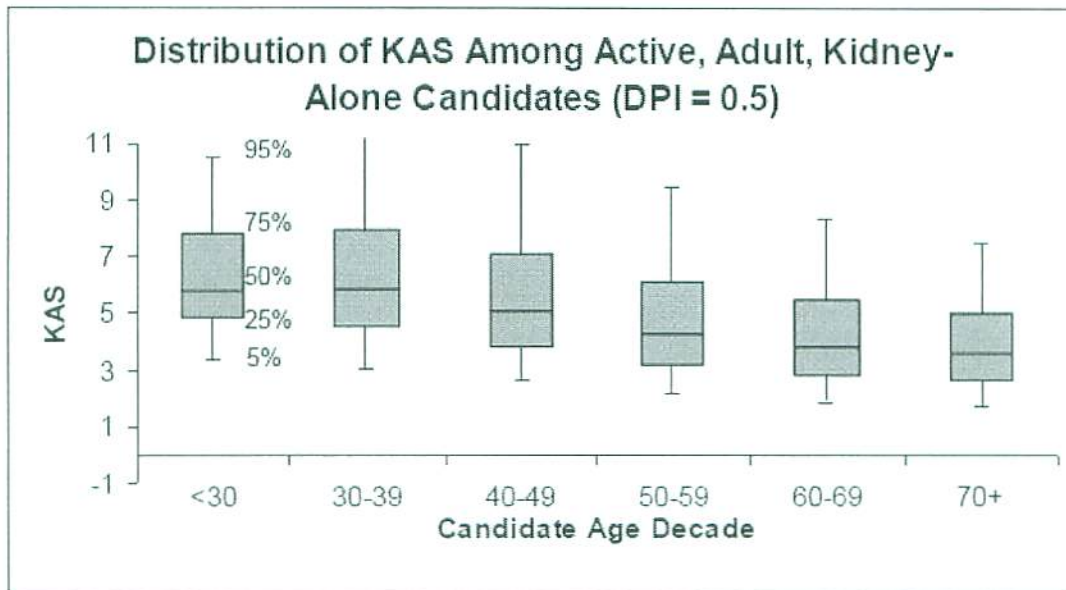
10) The RFI document indicates that kidney allocation is different from allocation of organs to patients in need of lifesaving grafts, and that more than just waiting list mortality and post-transplant survival should be considered. However, LYFT

comprises purely mortality risks, since it is the combination of survival with or without a transplant, and it does not account for any other factors. Our patients do not uniformly discount the QOL while waiting for a transplant, and numerous other issues are considered by patients and their caregivers in determining whether to accept a given kidney offer.

11) The proposed KAS-based system uses median survival estimates to calculate survival with and without a transplant, with no truncation or discounting of survival times. This severely disadvantages older candidates, since no matter what treatment they receive they will always have less life available and can never achieve high LYFT scores. This assumption also presupposes that each recipient will weight whatever years he or she gains from a transplant equally and with equal value. This is an extremely paternalistic assumption, one which has not been widely discussed or explained to patients or the transplant community. Moreover, the use of time horizons without any discounting of extra years gained is not a generally accepted principle in health care research and the models presented here are not that accurate anyway (see below). The RFI document mentions that other alternatives with truncated survival times were assessed by the KC but discarded because some kidney recipients have long survival times. However, there is no discussion of why longer survival times would make truncated survival calculations unacceptable. When the effect of varying the time horizons is examined, it appears that the KC chose the current model because it allocates kidneys preferentially to younger candidates. While the LYFT model is touted as providing net benefit, the vast majority of the benefit gained is in post-transplant survival. This emphasis on post-transplant survival overwhelms the benefit seen by decreasing deaths on the waiting list by early transplantation in the Type 2 diabetics and older patients. We strongly believe that the consequences of using the chosen time horizon must be formally presented and outlined for patients before there are any further considerations of implementing this system and other models with other timeframes need to be more openly considered.

12) Specifically regarding LYFT variables and calculations, we believe serious deficiencies have not been addressed. In the 20 August, 2008 response to ASTS's initial questions, the SRTR indicated that the components of LYFT achieved relatively poor results for predicting short-term (c statistic = 0.66) and long-term (c statistic = 0.60) patient survival without a transplant, and for predicting short (c statistic = 0.67) and long-term (c statistic = 0.68) patient survival with a transplant. This means that at best, the LYFT will be accurate for only 60-70% of patients. Furthermore, the c statistic for graft survival is 57% for 4-15 years. As LYFT uses very long time horizons, it would be expected that the ability to predict the outcome in the time horizons considered will be only slightly better than a coin flip, and that the predictability is dependent nearly completely on the age of the patient.

The problem that accuracy of prediction creates can be seen in this figure from the previous KC response to ASTS.



For the median kidney, there is still a trend in KAS with age, although there is substantial overlap even between candidates with extreme ages (<30 and 70+).

For the median DPI kidney, candidate KAS scores overlap considerably. With the poor predictability, giving the kidney to one particular individual is going to be seen as a relatively arbitrary decision.

This degree of accuracy is far below the current standards for mathematical models, both for publication in the literature, and for implementation as part of organ allocation policy. For example, the MELD score was far more accurate at predicting a patient at risk of death. Moreover, unlike what is standard in model validations, the proposed LYFT model has not been validated on separate cohorts of patients. *We think it is ill advised at best to tell patients that the LYFT score will predict the benefit an individual will receive from transplant. In fact, 30-40% of the time, it will be wrong. We feel strongly that that organ allocation policy must be based on much more accurate, validated predictive models to not only maintain equity, but more importantly, to maintain credibility.* Implementing a flawed and inaccurate system that is “the best we can do with the available data” has not been acceptable in other organ allocation policy development, and, because of the much larger patient population affected, is even more unacceptable for kidney allocation.

13) The RFI justifies the inclusion of candidate age by claiming that this is an objective medical criterion as required by the Final Rule. We disagree. While age is an objective measure, it is not a unique “medical criterion” since all living things (plants, animals, and humans) have a higher risk of dying the older they become. Increasing age is a risk factor for death for sequoia trees and corn stalks, just as it is for mosquitoes and humans. Age is not a measure of health status, but is just a covariate in the assessment of health status and, as such, does not *a priori* mean it should be included in allocation

policy. In fact, age was intentionally left out of liver allocation policy, even though it is associated with liver waiting list and transplant outcome to avoid the very value judgments that we find problematic in this proposed kidney allocation policy. It is reasonable to use age among other variables to measure the results of allocation policy, but doing so does not necessarily justify using age for the allocation policy itself. We feel strongly that when age is used in a policy that defines access to treatment, it should only be done with the general consent of everyone involved. For example, physicians and hospitals may allocate scarce ICU beds based on the age of a patient in certain medical situations and on individual bases. However, a hospital that had a standing policy that *always* dictated that older patients would have less chance of getting an ICU bed would not be tolerated for long. Furthermore, just because a piece of information is easily available does not make it automatically acceptable to use it for allocation policy.

14) We suspect the inaccuracy of the LYFT model is due to the exclusion or omission of some of the variables that have been consistently documented in the literature to be important in determining outcome for end-stage renal disease (ESRD) and renal transplant patients. We think the process of determining the LYFT score should be subjected to expert panel review, possibly by the Institute of Medicine. Cardiovascular risk is the most often cited contributor to ESRD and renal transplant mortality, but the RFI document indicates that the classification of data collected by the UNOS/OPTN on angina, drug-treated hypertension, peripheral vascular disease and New York Heart Association (NYHA) is unreliable. It may be true that these data are not collected accurately or consistently in the UNOS/OPTN system, but this does not diminish their importance. As mentioned above, during the development of the liver and lung allocation systems, policy-makers identified data elements that were not included in the UNOS data, but that were deemed critical for development of valid models. They used other sources for initial model building and validation, sought approval for inclusion of these additional data elements into the UNOS data collection system, and ultimately included them in allocation models that are now in place. *This has not been done for kidney allocation, but it could and should be. The ASTS would be pleased to help in this effort.*

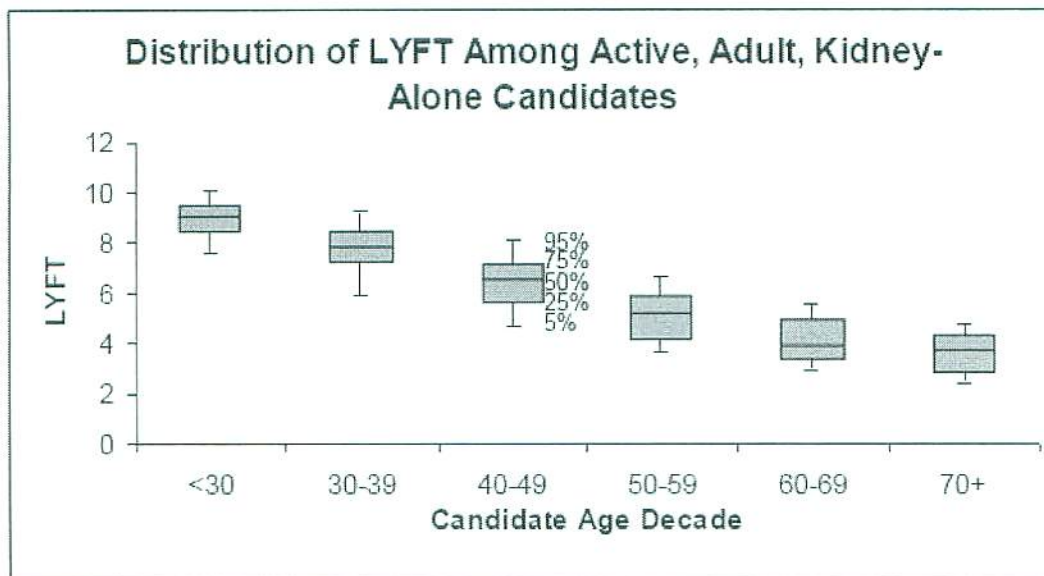
15) There are now several reports documenting the Charleson Comorbidity Index (CCI) as a reliable and reproducible measure of comorbidities in a wide variety of clinical conditions, including renal and liver transplantation. Data for the CCI are collected as part of the National Inpatient Sample and are publicly available. Incorporation of measures like the CCI would likely improve LYFT's accuracy. Our membership feels strongly that including important measures like the CCI, validating any models on cohorts other than those used to derive the models, and then presenting the accuracy of the predictive models publicly should be the only way to move forward with any new organ allocation proposal that utilizes predictive models.

16) Race, like age, is another covariate frequently associated with ESRD and transplant results. It is not clear why this variable was cited in the KC committee response to ASTS as not being objective. No justification is provided for omitting race from the LYFT calculation. Observer-reported race is a variable used in almost every healthcare

database, and, accurate or not, it is consistently associated with outcomes. We note that donor race (and donor hypertension by the way) is included in the DPI. Why is the observer-reported race designation in the donor data more accurate or acceptable than in the candidate data? Furthermore, the Kidney-Pancreas Simulated Allocation Model (KPSAM) results are stratified by race. Since, as the RFI document describes, the KPSAM uses actual UNOS/OPTN data to project outcomes under various new allocation proposals, we question why the KPSAM results indicating transplants by race are accurate at all if the race designation is unacceptably inaccurate in the underlying data inputs for the KPSAM. In fact, most studies suggest that African-American dialysis patients have better survival on dialysis, but have worse post-transplant graft survival than their white counterparts (i.e., less LYFT than whites). The KPSAM results suggest that the numbers of African-Americans who receive transplants under this proposed system are actually significantly increased, indicating that the goal of maximizing LYFT is not necessarily maintained for these patients.

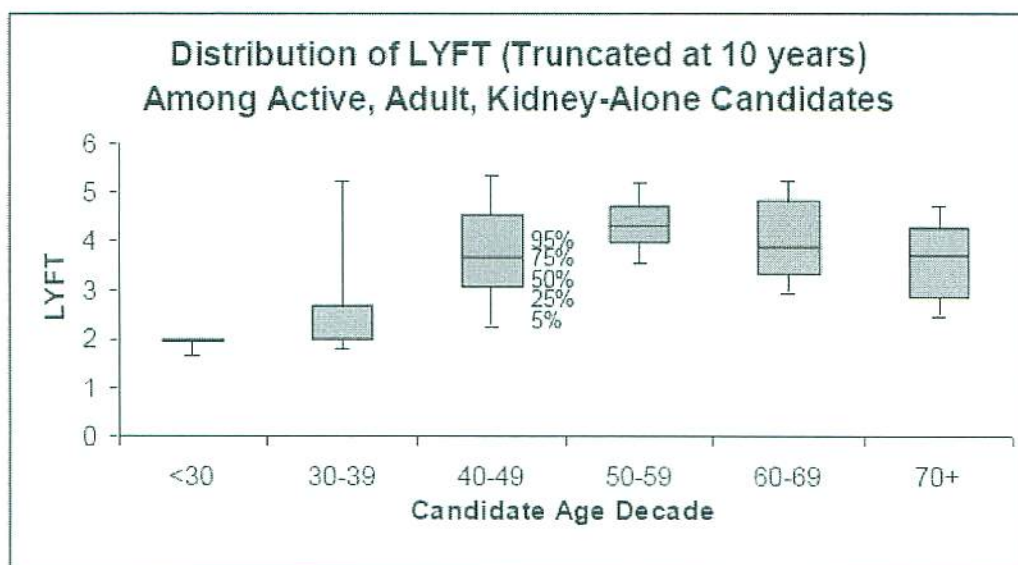
We recognize that the KC may have decided that including race in organ allocation policy may not be acceptable on a cultural, sociological level if doing so would reduce access to transplant for candidates of color. This apparent value judgment on the part of the KC to exclude this variable and accept the resulting reduction in model accuracy may be acceptable for greater gains in individual justice. Importantly though, excluding race because of societal concerns about maintaining justice in access to transplants raises a question. Why then is it acceptable to include age in the LYFT calculation and thereby limit access to the best kidneys for older patients? If it is acceptable to *omit race* and consequently accept a less accurate model, and, by extension, accept less than the maximum gain in life years from transplant, why then is it acceptable to *include age*? Apparently the KC has decided that this trade-off is acceptable. It may be, but patients and the transplant community have not had the opportunity to weigh in on this judgment and our membership feels this trade-off in justice is not necessarily justified by the small gain in utility accomplished by this proposal.

17) Previously, the KC responded to the ASTS regarding the time horizons used in the LYFT model. LYFT currently uses median survival times. The ASTS had asked about looking at other survival times, specifically at the effect of truncation of the survival times rather than the median survival time. We feel it is important for the community to understand the effect of using median survival times rather than truncating the times at 10 or 15 years. The times chosen have a critical impact on kidney allocation in the model. The diagram below, taken from the UNOS/OPTN response to the ASTS, shows the distribution of LYFT among transplant candidates in the proposed model. That the allocation of kidneys favors younger recipients can clearly be seen.

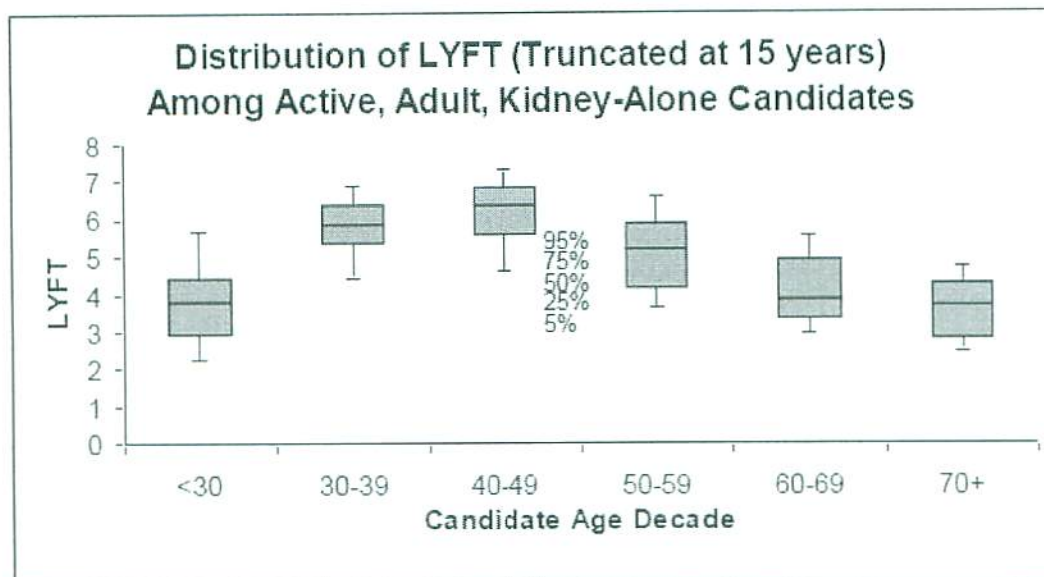


The figure above is based on median lifetimes (without discounting or truncation) and is shown for comparison purposes.

With shorter time horizons, the LFYT score favors an older group of patients, as shown here, but similar effects would be expected for favoring diabetics when the time horizons are shortened. The two figures below show the allocation when the time horizons are truncated at 10 and 15 years.



Truncated at 10 years, the increase in life among candidates under the age of 30 is largely excluded (see above figure).



Truncated at 15 years, the increase in life among candidates under the age of 40 is only partially captured (see above figure).

The reason that changing the time horizons changes the LYFT score is because shorter time horizons increase the weight that waiting list survival has in the net benefit calculation; that is, older patients (and diabetic patients) have a greater decrease in waitlist mortality with transplantation than do younger patients.

The above combination—a model with an infinite time horizon, no discounting of survival times, exclusion of co-morbidity, inclusion of age but exclusion of race, exclusion of other factors known to impact transplant outcome (e.g., pre-transplant non-adherence), and that gives each year an equal QOL—results in a model that directs better kidneys to younger candidates and the less good kidneys to older candidates. We would like the committee to demonstrate how much of the net benefit derives from decrease in waitlist mortality versus a decrease in post transplant mortality for each of the time models above such as truncation at 5, 10, and 15 years versus the median survival time model.

We believe that the net benefit of transplantation should be weighted to the decrease in mortality associated with waiting for transplantation, rather than fulfilling the quest to transplant the younger patient. Perhaps a combined approach of provision of the best kidneys to patients under the age of 35 similar to the pediatric allocation currently with truncation of the survival at 10 years would provide a better model for LYFT. It would certainly be easier to explain to the public. ASTS cannot accept the ethical value judgments that have been made that underlie the model, and do not believe that the decision to accept a relatively inaccurate predictive model is in the best interest of our patients.

18) We feel the DPI does represent an improvement over dichotomous characterization of donor risks. However, as indicated above, we feel that mathematical models used as a basis for organ allocation should be subjected to peer review before they are incorporated into policy. It is therefore premature to implement any change in kidney allocation policy that includes the DPI before this peer review has taken place.

19) There is no rationale for equating simultaneous kidney pancreas (SPK) transplantation with simultaneous liver/kidney or heart/kidney transplants. SPK is not a life-saving transplant. SPK transplants do provide QOL benefits, but mandating that kidney allocation must follow pancreas allocation has large implications for the kidney-only candidate pool that have not been widely discussed. No data are provided regarding the impact this policy would have on candidates waiting for kidney-only transplants. Moreover, if such an advantage would be granted to SPK candidates, it will be critical to have accurate and reproducible listing criteria for SPK candidates that will prevent gaming of the system. No such criteria are provided. The RFI suggests that this proposed change would improve the efficiency of the allocation system, but does not mention how these improvements are measured or estimated. Increasing the number of organs transplanted per donor is an important goal, but should not be the main thrust of organ allocation policy, especially if it reduces access for other patients, or results in poorer outcomes for some groups of recipients.

20) In a letter to UNOS/OPTN, we have previously expressed our concerns with the proposed cPRA methodologies. While we generally support giving extra priority to highly sensitized candidates, the cPRA assays and their interpretation open the possibility for significant variation, gaming of the system, and introduction of inequity. As cPRA has not been included in any allocation system, the use of this in the KARS model is based on extrapolation from PRA data that is unwarranted. We feel that this system should be well established and refined before being incorporated into a larger change in kidney allocation policy. As cPRA is being discussed separately from the RFI, we plan to continue to interact with the UNOS/OPTN on the ideal way to characterize and define the highly sensitized candidate.

SUMMARY COMMENTS AND SUGGESTIONS

We recognize that one flaw in the current system that the KC has tried to address is the allocation of a kidney from a healthy young trauma victim to an old recipient with a limited lifespan, even though a transplant would benefit that older recipient. But it appears that this is the *only* problem LYFT has addressed, and the emphasis on this problem by the KC has created methodological and ethical issues that have not been addressed. We believe there are simpler ways to address this problem such as directing younger kidneys to younger patients. For the data of wait list additions of patients <35 years and the number of deceased donor kidneys from donors of the same age group, it would appear that there would be enough kidneys to transplant this population with age matched kidneys though there may be a need for wider sharing. The other limitations of the current system, which we have outlined in our response, would not be affected at all

if the new proposal were implemented. Finally, feedback from our patients and colleagues consistently indicates that the proposed system is too complex and cumbersome.

There are many other possible solutions to improve the matching of kidneys with long projected function times to candidates with long projected post-transplant survival times that would be much simpler, would not rely on relatively inaccurate statistical models, and would not engender the intense justice-versus-utility tradeoffs. A very straightforward example that may very well achieve most of the purported advantages of KAS might be to require that deceased donor kidneys from donors less than 35 years old be preferentially offered to candidates less than 35 years old (a modification of the current proposal giving priority to pediatric candidates).

We could require that all candidates indicate what range of donor risk (DPI) he or she is willing to accept. Arguably, this is not much different than the LYFT-based KAS proposal, but there is a fundamental difference. By allowing patients to designate the DPI they are willing to accept before a donor organ is offered, the system becomes a patient-based system, in contrast to the LYFT-based system, where the candidate's age mostly determines the type of kidney he or she will be offered, regardless of the patient's preference. Alternatively, we could just require that candidates greater than a certain age cannot designate accepting kidneys with the lowest DPI. This may or may not achieve the 0.4 years extra life-years that the LYFT-based system may achieve, but it will preserve patient autonomy and individual justice, and would require much less reorganization and reeducation. Conceptually, we believe this seems much easier for patients to understand and trust.

The draft proposal for a new kidney allocation plan does not include a transition plan. Our position is that the allocation plan is far from ready to go forward, but we urge the KC and the UNOS/OPTN to consider, at very early stages, how any future plan might be transitioned. For example, how would a 65-year-old with 1500 waiting days be handled in transition to a LYFT-based system? Under the current policy, such a patient would likely have an offer for a standard criteria kidney relatively soon. However, under the proposed system, this patient would have a much reduced chance at receiving a low-risk kidney offer. Patients and transplant programs will require advanced notice and a very detailed description and justification for whatever transition policy is developed, and no plan should be proposed without including this important aspect.

We suggest that the KC and UNOS/OPTN Board should consider stepwise implementation of some aspects of the proposed system. One first step might be to substitute DT for waiting time, without changing other aspects of the current allocation system. Doing so would be relatively uncomplicated and likely accepted by patients. Another step could be to complete the change to cPRA before changing any other policies related to cPRA. Finally, the DPI could be instituted before any implementation of a KAS allocation system.

In conclusion, the draft proposal is very premature. Many of the assumptions it contains require a much wider discussion, and certainly more than just one additional public forum. Compared to the current system, the one proposed appears to limit individual justice for very little gain in population utility. We do not feel this trade-off is worthwhile or in the best interest of our patients, or is necessarily the wisest use of the deceased donor pool. In addition, the omission of important predictive variables and the resulting low level of accuracy in the models limit the credibility and effectiveness of this system. Important questions also remain regarding operationalizing this system. It is too complicated and cumbersome for most patients to understand. We do not support the concepts or the specifics of the proposed change in allocation at this time, but would be pleased to continue to work with UNOS/OPTN and the wider transplant community to improve organ allocation policy.

Sincerely,

A handwritten signature in black ink, appearing to read 'JPR', with a stylized, cursive script.

John P. Roberts, MD
President