



ASTS Responses to OPTN Proposals Open for Public Comment

March 15, 20203

[Expand Required Simultaneous Liver-Kidney Allocation - Public Comment Proposal](#)

The revised SLK policy is being proposed in order to provide alignment for lung-kidney and heart-kidney which do share the kidney for eligible patients out to 500 NM. In order to provide similar access to transplant for SLK candidates, the proposal seeks to align the SLK and expand allocation of kidneys for SLK candidates with MELD 29 and higher out to 500 NM. The medical eligibility criteria for combined SLK remain the same. Under the current policy, OPOs may opt to share out to 500 NM for SLK, but it is not required. This has led to a considerable amount of variability around the country which is also not optimal.

A potential unintended consequence may be decreased access to the kidney transplant alone patients, specifically vulnerable populations. Additionally, there is concern the highest quality kidneys will also not be available to the kidney alone list. This proposal should be supported to align all multi-organ policies.

ASTS Position: Support



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[Update on Continuous Distribution of Livers and Intestines - Request for Feedback](#)

The ASTS is in support of the challenging work being undertaken by the UNOS Liver/Intestine Committee as it works to try to develop a continuous distribution system for liver and intestines. We are also generally supportive of the attributes the committee is considering. The most complex is related to the distance from the donor hospital. We urge the committee to assess the impact of lung continuous distribution model and then incorporate any lessons learned, before continuous distribution is adopted for other organs. For liver, it will be valuable to first review the impact of the recently implemented Acuity Circle model on geographic disparity and closely examining its impact across the country before moving to another change in geographic distribution via continuous distribution. It will be important that the new policy should learn from the outcomes we have just generated from the change to acuity circles.

The ASTS supports continuing with the use of the MELD/PELD score in the first iteration of the continuous distribution system, as opposed to changing to OPOM, because this will already be an unprecedented amount of change. If we change how we measure medical urgency at the same time as all the other components of the system, it will be hard to determine which parts of the system are leading to favorable or unfavorable outcomes. Given the liver/intestine allocation system just changed to a new system 2 years ago, the opportunity for modeling may be limited, as LSAM will not have the current system data available to use. One additional concern about OPOM is that by prioritizing those with HCC who are at the highest risk of waitlist drop out/waitlist mortality, we may inadvertently prioritize patients who are at risk of post LT recurrence of HCC and thus achieve worse post LT outcomes.

The ASTS supports trying to incorporate a post-transplant survival factor, but we agree with the Liver/Intestine Committee that at present, there is not a reliable post-transplant survival prediction model and therefore the ASTS supports the committee's decision to not include this at the present time.

Whether the committee should include a factor for height or BSA will depend on the anticipated impact of choosing one versus the other. It is likely that either option may be beneficial, though it is not clear how obesity or massive ascites may impact the calculation of BSA and the predictiveness of this as a surrogate for difficult to match. Patients of short stature with massive ascites may be able to accept larger livers though this is generally not true for patients with obesity.

The ASTS is supportive of highly prioritizing prior living liver donors who subsequently require liver transplantation, and those that are closer to the time of donation should be prioritized even higher. This is anticipated to be very rare.

The ASTS is supportive of consideration of incentivizing split liver in the new system, though the ASTS recognizes the challenges of split liver including increased frequency fatty infiltration of the donor liver and potentially high acuity of the index recipient. The low frequency of split livers may not warrant adding a high amount of complexity to the allocation system. It would be valuable to determine if there are any lessons learned from the Region 8 split liver variance that can be reviewed.

Placement efficiency and population density are the most complex components of the new proposed system. It is difficult to justify placement efficiency ahead of disease acuity, yet it is also impossible to allocate across a large portion of the entire US. Importantly, transplant hospitals and donor hospitals and population densities are not evenly distributed. It is important to distribute over a broad enough area so that access and geographic disparity do not worsen in sparsely populated areas, but distributing over large areas may not be necessary in densely population areas under a new system.

The ASTS may support a donor quality scale if one was reliable and readily available. In the absence of this, DCD/age of 70 are reasonable donor quality surrogates. Donor steatosis is valuable but not reliably available.

ASTS cannot support or disagree with this public comment update on continuous distribution of liver and intestines as there are no substantial details included. ASTS does feel strongly that OPTN needs to review the actual data on the recent system outcomes on liver allocation/distribution over the last few years to understand how the most recent changes in liver allocation/distribution have affected outcomes, efficiencies, and costs of liver transplantation. OPTN also needs to show the data that becomes available on other organs, such as lung, that may utilize continuous distribution before others to understand if the outcomes achieved were as simulated.

ASTS Position: Neutral



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[National Liver Review Board \(NLRB\) Guidance for Multivisceral Transplant Candidates - Public Comment Proposal](#)

ASTS agrees with the committee's recommendation to allow for automatic exception points for adult MVT candidates and for them to be considered for an initial exception score equal to MMaT plus six with three additional MELD points every 90 days. We also agree that priority in allocation will remain with the liver alone candidates with lab MELD equal to the MVT candidates MELD exception points, thereby allocating to the patient with the higher lab MELD first when allocation MELD points are equivalent.

We support the proposal that the center must provide the reason for the liver + intestine, or liver + intestine + other organs. However, it is important the request does include the specific indication for each additional organ requested.

We do not see any reason to request more specific criteria for MVT exception beyond the requirement for liver-intestine transplantation with or without other abdominal organs.

We agree with early and continual review of the outcome of this MVT exception point policy to ensure that severely ill liver-alone candidates are not put in undue jeopardy by the MVT exception point policy.

ASTS Position: Support



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Ethical Evaluation of Multiple Listing – White Paper

The ASTS strongly opposes the OPTN Ethics Committee white paper proposal of limiting patients' access to multiple listing. The central argument in this paper is that the OPTN should restrict multiple listing is based on the principle of equity. What is interesting is that the Ethics Committee affirms the ethical justification of multiple evaluations based on patient autonomy to find the center that aligns with their needs, preferences and clinical characteristics because the exact same inequity that the committee is concerned about with multiple listing (e.g., limited to patients with the resources to travel to additional transplant programs for evaluation, attain lodging, receive time off work and potentially pay for an additional transplant evaluation) is present with multiple evaluations. The assumption made in the introduction to the paper is that only patients with financial means have access to the practice of multiple listing because of the amount of time and money it costs to be listed in multiple places. While some patients may choose multiple listing solely because they can afford to do so, other patients may opt for multiple listing for other reasons. They may, for example, have family members in the vicinity of another transplant center meaning they have social support and lodging in two places that have access to transplant centers. They may choose two transplant centers that are geographically close to each other but have varying acceptance practices (e.g., one uses a high number of DCD organs, and one uses a high number of extended criteria grafts). Basing the ethical analysis of multiple listing on equity concerns about potential recipients ignores the fact that there are significant differences about the distribution of transplant centers across the US. While it may be financially prohibitive for some patients to travel by plane, it may be very feasible to travel by car to different centers.

Restricting multiple listings limits patients' autonomy is in direct conflict with the Final Rule. If organs are allowed to freely travel across the US to eliminate geographic disparities, why should patients be restricted in choosing their transplant center(s)? Both practices aim at maximizing the chances of obtaining a transplant. The patient listed in multiple centers, is still listed in each single location according to the same universal criteria and can still only receive one organ for transplant. These patients are not taking away a unique resource or cheating the system. Moreover, albeit still in need of improvement, many efforts have been made to assure that patients are properly informed about the characteristics of the transplant center they choose. Any patient should be allowed to decide whether, based on the available information about the transplantation metrics of different centers, to opt to enhance her chances of transplantation by adding another center to the one where she is already listed. This might happen within the same urban area or across state lines. Limiting this decision seems to also nullify any efforts to inform our patients about the characteristics of the center where they are listed. The ASTS recognizes that there may many different reasons that bring patients to multiple listing and values patients' autonomy in making decision regarding which center to choose. This decision about where to seek listing for transplantation should be the sole prerogative of the patient and not regulated by UNOS/OPTN.

ASTS Position: Strongly Oppose



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[Identify Priority Shares in Kidney Multi-Organ Allocation - Concept Paper](#)

How do transplant professionals recommend improving equity in access to transplant between kidney-alone and kidney multi-organ transplant (MOT) candidates?

Kidney transplant alone (KTA) candidates make up much of the volume of patients on the solid organ transplant waitlist, the longest wait time, and their “medical necessity” is often underestimated since we have HD as an option, as waitlist mortality is still a significant occurrence and an increasingly important outcome measure. We should consider the impact to this group of patients as it relates to kidneys being allocated for MOT.

Should OPOs be required to offer kidneys to some kidney-alone candidates prior to offering kidneys to multi-organ candidates? If yes – what characteristics should prioritize kidney-alone candidates for offers prior to multi-organ candidates?

Yes, during allocation, many OPOs “hold” kidneys for possible MOT scenarios and do not prioritize timely allocation. Many kidneys can wait, but ischemic time especially matters for:

- Pediatric recipients (and its potential effect on DGF)
- Higher KDPI kidneys

Allocating kidneys *after* cross clamp is not an ideal time to be dealing with an unplaced organ.

Also, there are scenarios where access to kidney should be prioritized over MOT as it relates to access to future organ offers.

- Highly sensitized KTA
- Highly sensitized simultaneous pancreas and kidney (SPK)

Should prior living donors receive offers prior to kidney multi-organ candidates?

Yes, the numbers of these patients are very low and given the nature of kidney donation to save lives, they should receive priority over most MOT.

Should some or all pediatric kidney-alone candidates get additional priority for low KDPI kidneys relative to kidney multi-organ candidates?

Yes, children needing a kidney transplant should be a top priority and should get priority over most MOT.

In the absence of policy relating to kidney laterality, how do OPOs currently decide when to offer the left vs. right kidney?

Currently choice is usually given to the MOT candidate center.

Should the OPTN develop policy on when to offer the left vs. right kidney?

Yes, choice should be given to the kidney alone candidate or SPK candidate in most circumstances.

Is it appropriate for policy to distinguish an organ offer order between liver-kidney, heart-kidney, lung-kidney, and pancreas-kidney candidates?

Liver-kidney (SLK), heart-kidney (SHK), lung-kidney should be viewed similarly as the kidney is not the primary life saving organ for the transplant; rather it's the liver, heart, or lung. For an SPK it can be viewed differently, as the lifesaving organ is more often the kidney.

If so, what data should be used to inform such an allocation order?

Kidney outcomes in SPK recipients generally surpass kidney alone outcomes in many instances, however kidney outcomes in liver-kidney, heart-kidney, lung-kidney typically do not surpass kidney alone outcomes in these MOT situations. We should consider utility and long-term outcomes in more of the decision making. As one example, it is not uncommon that a kidney is allocated to a low status SLK or SHK over a pediatric recipient who will likely have more life years served from receiving that kidney.

How can the OPTN provide the necessary level of direction for multi-organ allocation without impinging upon the ability of OPOs to place organs efficiently?

Prioritizing pediatric, prior living donors and highly sensitized kidney alone and SPK recipients will go a long way to achieve more equity for kidney candidates and increase the efficiency and utilization of kidney placement.

Potential Specific Proposed Solutions:

- 1) If a match run has patients with 100% PRA. One kidney should be mandatory to the KTA list.
- 2) If a match run has a patient with 98-100% PRA on the SPK list. One kidney should be reserved for this population.
- 3) High priority (status 1) SHK, and MELD>35 SLK should likely remain a priority.
- 4) If no medically urgent SLK and SHK, before its moved move to lower priority MELD or status, then one kidney should be preserved for: pediatrics, previous living donor.
- 5) Medically urgent KTA should always be offered a kidney.
- 6) 2 hours before scheduled OR, any kidneys not offered to MOT should be primary offer to KTA list. (No more "holding", for a MOT backup)

ASTS Position: Strongly Support



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[Modify Heart Policy for Intended Incompatible Blood Type \(ABOi\) Offers to Pediatric Candidates – Public Comment Proposal](#)

What factors or considerations are preventing transplant programs and/or candidates and candidate support teams from indicating a willingness to accept an intended incompatible blood type donor heart or heart-lungs?

A survey of pediatric transplant cardiologists/pulmonologists and surgeons would be encouraged to answer this question. The ASTS suspects a lack of outcome data would be the reason.

What steps can be taken to improve the use of this policy, even if no changes are made?

The ASTS encourages OPTN/UNOS to gather outcome data and disseminate it, along with disseminating any policy changes. We encourage outcome data for ABOi transplants to be made available in the proposal.

Are candidates who are registered on the heart waiting list put at unnecessary risk by the proposed changes to the eligibility criteria for receiving a heart from an intended blood group incompatible deceased donor?

The ASTS does not think this will be a concern if there are steps involving an intentional acceptance of the incompatible donor.

To what extent might adult heart candidates be impacted by increasing pediatric candidates' access to intended incompatible blood type donor hearts and heart-lungs?

The ASTS does not think adult heart candidates would be substantially impacted by this change.

Are pediatric candidates who are registered on the lung waiting list put at unnecessary risk by the proposed changes to the eligibility criteria for receiving a heart-lung from an intended blood group incompatible deceased donor?

The ASTS does not think this will be a concern if there are steps involving an intentional acceptance of the incompatible donor. To our knowledge the data for ABO incompatible heart-lung, lung transplant is extremely limited.

The proposal will expand eligibility to receive a heart from an intended blood group incompatible deceased donor to pediatric heart status 2 candidates. Is that appropriate? Should only the pediatric

heart status 1A and status 2A candidates continue to be eligible? Why or why not? Should a pediatric candidate be hospitalized at the time of listing to qualify for eligibility?

The availability and use of such organs is quite limited. It would be reasonable to remove restrictions based on status and then audit use of organs to determine its impact. The impact would likely be small.

Policy 6.6.B: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts currently states that a “candidate must not have received treatments that may have reduced isoheamagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.” The proposal maintains the timeframe of 30 days from when the blood sample was collected for candidates with titers of 1:16 or less. Is 30 days the appropriate timeframe? Why or why not? If not, what is the appropriate timeframe?

The ASTS recommends consulting with experts in this particular area to answer this question.

Are there opportunities to make pediatric candidates, their families, and their caregivers aware of the opportunity to accept ABOi donor hearts and lungs?

Knowledge of these proposals should be disseminated amongst recipients and transplant centers to the extent possible. Opportunity might lie in pediatric patient support groups.

ASTS Position: Support



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[Align OPTN KPD Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements](#)

The UNOS KPD program is one of the smallest KPD exchanges in the US, and currently addresses less than 50 transplants per year. Larger exchanges such as NKR facilitate more than 1000 KPD exchanges, so any changes to UNOS KPD policy will not be significantly impactful to the KPD patient population at large. The psychosocial and medical re-evaluation requirements are reasonable given the current program performance – it takes almost 6 months to run the first crossmatch for the first patient. If 20-30 programs that are involved with UNOS KPD as their KPD conduit, this is not an undue burden. There are very few patients in the UNOS KPD, so the number of patients per program are few as well. Medical and psychosocial elements collected should reflect the safety of the living donor to go forward with surgery in a timely manner. The donor reevaluation should be related to the first date the donor has been active in the OPTN KPDPP system,. The 60-day prior notice is reasonable as is the 90-day interval between notification and potential donor eligibility related to donor ineligibility. Blood type alignment requirements are appropriate.

The reality of this proposal is that it does make some of the processes around UNOS KPDPP better, but the program itself has inherent operational inefficiencies that are evident from the data compared to other exchanges. These changes are unlikely to be transformative in facilitating many more UNOS KPD exchanges.

ASTS Position: Support



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Optimizing Usage of Offer Filters - Public Comment Proposal

The ASTS strongly supports the OPTN Proposal: Optimizing Usage of Offer Filters. This proposal is an excellent step towards increasing efficiency in organ placement and utilization.

We strongly support the additional filter criteria that are being proposed by the committee. These criteria are commonly utilized current offers and will likely improve efficiency. We suggest that the committee consider the following additional filter options:

1. Candidate EPTS (this would allow centers to exclude lower EPTS patients from higher KDPI kidneys with additional risk factor combinations);
2. Normothermic reperfusion as a factor in addition to DCD (NRP can affect a center's threshold for acceptable warm time);
3. Donor dialysis or CVVH within 24 or 48 hours of death.

Additionally, the committee should consider excluding centers with less than 2 years of data (new transplant centers) prior to automatic filtering or providing those centers more frequent data.

When educating patients, it may be beneficial to provide sufficient background in the variability of current organ acceptance practices, both between centers and even within centers (based on call team); this background may help reassure patients that the proposal is a move towards improved transparency and efficiency. Additionally, patients will need reassurance that underserved groups cannot be filtered out through this system. A complicating factor in education is that the patient likely has little control over these filters, particularly if filters become mandatory. It should be clear that this proposal does not offer the patient individual selection of which filters will apply to them.

Thank you to the OPTN and the Operations and Safety Committee for their work on this important proposal.

ASTS Position: Strongly Support



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March 15, 2023

Continuous Distribution of Kidneys and Pancreas – Committee Update

The ASTS is in support of the concepts behind the Continuous Distribution of Kidneys and Pancreata being undertaken by the OPTN committees. This is not truly a proposal nor are there final details being submitted for comment, so we cannot agree or disagree with this Committee Update as a whole. We will comment on particulars within your latest document for this Public Comment Period ending March 15, 2023.

We agree with the concept discussed that kidney allocation needs to weigh the longevity of deceased donor grafts more heavily in the allocation system design. We agree with having better correlation with the KPDI and EPTS as per the prior LYFT proposal during KAS development. The system must change the major advantage the high CPRA candidates (CPRA 99.51 to 99.98) have in receiving organ offers, especially when this is in opposition to longevity considerations and also to fairness considerations as most of these high CPRA candidates are receiving their subsequent transplant, not their first transplant, and with much shorter waiting time than the average recipient.

We agree with the following three concepts:

Increased Longevity: “This scenario increased the weight/importance of transplant outcomes from 10 percent to 40 percent divided between human leukocyte antigen DR (HLA-DR) and longevity matching. The weights for all other attributes were decreased proportionally.”

The details of how longevity is estimated are very important. In the original LYFT simulations, longevity of patient survival was based on the actual kidney being offered with candidate, donor and interactive variables for each offer. This considers HLA matching, potential function of organ (KDPI and other interactions), and potential survival of recipient (EPTS with interactive terms) for each organ offer. This also needs to appropriately measure the decreased expectations for subsequent transplants compared to first transplant recipients.

Increased Placement Efficiency/All Donor Efficiency: “This scenario increased the weight/importance of proximity efficiency from 10 percent to 30 percent. The weights for all other attributes were decreased proportionally.”

ASTS feels the distance should involve population densities so organs may need to travel less far in highly dense areas, but further in lower population density areas of our country to allow for relatively equal access.

Harder to Place Kidneys/High KDPI Efficiency: “This scenario increased placement efficiency for harder to place kidneys (high KDPI) with an increased donor weight modifier for KDPI 86-100 percent.”

ASTS believes the placement of these hard to place organs is complex and must involve the groups who actually offer the organs and accept the organs in most programs since they alone understand the challenges of transplanting these organs at all hours of the day. Centers need better organ filters so they can more granularly list patients for various types of hard to place organs. In turn, centers need to be accountable for listing their patients appropriately. These organs also need oversight forgiveness in addition to the standard "risk adjustment" which is not felt by most centers to truly estimate risk, especially if we want centers to transplant more of these kidneys which likely were not truly in the set of organs developing the prior risk adjustment variables.

The ASTS is very concerned that once this concept of Continuous Allocation for Kidney and Pancreas becomes policy, the point assignments and other adjustments to the allocation factors could be done by a small group of individuals under operational rules falling outside the policy development cycle with public input. We would strongly suggest a provision to all the Continuous Allocation distribution organ proposals that mandates that any change in point assignment or other calculation that results in a change in simulated allocation to more than 5% of recipients be put forth for formal Public Comment. This would alleviate concerns that a small group could have unfair influence on national organ allocation/distribution.

Summary of ASTS Suggestions for Kidney and Pancreas Committee Consideration:

Distribution consideration based not only on distance, but population density and distance to help increase the proximity efficiency attribute weight and not disadvantage rural candidates where longer distances are required for fair access.

Pediatric candidates:

Require each transplant program to adjust distance acceptable to their program. Review this annually and consider adjusting allowance of distance acceptable to program.

We agree with adjusting the CPRA priority. CPRA points should allow for equal access, not increased access as has been the case in the current KAS. We also agree that high CPRA should have a negative value in longevity considerations.

Dual Kidney:

Considerations for improved utilization:

- Allow centers to only list a small percentage of their candidate wait list as accepting Dual Kidneys so real thought is put into this decision and the best candidates are chosen and ready to be transplanted.
- Initial allocation of dual kidneys based more stringently on objective criteria such as eGFR and/or donor age or size of donor/kidneys. OPOs are not offering many kidneys out as dual kidneys until after they have many declines for single kidney alone offers. Dual kidney offers should be the primary offer for some donors.

En Bloc Kidneys:

- Allocation of en bloc kidneys based more stringently on size and/or age of donor.
- Allow centers to list a small percentage of their WL for these organs

Pancreas allocation:

Agree that for facilitated pancreas offers, some number of offers to standard programs on the WL

should be done. This could be as short as two different programs refusing the offer for the top candidates on the standard WL, but it should encompass some standard offer attempt.

KP offers:

KP candidates could be given a large number of points for CAS and limited by distance to mimic the current circles since this has been working per the report. For example, give all the KP candidates an additional 20 points within 250 NM and they would appear above all but the most highly sensitized kidney alone candidates within that area.

Kidney Minimum Acceptance Criteria (MAC) should be updated to allow for more granular choices by the transplant programs for their patients.

'Offer Filters' should allow transplant programs to set several different filters for various groups of patients so they can set filters based on what the programs consider acceptable offers for those different groups of candidates. For example, a center can create five different groups within their waiting list and assign each patient within one of those groups to the appropriate Offer Filter. This should help efficiency of allocation and help programs remain within the expected organ Acceptance Rate metric while still entertaining more difficult to place organs for some of the candidates on their list.

Released Organs:

We agree with the discussion as written.

Kidney and Pancreas Review Boards Workgroup:

We agree with the discussion as written.

ASTS Position: Neutral