ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Apply Transplant Program Notification Requirements for VCA Program Inactivation

The American Society of Transplant Surgeons (ASTS) is pleased to provide the following feedback to the OPTN VCA Transplantation Committee:

ASTS opposes the proposal to remove the exclusion of VCA programs from *OPTN Bylaw Appendix K: Transplant Program Inactivity, Withdrawal, and Termination.*

Relevant considerations include that the original exclusion was based on low transplant volumes for VCA programs. The latest OPTN/SRTR VCA report continues to demonstrate stability in the annual low volumes of VCA other than uterus of between 2 and 7 cases per year (OPTN/SRTR 2020 Annual Data Report: VCA. Am J Transplant. 2022 Mar;22 Suppl 2:623-647). Similarly, the number of waiting candidates remains low at less than 20 patients each year. The increased complexity of the approval process of VCA programs combined with new inactivity requirements could foreseeably decrease the number of active VCA programs and continue to decrease the availability and patient access to specific VCA programs.

ASTS Position: Oppose

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Continued Review of NLRB Policy and Guidance

The American Society of Transplant Surgeons appreciates the opportunity to comment on the Continued Review of NLRB Policy and Guidance.

The proposed creation of guidance for pediatric candidates with CF, specifically the proposed FEV1 thresholds set at less than 70% or greater than or equal to a 5% annual decline.

ASTS largely supports this proposal as written. However, we are concerned that malnutrition in children with cystic fibrosis may be viewed subjectively and may be related to the pancreatic disease they have—not their liver disease. We support the modification regarding failure of treatments for complications and modified guidelines for pulmonary testing.

The proposed changes to guidance for candidates with hepatic adenomas.
ASTS supports the proposal as written.

The proposed changes to guidance for candidates with Budd Chiari.
ASTS supports the proposal as written.

ASTS Position: Support

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September 28, 2022

Continuous Distribution of Kidneys and Pancreata Update

The American Society of Transplant Surgeons (ASTS) is pleased to provide the following feedback for the OPTN Kidney and Pancreas Transplantation Committees on the Continuous Distribution of Kidneys and Pancreata Update.

When considering the current 250nm sharing circles, it must be noted that the two proximity points are unnecessary in this circle and tends to hamper transplants to rural patients listed at their nearby rural transplant centers—that is, further from the busier urban trauma donor hospitals. ASTS believes we have moved too far away from allocating with a major importance on the longevity of the transplant survival. This will only result in need for re-transplant in the near future. We believe that we need to balance this with the post-transplant survival metric as an overall system goal. Putting a great deal of emphasis on highly sensitized candidates generally leads to more re-transplants and a shorter graft survival.

Additionally, prior living donors should have rapid access to transplant, if required. This is a cornerstone of our living donor efforts that may result in many more transplants than deceased donor organs utilized for this prior living donor population.

Highly sensitized patients have been given unfairly rapid access to transplant with known decreased long-term survival. Patients with CPRA < 99.9 should no longer be at the very top of the allocation list as their time to transplant has been shown to be much shorter than the average patient. The increased allocation points were created to make access fair and equal, not to overly advantage higher CPRA candidates. Highly sensitized patients should not have access to top 20% KDPI organ donors unless they have an EPTS in the top 20%.

Additionally, we urge the Committees to include a discussion on equity of access for those awaiting their first versus subsequent deceased donor organ.

Specific Comments to Continuous Distribution Committee Update

Table 1: Kidney

3rd row: ASTS would agree with some sort of continuous longevity matching using KPDI and the unabridged EPTS.

4th row: Blood Type: please remove the current unfair advantage of Blood Type B candidates listed for non-A1 donors. These B candidates should simply be intermixed with the A candidates, not put at the

top of the A list. We believe your newly proposed point system for B candidates who can access non-A1 donors should do this.

KAL safety net: ASTS agrees that safety net patients should have access to top 20 KDPI only for those with EPTS in top 20%.

Last row: ASTS would suggest no point difference within the 250nm initial allocation circle, that is, all points receive the same number of proximity points. Between 250 and 500nm, the ASTS would support a slope down to 25%, with a gradual slope out from 500nm.

Table 2: Pancreas, KP, Islets

Proximity Efficiency: we would suggest no point difference within the 250nm initial allocation circle, that is, all points receive the same number of proximity points. Between 250 and 500nm should be a second set of similar allocation points, then no additional points outside of 500 nm.

Medical Urgency: All candidates listed for Medical Urgency must have documentation completed before being granted such status. The Kidney Committee should set an upper limit of expected Medical Urgency Candidates a year (example 0.5% or less of waiting list). Programs that list more than this number should have all listings reviewed.

HLA Matching: IF DR matching does not limit access to minority populations, then DR matching should be encouraged due to increased longevity of grafts and decreased sensitization.

ASTS agrees with a continuous KDPI and EPTS allocation system. We understand that actual curves have not been created. We would support that Top 20% KDPI curves highly prioritize Top 20% EPTS candidates and perhaps give some access to Top 21 to 40%, but no access above EPTS 40%. KDPI over 75% should be the reciprocal of the Top 20% KDPI organs giving preferred access to EPTS above 80 candidates and then to 61 to 80 EPTS candidates. The extended EPTS scoring system from the original LYFT simulations will likely need to be used with more variables to differentiate the over 20 EPTS candidates.

ASTS agrees with simply giving pediatric candidates low KDPI values. From numerous publications, many pediatric graft losses are due to non-compliance, so an accurate EPTS will likely be difficult to construct with acceptable variables.

CPRA: ASTS would like the Kidney Committee / SRTR to closely look at the high amounts of CPRA points given to those with CPRA > 90 and < 99.9%. There appears to be an unfair rapid access to patients receiving more than a couple of CPRA points with the larger 250nm circle as the number of available kidneys is now greater for initial level of allocation. The CPRA scale should be created to allow <u>equal access</u>, but not more rapid access for sensitized patients.

Pediatric priority: We caution the Kidney Committee not to encourage the use of less optimal donor grafts (KDPI over 35%) for pediatric candidates. It is truly rare that with the current 250nm circles, a pediatric candidate does not receive a Top 35% KPDI offer within a reasonable time frame (unless highly sensitized). For centers who believe they are not receiving offers, they should review the offers with their team.

ASTS agrees with waiting time being kept linear throughout and not making it unnecessarily complicated. We agree with keeping waiting time accumulation starting at eGFR 20 ml/min pre-dialysis as incentive to refer early for transplantation which may increase living donor transplant options.

KAL: ASTS agrees with access to Top 20% KDPI organs for candidates with EPTS Top 20%.

Proximity Efficiency: ASTS would suggest no point differential for sharing within 250nm of the donor hospital as this is usually the distance for driving compared to flying for longer distances. Giving points within the 250nm circle, such as within 50nm simply advantages the transplant centers closer to the trauma hospitals, and unnecessarily disadvantages patients and transplant centers in more rural areas that are still within driving distance of the donor hospital. The few hours of driving add very little to the cost of transportation or to the CIT, has no impact on graft survival, and was not supported by the AHP exercise. The proximity points within a 250nm area only serves to disadvantage those who live further from trauma/donor hospitals and wait longer than those patients whose transplant center is closer to the donor hospital. This can result in an outcome that favors patients who have the means to drive further to large metropolitan hospitals to gain waiting time points over those who are forced to stay at their nearby transplant center that may be rural. (An example of this is the waiting time differential for patients at Augusta Health (MCG) compared to the Atlanta centers which are closer to the major trauma/donor hospitals.)

For higher KDPI organs, more efficient placement will likely occur if you limit the number of patients who can be listed by a center for high KPDI organs at any one time, so the centers have more incentive to use the higher KPDI organs into the appropriate patients on their waiting list. Again, giving large number of points to centers nearer the donor hospitals will give these centers' patients an unfair advantage over rural hospitals' patients.

En Bloc kidneys require much more work effort and skill to implant with a higher risk of thrombosis. The KDPI should be set to reward, not punish, utilization of these organs giving transplant centers some leeway for increased risk of thrombosis.

Released organs: First, the definition of a 'released organ' is not very clear in the document provided. Please provide a clear definition. It appears to be a declined organ once the organ has already arrived at a transplant center. If this is the definition, then proximity points for efficiency of placing released kidneys should be based on KDPI and time from crossclamp as lower KDPI organs are usually easy to place.

ASTS Position: Neutral/Abstain

ASTS Responses to OPTN Proposals Open for Public Comment

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Continuous Distribution of Livers and Intestines Concept Paper

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to provide the following feedback to the OPTN Liver and Intestinal Organ Transplantation Committee.

Which attributes should the Committee continue to consider for inclusion in the first iteration of continuous distribution?

The five attributes listed are consistent. Since Medical Urgency is the primary factor in current allocation, it would be difficult to change that to a less weighted attribute.

Are there other attributes the Committee should consider that are not included in the list provided above?

In the sub-score for Post-Transplant Survival, the Committee states they are attempting to reduce futile transplants; however, this is difficult to quantify. An idea would be to *de-emphasize patients with calculated MELD scores above 40.* MELD score is capped at 40, but we recognize it is capped because the benefit of transplant may diminish if the patient is sicker than that. De-emphasizing patients with scores above 40 may reduce futile transplants.

In the sub-score for Patient Biology, they are looking for characteristics for difficult to match and complex transplants. Blood type, size mismatch and re-transplants are all appropriate variables. We suggest *portal vein thrombosis* be an additional variable added to this.

In the Placement Efficiency Sub-score, we feel donor factors should be considered for proximity points. Livers from donors aged above 70 and DCD livers cannot tolerate prolonged ischemic times, so recipients closer to the donor should be given additional points.

As for social determinants of health (SDH), inclusion is fraught with problems but inclusion of post-transplant survival without consideration of SDH runs the significant risk of further disadvantaging underserved populations. Some form of inclusion in the first iteration is important.

Are there any attributes that exist in current policy that should not be included in continuous distribution?

Attempts to introduce the HCC stratification score and the OPOM are too complex and as yet untested rigorously enough to introduce these in first iteration of the continuous distribution; HLA matching and sarcopenia scores should also not be included. The HLA matching does not significantly make a difference, and the sarcopenia scoring is very subjective. Similarly, Social Determinants of Health (SDH)

are very hard to quantify and will unnecessarily complicate this system if introduced. Further refinement of the MELD score, as has been done in the past, may be more palatable.

In the sub-score for Patient Access, "willingness to accept a split liver" is considered one of the variables for priority and we suggest that this score *only* play into the Composite Score when a split liver is being offered.

Any other feedback on the plan to develop continuous distribution of livers and intestines.

We are still in the experimental phase of using liver pumps for transport and storage. This may allow for longer ischemic times and use of more marginal organs. This has not yet figured into any calculation of score points. The Committee needs to do an analysis of this for the future.

ASTS Position: Neutral/Abstain

ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Enhancement to OPTN Donor Data and Matching System Clinical Collection

The American Society of Transplant Surgeons is pleased to comment on the proposed policy and strongly supports the proposed enhancements to the OPTN Donor Data and Matching System Clinical Collection.

1. Are there additional data fields that could improve offer evaluation for DCD donors?

Yes. Fields for Use of Normothermic Regional Perfusion (NRP) and Ex-vivo machine perfusion including specific information on temperature or system used would be helpful and should be prominently displayed.

2. Should a validator question, such as "controlled DCD?" be included, to reduce administrative burden and streamline data reporting?

Yes, as currently there are very few Uncontrolled DCD offers being made. Additional questions such as if Normothermic Regional Perfusion (NRP) was used would also be helpful to transplant centers.

3. Will the proposed data collection be burdensome for OPOs to report? How can implementation be eased for OPO members?

This proposal would require programming changes in the OPTN Computer System, specifically, the OPTN Donor Data and Matching System. OPTN Donor Data and Matching System alignment will include updating the mobile Donor Data and Matching System application to display the new fields. This will require a small amount of additional data entry for OPO staff. This will have some costs but will also allow for better communication between OPOs and Transplant Centers and possibly facilitate more DCD transplants if the data is easily accessibly by the transplant centers. The cost and burden to OPTN and OPOs are likely to be outweighed by the benefits to transplant centers in terms of efficiency.

4. Should a new, separate page be created within the donor summary in the OPTN Donor Data and Matching System to report DCD progression information, including vitals such as heart rate, blood pressure, and oxygen saturation?

Due to variations in data collected at each OPO it may be difficult to accomplish creating a new and separate page in DonorNet. Uploading of the individual DCD worksheet in the attachments is likely to be more efficient and expedient to the evaluating transplant center.

ASTS Position: Strongly Support

ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Modify Candidate Waiting Time Dates Affected by Race-Based eGFR Calculations

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to provide the following feedback to the OPTN Minority Affairs and Kidney Transplantation Committee.

Do community members agree with the proposed eGFR waiting time modification pathway?
Yes.

Do community members propose an alternative eGFR waiting time modification pathway?
No.

What kind of education resources would assist programs in participating?
ASTS suggests a webinar advertised on the UNOS homepage.

What potential unintended consequences or challenges should be considered during this proposal's development?
This policy will result in additional work for transplant coordinators, although this is only for a few patients in each center.

Do those consequences or challenges outweigh the benefits of the proposed waiting time modification pathway?
No. ASTS feels this is an important proposal.

Are there other waiting time modification scenarios that the members would like the committees to consider?
No.

Does the community agree with the proposed scope, timeframe and required documentation?
Yes, however, ASTS feels that reporting could be improved if it was mandatory to increase adherence to the policy.

ASTS Position: Strongly Support

ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Modify Heart Policy to Address Patient Safety Following Device Recall

The American Society of Transplant Surgeons (ASTS) is pleased to provide the following feedback on modifying heart policies to address patient safety following a device recall.

Should the approved emergency policy changes be considered for permanent policy by the OPTN Board of Directors?

No, the policy should not be permanent. The recall should not automatically enable an MCS recipient with functioning pumps, without any issues, circumvent the current policies that would facilitate a status 3 or status 2 listing that are currently in place.

What, if any, data analyses, peer-reviewed literature, or evidence-based medical judgments, provide evidence demonstrating that a patient with FDA-recalled heart device should be assigned to adult heart status 2 or adult heart status 3 by policy criteria, rather than a candidate's transplant physician determining whether assignment to status 1, 2, or 3 by exception is appropriate?

To our knowledge, there is no evidence that a patient with an FDA-recalled heart device should be assigned to adult heart status 2 or heart status 3; it appears to be a fear of patient risk. It is difficult to justify a status 1 exemption with a pump that has demonstrated no errors/malfunctions. This "risk" of pump stoppage is there with all MCS in principle.

Is 14 days the appropriate amount of time for a candidate impacted by an FDA-recalled device to be initially assigned to status 1, 2, or 3 under the approved policy? Why or why not?
Is 14 days the appropriate amount of time for an extension of the assignment by exception? Why or why not?

The counterargument is that the morbidity of an exchange would outweigh the risk of transplant. A better use of extending an exception time should be reserved to those candidates who have had pump alarms or malfunctions.

In addition to the Member Compliance and Policy Evaluation actions identified in the proposal, what other actions can be taken to ensure the new exception pathway is only used for appropriate purposes as intended by the Heart Committee?

This appears to be a small number of the overall heart cohort and regional review or MPSC review would seem appropriate on all cases.

Are there any types of implanted devices that could be subject to an FDA device recall that should not qualify under the policy modifications? Describe why.

This question depends on the specific recall, the scope of the remedy (if any) and the risk of a poor outcome if an adverse event occurs.

Are there any types of devices that are not implanted that should be permitted to qualify under the policy modifications? Describe why.

No, temporary non-durable support should not be included as they are intended to be short-term and disposable. If a center is using a short-term device off label for longer than the prescribed policy, then they should proceed to durable MCS or other medical measures. Those policies are in place and appropriate.

Are the proposed data element and the associated data definition clear and understandable?

Yes.

Are the acceptable forms of documentation regarding the recall of the device identified in the proposal widely available?

Yes.

ASTS Position: Oppose

ASTS Responses to OPTN Proposals Open for Public Comment

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Optimizing Usage of Kidney Offer Filters

The American Society of Transplant Surgeons (ASTS) thanks the OPTN Operations and Safety Committee for their work on kidney offer filters. ASTS supports optimization of kidney offer filters in order to improve efficiency in organ allocation and increase organ utilization.

ASTS supports the initial implementation of default offer filters (option 1) that will automatically enable identified filters for all centers unless centers specifically opt-out. Once the default, non-mandatory filters are initially implemented (perhaps 6 months), filters could then become mandatory based on recently collected data.

Mandatory filters will improve organ utilization, but the implementation should not prevent centers from changing their acceptance patterns over time. Without the ability to change acceptance patterns, centers will be limited to selecting donors based on past behavior. Programs may be disadvantaged based on size or geography (travel distance and CIT). By implementing filters that are less restrictive than the model identified filters (option 3), centers will have room to alter behavior.

When mandatory filters are implemented, ASTS recommends a straightforward pathway for programs to request filter liberalization (rather than complete removal). Circumstances for liberalizing a center's filter might include low volume centers, changes in center staff (transplant physicians/surgeons), or a significant change in a center's SRTR outcome data. If filter liberalization is requested by a center but the center continues to decline organs after a 6-month period, ASTS agrees that the mandatory filter should reset automatically.

ASTS also supports the proposed evidence thresholds but suggests changing the number of donors filtered from 20 to 100 donors. In the model data provided, this threshold balances a significant change in the number of non-accepted offers bypassed, with a small impact on accepted offers that are bypassed. Additionally, the mandatory filters should not apply to certain hard to match candidates (cPRA >97%, 0 antigen mismatch). ASTS proposes that acceptance data for adjusting model identified offer filters should be re-evaluated for transplant programs every 6 months when new SRTR data is published.

ASTS Position: Support

ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Redefining Provisional Yes and the Approach to Organ Offer and Acceptance

The American Society of Transplant Surgeons (ASTS) is generally in favor of reforming the approach to organ offer and acceptance to improve efficiency of placement. Redefining the Provisional Yes is certainly a part of it, but fundamental revisions beyond this are needed to modify/improve processes within the organ offer/placement pathway to optimize this ecosystem. This includes but is not limited to, incentives for programs and OPOs to promote efficiency, establishing standard criteria for conduct of organ procurements, establishing criteria for procurement surgeons, and optimizing safety/efficiency of organ transport.

The three-tiered system proposed adds granularity to understand where in the placement process the centers are, in addition to increasing the accountability of responding programs somewhat. The drawbacks include potential micromanagement of the placement pathway when practices vary around the country, leading to programs feeling locked into pathways that don't fit into their optimal workflow.

Tiered Framework

- **What should happen if the first program refuses the organ offer (in Tier I)?**

In the first version of this endeavor, it would be best not to penalize programs that turn down after Tier 1. Rather, it would be considered valuable to assess the success of this new system and should be used for evaluating at periodic intervals.

- **What information should OPOs be required to complete for a Tier III offer evaluation?**

OPOs should have the donor record completed and ready as with the current system prior to sending out offers.

- **Are there tools that should be considered that could help facilitate this three-tiered model?**

Transparency would be critical for success of any model. Therefore, the proposal to not white out OPO information is welcomed. In addition, there may not be a need to white out center information as well, as this will likely not impact confidentiality.

Associated Requirements within Tiers

- **Are the requirements within each tier reasonable?**

Generally, yes, with the caveat that there is a risk of overprescribing the requirements for each tier. For example, it may not be reasonable for the tiers to determine when candidate availability should be determined. The proposal suggests Tier 1, but many programs do that much earlier in the process.

• Should OPOs limit offers based on tiers? Should this be based on the number of organ offer responses that are confirmed?

Yes, this will be a key element to improving efficiency and getting center buy-in. The initial number of offers should be based on the number within which the organ has a reasonable chance of getting placed. This may need a sophisticated algorithm which should be developed based on donor factors, organ characteristics, and other variables such as geography, time to procurement, etc. The number of offers should come down as the tiers move up to 1.

• Should there be expectations outlined that are specific to offers sent pre- and post-recovery?

Rather than having a dichotomous plan for pre- vs. post-procurement, a continuous variable based on proximity to clamp time (on either side pre- or post-), in combination with other factors could be used for decisions on number of offers (as stated in the response to the previous question)

Tier Thresholds (number of offers sent)

• Do you agree with the recommended thresholds for each tier?

Generally, yes. Each tier should incrementally increase the accountability for provisionally accepting the organ.

• What threshold should be considered for Tier III for when should a program receive the initial notification?

If the program has expressed an interest in receiving such organ offers as the one being offered (during the listing process), they should not be bypassed.

Time Limit on Offers

• Do you agree with the recommendations on time limits on offers for Tier I and Tier II?

Yes.

• Should there be different considerations for offers sent pre- and post-recovery? If so, what should those considerations be?

Yes.

• Should there be a time limit for Tier III to respond to a notification on an organ offer?

Yes, and it should be consistent with current standards for the Provisional Yes.

ASTS Position: Neutral/Abstain

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Review of Liver and Intestine Variances in OPTN Policy

The American Society of Transplant Surgeons (ASTS) is pleased to provide the following feedback to the OPTN Liver and Intestinal Organ Transplantation Committee.

Does the community support aligning the expiration dates for the four liver variances in OPTN policy to expire upon implementation of continuous distribution of livers and intestines?

ASTS supports this proposal as written and aligning the end dates so the variances close when continuous distribution goes into effect, with the caveat that there is implementation of continuous distribution in a reasonable time period in the future.

ASTS Position: Support

ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution

The American Society of Transplant Surgeons appreciates the opportunity to provide feedback to the OPTN Lung Transplantation Committee.

Should the Committee add information in the guidance on how to request a priority 1 equivalent score for pediatric candidates in the new allocation system?

Yes, ASTS supports adding additional guidance on prioritizing high acuity pediatric candidate populations.

Should the Chair be a voting member of the Lung Review Board?

Not necessarily.

Are there other specific candidate diagnoses, symptoms, or characteristics for which the Committee should consider providing more specific guidance?

No.

Should a quorum of review board members be required to deny an exception request?

Yes.

Is it clear how the appeals process works?

Yes, the process appears clear. However, we are concerned about the voting guidelines in the proposal. As described, nine review board members from different program would be assigned a case and would have five days to review; this seems reasonable. The difficulty arrives in the further details: reviewers who don't respond in three days would be replaced and the review would be decided in five days even if there is only one response in that time frame. Perhaps all nine programs should receive the five days to respond and a minimum of five responses necessary for a decision. After three days, the program's alternate reviewer might be approached or perhaps the chair would be able to cast a vote for reviews in which the minimum number of responses is not received in five days. ASTS is also concerned when the "countdown" starts for these five days, and we propose that all reviews are sent out in the morning of the first day so that a full three out of five days are available to respond.

Do lung transplant programs anticipate any barriers to participating in the new Lung Review Board or using the updated exceptions process?

There would not be additional major barriers to transplant centers.

What resources should the OPTN provide to assist lung transplant programs in submitting exception requests in the continuous distribution lung allocation system?

The OPTN should further refine the online portal.

ASTS Position: Neutral/Abstain

ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Transparency in Program Selection

The American Society of Transplant Surgeons is pleased to provide the following feedback to the OPTN Ethics Committee.

Do community members think that it is important to know what criteria transplant programs use to evaluate patients for listing?

Yes.

What are other factors that would be important to you in selecting a program?

Besides medical criteria (e.g., absolute contra-indications) it would be important to report their criteria for social support and compliance.

What best practices have transplant programs developed for increasing transparency?

Programs have reported criteria objectively in program policies and updated them annually. However, we are hesitant to label these as "best practices" since no transplant program has the "best" practice.

It would be most informative to use the current demographic data already in the current public Scientific Registry of Transplant Recipients (SRTR) program-specific reports (PSRs) that describes the waiting list candidates and transplanted patients at each program. This publicly available document gives patients access to the general idea of a particular center's actual practice.

Do clinicians/transplant professionals think this information, shared with patients, would strengthen the doctor-patient relationship, and/or provide better care for patients?

ASTS has no comment on this portion.

ASTS Position: Support

ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Update Data Collection for Lung Mortality Models

The American Society of Transplant is pleased to provide the following feedback to the OPTN Lung Transplantation Committee.

Are the proposed data changes and data definitions clear?
Yes, for the most part.
Under prior lung surgery:

VATS is a technique used for surgery and not a type of operation itself. The data collection should be modified to whether each of the surgeries performed was done VATS or open (i.e., VATS lobectomy vs. open lobectomy, VATS wedge resection vs. open wedge resection, etc.)

What clinical parameters, if any, would you add to the diagnosis-specific data definitions of exacerbations?

The need for hospitalization might be a marker for more serious deterioration and should be included for exacerbations of COPD and CF. For example: did some of the exacerbations require hospitalization (yes/no). Alternatively, the number of exacerbations that required hospitalization in the last year, as well as total number of exacerbations.

Is it clear how data should be submitted related to assisted ventilation and supplemental oxygen, and how values entered in these fields or other assigned values will be incorporated into the lung CAS?

Yes, the proposal is clear. The exact definitions will need to be made clear to programs at the site of data collection so that the individual entering the data is able to do so correctly. The data is burdensome, but it is understandable why it should be collected. In the future OPTN should seek to simplify this if possible.

Are there any other clinical criteria that should be added to better estimate a candidate's waiting list survival or post-transplant outcomes?

Simple measures of frailty should be collected; there is growing literature that these may be predictive of waitlist mortality and perhaps post-transplant mortality.

Should any of the proposed clinical criteria not be included in the OPTN Waiting List?

No.

Is there a need to retain any of the clinical criteria proposed for removal?

No.

ASTS Position: Support

ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Update Kidney Paired Donation Policy

The American Society of Transplant Surgeons (ASTS) is pleased to provide the following feedback to the OPTN Kidney Transplantation Committee.

The recent OPTN proposal on kidney paired donation aims to modernize and update OPTN Policy 13 which has provided a framework for the OPTN Kidney Paired Donation Pilot Program, which has been operational as a national offering since 2010. As of July 6, 2022, there are approximately 60 programs participating in UNOS KPDPP. There have been considerable changes in modern KPD practice, most of which have evolved in the practice of other larger paired exchanges.

Do the deadlines provide sufficient time to perform the required tasks and review the match offer? Is the 60-day deadline from time of match offer to recovery and transplant surgery appropriate?

The deadlines outlined in the policy proposal do allow for completion of required tasks and match offer review within a reasonable time frame for most kidney transplant programs. There may be some limitations to meeting the deadlines for smaller programs. The 60-day deadline from match offer to recovery and transplant surgery is also a reasonable timeline, but smaller or rural programs may contest this related to issues surrounding operating room availability. Programs will need to respond by only entering donors into the KPDPP if they are ready to go to surgery in the immediate term. This timeframe will also implicitly increase communication between the donor and the donor recovery hospital to ensure effective KPD practice.

Should the deadline for the provision of a preliminary response be shortened to one business day from receipt of match offer, or is two business days more appropriate? If so, why?

The deadline for provision of a preliminary response for match offer receipt should be two business days

How can overuse of extension requests be discouraged? How can better performance be incentivized in the program?

Better performance can be incentivized through a points-based system that could, as an example, provide centers with priority for end-of-chain kidneys.

Should clinical donor information, such as renal images, be specified as required donor information made accessible to the matched candidate's transplant hospital within the three-business day deadline? If so, why?

Yes, this promotes a best practice in KPD by optimizing the decision-making process by transplant hospitals. It supports transplant professionals and transplant recipients. Transplant surgeons and other providers must have the right clinical information to truly understand the offers they are accepting and denying. This type of approach is utilized in other kidney exchanges.

Should the donor's entire evaluation record, including renal images, be made available in the OPTN KPD System at time of match offer? If so, what is the rationale?

The availability of the entire donor evaluation record at the time of offer provides the hospitals and clinical staff (surgeons and nephrologists) with the full picture to facilitate rapid and safe offer decision-making. While there may be some additional burden to programs to get images uploaded for review, UNOS has existing technology that they use in the deceased donor system in DonorNet that could help transplant hospitals with this task.

Should policy specify that transplant programs obtain a signature from bridge donors confirming informed consent and the estimated period of willingness to be a bridge donor? If so, why?

Transplant programs should be aware of the best practices related to bridge donors, and UNOS should serve as a conduit for dissemination of that information. However, additional policy requirements will not necessarily increase patient safety in anyway. Rather, transplant programs should be encouraged to establish and maintain a bridge donor policy that works for their program, patients, and providers. Adherence to their own policy should be expected for the purposes of regulation. This model mirrors what is in place for multiple other UNOS policies.

ASTS would like to note that this program is only one of many paired exchanges that programs can use; UNOS should be careful about being too proscriptive in creating rules. This may act as a disincentive for programs to participate in the UNOS KPDPP, which would be an unintended consequence.

ASTS Position: Support

ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Update Multi-Organ Allocation for Continuous Distribution of Lungs

The American Society of Transplant Surgeons provides the following feedback to the OPTN Lung Transplantation Committee.

Does the score threshold of 25 appropriately balance access to transplant between lung multi-organ candidates and kidney, liver, and heart single-organ candidates?

Decreasing the Composite Allocation Score (CAS) threshold of 28 to 25 would increase access to multi-organ lung transplants which the training organ would often be at a disadvantage in the non-CAS era. Based on the modeling, the decrease would increase access for MOT (based on Table 1 and 2).

Once all organs are in continuous distribution, how might the Committee update lung multiorgan allocation across a continuous spectrum?

This is difficult to determine as the modeling attempts, though does not account for, differences in practice, expertise, and aggressiveness between and within centers.

ASTS does not feel that this impacts patients dramatically in either a positive or negative way; we are unsure if this would be beneficial, since it is a relatively small percentage of patients compared to the overall transplant patient population.

ASTS Position: Neutral/Abstain