**ASTS Responses to UNOS Proposals Open for Public Comment**

**September 30, 2021**

---

1. **Update Data Collection to Align with US Public Health Service Guideline 2020**

The American Society of Transplant Surgeons (ASTS) supports the OPTN proposal to update data collection for organ donors to align with the U.S. Public Health Service Guideline 2020. Since the new guidelines were established, DonorNet lists the following field for risk assessment, "According to the OPTN policy in effect on the date of referral, does the donor have risk factors for blood-borne disease transmission." This field is a yes/no conditional field and does not provide granularity if the donor meets risk criteria. The proposal establishes a discrete field for listing the risk criteria, if any. This will not only make the data more comprehensive, but it will also make it much easier to analyze trends and assess the new policy and its' effect on organ utilization.

2. **Update Human Leukocyte Antigen (HLA) Equivalency Tables**

The American Society of Transplant Surgeons (ASTS) supports the OPTN proposal to require DPA typing and other items in the proposal for the following reasons. 1) It will improve safety (and presumably outcomes) in that unacceptable antigens can be assigned for DPA, depending on the center. 2) Over time, this will allow the use of DP loci to refine the CPRA calculator (recipients with DQA and DPA antibodies don't get the benefit of the CPRA points). 3) It is not a major burden on HLA labs since most of them are doing it already and there is no technological barrier to implementing it.

3. **Data Collection to Evaluate Organ Logistics and Allocation**

The American Society of Transplant Surgeons (ASTS) supports the proposal for data collection to evaluate organ logistics and allocation. The deletions are reasonable. The data additions will add granularity around logistics, important timepoints, and new fields to capture new information on transportation and organ preservation/ex-vivo perfusion where applicable. The data to be collected are unlikely to add significant burden to OPO or Transplant Center staff.

4. **Require Lower Respiratory SARS-CoV-2 Testing for Lung Donors**

The American Society of Transplant Surgeons (ASTS) strongly supports making permanent the OPTN Executive Committee's policy requiring lower respiratory testing (by NAT) for all lung donors to address the significant patient safety implications of donor-derived COVID-19 and the risk of patient mortality.

## 5. Ethical Considerations of Continuous Distribution in Organ Allocation

The American Society of Transplantation (ASTS) supports the OPTN white paper on ethical considerations of transitioning to a Continuous Distribution organ allocation system, using lung allocation as an example. In the section on the assessment of continuous distribution on equity (pp. 17-18), the paper states that "removal of distinct geographic boundaries supports equity," and goes on to justify this statement. This paper must acknowledge that continuous distribution will only remove distinct geographic boundaries from the allocation system but not from organ distribution, as OPOs will continue to operate within their respective donor service areas (DSA). We believe that to truly remove boundaries, the system must remove the impact of hard borders on cost. Export surcharges and import fees exacted upon transplant programs for organs that cross DSA boundaries create a financial disparity between patients located within a DSA border versus those who are outside of the DSA border. There is an ethical obligation of the transplant community to remove the financial disparities associated with moving organs across DSA boundaries in order to address the ethical principle of equity in organ allocation using a continuous distribution system.

One area in which this white paper falls short is the focus on individual and population based-patient related outcomes as practically the only metrics to consider in the assessment and implementation of a continuous distribution system. We acknowledge that the paper mentions cold time and shipping charges as additional considerations, but we recommend that additional analysis of efficiency is necessary for monitoring the effects of continues distribution. While the ASTS agrees that patient outcomes are a primary consideration, other system-level variables need to be considered. Costs, resource utilization and workload all need to be considered in how the change in allocation is affecting the organ transplant system in the United States. For example, if continuous distribution significantly increases the amount of time it takes for organ allocation, thereby increasing the workload on organ procurement organization and hospitals, this will put stress on hospitals, especially those with limited bed capacity, and require additional OPO staff, both of which will also drive up costs.

## 6. Review of the National Liver Review Board (NLRB) Diagnoses and Update to Alcohol-Associated Diagnoses

The American Society of Transplant Surgeons (ASTS) strongly supports this proposal and recommends continued study of the area. On balance, this proposal will likely improve both access and equity, while not having a negative impact on any specific population. The expense of implementation, and the burden on transplant centers appears low to minimal. The likelihood of adverse unintended consequences also seems low, and the overall approach of using an iterative and evidence-based process for informing NLRB policy is sound. This well-conceived proposal reflects the work of multiple informed stakeholders and is an example of using evidence-based, iterative review to improve transplant care and regulatory performance.

## 7. Update on Continuous Distribution of Kidneys and Pancreata

The American Society of Transplant Surgeons (ASTS) strongly supports efforts to move to a continuous allocation system with the goal to increase distribution of organs while providing system

transparency. However, we oppose this proposal with the concern that it is too broad and too vague to provide specific feedback. It is unclear to us how this enormously complex, even arcane, re-engineering of the entire allocation system would advance the key strategic goal of increasing the number of transplants performed. It is unclear how this project would increase the efficiency of the transplant system, improve access for candidates, improve post-transplant outcomes, or increase organ utilization. The policy's concept proposes to use variables to construct and weight allocation that is believed to improve equity for specific populations but would also seem to be synonymous with decreasing access for other populations. This and the likelihood of other adverse unintended consequences seems extremely high. Until the OPTN provides a more cogent explanation of the reasons the community should embark on this journey, we refrain from making any recommendations at this time. We need more information on the goals of this project and a clear explication of how moving to continuous distribution would advance critical strategic goals. We encourage the OPTN to provide a clearer statement of goals, intent, and rationale for this project, as well as tools to help us understand the implications of such a radical shift in the allocation system.

## 8. Amend Status Extension Requirements in Adult Heart Allocation Policy

The American Society of Transplant Surgeons (ASTS) strongly supports this policy proposal. The ongoing assessment to define and align listing status with the medical urgencies, balancing transplant and alternative strategies (e.g., inotropes and mechanical circulatory support) is beneficial and appropriate. This alignment would help minimize "gaming" of the status levels and the use of temporary mechanical support.

As requested, we provide feedback on the following questions from the OPTN Heart Transplantation Committee.

1. *Should the proposed changes to Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis include a temporal relationship when a patient experiences the medical conditions described and when the treatments are provided?* Yes, a temporal component should be included. Additionally, one could propose adding the placement of temporary mechanical support was an elective decision (e.g., admission from home not in shock) or as a result of progressive decline and end organ malperfusion.
2. *Are the medical conditions and treatments included in the proposed changes to the above mentioned policy described so that they may be easily understood and consistently interpreted by transplant program staff?* Yes, the conditions and treatments are easily understood and should be interpretable.
3. *Is Status 3 the appropriate status to transition a patient who was assigned to, but no longer meets, the eligibility criteria established for Policy 6.1.A. iii?* Yes, assigning status 3 for a history of a recent life threatening arrhythmia is reasonable though the addition of a time limit of status 3 eligibility should be added. Then the candidate should revert back to a status 4 listing if there are no further life threatening arrhythmias.
4. *Are the other requirements and/or criteria to extending a candidate's assignment at an adult heart status unclear in terms of what information must be submitted?* No, this is not unclear.
5. *Are there other requirements and/or criteria related to extending a candidate's assignment at an adult heart status that are inconsistent in terms of treating patients with similarly situated medical urgencies?* No, the requirements and criteria are not inconsistent with treating patients with similar urgencies.

6. *Should all adult heart policies require submission of objective evidence of a candidate's medical condition demonstrating a continued need for the established therapy in order to extend the candidate's assignment to the status?* Yes, the adult heart policies should require submission of objective evidence of medical condition in order to extend the status upgrade assignment.
7. *Should the Committee have considered changes to extension requirements/criteria in other specific adult heart policies? If yes, which policies and why?* No, the current policy is appropriate for the "Status Extension Requirements in Adult Heart Allocation Policy."

## 9. Reassess Inclusion of Race in Estimated Glomerular Filtration Rate (eGFR) Equation

The American Society of Transplant Surgeons (ASTS) appreciates the request for feedback from the OPTN Committees on Minority Affairs and Kidney Transplantation regarding the Estimated Glomerular Filtration (eGFR) rate tool and its highly negative impact on the community. The ASTS strongly supports the OPTN document in the recommendation to eliminate the use of race in the calculation of eGFR. We know that the use of race in such a way is a vestige of misguided and archaic beliefs in a supposed biological difference between Black people and people of other races. However, as our understanding of human biology has evolved over the years, so should our use of these common clinical metrics.

It is important to begin by noting some overarching clinical truisms about race and transplantation. First, race is a social construct that is often used in clinical decision making and research as a surrogate for specific (and increasingly identifiable) biological processes. As noted by several NIH leaders in 2018, "imprecise use of race and ethnicity data as population descriptors in genomics research has the potential to miscommunicate the complex relationships among an individual's social identity, ancestry, socioeconomic status, and health, while also perpetuating misguided notions that discrete genetic groups exist."[1] More precise biologic markers are now available or potentially discoverable that have the potential to more accurately reflect genetic variants (e.g., APOL1 testing) to guide the design of clinical tools in our field and others. As we continue to make progress in the identification of biologic markers, it is our expectation that the imprecise and potentially harmful[2] use of race as a surrogate for biologic markers or genetic ancestry in clinical tools will discontinue. We are buoyed by recent medical advances that will replace race with more precise biologic markers.

By systematically reporting both an eGFR for Black patients and an eGFR for all other patients, we are perpetuating the notion that there is a fundamental difference in organ function between these two populations. We are encouraging healthcare providers to see these two groups as different. We are allowing a subset of the population to be "othered" in a way that could have a profound impact on everything from antibiotic dosing to kidney transplantation. The over 30 million patients with ESRD in this country deserve an equal opportunity for kidney transplantation. We know that an eGFR less than 20 ml/min is a key lab value that allows patients to be eligible for a transplant. The fact that two clinically identical individuals could have different eGFR calculations and therefore different transplant eligibility is not a reality that we can continue to accept. This is particularly important given the disproportionately high number of Black patients who have ESRD and the fact that Black people are given a higher eGFR based on the same serum creatinine in the current system.

ASTS believes a few centers have already eliminated the use of the eGFR tool or have replaced it with a race neutral mechanism, while other centers are waiting for an OPTN policy change to formally remove it from their practice. We anticipate the use of a race neutral eGFR would increase listing, improve access, encourage earlier evaluations, and reduce wait times for black and minority patients. With the implementation of a race-neutral eGFR, transplant centers will only need to educate their coordinators and nephrology staff on listing referrals; otherwise the transition would be straightforward. ASTS recommends the OPTN establish standards by which centers provide educational resources for their staff and related health care professionals.

Transparency during implementation is key for patients and families. During this phase, we are concerned that variations in centers' abilities to openly allow patients' access to the listing process, may impact referral/care patterns and cause staffing and outreach challenges or create delays in waitlisting. Another unintended consequence is that we may have fewer data points to help us distinguish disparities in access because we are not taking race into consideration. Finally, medical formulas should be race neutral, as race is not a biological factor.

The field of medicine is not perfect. It has been shaped by the knowledge and understanding of individuals who are not immune to social systems such as racism and prejudice. But as we continue to identify areas within medicine that contain remnants of misguided race-based assumptions, it is our role as providers to eliminate them from clinical practice. The ASTS supports this change.

References:


1. Bonham VL, Green ED, Pérez-Stable EJ. Examining How Race, Ethnicity, and Ancestry Data Are Used in Biomedical Research. JAMA. 2018 Oct 16;320(15):1533-1534. doi: 10.1001/jama.2018.13609. PMID: 30264136; PMCID: PMC6640836.
2. Vyas DA, Eisenstein LG, Jones DS. Hidden in Plain Sight - Reconsidering the Use of Race Correction in Clinical Algorithms. N Engl J Med. 2020 Aug 27;383(9):874-882. doi: 10.1056/NEJMms2004740. Epub 2020 Jun 17. PMID: 32853499.


## 10. Report Primary Graft Dysfunction in Heart Transplant Recipients

The American Society of Transplant Surgeons (ASTS) is neutral on this policy proposal. In heart transplantation PGD, though a very important metric of periop and long-term outcomes, has been somewhat ill defined. The proposed data elements begin to address the development of a concrete definition. The hemodynamic assessment, the medication use, and dosing additions coupled with the outcome data already collected would facilitate the development of a more specific PGD definition. ASTS supports the concept to better define PGD but recommends the OPTN facilitate a pilot project to vet and establish the validity of the proposed data elements before finalizing the policy.

ASTS provides the following feedback on questions posed by the OPTN Heart Transplantation Committee.

1. *Data elements: Are there additional data elements that should be considered for inclusion? Exclusion?*
    a. *Do any of the proposed data elements create unreasonable burden to collect and report?* The data elements are reasonable though the primary metric being assessed, PGD, LVD,

and RVD are qualitative in nature and do not provide good definition for PGD. The hemodynamic data are good to include. The use of inotropes, nitric oxide and epoprostenol are good to include though the duration is of importance in gauging degree of heart dysfunction, not only their initiation. Flolan (Page 9) is a trade name and the use of epoprostenol would be more appropriate.

b. *Would any modification reduce the level of effort required?* A concern for "ease" of collection and use of EMR is that automatically transferred and recorded data, lack some fidelity. The time and conditions on where the hemodynamics and the dose of medications collected could cause added data collection and need for validation.

c. *Could any modifications better align with patient data currently reported in a program's electronic medical records (EMR)?* The time of the data elements collection at T0, T24, T48, and T72 would be important.

*Timing of data collection: Does offering a window of +or- 4 hours at 24 and 72 hours from arrival at ICU reduce the need to modify existing workflows? Will this window significantly impact the ability to compare patient outcomes? Is arrival at ICU an appropriate starting point? Should additional time points be considered in addition to 24 and 72 hours (+or- 4 hours)?* A time of 48 hours would be reasonable as is having a window of time. Overall, it would be reasonable to collect at T0, T24, T48, and T72 to minimize impact on workflow and allow for comparison.

2. *Inotrope and Vasopressor Reporting:*
   a. *Are the proposed ranges of inotrope and vasopressor dosing applicable to pediatric patients?* Yes, the dosing would be appropriate as they are listed at weight based doses.

   b. *Are the proposed ranges appropriately stratified to indicate high, medium, and low dosages?* The ranges would be appropriate stratification as well.

   c. *Is collecting vasopressor dosing in mcg/kg/mins with the option of also reporting in mcg/mins reasonable or is there another preferred unit of measure that would allow easier reporting or alignment with what is reported in a program's EMR?* Whether a center reports as mcg/kg/mins or in mcg/mins is not necessarily relevant as long as the weight based dosing and stratification is what is reported out from OPTN and for broad comparisons of outcomes and management (not applicable for vasopressin though would be for phenylephrine and norepinephrine).

3. *Other: What challenges would this request present for transplant programs responsible for collecting the additional data? Is the data requested readily accessible? Should the data collection be part of the "Clinical Information: POST TRANSPLANT" section of the TRR, or is there a more appropriate section? Are there differences and/or similarities between adult and pediatric PGD the Heart Committee should consider as part of its future reviews? How can the Committee ensure the data collection is reported consistently by all transplant programs?* The challenge would be in identifying the data point to report at the time window. The data are/would be readily accessible to the transplant center though a manual extraction or a recording which would be the most likely real-world event. Including the data in "Clinical

Information: Post Transplant" is reasonable and appropriate. Ensuring data entry ease via buttons or drop downs and minimizing free text would facilitate collection.

## 11. Enhance Transplant Program Performance Monitoring System

The American Society of Transplant Surgeons (ASTS) strongly opposes this policy proposal as written. ASTS applauds the OPTN for its initiative in its undertaking to revise the metrics used by the MPSC for performance review. The ASTS also believes that such efforts should be collaborative and in cooperation with UNOS and other transplant organizations - with the goal of improving patient outcomes. Regulatory metrics are complex and have significant unintended consequences. For example, it is well recognized that the current MPSC one-year outcome metrics, along with the SRTR five-star public ratings, do not allow patients to achieve optimal transplant opportunities as they strongly disincentivize transplant programs from accepting organs at risk of discard and from transplanting older and medically complex recipients. The available clinical literature strongly supports that transplant programs that are flagged by the MPSC for performance review curtail transplantation. In light of the large number of potential transplant recipients who die awaiting a life-saving transplant, it is clear that the OPTN's mission of enhancing patient safety is best served by eliminating disincentives to transplantation created in part by the transplant program monitoring processes, including disincentives created by the current MPSC outcomes-based triggers for performance review.

In addition, the newly proposed MPSC performance review criteria do not further the cause of patient safety as both wait list mortality and organ acceptance rates depend on multiple geographic, clinical and organ distribution issues that are not captured by current data. Importantly, the proposed MPSC performance review criteria do not appear to improve quality, increase the number of transplants, or promote innovation.

The proposed revised metrics have the potential to increase, rather than reduce, risk aversive patient and organ selection and to reduce, rather than increase, the number of clinically appropriate transplants performed. Specifically, the addition of waitlist mortality to the metrics that trigger performance review has the potential to incentivize exclusion of sicker patients and those with lower socio-economic status from transplant program waiting lists. The inclusion of an organ acceptance metric as a trigger for performance review has the potential to encourage transplant programs to narrow their organ acceptance criteria to avoid being flagged—that is, to narrow the organs that it will be offered in order to avoid review based on the organ acceptance metric. This will ultimately result in fewer transplants, more waitlist deaths, and increased rather than decreased organ discards. In our view, the current proposal does not address the critical flaw inherent in the current flagging criteria (i.e. the criteria's reinforcement of risk averse recipient and organ selection) and applying these multiple regulatory metrics concomitantly has the potential to exacerbate current transplant program risk aversion decreasing transplants for patients in the U.S.

We urge the OPTN to adopt a focused approach to transplant program oversight that has a single goal: To increase the availability of clinically appropriate transplantation while maintaining or improving quality. Our suggested approach is comprised of two components:

- Reform the current outcomes metrics to establish a tiered risk-adjusted pass/fail system under which the "pass rate" is established in a manner that ensures a defined excellent outcome and a patient benefit of transplantation as compared with the available clinical alternatives (e.g.

dialysis, in the case of renal transplants) rather than an "expected" survival rate which is unpredictable and has increased each year due to centers' increasingly risk averse patient and graft selection from the prior years.
- Implement Systems and Quality Improvement Projects that focus on improving access to transplantation through non-punitive pilot programs.

**A. Patient-Centered Outcomes Metric**

Any effort to reform the MPSC's oversight of transplant programs should begin with reform of outcome metrics that are currently used to trigger performance review. For the reasons set forth in the *ASTS Recommendations for the Optimization of Transplant Center Assessment* (January 12, 2021 (See #1 in References), we urge the OPTN to establish an easily understood binary (pass/fail) metric under which a transplant program's "pass rate" is established by reference to national annually predetermined excellent outcomes that are pinned to the available clinical alternatives. For example, based on SRTR data, the mean age of a renal transplant recipient at time of transplant is approximately *58 years* old and that the mean renal transplant recipient has been on dialysis for *3.5 years* at the time of transplant. Assume further that the one-year patient survival for patients in this age cohort who have just begun dialysis is 89% (USRDS data). Under these circumstances, a renal transplant program that exceeds this benchmark would not be flagged for MPSC review. This basic concept could be further refined to ensure that chosen survival rates are high enough to protect patient safety and justify the risk and cost of transplantation.

In its deliberations and its policy proposal, the OPTN rejected this approach on the grounds that it is not risk adjusted and will increase, rather than decrease risk aversion. We believe that if the "pass/fail" rate is determined in the manner suggested—as a straightforward fixed level of performance—it will provide transplant programs with the predictability necessary for them to increase the level of risk that they will accept. We believe that, for example, establishing the pass/fail threshold at or above 90% graft/patient survival would significantly increase the level of risk that programs would be willing to accept. Moreover, risk adjustment could also be included in the system in a number of ways. Risk adjusted outcomes could be used, if necessary, in a secondary analysis. The initial pass-fail determination could be made without risk adjustment and full risk adjustment could be applied to those transplant centers that do not meet the organ or patient survival pass-fail threshold to determine whether that center's performance would meet the risk-adjusted threshold. Centers would need to fail to meet both the unadjusted pass/fail threshold and the risk adjusted expected outcome threshold to undergo MPSC performance review. Thus, this system will establish easy to understand thresholds as well as provide risk adjustment analysis as needed to encourage transplantation in our country.

We urge the OPTN to make this change to the outcomes metrics as a first step on a trial basis and in conjunction with the elimination of the SRTR created PSR "star ratings" to assess whether, and to what extent, transplant programs respond to improvements in more appropriately selective regulatory enforcement.

We believe that increased transplantation resulting from the elimination of disincentives to transplantation may increase access to transplantation in a manner that modifies waitlist mortality and impacts organ acceptance practices, so that imposing additional metrics relating to these areas may be unnecessary. Any further modification of the MPSC flagging metrics that may be necessary to further encourage clinically appropriate transplantation could be implemented in a step-wise

fashion to avoid a dramatic increase in risk-averse behavior and a subsequent restriction in access to transplant for patients.

**Systems and Quality Improvement Projects**

We believe that adoption of patient-centric outcomes metrics should be accompanied by the initiation of Systems and Quality Improvement Projects that likewise focus on increasing the availability of transplantation.

Additional Systems and Quality Improvement Projects focused on increasing the availability of transplantation might include, for example:

- A project that excludes from any outcomes-related MPSC metric (but not data submission requirements) transplants performed under research protocols approved by the MPSC, so long as outcomes data is submitted to the OPTN for study purposes.
- A project that excludes from any outcomes-related MPSC metric (but not data submission requirements) transplants of certain organs at particularly significant risk of discard (as defined by the OPTN, so long as outcomes data is submitted to the OPTN for study purposes).
- A project that increases the flexibility of transplant programs to accept organs at risk of discard (as defined by the OPTN based on current discard data) for pre-identified recipients on the match run, regardless of that potential recipient's place on the waiting list.

We look forward to working with the OPTN on these and other avenues to improve the availability while maintaining the quality of organ transplantation, and we urge the OPTN to adopt our proposed approach to transplant program oversight to further this goal.

**B. Direct Response to Current Proposed Metric Changes: Flagging Thresholds**

Regardless of whether or not the OPTN adopts the alternative approach to MPSC performance review described above, we strongly urge the OPTN to modify its flagging thresholds to appropriately reduce the number of transplant programs that needlessly undergo performance review. This change is critical to reduce the disincentive to transplantation created by the current performance review process. It is well documented in publications that transplant programs become considerably more risk averse after having been flagged. Reducing the number of programs flagged has the potential to reduce the risk aversion of transplant programs as a whole with no documented risk to patient safety.

It appears clear that the current flagging criteria are over inclusive. Approximately one third of unique transplant programs are flagged every three years, and an average of 10-12% are flagged every six-month review cycle (see #2 in references). Yet very few programs flagged for outcome queries have ever been shown to have true patient safety concerns. This level of regulatory oversight has made the fear of flagging pervasive and has contributed significantly to risk averse patient and organ selection by transplant programs while delivering no well documented benefit to patient safety.

For this reason, regardless of what metrics are used, we believe that no more than 2.5% of programs should be flagged as being in the Red Flag zone for any solid organ for each PSR. This approach more accurately targets true outliers and has the potential to substantially reduce risk averse behavior by

transplant programs. The currently proposed Red Flag zone criteria were set with an eye on not exceeding the number of currently flagged programs in the U.S. While maintaining adequate oversight is important in attempting to maintain a certain number of flagged programs, it appears somewhat random and not scientific.

It is our understanding that the purpose of MPSC performance review is to ensure patient safety. The ASTS believes that ensuring patient safety should be a priority to all those working in the field and that peer review and oversight are important elements of ensuring patient safety. In light of the positive safety profile of transplantation as a whole, MPSC performance reviews should be relatively infrequent. There is no body of published data that supports improved patient safety due to the current large number of U.S. transplant programs undergoing MPSC performance reviews. There is published data, however, showing the negative consequences of the large number of MPSC performance reviews – fewer transplants to U.S. patients and therefore harm to U.S. patients.

**Summary**

Summarizing, we would strongly urge the OPTN to adopt a simplified proposal which includes a fixed 1-year post transplant patient survival metric. The bar for expected survival should be determined on expected patient survival with the alternative therapy when available (dialysis, or LVAD survival or other best medical management) and should be high enough to justify the risk and cost of transplantation and protect patient safety. This will allow for more patients to be listed for transplant, more grafts to be accepted, more transplants to be performed, and will allow centers to innovate and develop new transplant options while remaining within the accepted standard. If centers fall below this first measure, a second risk adjusted analysis should be performed using very well-defined variables such as recipient/donor age, DCD, etc. Centers that meet the unadjusted pass/fail threshold or the risk adjusted analysis should not be flagged for performance review. No additional metrics should be added unless and until the impact of this change is evaluated.

Regardless of whether or not this recommendation is adopted we strongly believe that Red Zone flagging criteria should be established at levels that ensure that no more than 2.5% of programs—the true outliers—are flagged for each review cycle. This change has the potential to increase U.S. patient transplant opportunities due to reduced risk aversion by transplant programs and to save lives.

Finally, ASTS believes that statistical significance of self-prescribed thresholds are not clinically meaningful. The current OPTN/MPSC practice of deeming about 10% of all organ programs in need of performance review every 6 months is not well founded in the professional quality realm. ASTS thinks the OPTN proposal, while thoughtful and indeed sophisticated, will not result in substantial positive change in behavior. In addition, applying multiple metrics at the same time could negatively impact the transplant eco-system. The ASTS continues to be optimistic about transplantation and believes that we have one of the best and safest transplant systems in the world. We look forward to working with all involved in introducing more collaboration to the field.

Our responses to questions raised in the OPTN proposal are included as an Attachment.

References

1. https://asts.org/docs/default-source/regulatory/asts-white-paper-on-optimization-of-transplant-center-assessment-january-12-2021.pdf?sfvrsn=43a46d3_2
2. Schold, J. , Miller, C. , Henry, M. , Buccini, L. , Flechner, S. , Goldfarb, D. , Poggio, E. , Andreoni, K. & (2017). Evaluation of Flagging Criteria of United States Kidney Transplant Center Performance. Transplantation, 101 (6), 1373-1380. doi: 10.1097/TP.0000000000001373.

**Attachment**

**The OPTN Membership & Professional Standards Committee requests feedback on:**

1. *Do you think transplant programs that fall within the performance improvement or "yellow" zone would take advantage of offered assistance and if so, what types of assistance would be most helpful?*

   Interaction within the defined "yellow" zone is voluntary, and reaction to notification of "yellow" zone status will likely vary based on the unique situation, resources, and culture of each program. Access will range from use of educational material and best-practices information to significant interaction with the MPSC such as peer-peer engagement or other interactions.

   The MPSC should be prepared for the possibility that interaction with programs in the "yellow" zone (YZ) will be very labor intensive. Raising the hazard ratios for the YZ and RZ, thus decreasing the number of anticipated YZ and RZ flags would decrease the likelihood of unmanageable MPSC workloads emerging from this policy change.

2. *Would you support the future addition or replacement of the 1-year post-transplant graft survival with a longer-term period-prevalent survival metric, such as a 5-year period prevalent post-transplant graft survival?*

   The fundamental problem is that the longer-term the outcome measure, the more tenuous the link to the actual performance of the Transplant Center (TC) in the perioperative phase and the less control the TC has over those patients forming the long-term cohort. The assessment of the pros and cons would depend on the weighting given to a long-term metric and the hazard ratios or thresholds utilized to determine flagging for the metric. This would be more a measure of patient socio-economic status than transplant center performance as those with better insurance would have better community care over the five-year term.

3. *One of the desired attributes of a good monitoring system is the monitored entity understands the measures being used. In order to ensure this understanding: What types of resources do you anticipate needing to respond to these new metrics?*

   a. *Are you comfortable with the concept of risk adjustment or do you think additional education on risk adjustment is needed?*

      The problem with risk adjustment is that it results in a moving target for centers. What was an acceptable survival last year may not be accepted in the next cycle, based on changes to the model which cannot be predicted by programs. A second

problem is that some factors that are currently in the model, such as peripheral vascular disease and diabetes have a very wide spectrum of disease morbidity, and centers that are more familiar with the PSR models are coding for these risks more liberally than others. A third problem with risk adjustment is that not all variables known to impact survival are included in the model and the process for including variables is opaque. Because of these and other factors, we do not believe that risk adjustment is trusted by transplant centers.

The theory of risk adjustment makes obvious sense, but in reality, the granularity of the patient data necessary to achieve meaningful and fair risk adjustment is simply impossible to obtain.

b. *What education resources do you need to describe these metrics to your patients?*

We do not believe that the new metrics should be adopted, nor do we believe that metrics that require significant patient education are likely to be useful. Any metrics that are adopted should be sufficiently meaningful to patients and sufficiently straightforward to require little or no explanation from health care professionals.

## 12. Guidance for Data Collection Regarding Classification of Citizenship Status

The American Society of Transplant Surgeons (ASTS) supports the concept of the OPTN guidance document with the following reservations. We would like further clarification on or elimination of the term "residency." We need a category that encompasses an important proportion of people in the United States that are living here but are not "residents" ( e.g. Underrepresented in Medicine (URM) under working visa, student visas or the ones that have migrated but have not yet obtained their legal "residency"). We do not support the use of terminology that has intrinsic "legal" connotations. This may affect the quality of information collected, as most of the information is self-reported and depends on specific interpretation from patients, families, transplant coordinators, staff, or OPO staff. Most of these people do not have access to OPTN information and will not know what it means. People are afraid to use wrong "legal terminology" and that affects how the information is reported. One concern is that this may increase the disparity in organ donation and transplantation for the proportion of individuals who are living in the United States but are not "residents." There is some data suggesting that undocumented people in the United States donate more organs compared to what they are receiving, increasing disparities and inequities. We would suggest using different "terminology" without legal implications to minimize confusion in the people that will self-report it.

## 13. Establish Membership Requirements for Uterus Transplant Programs

The American Society of Transplant Surgeons (ASTS) strongly supports the OPTN's Vascularized Composite Allograft (VCA) Transplantation Committee's proposed membership requirements for uterus transplant programs with the following change.

1. *Do the proposed changes to the list of covered body parts that are considered VCAs under the OPTN Final Rule definition appropriately represent the types of genitourinary organs that might*

*be transplanted together under current clinical practice? See: Uterus: includes uterus, cervix, vagina, External male genitalia: Includes penis and scrotum, Other genitourinary organ: Includes internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder.*

Currently, the genitourinary organ category of covered VCAs as defined includes "uterus, internal and external male and female genitalia, and urinary bladder." The new proposal separates the "genitourinary organ" into three categories of VCA: 1. uterus, 2. external male genitalia, and 3. other genitourinary organs. ASTS supports the division into only two separate categories. Specifically, "external and internal female genitalia" and "external and internal male genitalia and bladder" with the elimination of the "other genitourinary organs." The expertise and infrastructure required to performed vascularized transplant female related genitalia is similar, thus, requirements integrating all these under the same category is beneficial for patient safety, for new and existing transplant teams, for infrastructure, for resources, for data collection, and for innovation. Similar reasoning applies for vascularized transplant male related genitalia adding bladder. As such, removing the "other" category altogether [i.e. in the current and in the proposed list of covered body parts that includes both female and male GU organs under one category].

2. *Do the proposed membership requirements for uterus transplant programs provide adequate flexibility to account for variation in the uterus transplant field in how hospitals develop multidisciplinary teams?*

The current membership requirements do not include any requirements specific to uterus transplantation and do not reflect the expertise required. Currently, the uterus transplant programs are subject to the same requirements as programs performing transplants of other genitourinary organs like the penis. The new proposal suggests a division and more tailored membership requirements specific for uterus transplant programs. The role of primary obstetrician-gynecologist is added to the roles of primary surgeon and primary physician. The same individual can be named for >1 role. ASTS supports the proposed membership requirements and agrees that they provide flexibility for uterus transplant programs to ensure qualified staff to safely perform uterus transplants.

3. *Will the proposed membership requirements ensure that approved uterus transplant programs have the expertise needed to safely perform uterus transplants, and, as applicable living donor uterus recovery?*

The proposed requirements for living donor uterus transplant programs and living donor uterus surgeon align with the recently approved proposal by the OPTN Board of Directors to update Policy 14 (Living Donation) to include all living donors, including living uterus donors and the current requirements for the living donor liver surgeon. ASTS supports the proposed requirement without changes.

4. *Are there any requirements that should be removed or relaxed, or any additional requirements that should be included?*

ASTS recommends revision of the requirement for living donor uterus surgeon requirements (J.5.D.) to the following, "At least 2 living donor uterus recoveries must be directly observed or participated

as primary surgeon or co-surgeon." The VCA committee does not believe it feasible for a potential living donor surgeon to receive credentialing at one of the very few institutions that perform living donor uterus recoveries to be primary or co-surgeon, and that observation by an experienced surgeon should be adequate exposure.

5. *Do members understand which procedures qualify as "radical hysterectomies"?*

The proposal defines radical hysterectomy as removal of the uterus, cervix, the upper part of the vagina, and tissues next to the uterus (the parametria and the uterosacral ligaments). ASTS agrees with this definition.

## 14. Establish Continuous Distribution of Lungs

The American Society of Transplant Surgeons (ASTS) supports the OPTN policy proposal with the following response to the OPTN Lung Transplantation Committee's request for feedback.

1. *Are the weights on each attribute ideal?* Yes. See remaining data requested in the following comment (see bold or last 3 sentences under 1.a.).

    a. *Should waitlist survival and post-transplant outcomes be equally weighted, or should waitlist survival receive twice as much weight as post-transplant outcomes?* Currently the weighting is 2:1, waitlist mortality and post-transplant survival respectively. This is likely a function of not including post-transplant survival, but rather, transplant benefit in the post-transplant model that includes both waitlist mortality and transplant survival. Therefore, overall waitlist mortality is counted twice. According to the proposed models using TSAM calculations, it appears that the overall optimal combination is to weigh waitlist survival and post-transplant survival equally. This seems reasonable and aligns with community sentiment from recent surveys. **What is not discussed in this specific request for feedback is what duration of post-transplant survival should be included in the model. We do not recall seeing data on the impact of the duration of post-transplant survival on the various outcomes measure to be reported by the OPTN; and importantly, we have concerns in the predictive capabilities for SRTR modeling past 3 years. These should be provided for the community to review.**

    b. *Is 10% the correct weight for efficiency (5% each for travel efficiency and proximity efficiency)*? Based on the estimates provided by the OPTN, this seems to be a reasonable weighting as it appears to increase emphasis on truly local donors to be prioritized towards teams that would not require air travel while modestly increasing average air travel distances when that is required.

2. *Are changes to exceptions appropriate?* Yes.

    a. *Is 5 days sufficient time to allow reviewers to vote on exception applications?* These are timely requests and should be processed within 5 days.

    b. *Is there a need to allow centers to list a candidate at an exception score while awaiting a decision on appeal after an initial denial?* No, we do not believe that centers should be

listing candidates at exception scores while awaiting a decision on appeal after initial denial. That practice introduces a level of subjectivism and practice variability that may be harmful to the overall allocation system.

3. *Are the changes to multi-organ allocation appropriate?* Yes at this juncture.

    a. *Is the composite allocation score of 28 the right cut-off?* It is not possible to understand how the changes will impact multi-organ allocation, nor do we have enough insight to make accurate predictions. However, the logic behind selecting 28 as a cut-off seems appropriate. This will obviously be a stop-gap measure as all the organs undergo alterations in their allocation based on the theory of continuous distribution. Unfortunately, that process will take years to mature.

    b. *Does the proposal need to be adjusted to allow OPOs more discretion to offer from the heart list before offering the heart to candidates in need on the lung list who have a composite allocation score of at least 28?* The proposal should not be adjusted to allow OPO's more discretion at this juncture, but rather the impact should be closely monitored after implementation and real-time decisions and modifications able to be made by the Thoracic Committee and Executive Committee of the OPTN.

4. *How many decimal places are useful for inclusion in reference numbers and equations?* Two.

## 15. Update on OPTN Regional Review Project

ASTS applauds the efforts of UNOS and the OPTN to review the Regional Meeting structure by having an outside vendor perform a thorough discussion with the entire transplant community. After reading the vendor report and discussing this thoroughly within our society, the ASTS feels strongly that the geographic Regional Model for meetings is still very useful to the transplant community as a whole and is still the best structural option going forward, perhaps with additional support as needed.

Beyond the traditional allocation units, transplant professionals and community members share many commonalities and concerns within the traditional Regions, and this would continue to apply in modified geographic groups. There are still vital relationships that are fostered at these meetings, especially between transplant centers and OPOs as we move more toward local procurements and shipping of organs beyond kidneys. Patients and donor families develop important relationships with both OPOs and transplant center representatives at these meetings.

While we appreciate the vendor's concerns of the possible need for separate cohorting of transplant community members who are not professionally involved in transplantation on a daily basis, we feel these community members learn a great deal by being at the general Regional meetings and by listening to all the discussions. If the OPTN feels they need to offer additional learning opportunities for these community groups, that should be in addition to the general Regional meeting opportunity. The ASTS believes strongly that there is valuable information and various opinions that can only be learned and heard at these Regional meetings. These community members would not hear the Regional concerns and likely the multiple points of views on OPTN, transplant center, OPO, or patient matters at a 'national' meeting of these individuals or groups hosted by the OPTN. Virtual

offerings of these Regional meetings would benefit even greater participation. The option of redrawing some geographic boundaries for the Regional Meetings may make travel more convenient. These options should be explored as suggested by the vendor.

An important issue raised by the review was the lack of clarity the Board of Directors (BOD) display in responding to feedback or comments from Regional Meeting participation/votes. ASTS agrees that the BOD should more directly respond to these comments by the larger transplant community. ASTS also feels that these Regional groups should still have a Board vote through a councilor type representative as that representation on the Board draws many to these meetings and does create the sense of representation at the Board. The OPTN needs to clarify what it believes the role of Regional councilors should be, specifically their role in representation at board meetings. What does the OPTN propose as the representative structure on the Board? If Regional Councilors are to remain, how should they rise to their positions? The ASTS believes the Regional Councilors are an important voice in democratically representing the transplant community.

ASTS does agree with the vendor findings that the Board should communicate continually throughout the year with the transplant community and not just at the time around the two Board meetings. Education for patients, donor families, and other transplant community members who are not involved in the technical aspects of transplantation is vital to their participation in the process.

In regard to the size of the BOD, the ASTS understands the membership requirements per NOTA and therefore the unwieldy size of a 42-member board. This is more than three times the size of the average public sector board. Although we understand the intention behind having so many non-transplant professionals on the board, it is clear that most of these individuals are uncertain about the details of the important decisions they are making while on the board, even after available education as many of these policies are highly detailed and with nuances that are difficult to appreciate for those who do not participate in the technical aspects of transplantation. The ASTS would like to emphasize the value of the patient and donor family voice in the process of transplantation. The OPTN should provide donor families/patients with various types of educational opportunities throughout the year to close the gap between education and representation. Perhaps HRSA should discuss the value of having a combination of voting and non-voting members on the BOD and consider downsizing the voting members of the BOD for more efficiency.

In direct response to your considerations listed online, the ASTS suggests the following:

- What is the optimal governance structure to best perform OPTN functions?
    - Board size (42 members) is too large for efficient running of any BOD.
    - Geographic representation with a voting councilor needs to be maintained.
    - Voting Board Members should be mostly transplant professionals due to highly specialized content of most board proposals.
    - Patients and Donor Families must have a voice in OPTN and on the BOD, and OPTN needs to continue to supply more frequent education to this group.
- How should the OPTN organize members into smaller forums?
  ASTS supports a structure similar to the current Geographic Regional one to keep the large benefit of gathering various transplant professional types in one location to share commonalities of concerns and improve working relationships. Patients and donor families,

as well as others who are not directly involved in transplantation on a daily basis, learn a great deal from these gatherings and have the opportunity to hear different opinions. Additional opportunities for these members to meet in either virtual or in person events may be additive to their experience. Additional and more frequent education for the entirety of the community should be a continual goal for the OPTN.

- How should the OPTN ensure members have a voice in policy?
    - A vote on the BOD via Geographic representation is fundamental to the OPTN and must continue. The Board should continue to have representation at the local Geographic meetings to directly communicate with its members throughout the country.
    - The direct representation of various professional groups is vital to giving voice to all involved daily in transplantation.
    - With current technology, BOD meetings should be available not just via in-person options, but also via virtual technology so any interested members can participate without undue hardship due to expense of travel or missing work.
    - The current online public comment process is very good and should continue. BOD members should be given more detailed summaries of the comments made on this website with true representation of all opinions.
- How can Regions, or an alternate construct, serve members and enable OPTN's strategic goals? Regions should continue to host at least twice a year meetings with direct communication with the OPTN leadership and BOD members. As mentioned above, this proximity allows for invaluable communication of various transplant community members with each other, improves daily working relationships and encourages clinical research projects.
- What role should geography play in the OPTN structure and functions? ASTS supports a structure similar to the current Geographic meeting model. At the minimum, traveling to a local venue is more convenient for all. But as mentioned previously, this proximity allows for invaluable communication of various transplant community members with each other, improves daily working relationships and encourages clinical research projects. The OPTN and its BOD should engage with these various regional meetings in vital two-way communication and bring this information back to the entire BOD.

  HRSA representatives should also participate more openly and provide more transparency in these Regional meetings. Far too often, HRSA has strong opinions, even what one would consider mandates, on public policies out for comment. HRSA representatives do not make these strong opinions or mandates known to the public in a transparent manner.