Proposal: Refit Kidney Donor Profile Index without Race and Hepatitis C Virus

- **Do community members support the Committee's proposal to refit the KDPI model rather than using the "zero out" method or APOL1 testing?**

  The OPTN has a duty to implement policies based on sound medical judgement and evidence.
  While the early results of APOL1 testing are interesting, there is not currently enough evidence regarding its efficacy to include it in this policy. The ASTS would highly recommend that the Committee continue to monitor further developments in this research and reassess the potential value of its future inclusion.

- **Do transplant professionals believe this policy change will impact acceptance behavior when using KDPI to assess deceased donor kidneys for transplant?**

  Given the community's adoption of race-neutral calculations generally and advocacy in advancing HCV+ to HCV- transplant, it is difficult to postulate on the direct impact this policy change, if passed, would have on acceptance behavior. However, the theory of cause and effect would suggest that it would be reasonable to assume some changes, particularly given the modeling suggests the number of donors moving into a KDPI sequence of < 85% would be offset by an almost equal number of donors moving into a KDPI sequence of > 85%.

  This proposal perhaps would be better described as a necessary modification reflective of current practice with regards to these two very specific factors. Further work to improve overall acceptance rates is still needed.

- **Do community members have feedback on the SRTR modeling results related to the updated cohort, change in coefficients, or donor movement between KDPI sequences?**

  We do not.

  ASTS Position: Support

Proposal: Standardize Six Minute Walk for Lung Allocation

1. Do you support the proposed policy requirement to perform an oxygen titration test ahead of the initial six-minute walk test for candidates at least 12 years old, and for candidates approaching 12 years of age?
    - Yes.

2. Should policy specify a timeframe within which the oxygen titration test must be completed ahead of the six-minute walk test?
    - The oxygen titration test should be performed within 6 months of the 6-minute walk test, or sooner if clinical condition has changed.

3. If the policy change were to go into effect on September 5, 2024, would that give lung transplant programs adequate time to prepare for implementation?
    - We believe the OPTN should allow 6 months from approval to implementation.

4. Are the data definition changes clear, and would you recommend any changes?
    - Clear

5. Is the guidance clear, and would you recommend any changes?
    - Clear

6. Does this proposal strike the right balance between promoting data quality for the six-minute walk distance and managing burden on lung candidates and lung transplant programs?
    - Seems reasonable in terms of burden on programs, without a notable burden on candidates.

7. What, if any, consideration should be given for altitude for candidates who live at a significantly different altitude compared to the transplant hospital where they are registered?
    - We would suggest oxygen titration and 6MWT to be done at the transplant center. In our experience, non-transplant center 6MWT can be variable in quality. Allowing different locations for 6MWT (i.e. at higher altitude near the patient's residence) would only introduce more sources of error in measurements and reporting. To fix this, CAS would have to introduce a correction factor for altitude if testing is done at a significantly lower altitude from residence, which would not be feasible at this time.

ASTS Position: Support

Proposal: Standardize the Patient Safety Contact and Reduce Duplicate Reporting

This proposal for public comment revises OPTN Policy 15: Identification of Transmissible Diseases. We support a culture of safety and laud the OPTN for working to improve communication between transplant stakeholders. We oppose the policy proposal as written because of the language requiring two individual Patient Safety Contacts who collectively would be available at all times to receive communication regarding potential disease transmission and related events. While it seems straightforward, finding two individuals to fill these rolls and ensuring that they never get sick or go on vacation at the same time will be challenging for THs and will actually have the unintended consequence of increasing the likelihood of missed safety reporting information rather than improving it. The Primary and Secondary Safety Contacts should be allowed to be a groups (for example, the post-transplant coordinator team, the On-call coordinator team, the Quality team etc.). They key improvement needed is to standardize the means of contact (i.e., the requirement to have an actual phone number, rather than a pager, for example), and that could be accomplished without the onerous imposition of the requirement for two individuals to collectively be on call at all times. Pragmatically and operationally, it will be much more logical and more const-effective for THs to provide more reliable contact information for groups that can easily collectively ensure availability and follow-up than to create a separate call structure. More importantly, using existing structures but improving the monitoring of those structures for availability will be much less prone to errors than the model proposed in this policy.

The Committee requests the following feedback:

• Do you support the additional requirements for the Patient Safety Contact? • Do you support the requirement of a listed secondary contact?

Not as written in this policy proposal. See comments above.

• Do you support the requirement that a listed Patient Safety Contact must work at the OPO or transplant program for which they are listed?

Yes, although contracted employees who work for a third party should also be included under the rubric of those who qualify as employees of the OPO or TH.

• Are there any additional requirements the Committee should consider for the Patient Safety Contact?

No.

• Does eliminating the need for OPOs to report recipient illness to the OPTN open the potential for missed reporting to the OPTN Patient Safety Reporting Portal?

Yes, but that risk is reasonable and mitigated adequately.

• Is the monitoring plan for this policy change sufficient?

Yes.

ASTS Position: Oppose

Proposal: Update on the Continuous Distribution of Hearts

1. Should candidates assigned to adult heart status 4 using the LVAD criterion be allowed to receive a higher percentage of medical urgency priority points than candidates assigned to the highest medical urgency rating groups, such as candidates on VA ECMO?
    - No- A patient with a VAD will be awarded "points" with time on waitlist as well as priority if a VAD complication occurs. With increasing access to donors, a patient's preference to avoid VAD in favor of transplant is reasonable. A patient should not be given priority for willingness to undergo two operations (VAD then transplant) if transplant is an otherwise reasonable medical option.

2. Are the attributes the Committee has identified for inclusion in the first version of the continuous distribution of heart allocation framework appropriate? Do you agree with the Committee's decision to include each attribute in the first version of Heart CD? Why or why not?
    - The attributes are appropriate for inclusion. However, the current proposal does not include objective recipient specific physiologic variables that can further stratify a recipient's clinical condition and waitlist survival when listed for transplant. Post-transplant survival is another important metric that has been left out of the first version of Heart CD. The committee should strongly reconsider inclusion of post-transplant survival in the Heart CD model as this is the most important metric for potential recipients and donor families.

3. Are there other attributes that the Committee should consider when developing the first version of the continuous distribution of heart allocation framework, and why? What data analysis of information is available to support their inclusion?
    - The committee should consider other measures of recipient physiology that can be used to assess wait list survival. Please see recently published data (JAMA. 2024;331(6):500-509. doi:10.1001/jama.2023.27029).
    - The Committee should consider the emerging and increasing role of technology in donor allograft procurement and the subsequent impact of such technologies on placement efficiency. Current devices are allowing longer travel and ischemic times. While this may negatively impact placement efficiency, programs utilizing technology for allograft procurement should not be penalized for considering otherwise "hard to place" allografts in non-local regions.

4. Considering the individual attributes, what information should the Heart Committee use to evaluate success toward the outcome of that specific attribute?
    - 1) Transplant rate (especially to patients with blood type O, LVAD, or extremes of height); 2) Post-transplant survival

5. Are there any allocation factors or attributes in current heart allocation policy that should not be included in the first version of continuous distribution? Why?

- The ease of which exceptions are allowed to be requested should be reduced. The inclusion of recipient objective physiologic variables will drastically reduce the need for exceptions. If exceptions are still felt necessary in continuous distribution, perhaps a pre-defined set of points for only certain factors (limitations of vascular access, device infections, malignant arrhythmias, etc.) could be outlined such that these additional exception points do not supersede the weight given to an individual attribute.

6. From the patient, donor, family perspective, what do you consider to be the most key factors for allocating donor hearts?
    - Post-transplant allograft and recipient survival are the most important factors for allocating donor hearts. Therefore, use of a post-transplant survival score as an attribute in continuous distribution should be reconsidered for heart continuous distribution.

ASTS Position: Oppose

ASTS
American Society of Transplant Surgeons

Proposal: National Liver Review Board (NLRB) Updates Related to Transplant Oncology

1. Do you agree with the proposed guidance and score recommendation for colorectal liver metastases? If not, please elaborate.

   Oppose, Due to lack of evidence to support liver transplant for metastatic colorectal liver mets, the ASTS cannot endorse the proposed guidance and score recommendations for colorectal liver mets.

2. Do you agree with the proposed guidance and score recommendation for intrahepatic cholangiocarcinoma? If not, please elaborate.
   - We have significant concerns about language re: biopsies. Though a biopsy might be helpful, it will likely be difficult to obtain due to liver disease, tumor location and size. A biopsy should therefore not be mandatory.
   - Further, We support a policy for intrahepatic Cholangiocarcinoma which would be similar to that developed for standard HCC exceptions.
     i. Prior to applying for a standardized MELD or PELD exception, the candidate must undergo a thorough assessment that includes *all* of the following:

        1. An evaluation of the number and size of lesions before locoregional therapy that do not meet meet Class 5 criteria for HCC using a dynamic contrast enhanced computed tomography (CT) or magnetic resonance imaging (MRI) and may be considered as iCCA
        2. A CT of the chest to rule out metastatic disease.
        3. A CT or MRI to rule out any other sites of extrahepatic spread or macrovascular involvement
        4. An indication that the candidate is not eligible for resection
        5. An indication whether the candidate has undergone locoregional therapy
        6. The candidate's CA 19-9 level

        The transplant hospital must maintain documentation of the radiologic images and assessments of all lesions in the candidate's medical record.

        For those candidates who receive a liver transplant while receiving additional priority under the intrahepatic Cholangiocarcinoma exception criteria, the transplant hospital must submit the *Post-Transplant Explant Pathology Form* to the OPTN within 60 days of transplant. If the *Post-Transplant Explant Pathology Form* does not show evidence of iCCA or liver-directed therapy for iCCA, the transplant program must also submit documentation or imaging studies confirming iCCA at the time of assignment.

3. Do you agree with broadening the Adult HCC Review Board and guidance document to encompass additional liver cancers and tumors? If not, please elaborate.
    - Strongly support

4. Do you anticipate that the additional cases that Adult Transplant Oncology Review Board is proposed to review will overburden the reviewers? If so, what is your proposed solution?
    - We strongly support an increase in the number of members on the review board so as to not overburden reviewers.
    - Further, we would encourage the OPTN to develop a data driven form (check boxes) that can be used for entering relevant data for these new exception criteria to facilitate the process.

5. Do you agree with adding guidance for hepatic adenomas, neuroendocrine tumors, and hepatic epithelioid hemangioendotheliomas to the Adult Transplant Oncology guidance document?
    - Yes, we agree that this should be moved. We also suggest there be consideration for standard MELD exceptions (t-3) for these cases; though they will be of limited numeric impact (< 90 q year), it will help to reduce the burden on the newly expanded transplant oncology review board.

6. Are there other non-standard exception requests related to liver cancers or tumors that should be addressed by the Adult Transplant Oncology Review Board and associated guidance document?
    - We strongly suggest that these innovations be implemented with caution until efficacy equity is demonstrated.

The Task Force notes that this is an important step forward and are grateful for the thoughtful consideration with which this document has been prepared. With the exception of the proposal for liver transplant for colorectal mets which the ASTS cannot endorse due to lack of level 1 evidence to support and the suggested changes for iCCA, the task force recommends that the ASTS consider strong endorsement for the rest of the proposal.

ASTS Position: Strongly Support

ASTS
American Society of Transplant Surgeons

Proposal: Clarify Requirements for Pronouncement of Death

The following concerns the OPTN *Public Comment Proposal to Clarify Requirements for Pronouncement of Death*, sponsored by the OPTN Organ Procurement Organization Committee. Proposed changes to OPTN policies 2.14.A and 2.15.G are intended to clarify that a hospital provider who declares the death of a potential deceased donor cannot be involved in any aspect of the organ recovery procedure or transplantation of that donor's organs.

The ASTS appreciates the opportunity to comment on this proposal. We support the proposal as written.

We strongly agree that is important to maintain a clear separation between providers involved in patient care before donation and those involved in organ recovery and subsequent transplant procedures.

We agree that the professional description of providers who may potentially declare a patient's death should not be limited to physician.

The OPO committee is requesting public comment, including input on the following questions:

• Are there concerns about these changes impacting patient or donor care?

> The ASTS does not believe these policy language changes would practically alter the thoughtful and ethical care being rendered to critically ill people in the United States every day.

• Are there any ethical considerations with these changes?

> We agree with maintaining a clear separation of scope of duties between providers involved in a patient's care and those involved in recovery of organs from that patient and transplantations made possible as a result.

• Does the proposed policy language provide adequate clarity for donor hospital healthcare workers who may also provide on-call support for OPOs?

> Yes.

• Does this proposal help to increase or maintain the public trust in the declaration of death of potential organ donors?

> The proposal is reasonable. It is not likely to increase trust but will not erode trust.

ASTS Position: Support

ASTS
American Society of Transplant Surgeons

Proposal: OPTN Strategic Plan: 2024 – 2027

This proposal for public comment provides the OPTN's Strategic Plan goals for 2024-2027. The biggest changes from prior OPTN strategic plans are the provision of more focused strategic goals and a more robust focus on metrics to assess success or failure in efforts to achieve those goals. Prior goals have been relatively vague, such as the prior strategic goal to increase transplants performed. The new strategic plan is an admission by the OPTN that a more focused approach is needed and that aspirations such as "increasing the number of transplants" are really more foundational and descriptive rather than constructive strategic goals.

The three goals advanced in this strategic plan are: Improve Offer Acceptance Rate, Optimize Organ Use, and Enhance OPTN Efficiency. Success in achieving these goals will support the broader foundational aspirations of previous strategic plans while being more focused and thus potentially more useful in focusing the work of the OPTN in advancing towards both the strategic plan goals and the more general foundational goals of the OPTN and the greater transplant community. This is a laudable philosophic change, as is the renewed focus on metrics and flexibility.

The three goals selected are appropriate, as they will, in isolation and as a group, address some of the critical shortcomings of the current transplant endeavor. We are supportive of the philosophic change in the approach to selecting strategic plan goals and are likewise supportive of the goals selected and the overarching aspirations of the OPTN in this regard.

The Committee seeks public comment on whether this set of goals and their associated objectives and metrics are appropriate. Specifically, the Committee requests the following feedback:

• Do you agree with the Board's proposed areas of strategic focus for the 2024-2027 plan?
Yes.

• Is a goal or objective missing from this plan that should be considered a strategic priority?
No.

• Are there goals or objectives that should not be included in this plan? If so, should they be maintained in the OPTN's future operations or discontinued altogether?
No. The three goals selected are appropriate and synergistic.

• Are the stated performance metrics sufficient, measurable, and specific? Are metrics missing from this plan that are needed to provide a holistic view of progress on strategic priorities?
No.

• What organs are at the greatest risk of non-use?
From a volume standpoint: kidneys. From a likelihood of non-utilization standpoint: pancreas, lung, and intestines.

ASTS Position: Strongly Support

Proposal: [Promote Efficiency of Lung Allocation]

• Do patients and donor family members support efforts to improve the efficiency of lung allocation and place donor lungs more rapidly with a potential transplant recipient?
Although this is hard to gauge, our sense would be that patients/families do favor increased efficiency throughout the transplant process but not at the cost of results.

• Do lung transplant programs support the proposed new data fields to assist in evaluating offers?
Yes, in particular previous sternotomy. We suggest including a sub-category within sternotomy for non-cardiac thoracic surgery (such as thymic resection). It is unclear that elucidating presence of a nut allergy is likely to have substantial impact.

• For adult and pediatric lung transplant programs, what additional donor information or offer filters would be useful for your program?
Additional donor information that might be useful to assess for a filter- presence of an autoimmune disease in the donor that has potential to impact the lungs (e.g. SLE); presence of certain CNS tumors (e.g. glioblastoma multi-forme); certain causes of death (e.g. asphyxia, drowning); certain features of the neuro exam for potential DCD donors

• Do OPOs anticipate any challenges with reporting the additional donor data?
Not applicable.

• Are the proposed data definitions easy to understand or is additional clarification needed regarding the intent of the data collection?
The proposed definitions are clear. We suggest including a sub-category within sternotomy for non-cardiac thoracic surgery (such as thymic resection).

• Do OPOs and lung transplant programs support the potential system enhancement to add a "Bypass bilateral and other lung" button to bypass candidates who would not accept an offer if only a single lung is available?
Yes, we agree that this should improve efficiency.

• Do lung transplant programs support the potential system enhancement to opt in to offers from geographically isolated areas (Hawaii, Alaska, and Puerto Rico)?
Yes.

-Would transplant programs support adding this feature for other organs as well as lung?
We would support this for hearts as well.

• How else might the OPTN improve the efficiency of lung allocation for both transplant programs and OPOs?
The OPTN may establish policies and procedures for expedited allocation of thoracic organs when pre-determined criteria are met. Changing policies so that when DCD donors progress to brain death after organs have been allocated the system does not re-allocate immediately, instead the centers that had accepted the organs are allowed to re-evaluate the offer acceptance first before

re-allocation. We suggest creating a process for sharing recovery resources to improve travel efficiency—perhaps one in which transplant centers that assist with local recoveries are rewarded with quid pro quo or some other recognition.

ASTS Position: Support