

**AST Committee Feedback Form for OPTN/UNOS Public Comment Proposals
January 21 – March 23, 2021 Public Comment Period**

The AST Board of Directors approved the following responses to the OPTN/UNOS Spring 2021 Public Comment period. All responses were developed after review of feedback from the Society's Communities of Practice and Policy Committee.

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Proposal Title: Modifications to the Deceased Donor Registration (DDR) Form

The American Society of Transplantation is supportive of this proposal in concept, and offers the following feedback:

Data Element Removal

Tattoos –We are supportive of removing this data element.

Cancer free interval – Would recommend continued collection as this is relevant information for consideration of acceptance and post-transplant monitoring despite the reliability. Theoretically, reliability can potentially be an issue for any historical information.

Data Element Modification

Coronary angiogram – Would consider revising options available to provide more detailed information about the donor specimen. These could include 1. No, 2. Yes, normal (no evidence of coronary artery disease), 3. Yes, Abnormal, but non-obstructive (all stenosis determined to be <70%) and 4. Yes, Abnormal and obstructive (presence of any stenosis determined to be >70%)

Specific Feedback Requested	AST comments
Should both recovery date and cross clamp date/time be collected?	We agree that the current use of “recovery date” as a data element on the DDR can create additional confusion for transplant staff. We agree that collecting the date of cross clamp is more accurate and may result in less chance for data entry errors. We support removal of recovery date, but acknowledge that on rare occasions, specific scenarios may arise in which the recovery date and cross-clamp date are different and may be clinically relevant.
Should donor citizenship still be collected on the DDR?	We agree that the term “citizenship” may not be as meaningful during a donor offer. For example, though a donor may not be a U.S. citizen, this does not indicate whether they recently traveled. Furthermore, there are many non-U.S. citizens residing in the country, and whether they are a citizen does not preclude them from being a donor. There was some discussion regarding the role that citizenship has on whether a potential recipient is insured or not. However, this would not affect the donor or the information collected on the DDR. We support removal of citizenship.
Donor Management: Should the list of medications be updated? Should dosages and duration be collected instead of yes, no, or unknown? Should these medications only be provided at certain time points (for example, time of extubation, initiation of	The Society’s members commented that transplant staff, in making a decision on an organ offer, do not normally use the information listed in this section of the DDR. However, if there were centers that did use this information, then including

<p>agonal phase, initiation of flush) instead of within 24 hours prior to crossclamp?</p>	<p>the dosage of insulin would be helpful. The current list of medications provided appears comprehensive enough at this time. Dosages and duration should be collected, regarding anti-hypertensives, vasodilators, steroids and diuretics. Additionally, it may be useful to extend the timeframe to longer than the 24 hours prior to crossclamp (i.e., the past 48-72 hours). The combination of this additional information can provide an overall sense and assessment of donor stability and eliminate additional questions to the OPO coordinator on call.</p>
<p>Should there be a specific timeframe for reporting transfusions during the terminal hospitalization?</p>	<p>Two separate issues are of concern with the volume of transfusion including reliability of donor infection assessment (as identified in the PHS guidelines) and donor stability. To address both issues in this section we would recommend proceeding with the recommended changes but include a separate statement to indicate the total volume within the <i>last</i> 24 hours prior to crossclamp or recovery.</p> <p>For pediatric donors, volume of transfusion is preferred instead of number of transfusions.</p>
<p>Clinical infection confirmed by culture: Should this field be modified to capture more granular data?</p>	<p>We agree that in current practice, if there are questions regarding donor cultures or infections, transplant staff will reach out and contact the OPO for clarification. This is common practice for most transplant hospitals. As such, we do not suggest collecting any additional information at this time.</p>
<p>Cocaine use or Drug Use (ever): Does the information in the proposed changes below provide more useful information on drug use than the current yes, no, and unknown response options?</p>	<p>The proposed changes appear to provide more specific and interpretable data regarding donor effects. We are supportive of proceeding with the currently proposed changes.</p>
<p>Should the OPTN collect additional information on Chagas and TB including specific risk factors for each in order to evaluate patient safety and transplant outcomes?</p>	<p>Current information provided in the demographic information could be interpreted to assess for risk of Chagas and TB. A separate section to assess for specific risk factors appears unnecessary currently.</p>
<p>Organ recovery section: Should this information still be collected on the DDR?</p>	<p>We believe this information should continue to be collected with controlled DCD. Serial data collection should continue to occur every 5 minutes (SBP, DPB, mean BP, MAP and O2 saturation).</p>

We would also like to express reservations about the additional data burden the above, and other proposed recommendations, will have on OPO recovery staff personnel. We realize that requesting additional data collection, data entry and data follow-up, will increase the amount of time OPO staff spend in compiling this data and submitting to the OPTN. While we do realize that data collection must be continuously honed and improved, we do not support additional data collection for the sake of collecting it. As per the OPTN Data Vision Statement approved December 2016, the overall intent is to provide value to patients, OPTN members, the organ donation/transplantation community, and the general public including the following:

- Whenever possible, data collected in center or OPO electronic health records, and other databases should be accessible to the OPTN without the need for additional data entry.
- Variables collected should specifically support the data uses outlined above and should be re-evaluated on a regular basis.
- Data collected should be accurate (based on clear definitions), complete, timely, and subject to ongoing quality control audits/efforts.

So, while we agree that data elements collected on TIEDI forms should be regularly evaluated, we strongly believe that any additional data element proposed for collection by the OPTN should be thoroughly discussed by all stakeholders, that transplant community feedback from this public comment be taken under significant consideration by the OPTN, and that revisions to any subsequent policy are made based on the community's feedback.

Proposal Title: Require Notification of Human Leukocyte Antigen (HLA) Typing Changes

The American Society of Transplantation strongly supports this policy change to ensure the accuracy of Histocompatibility data within UNet to improve patient safety and transplant outcomes. We agree with the suggested automated electronic notification be included in the implementation.

The suggested timeframes appear reasonable given patient safety and the large number of imported organs (outside typing) for highly sensitized candidates. However, we suggest consideration to reduce the timeframe for the OPO to notify all accepting transplant programs to 8 hours from the proposed 12 hours.

We also suggest a second minor addition for your consideration:

Notification of a “Critical HLA Discrepancy” be sent to both the OPO and originating HLA Lab within 1 hour. This will immediately engage all parties and expedite the resolution of the HLA typing discrepancy.

Proposal Title: Clarify Multi-Organ Allocation Policy

The American Society of Transplantation is generally supportive of the intent of this proposal, proposal in concept, we do have concerns regarding readiness and completeness to move this proposal forward, as offered, to the Board for consideration. These changes are necessary, but not totally sufficient. This is an important issue to address in policy, and we absolutely agree that national standards should be set in policy, as there is variation in how these allocations are managed today. However, the current proposal does not fully address all questions, and will benefit from further enhancement and expansion to fill these gaps before approval and implementation.

As an example, we are concerned that children awaiting kidney transplant are already disadvantaged by the current priority given to multi-organ candidates. This policy has the potential to further exacerbate this negative impact for these children. We ask that this be considered prior to final approval of this policy. For example, one way to mitigate this concern would be to permit allocation of only one kidney to an adult multiorgan candidate from any pediatric donor. Possible considerations to mitigate the effect of multiorgan transplant allocation priority on children would be to permit allocation of only one kidney to an adult multiorgan candidate from any pediatric donor or any donor with a KDPI < 35.

We offer the following feedback for consideration.

The Committee specifically asks for feedback on the following:

1. Is Heart Adult Status 1, 2, 3 and Pediatric Status 1A and 1B appropriate thresholds for when OPOs must offer a liver or kidney to a multi-organ candidate listed for those organs?

The threshold for heart does incorporate the vast majority of Heart MOTs in 2019. While 18% of heart-liver transplants and 23% heart-kidney would have been excluded, maintaining priority for the most acute patients identifies those with the most elevated urgency. The threshold would achieve a minimum cutoff, which impacts be a minimal number of transplants and if it were any lower than the threshold would essentially be rendered moot. This is probably acceptable for this rudimentary first pass. However, it is clear that ANY heart candidate with GFR<30 has a worse outcome and thus even lower Status 4-6 in adults or Status 2 in pediatrics is disadvantaged. Rapid addressment of the challenges of dual organ candidates and appropriate risk stratification methods should continue.

We have concerns regarding Status 1A liver candidates being bypassed for a liver to go with a heart to Status 2 or 3 heart candidates. Often times, even the most critical of these patients are not imminently at risk of death and tend to be more stable than liver Status 1 candidates.

2. Is a lung allocation score of greater than 35 an appropriate threshold for when, OPOs must offer a liver or kidney to a multi-organ candidate listed for those organs?

No. A patient with a LAS just above 35 is not at high risk for dying from their lung disease. Often times, even the most critical of these patients are not imminently at risk of death and tend to be more stable than liver Status 1 candidates. The data used to support the LAS >35 threshold seems to be based on the fact that all candidates who received a lung-liver transplant had a LAS >35, and this threshold would be inclusive of all 2019 cases. (The 2019 data has limited numbers and suggest no clear site for threshold other than a LAS of 35+.) We believe that further thought needs to be given to determining this threshold which should be higher.

This policy proposal currently excludes 0-11-year-old pediatric lung multiorgan candidates because they do not have a LAS. We recommend that, rather than removing these pediatric candidates from the match run, they be included in the policy. The number of patients that would fall into this category is extremely small, as this a lung-liver or lung-kidney transplant in this age group is a rare event. We ask that the sponsoring committee explore inclusive solutions for these young pediatric candidates rather than an exclusion here, as we believe this is a gap in the current policy proposal.

3. Is 500 NM an appropriate distance for when OPOs must offer a liver or kidney to a multi-organ candidate meeting the proposed criteria?

The 500 NM mandatory offer seems a foregone conclusion given that thoracic allocation already uses this distance and the OPOs are probably often already operating under this principle, although liver and kidney transplant centers may not necessarily expect this practice, hence there is a need for clarification. Although the current policy doesn't stipulate this specifically and this protocol clarification should alleviate that confusion.

From the pediatric perspective, we do have concerns about the expansion to 500NM, and its potential effect on kidney access (for example) for non-multi-organ candidates. While many of pediatric members would support the proposed change, we would also ask that there be ongoing review of the effects on access for non-multi-organ candidates.

4. Do you believe all multi-organ policies should be located in the same section of policy?

Centralizing all multi-organ policies is reasonable to avoid confusion. Page 8 leads to ambiguity as it implies that the OPO decides which match to start with and thus this could negate the entire multiorgan allocation policy. An OPO that chose to start with liver or kidney match would place those organs before the lung or heart match was run. This would then create the uncomfortable situation of "withdrawing" an organ offer after acceptance or potentially jeopardizing a very ill dual organ candidate from surviving to transplant. We advocate for clarification that abdominal organs below some established level of severity (i.e. MELD under 35) are not allocated prior to a lung and heart match run to confirm no dual candidate is inadvertently skipped.

Several organ specific concerns were also shared by our communities of practice:

- More consideration needs to be given to allocating kidneys with hearts for Status 4 patients.
- A safety net for kidneys following heart and lung transplant needs to be established prior to implementation to ensure there is some capacity to rescue patients who needed a kidney and were not able to get it based on these new regulations.
- Multivisceral transplantation needs to be included with a priority to allocate other organs with an intestine, rather than having the liver be the driver of MVT. These changes will have extremely small effects in terms of allocation and are unlikely to materially affect waiting times in other organs. But for the affected patients, these are very significant issues. Implementing without addressing them may have disastrous consequences for these small but very sick patient populations.
- This policy will affect roughly 200 Kidneys (allocated to Heart), 45 (liver to heart), 12 (liver to lung), and 13 (kidney to lung) candidates. This represents approximately 1% of kidney transplants. Things that could be addressed explicitly by this policy remain the following:

- If kidney or liver deceased organ is not utilized for any particular reason, how will OPO's re-allocate this organ. E.g., If the kidney or liver deceased organ has now travelled a much further distance than current policy.
- Did the work group consider adding Heart Adult Status 4 to the policy? If yes, what were the pros and cons for that? If not, what were the reasons to not consider this?
- We do agree with the other statuses for livers and kidneys.
- Overall, we still need to have an actual definition for the criteria for needing a multi-organ transplant (esp. for kidneys), and a safety net feature for heart-CKD pts.

Proposal Title: Develop Measures for Heart Primary Graft Dysfunction

The American Society of Transplantation is supportive of this proposal in concept, and offers the following feedback for consideration:

Given the mortality associated with PGD, collection of both donor, recipient and intra-operative data is imperative to permit a better understanding of this condition. With regard to PGD related data elements for assessing transplant related mortality, the suggested potential data elements for addition to the TRR form are reasonable. However, a more expansive set of data elements will be needed.

The timing of collection of hemodynamic data needs to be carefully considered. In patients with defined PGD, the worst hemodynamic parameters and highest doses of inotropes at 24 hours (defined as 1st 24 hours out of OR) would ideally be collected as PGD consensus definition has a 24-hour timeframe. Repeat parameters at 72 hours (+/- 4 hours) should also be collected. Additionally, consideration should be given to capture hemodynamic data measured at the time of a first biopsy (if performed in the first 7-10 days) to determine the persistence or resolution of PGD. Finally, PGD grade should be included (i.e. whether moderate or severe).

There is significant literature to suggest that Pre-tx recipient factors contribute to the risk of PGD. These data should be collected if not already available, including mechanical circulatory support (temporary or durable and type, duration of temporary support), inotropes including doses, medications at transplant including amiodarone, ACEI, ARB, ARNI.

Given developments with ex vivo perfusion and evolving technologies (e.g., new preservation solutions and techniques), it is important to collect donor data. These should include organ preservation technique, ex vivo Y/N, preservation solution, warm ischemic time. Elements from the UNOS donor management registry could possibly be incorporated for this purpose. However, collecting more detailed data to include amount of perfusion solution and bag pressure may be cumbersome and onerous.

For DCD (direct procurement method), time to asystole after withdrawal of life support, warm ischemic time, back table time and total ischemic time, time from admission to declaration of death should be collected.

Where ex vivo platforms are used, both warm and cold ischemic times should be collected, time on device and maximum lactate values.

Transplant perioperative factors such as transfusions (number and type of units) may be important.

We concur with the removal of airways dehiscence as it is not applicable to heart transplantation. Primary Graft Non-Function should be replaced by Primary Graft Dysfunction as it now has a definition by consensus. Acute rejection should stipulate type and severity by ISHLT Classification, whether mixed or biopsy negative. Chronic rejection should also be removed and replaced with cardiac allograft vasculopathy but may not be relevant if data is collected early after transplant (see below).

The collection of additional data may provide challenges for programs, but this could possibly be counterbalanced by removal of less relevant elements and automation of collection of certain data elements from EMR systems.

Transplant programs should have easier access to data elements due to EMR systems in place.

The TRR is a reasonable tool to use in the absence of a relational database.

The data collection should be part of collection of EARLY post-transplant data.

Issues relating to ABO incompatible transplants, use of different temporary and durable mechanical support devices and congenital heart disease may be unique to collecting PGD data for pediatric transplants.

Simplification of data elements (e.g., use of PGD grading scale) and avoidance of free-text data elements would ensure consistency in data collection.

OPOs should be able to provide important information about DCD donors, including etiology, admission time, donor support, hemodynamics.

From the pediatric perspective:

The data elements seem reasonable. We do not recommend including mild but should include moderate to severe PGD with a clear definition of each. We do feel that some donor elements should be collected. This work has previously been done by ISHLT and published as a consensus document (Report from a consensus conference on primary graft dysfunction after cardiac transplantation). We recommend using the data recommended in this document as a lot of time, effort and thought was put into its development. Donor risk factors used in this document included age, cause of death, trauma, cardiac dysfunction, inotropic support, comorbidities (DM, HTN), downtime of cardiac arrest, drug use (alcohol, cocaine, amphetamines), Left ventricular hypertrophy, valvular disease, hormone treatment, CAD/wall motion abnormalities on TTE, sepsis, alternate list/marginal donor allocation-not increased risk, troponin trend and hypernatremia.

We suggest that it is important to avoid the temptation to include or address items that DO NOT factor into PGD (e.g. rejection).

From Table 1:

PGD, LV dysfunction, RV dysfunction, we recommend that the definitions be VERY clear and include when the events occur. From a consistency perspective, we recommend that “Y/N” not be used for PGD as that is too vague without a clear definition.

We would NOT collect hemodynamics as this likely will not be available for many patients and is very labor intensive. Likewise, we would not include drug doses as this will be very labor intensive as well particularly in pediatrics where dosing is not a single standard dose.

We also believe that the challenges of collecting WIT and organ preservation techniques will likely outweigh the benefit. The only exception would be to indicate DCD and whether ex vivo perfusion is used

Timing:

There are differences between adults and pediatrics, so the committee should ensure pediatric input. We strongly suggest sticking to the 24-hour definition. 24 hours is an accepted definition and meets with the current practices and studies internationally. If changed to the 72 hours, then the U.S. would differ from the consensus guidelines and the studies published since 2013, and blur the field from a PGD perspective. We recommend reporting the highest value in that 24-hour period (or the maximal support).

Proposal Title: Update Transplant Program Key Personnel Training and Experience Requirements

The American Society of Transplantation is supportive of this proposal to address potential changes to transplant program primary surgeon and primary physician training and experience requirements in concept, and offers the following comments:

Five overarching principles are defined: currency of experience; consolidation of pathways; consistency of organ-specific requirements; stratification based on previous experience; incorporating an option allowing for foreign training and transplant experience.

Comments:

Page 4 - Currency

This appropriately emphasizes the need for the primary physician/surgeon to have current experience and includes the establishment of periodic assessment of compliance with membership requirements. The requirements for and process of periodic assessment need to be further defined.

Establish a five-year term and renewal process for the primary physician/surgeon to assure that transplant experience and knowledge of OPTN bylaws and policies remain current.

This is addressed in another section, but the only caveat would be to consider that the renewal process should consider certain specifics that may be appropriate at initial election for primary physician/surgeon (albeit not at renewal). An example would be 'witnessed procurements in an experienced primary physician' – these should not be required for person in their role as an experienced primary (and they should not have to re-demonstrate that experience at renewal). The bottom line is that the requirements for renewal will be different than the initial qualifications and that these will be reasonable to expect from any practicing primary who is still highly involved in transplantation.

Page 5 – Consolidation

It has been a challenge show currency in procurements for a surgeon and for a physician who has been out of fellowship or residency for more than 2-5 years. Once they become faculty at a transplant institute, there is minimal likelihood of them doing a procurement. Many large, academic programs have surgeons who are procurement surgeons. Thus, the concept of a combined fellowship and clinical experience through a consolidated single pathway is ideal.

We do have some reservations about consolidation of the fellowship and clinical experience pathways into one pathway. Currently, as per OPTN bylaws, the candidates applying for a primary surgeon or physician position via clinical experience pathway require a higher number of procedure logs compared to those applying via a fellowship pathway (e.g., performance of 45 kidney transplants over a 2–5-year period vs. 30 kidney transplants during the 2-year fellowship period for surgeons). The plan to consolidate the fellowship and clinical experience pathways implies less stringent criteria to become eligible for primary position via clinical experience pathway than what we have now. Consolidating the pathways may undermine the value of more structured fellowship programs and consequently the training of candidates, especially for Transplant Nephrology in the times when AST accredited transplant nephrology fellowship applicant pool is already depleted.

From a pediatric perspective, the consolidation of fellowship and clinical experience is appropriate for a limited time frame. With the new pediatric program certifications, some have been asked to submit logs

from patients from more than 10 years ago. This should not be required if you have been approved prior and if you are still working as a transplant medical director. Limiting procurement requirement for surgeons and observation requirements for physicians to surgeons or physicians that have not been a primary in last 10 years would help. We are supportive with the online OPTN certification. Although, we suggest that UNOS might require a letter from the applicant's current facility stating they are the current acting medical director meeting minimum volume standards.

Page 5 – Stratification of Select Key Personnel Requirements:

One of the most common issues is the inability of senior clinicians with significant experience to produce documentation for some aspects of their experience that they may have gained early in their career or during their fellowship but no longer routinely perform as a senior clinician, such as procurements for surgeons or observations of transplants and procurements for physicians. If someone has previously served as a primary physician in another institution, we believe the requirements for primary physician should be more consistent with that of the maintenance requirements being considered for someone who is a primary physician at a facility. The need to demonstrate currency should be consistent with current primary physicians or surgeons and should be updated every 5 years, not 10. But the requirements should be more on volume and outcomes in a one-two page form.

This section appears generically to have addressed the point above about differentiating initial requirements vs renewal requirements

We agree with the proposal to exempt individuals from certain requirements if they have previously served as a primary (proposed within 10 years).

We wonder about an exemption for senior transplant physicians who have been functioning as high-level transplant attendings for a threshold number of years (perhaps 5 or 10 years) also being exempt from certain initial requirements (that we believe are geared at new physicians becoming primaries soon after completing training). For example, an experienced transplant attending (> 10 years' experience for example at an established program) becoming a primary physician may find it difficult to find old case logs for procurements/implants witnessed during transplant fellowships > 10 years earlier. Given the significant experience as a full-time established transplant attending it may be appropriate to waive certain requirements similar to those being proposed for primaries that had previously served as a primary within 10 years.

Page 6 – Requirements that appear in both primary transplant surgeon and primary transplant physician requirements.

Current certification; add: "or meet defined equivalency criteria"

Page 8- On-Site

We recommend further consideration into defining on site (or its removal) so the mandate can be clearly followed and fairly assessed. The OPTN defines what they don't expect on site to be defined as (e.g. – not physically present) but do not currently define what they do expect it to be. If not addressed, this will be ambiguously interpreted.

Maintain the requirement that "the primary surgeon and physician be physically available to provide leadership to the program, actively participate in the provision of transplant services, and ensure the operation of the program is in compliance with OPTN obligations."

Consider requirement that the transplant center/hospital be the physician/surgeon's primary location of practice. (although consider an exception being for those who have separate adult and pediatric programs that are part of the same health system but may be physically different locations)

Some of the AST membership questioned the rationale for a single individual being allowed to serve in a primary role for multiple programs and would like the MPSC to elaborate and clarify when this would be permitted. As noted above, unique circumstances may exist for adult/pediatric programs that are part of the same health system.

Page 8 – Board Certification

There is variability here within the U.S. system – meaning that there are sanctioned boards for transplant in some areas (Heart/Kidney etc.) and not in others (Lung)... It might be reasonable to mandate board certification in the area of organ specific transplantation if that exists (Heart/Kidney others) and to expect Board Certification in the underlying related subspecialty of medicine/surgery in those organs that don't have a transplant specific board (i.e. BC in Pulmonary Medicine for Lung Transplant)

Page 9 – OPTN orientation curriculum

We are supportive of this new requirement for transplant program key personnel as it provides a unique opportunity for individuals to be educated on OPTN policies and procedure and the transplant system. We would request consideration that the requirement window of ten years be narrowed to five years for transplant surgeons and physicians who have not recently served as a primary surgeon or physician given the frequency of bylaw and policy changes.

We agree that OPTN orientation curriculum would be helpful to all the candidates applying for a primary position for the first time. The curriculum may include education in OPTN bylaws, transplant system, leadership course, and roles and responsibilities of the program primaries. As this OPTN orientation curriculum is yet to be developed, we would encourage that curriculum include a thorough overview of the transplant multidisciplinary team including member roles and requirements. Ideally, we would suggest incorporating multidisciplinary team members into the development of this curriculum. Additionally, we suggest consideration that this curriculum or a similar curriculum be available in the future for other members of the multidisciplinary team

A recently published paper by AST Medical Directors Task Force has described the roles and responsibilities of medical directors of kidney transplant programs ("*A.C Wiseman et al. Defining the roles and responsibilities of the kidney transplant medical director: A necessary step for future training, mentoring, and professional development. Am J Transplant. 2020 Oct 5*"). In addition, AST's Kidney Pancreas Community of Practice and the AST Medical Directors Task Force recently conducted a survey of primary physicians of kidney and pancreas transplant programs to assess their demographics, training pathways, job satisfaction, and their roles and responsibilities vis-à-vis primary surgeons and transplant administrators (awaiting publication). The gamut of administrative responsibilities the program primaries are involved with (as described in Wiseman et al. paper and what we learnt from the medical director survey) include- demonstration in active participation in listing, QAPI, OPO, and OPTN/UNOS meetings, outreach, marketing, development of program goals and objectives, writing policies and protocols, ensuring adherence to OPTN/UNOS, CMS and other regulatory agencies' policies, and acting as a liaison with other departments/support services in the

hospital. We believe that these data would be helpful to the OPTN in defining the expected roles and responsibilities of primary physicians and surgeons.

Page 10 – Conditional approval

This pathway is intended to accommodate for sudden vacancies. Consider a process that allows non-primary transplant physicians/surgeons to formally establish “OPTN primary requirements/certification” as part of succession planning and to establish a pool of qualified individuals to fill vacancies.

Page 10-11- Primary transplant surgeon requirements

See previous comments re. OPTN curriculum

Transplant experience - no comment as document states that this will be determined in a later phase of the project.

Agree that the requirement for participation in pre-operative assessment and post-operative care adequately addresses the range of care.

We agree that the candidates applying for primary position must be required to have recent clinical experience (within past 2 years) at least in some aspects of transplantation (irrespective of whether they have served as primary in the past or not), and the requirements can be set by MPSC.

A primary surgeon should commit minimum 50% of time to practice of transplant and minimum 10% of time in transplant administration.

For the individuals trained in the United States and Canada applying for primary position, board certification is a requirement. For the individuals trained outside the United States and Canada applying for primary position, we suggest that they must be at least board eligible if not certified and must have U.S. transplant experience for a minimum 2-3 years before applying.

Page 12- Primary transplant physician requirements

See previous comments re. OPTN curriculum

We agree that the candidates applying for primary position must be required to have recent clinical experience (within past 2 years) at least in some aspects of transplantation (irrespective of whether they have served as primary in the past or not), and the requirements can be set by MPSC.

A primary physician should commit minimum 50% of time to practice of transplant and minimum 10% of time in transplant administration.

For the individuals trained in the United States and Canada applying for primary position, board certification is a requirement. For the individuals trained outside the United States and Canada applying for primary position, we suggest that they must be at least board eligible if not certified and must have US transplant experience for a minimum 2-3 years before applying.

Consider expanding requirement for observation of at-least two transplants and one procurement. Should not be a requirement for renewal (as per prior discussion)

No comment on number of recipients cared for and evaluations required as document states that this will be determined in a later phase of the project.

Requested feedback re whether a requirement for participation in evaluations, pre-operative care and post-transplant care adequately addresses the range of care for primary physicians. Consider adding the phrase “longitudinal post-transplant care” to emphasize the need for experience with care of patients at all points post-transplant.

Page 14 – Board Certification Equivalency

Agree that it is reasonable to have a pathway that considers alternatives to board certification for individuals trained outside of the U.S. or Canada. OPTN/MPSC should carefully consider whether it wants to be the arbiter of board equivalency as this will also be addressed by state licensing boards.

Maintain the requirement for board certification for individuals who trained in the U.S. or Canada

The requirement for “CME that is equivalent to requirements for board certified individuals” is appropriate but the document provides no means of documentation as would occur under maintenance of certification for board certified individuals

Letters of recommendation – agree on this requirement. MPSC may wish to consider whether these letters will be from references provided by the applicant or solicited by the MPSC.

In addition, ABIM should not be the only certification body. The NBPAS (National Board of Physicians and Surgeons) has been in existence nearing a decade, serving as a checks and balances vs ABIM.

Page 15- Transplant Experience Equivalency

Experience with the United States transplant system is critical for primary transplant physicians/surgeons given international variation in clinical practice and organ allocation.

Review and oversight of non-U.S. experience is complex but assuming the availability of appropriate documentation logs as well as MPSC subcommittee review this could be accomplished.

We suggest adding requirements similar to those for conditional approval to allow for ongoing review and oversight.

Attachment C, “Lists of aspects of care a surgeon or physician is currently required to document but are not included in the proposed framework”:

Consider revising the requirements for heart a lung primary surgeons and physicians to maintain consistent verbiage and order content as follows:

- Add “histocompatibility and tissue typing,” “immediate post-operative and continuing inpatient care,” “differential diagnosis of cardiac dysfunction in the allograft recipient,” “histological interpretation of allograft biopsies,” and “interpretation of ancillary tests for cardiac dysfunction” to the requirements for primary surgeons in a heart program.
- Add “histocompatibility and tissue typing,” “performing the transplant operation,” “immediate post-operative and continuing inpatient care,” “differential diagnosis of pulmonary dysfunction in the allograft recipient,” and “interpretation of ancillary tests for pulmonary dysfunction” to the requirements for primary surgeons in a lung program.

- Add “histocompatibility and tissue typing,” “immediate post-operative and continuing inpatient care,” “differential diagnosis of cardiac dysfunction in the allograft recipient,” and “interpretation of ancillary tests for cardiac dysfunction” to the requirements for primary physicians in a heart program.
- Add “histocompatibility and tissue typing,” “immediate post-operative and continuing inpatient care,” “differential diagnosis of pulmonary dysfunction in the allograft recipient,” and “interpretation of ancillary tests for pulmonary dysfunction” to the requirements for primary physicians in a lung program.

Proposal Title: Calculate Median MELD at Transplant around Donor Hospital and Update Sorting within Liver Allocation

The American Society of Transplantation offers the following comments regarding this proposal.

The proposal has received uniform support as it pertains to assuring that two exception candidates with the same exception diagnosis who are listed at different transplant programs (with variations in MMaT at those centers) do NOT receive different MELD exception scores on that match run. This proposal will clearly solve this issue.

However, there have been several areas of critical concern that the AST would like to convey.

1. Concern about impact on pediatric waitlisted patients:

The AST's Liver and Intestinal Community of Practice (COP) pediatric subcommittee and the Pediatric COP understand the reasons for this new proposal to address the waitlist issues in adults. However, they feel that this proposal may have significant negative impact on organ offers to pediatric patients, particularly the 12-18-year-olds listed with MELD exception scores. More than 40% of pediatric patients are listed with exception scores due to calculated MELD/PELD not accurately representing their waitlist mortality. We are concerned that the proposed modifications to rank sorting with prioritization of patients with a calculated MELD will decrease organ offers particularly to 12-18-year-olds and likely increase their waitlist morbidity and mortality. There has been no modeling of this new proposed system on how it will affect pediatric patients. Accordingly, we recommend that specific consideration or modeling on the impact of children on the waitlist be performed prior to this proposal being considered.

Furthermore, this proposal does not take into consideration that children have different reasons for exemptions than adults. As noted above the proposal will potentially reduce children's access to all types of liver transplant (whole and split). The Liver and Pediatric Committees are actively working on a PELD score revision that aims to increase utilization of calculated PELD scores and reduce reliance on exception scores. We strongly recommend that this score be developed before this proposal is considered. We ask that the committee consider allowing patients under the age of 18 to have their exception MELD or PELD considered as calculated in the new rank sorting system.

2. Access to LT for exception point candidates may be reduced:

On a general note, the AST also raises concerns that exception point candidates will be disadvantaged relative to calculated MELD patients, as they will automatically be prioritized below "calculated" MELD patients with the same allocation MELD, regardless of time on the list. This may be particularly problematic for exception candidates who are listed at transplant programs with a higher MMaT, who will likely now have very little access to organ offers originating from donor hospitals with lower MMaT.

3. Critical short-term analysis of consequences is necessary:

The AST feels strongly that there is a plan in place for critically evaluating access to liver transplant and waitlist outcomes for all exception candidates following implementation of this proposal. As a general concern, the acuity circles allocation model was just implemented last February, which coincided with the COVID pandemic. The pandemic has had unpredictable effects in transplant behavior so that we do not believe that the true impact of the acuity circles

allocation model has been evaluated. Making yet another change without having robust data on the impact of AC risks creating disparities that were not intended. It is critical that this is looked at closely, with plans in place to remedy any unintended consequences.

Proposal Title: 2021-2024 Strategic Plan

The American Society of Transplantation is supportive of the proposed 2021-2024 strategic plan. The Society is supportive of working on goals that increase efficient matching and continuous distribution but also believes that increasing living donation should be an area of focus. Focusing only on increasing deceased donation may not result in improved outcomes or increased overall transplant volume. The collective goal should be about increasing access to transplantation for all.

In response to the specific questions posed by the Executive Committee:

1) Do you agree with the Board's proposed areas of strategic focus for the 2021-2024 plan?

The ID COP agrees with the Board's proposed areas of strategic focus. Increasing the number of transplants, and improving equity, safety, and outcomes of transplantation are important goals. We especially want to emphasize a) the importance of increasing collaboration and performance improvement activities between OPOs and transplant programs as part of Goal 1, and b) improving equity in access to transplantation in racial minorities, patients of lower SES, and patients with geographic limitations. To that end, we include feedback under question #2 below.

2) Is a goal or initiative missing from this plan that should be considered a strategic priority? Will resource allocation benchmarks need to be changed to accommodate the addition?

Under Goal 1, we feel that there should be specific incentives to encourage increased collaboration between OPOs and transplant programs. The wide variability of approaches depending on region is something we feel needs to be tackled as a strategic priority. Actually having incentives in place to reduce this variability by encouraging the sharing of best practices and joint performance improvement activities between OPOs and transplant programs would be important. We also feel there should be more specific emphasis on ways to improve equity in access to transplantation in racial minorities, patients of lower SES, and patients with geographic limitations. To understand the barriers to access and implement solutions will need to involve specific resource allocation.

3) Are there goals or initiatives that should not be included in this plan? If so, should they be maintained in the OPTN's future operations or discontinued altogether?

We feel all the goals and initiatives included in this plan are important and do not feel any should be removed.

4) Are the stated performance metrics sufficient, measurable and specific?

The stated performance metrics are measurable and specific. We should ensure that the implementation of projects to achieve these metrics are given the resources they need to make sure UNOS is successful in achieving these important goals.

We appreciate the focus on efficiency and equity over the next 3 years. It is understood that the OPTN is not seeking efficiency at cost of safety/outcomes. Specific feedback on the individual goals, include:

GOAL 1

- The alignment of goals and metrics between OPOs and transplant programs will not happen without increasing transplants. We must ensure the accountability of both sides is aligned and enforced to help the transplant community achieve this goal. This might be achieved by implementing incentives and outcomes metrics, oversight, and accountability.
- The initiatives listed focus on increasing deceased donor transplants. In addition to increasing utilization of deceased donor organs, promoting living donation has to be a key ingredient of policy aimed at increasing overall transplantation. Initiatives in this direction, for example, educating wait-list patients on using social media as a tool to help find living donors, should be included.
- OPTN should consider a mentorship program where programs with a data proven track record of high acceptance rates and good outcomes could invite programs who wish to improve their numbers to have them spend a few days with the mentor program to learn what practices have led to their success.
- We support the need to develop transplant center metrics that go beyond 1-year graft survival. As has been proposed before, this is key to maximizing utilization of “less good” kidneys including high KDPI.
- We concur with the resource allocation for this goal, as the initiatives carry a substantial amount of effort, time and work force. The initiative for the development of transplant center metrics (beyond one-year outcomes) parallels work done over the last few years in both KPCOP and TCCCOP. There have been two AST consensus conferences (one in kidney and now one in heart) working on this issue. The Society agrees with working collaboratively with transplant centers, OPTN, APOO, individual OPOs, AST and other transplant societies to identify strategies to improve interactions between OPO’s and transplant centers to improve the number of transplants performed.
- We agree it will be beneficial to evaluate system efficiency in order to increase organ utilization using a number of unique approaches.

GOAL 2

- We ask that this goal include an effort to improve equity for pediatric candidates.
- Make sure there is an adequate representation of non-academic transplant centers with OPTN.
- We ask that the practice of creating policies based on broad perspectives from a varied group of advisors, volunteers to assure equitable access across all patient populations be continued and expanded, including adequate representation of non-academic transplant centers.

GOAL 3

- We concur with initiatives directed at decreasing waitlist mortality, increasing one-year graft and patient survival and increasing 5 year graft and patient survival rates.

GOAL 4

- We would suggest that these metrics include a key metric pertinent to living donor outcomes as well.

Proposal Title: Updating National Liver Review Board Guidance and Policy Clarification

The American Society of Transplantation is grateful for the continued review of the NLRB guidance criteria and supports the proposal as written with no further comment.

Proposal Title: General Considerations in Assessment for Transplant Candidacy (White Paper)

The American Society of Transplantation is generally supportive of this paper in concept. This is an important and timely topic, particularly in the context of the AST's Inclusion, Diversity, and Access to Life (IDEAL) Task Force work. The paper tackles difficult issues and urges the reader to apply approaches consistently. We appreciate the revision's intent to define a more standardized process for non-medical considerations that are vital for consideration when assessing transplant candidacy, including medication access and adherence, but do believe that it may fall short of serving as not only an advocate of these concerns but as a steward of how to address them. The white paper covers ethical principles which are germane to consideration of the psychosocial issues which are frequently confronted by transplant programs. The strength of the document is the key message to consider all candidates equally, and not base adverse determinations only on the psychosocial aspects. While we appreciate and agree with many statements within this document, we believe that the inclusion of applied clinical ethics and relevant empirical literature from both organ transplantation and broader behavioral research will make it more robust. Additionally, we believe that it should also include specific guidance on how to operationalize these principles.

The determination of transplant candidacy is a complex clinical synthesis, which intertwines empirical, evidence-based assessments with normative judgments. Many normative judgments germane to transplant candidacy are predicated on the accurate prediction of future behaviors, assumptions about volitional and financial capacities for conforming to a recommended post-transplant management regimen, and structural inequalities in our healthcare system and society. As the paper outlines, these judgments are often made in the absence of a robust evidence base, can be subject to a host of misleading heuristics and biases, which by extension can result in discounting or invalidating the candidacy of vulnerable individuals. That said, these forward-looking predictions and clinical judgments are, to some extent, unavoidable.

Non-medical factors, while an important part of the holistic assessment of the transplant candidate, are often poorly defined, based on limited data, susceptible to bias, and used by programs to reject patients that may be more challenging to manage. Unfortunately, these patients are more likely to be ethnic and racial minorities, lower SES, and socially isolated. We emphatically support efforts to improve the transplant process by increasing consistency, minimizing or eliminating bias, and furthering the empirical literature on evaluation criteria for listing. Dismantling structural racism and other biased processes is of the highest priority. Equal application of standards without regard to ethnicity, socioeconomic status and immigration status is of the utmost importance. The background section criticizes the inclusion of non-medical transplant evaluation criteria but does not clearly define "non-medical criteria" nor suggest how these criteria can be relevant and/or helpful. The overall tone seems rather negative about this aspect of the evaluation process and without fully showing appreciation that these are not simple decisions determined at point of contact and recognition that transplant personnel try to work with patients to identify and mitigate risk factors for negative outcomes and foster positive ones. We suggest including some information about the benefit/importance of including these criteria as there is substantial evidence to suggest that various psychosocial criteria are related to outcomes.

Line 67: We appreciate it stating "ethnicity bias" but we suggest broadening this statement to include sexual orientation, gender, etc. or simply be stated as bias.

Lines 79-80: “Non-medical criteria” should be defined. Are you referring to psychosocial variables in general? Mental health status and history is a significant piece of “non-medical” criteria that is not currently included in this document and would benefit from the addition.

Lines 84-86: We believe that this is perhaps the most important statement in the document. We agree that inconsistent and/or subjective use of non-medical criteria leads to inconsistent distribution of medical goods. However, given the existing empirical literature on the impact of “non-medical” factors on outcomes, both in general and related to organ transplantation, perhaps recommendations should focus more on greater clarity, transparency, and refinement of these guidelines.

Life expectancy

Lines 109-122: This section largely discusses/focuses on “age” rather than life expectancy. We agree that using age alone, without the consideration of life expectancy, is a bias. However, evidence suggests medical criteria (e.g., comorbid conditions, frailty, etc.) impacts life expectancy. Therefore, we suggest that life expectancy is a medical criterion. We believe that separating age and life expectancy for discussion purposes here is important.

Potentially injurious behavior

First, we applaud the new title for this section. The prior version of this section was *Organ Failure Caused by Behavior* and in this version, it is *Potentially Injurious Behavior*. This new title is more encompassing of the complex behaviors known to impact health and health outcomes and less focused on the stigmatization of behaviors that may have contributed to organ failure. However, the included paragraphs do not show full understanding of the clinical complexities of the included behaviors. Also, collapsing these behaviors minimizes some of their complexities. For example, substance use disorders are quite different than not having access to healthy food choices. While there can be overlapping individual, sociocultural, and environmental factors across behaviors, determining the individual’s specific risks for negative outcomes deserves individual assessment and intervention (by personnel with the relevant expertise) in order to mitigate negative outcomes. In some cases, that will defer or prevent listing (e.g., active suicidal intent with plan, ongoing cocaine abuse). Each presentation warrants thorough evaluation, entails its own unique ethical considerations (for example, please see Beauchamp [1993] discussion on suicide, autonomy and mental capacity), and intervention as appropriate for the benefit of the patient.

Lines 125-131: Sources 30 and 31 are outdated. We respectfully disagree agree with the broad statement that the evidence is “essential but currently inconclusive” as we put forward that it depends on which behaviors are being examined. As one example, there is also a growing body of research that opioid use is linked to poor transplant outcomes (sources below).

- Lentine KL, Lam NN, Naik AS, et al. Prescription opioid use before and after kidney transplant: Implications for posttransplant outcomes. *American journal of transplantation*, 2018;18(12):2987-2999.
- Lentine KL, Lam NN, Schnitzler MA, et al. Predonation Prescription Opioid Use: A Novel Risk Factor for Readmission After Living Kidney Donation. *American journal of transplantation*. 2017;17(3):744-753.
- Lentine KL, Lam NN, Xiao H, et al. Associations of pre-transplant prescription narcotic use with clinical complications after kidney transplantation. *American journal of nephrology*. 2015;41(2):165-176.

- Lentine KL, Shah KS, Kobashigawa JA, et al. Prescription opioid use before and after heart transplant: Associations with posttransplant outcomes. *American journal of transplantation*. 2019;19(12):3405-3414.
- Lam NN, Schnitzler MA, Axelrod DA, et al. Outcome Implications of Benzodiazepines and Opioid Coprescriptions Before Kidney Transplantation. *American journal of transplantation*. 2018;18 (Supplement 4):295.

Lines 133-136: Some of the references should be updated or do not support the premise proposed. Specifically, Goldblatt et al is from 1965 and the relevant obesity literature has been considerably updated. Also, Adler, Glymour, and Fielding (2016) outlines that these behaviors contribute over a third of premature deaths. However, Adler et al. do not make comment on genetic factors nor do they explicitly state that these behaviors are or are not within the patient's ability to improve. Rather the article presents general policy recommendations to make resources for improving these behaviors more accessible to a wider cohort of individuals. We suggest that the statement referenced by #33 be removed, as simply because there is a genetic or economic basis to a condition does not render it non-modifiable.

Lines 140-143 and 145-147: These statements appear to assume that individuals who are assessing these behaviors are either not aware of or disregarding of the clinical knowledge necessary to assess and recommend appropriate mitigation strategies. Rather, in the interest of the patient, we should be intervening or assist in facilitating appropriate interventions to improve the patient condition (when indicated/appropriate).

Lines 154-156: Given the range of behaviors outlined here, it is difficult to fully support this statement as it does not allow for the clinical seriousness of some of these behaviors on the patient and the graft. While we agree that a patient with a history of substance abuse should not be excluded based solely on this history, if the candidate currently actively engaging in self-injurious behavior, it is our ethical duty to our patients to intervene. Depending on the specific behavior that may require deferring or ruling out organ transplantation until intervention can be performed and the self-injurious behavior can be improved. We agree this should be done in the context of the most up-to-date empirical literature, both based upon patient presentation and in relation to organ transplantation.

Also, of note reference 36 is on the Americans with Disabilities Act (ADA) and organ transplant: under the ADA, illicit substance abuse histories are eligible for disability status but only if the patient is no longer using/abusing illicit substances and actively participating/participated in rehabilitation. Regarding alcohol abuse, the ADA does offer protections for individuals with alcohol use disorders, but an employer can prohibit alcohol use in the workplace, may discipline, discharge, or deny employment if alcohol use adversely affects job performance, etc. This is consistent with the clinical approach to illicit substance and/or alcohol use disorders in organ transplantation. Namely, patient engagement in minimization of adverse effects in relation to organ transplant which can include abstinence, intervention, etc.

We also note that this section is missing a discussion regarding relapse to alcohol use. Many, if not most liver transplant programs will deny or de-list a patient who has relapsed to alcohol use. This is a common criterion, accordingly discussion of this issue is warranted and would be of benefit.

Adherence

We put forward that there are some objective measures of adherence, some of which (e.g., adherence to dialysis, attending transplant evaluation appointments) have been directly linked to post-transplant

adherence. Therefore, we suggest modifying the section to state that we should rely on these objective indicators of adherence when available and, as previously noted, to assist patients in problem-solving and resolving barriers when feasible.

We support the last sentence of this section as a critical and accurate statement shown time and time again, both in and out of transplantation. We believe that this section would benefit from updated citations.

Lines 169-171: We find this to be another important statement but believe that it is important to call it what it is... “implicit biases” rather than “implicit perceptions.”

Repeat transplantation

We agree with this section.

Incarceration status

We agree that incarceration status should not *a priori* exclude a patient from being considered for transplant. However, the logistics of such pose challenges and have to be weighed in the context of appropriate utilization of resources (e.g., time taken from other patients to coordinate this complex care).

Immigration status

We agree with this section and support associated revisions.

Social support

Although we appreciate the ethical considerations proposed by opposing social support as a criterion for transplant listing, the consideration for social support should be viewed with more nuance and requires a delicate balance of both ethical values and clinical considerations. Further, the existing literature examining social support factors on outcomes has significant limitations and does not account for existing routine clinical interventions aimed at strengthening social support. Also, additional literature cited in this report provides subjective data (providers’ perceptions) rather than objective percentages/number of patients declined due to lack of social support. Given the call for more objective indicators, it is important to obtain objective data (vs perceptions, which have a high risk of recall bias) before making significant regulatory changes. Supporting this, the cited research reported 70% of the providers surveyed supported the development of a more objective, standardized social support evaluation across all transplant centers, which can arguably create more equitable access to transplantation. Thus, the suggestion is not that social support does not matter or should not play a role in transplant candidacy. Rather, that it be measured objectively and in consideration of the needs of the patient to successfully care for a new organ. We agree that teams should help patients with limited supports find ways to meet their support needs and to do so in an equitable manner. However, we also find it reasonable for a transplant program to decline patients when patients and/or social supports do not participate in efforts to mobilize support systems.

Note: reference 48 and 49 appear to be the same reference.

Summary/Conclusion

We suggest adding to the Summary/Conclusion:

“Ultimately, the use of judgment in candidacy evaluations must be understood in the context of the ultimate moral and professional responsibility for post-transplant outcomes accorded transplant physicians and surgeons. Historically, adverse patient outcomes attributable to (for

example) demonstrated nonadherence, financial unsuitability, a lack (or foreseeable loss) of social support has not been judged to release transplant professionals and transplant programs from responsibility for patient outcomes. This ultimate responsibility inherently requires use of (fallible) judgment in candidacy determination. In parallel, it may be not preferable to penalize programs for making judgments which may result in adverse patient outcomes, in service to the goal of improving access to transplantation."

We offer the following additional comments for consideration:

- From an access standpoint, pharmacy benefits coverage should not only be assessed at the time of transplant listing but should be encouraged to be reassessed periodically or at minimum closer to anticipated transplantation. While we understand this is a dynamic, complicated process with many involved, patients' ability to have access to and coverage for their medications post-transplant is paramount to their success as data have shown non-adherence to be associated with a higher rate of rejection and graft loss.¹⁻⁸ Multidisciplinary team members should utilize available validated tools when able to objectively assess adherence, literacy, and comprehension as part of pre-transplant evaluation. Lastly, although social support alone should not preclude candidates for listing, a lack of support systems that may impact vital post-operative demands, specifically medication management, should be taken into consideration in order to address factors that may contribute to medication non-adherence and influence transplant outcomes. Transplant programs should proactively develop resources promoting adherence to assist candidates pre-transplant and to optimize post-transplant outcomes for recipients.

References

- Butler JA, Roderick P, Mullee M, Mason JC, Peveler RC. Frequency and impact of nonadherence to immunosuppressants after renal transplantation: A systematic review. *Transplantation*. 2004; 77: 769–789.
- Sellarés J, de Freitas DG, Mengel M, et al. Understanding the causes of kidney transplant failure: the dominant role of antibody-mediated rejection and nonadherence: attributing causes of kidney transplant loss. *Am J Transplant*. 2012;12(2):388-399.
- Berquist RK, Berquist WE, Esquivel CO, Cox KL, Wayman KI, Litt IF. Non-adherence to post-transplant care: Prevalence, risk factors and outcomes in adolescent liver transplant recipients. *Pediatr Transplant*. 2008;12(2):194-200.
- Pinsky BW, Takemoto SK, Lentine KL, Burroughs TE, Schnitzler MA, Salvalaggio PR. Transplant outcomes and economic costs associated with patient noncompliance to immunosuppression. *Am J Transplant*. 2009;9(11):2597-2606.
- Oliva M, Singh TP, Gauvreau K, Vanderpluym CJ, Bastardi HJ, Almond CS. Impact of medication non-adherence on survival after pediatric heart transplantation in the U.S.A. *J Heart Lung Transplant*. 2013;32(9):881-888.
- Nevins TE, Robiner WN, Thomas W. Predictive patterns of early medication adherence in renal transplantation. *Transplantation*. 2014;98(8):878-884.
- Hart A, Gustafson SK, Wey A, et al. The association between loss of Medicare, immunosuppressive medication use, and kidney transplant outcomes. *Am J Transplant*. 2019;19(7):1964-1971.
- Woodward RS, Schnitzler MA, Lowell JA, Spitznagel EL, Brennan DC. Effect of extended coverage of immunosuppressive medications by medicare on the survival of cadaveric renal transplants. *Am J Transplant*. 2001;1(1):69-73.

- We recognize that this is a large topic and the white paper focuses on adults and does not address pediatric patients or patients with disabilities. We suggest review of the AAP April 2020 recommendations. If pediatrics is not included, we would recommend that the introduction state that it focuses on adult patients.
- The document doesn't explore the reality that a past history of injurious behaviors, lack of social support or a history of repetitive non-adherence present grave risks to the loss of organs, that, once transplanted, cannot be reallocated to others if initial pre-transplant concerns prove to be well founded. The verbiage lays responsibility on the transplant centers to find methods to "fix" the issues for the candidates which is not always practical or possible. For example, a patient without a car or a phone, doesn't take his medicines or keep his appointments or lacks any support system is highly unlikely to have a successful transplant outcome. We believe that it is incumbent upon transplant professionals to be good stewards of a precious resource. We should not take this document as free license to allocate organs when there is a "high degree of certainty: that there will be a poor outcome. There must be a balance of advocacy for a patient and stewardship for the donor.
- The white paper does not address financial support as a barrier to transplantation and care. It would seem that this would be an important aspect to consider in a document such as this that addresses the ethical considerations raised by the use of non-medical criteria.

The white paper is descriptive, not prescriptive, and ultimately it is the transplant center's prerogative to transplant patients with psychosocial risk factors based on their risk averseness, available resources, and prior center outcomes. The goal of the white paper is to urge centers to reconsider individuals facing the challenges described in the white paper and try to provide resources and support to navigate the process of transplant.

The intent of white paper is good, but it would be very helpful if it directed centers to additional resources that may be needed to help higher risk patients. The white paper also makes no comment on changing transplant center reporting metrics to exempt them from potential poorer graft and patient outcomes due to the inclusion of such high-risk patients which may be helpful in incentivizing transplantation in these patients.