ASTS Response to OPTN Proposals Open for Public Comment

September 7, 2023

Modify Lung Allocation by Blood Type

1. **Do you support implementation of the proposed blood type rating scale?**
   Support

2. **Of the rating scales the Committee assessed, is there another rating scale that you think should be adopted?**
   Support. The committee appears to have diligently weighed the pros/cons of alternatives and adopted a reasonable solution. The only limitation would be in the accuracy of modeling- this will need time and follow-up to ascertain.

3. **Would you propose an alternative blood type rating scale?**
   Based on US population distribution; could be distributed in proportion to the blood type percentages in the US population (eg. type O is 45% type A is 40%). Alternatively looking at lung transplant statistics on both the listed patients and recipient population and compile the blood type distribution.

4. **Do you support the transition plan for candidates with pending biological disadvantages exception requests?**
   Support

5. **What should the Committee consider when monitoring this change?**
   Waitlist mortality and post-transplant outcome by blood type.

ASTS Position: Support

Deceased Donor Support Therapy Data Collection

While we are inclined as basic principle to view policy proposals that require additional data entry burden with a jaundiced eye, the potential benefits of the additional data collection required by this policy proposal outweigh the costs associated with the additional data collection burden.

We support efforts to streamline allocation and decrease the number of organs procured but ultimately not transplanted. We support efforts to increase the number of transplants performed. We recognize that renal replacement and related support systems are increasingly prevalent in deceased donor management and that many transplant hospitals are routinely utilizing kidneys from deceased donors receiving renal replacement therapy. The required data fields would have a significant impact on organ offer review and will be important components of additional organ offer filter resources.

• Are there any other donor support interventions not mentioned that should be considered?

No.

• Are there any additional data elements that could be added or eliminated related to this effort?

No.

• Is the recommendation to remove the current ECMO data and instead use this data collection effort to collect this information instead appropriate?

Yes.

o Is the recommendation of excluding the flow rate data field appropriate?

Yes. The information is not clinically relevant for our purposes.

o How does your respective program currently use/evaluate this data?

This data is often difficult to find, and we support this policy proposal in part because it will standardize reporting, improve transparency, and facilitate organ offer review.

• Do you agree with the recommendation to display the proposed data fields in the Meds and Fluids page of the OPTN Donor Data and Matching System?

That will suffice. Training resources will need to be provided for transplant hospital staff.

o Is there another label that would be more appropriate (ex. the Committee suggested a tab labeled “Donor Management”)?

This would be more intuitive for transplant professionals taking organ offers and reviewing these data fields. Consideration should be given to placing these data under a “Donor Management” tab.

ASTS Position: Support

Remove CRPA 99 -100% Form for Highly Sensitized Candidates

This policy proposal would delete OPTN Policy 8.4.F and any references to the policy elsewhere.

1). Deletion of 8.4.F will remove a barrier to access to transplantation for highly sensitized candidates. The policy set up an additional hurdle for patients and transplant hospitals that was unneeded, and the removal of 8.4.F will benefit candidates previously subject to its provisions.

2). Deletion of 8.4.F will decrease the data submission burden on transplant hospitals and HLA labs by eliminating the additional paperwork documenting that candidates do, in fact, have CPRAs of 99-100%. The removal of this burdensome requirement aligns the evidentiary basis of clinical status with other clinical indicators for listing. We congratulate the OPTN as well for proposing to eliminate the two associated waiting list data fields.

3). The proposal to eliminate 8.4.F is a salutary example of the OPTN engaging in post-implementation monitoring of the effects of policy changes. We are encouraged by the OPTN's examination of a spurious and counterproductive policy and the decision to eliminate that policy for the benefit of wait-listed candidates and the transplant ecosystem.

• Are there other barriers that highly sensitized candidates may face when being listed that the committee needs to consider addressing?

No.

• Are there other OPTN documentation requirements that the Committee should consider reviewing for efficiency or equity concerns?

No.

ASTS Position: Strongly Support

Update Guidance on Optimizing VCA Recovery

1. Are there additional effective practices the Committee should include in these recommendations to the transplant community?
   We recommend a qualitative research approach, such as a focus group(s), to address this question.
2. What barriers and challenges are keeping the transplant community from becoming more involved with VCA recovery and transplant?
   a. VCA recovery: OPOs are not given credit for placing these organs. This should be addressed.
   b. VCA transplant: insurance companies thus far have not covered uterus transplantation. This severely limits more widespread adoption.
3. What are the experiences of donor families regarding the VCA authorization process?
   We recommend a qualitative research approach, such as a focus group(s), to address this question.
4. What are the experiences of donor families, recipient families, and recipients with media and public relations strategies?
   We recommend a qualitative research approach, such as a focus group(s), to address this question.

ASTS Position: Support

Modify Organ Offer Acceptance Limit

This proposal is sponsored by the OPO committee and aims to reduce the number of accepted primary offers for the same patient which is allowed by policy from 2 to 1. This policy primarily impacts liver, lung, and heart wait-list candidates, though the vast majority are liver candidates (n=811 liver candidates with concurrently accepted offers during the 18 month study period from March 2021-Sept 2022, versus 62 lung candidates and 4 heart candidates). The primary goal of this is to reduce late turn-downs resulting in the need for reallocation and/or non-utilization. The average time to decline concurrently accepted livers is 1.5 hours before cross clamp and concurrently accepted lungs are declined 5 hours before cross clamp.

This is a well-meaning proposal and is attempting to address an important problem. However, there is no policy or guidance related to when OPOs allocate organs and when they intend to proceed to the operating room. It is common that the liver is allocated first and then the lung and heart organs second and third, despite the liver often requiring the shortest amount of time to allocate. Transplant centers often must accept a liver for a wait-listed candidate without knowing when that donor (or potential donor) will go to the operating room for organ procurement. However, that procurement may not occur for days, and may not occur at all for a host of reasons, and during that time it is imperative that the candidate be able to receive other offers. The committee presented data on the status of the patient who receives the liver or lung for subsequently turned-down concurrent offers and shows this is often a lower status patient. This is an important point—that late turn-downs often require OPOs to bypass sick patients to avoid non-utilization. However, it is also important to know what is the status of the recipient who accepts a concurrent offer—are these usually medically urgent patients? Second, what is the average time from offer acceptance to cross clamp for concurrently accepted offers?

Proposed ASTS Summary

ASTS opposes the policy as proposed to modify the organ acceptance limit from 2 down to 1 primary offer, as it is currently written. While the ASTS recognizes that the committee is trying to address a very important problem of late turn-down and the subsequent need to reallocate often to a less medically urgent recipient or even the potential for organ non-utilization, the primary driver of accepting two offers is uncertainty about when the donor will go to the operating room in the setting of a medically urgent patient who is at risk of death. Therefore, the ASTS suggests the committee adopt one of the proposed alternative solutions noted below, in recognition of the prolonged time from offer acceptance to cross clamp in a multi-organ donor.

- **Why should transplant programs be allowed to hold two primary acceptances while other candidates are also in need of a lifesaving organ?**

The primary reason that centers accept 2 offers is uncertainty about the timing of the operating room which in some OPOs can actually be several *days* after accepting the primary offer so the center is forced to stay in for two offers until OR time is set since there is not a way to know which one will go first, and this is relevant when the primary recipient is very sick and may die before the OR occurs (status 1 or high MELD or high lung status). The second reason is concern about whether the donor

organs will be suitable for transplant, such as in the case of steatosis or older donors or DCD or in rare cases without cross-sectional imaging, size considerations.

• Which options that the committee discussed are you supportive or not supportive of and why?

The ASTS is supportive of the option of allowing higher status patients to accept 2 concurrent primary offers. As noted above, this practice is driven by uncertainty about when the donor will go to the OR and to a lesser degree uncertainty about donor quality. The committee presented data on the medical status of recipients where the declined offers are ultimately placed, but it would be informative to know the medical urgency of the recipient who received the accepted offer.

The ASTS understands the committee's recommendation to not make an exception for DCD given this is a low percentage of concurrently accepted offers and would have an insignificant impact either way. However, the ASTS would still advise making an exception for DCD, at least for medically urgent candidates, given the uncertainty of whether the donor would arrest. Otherwise, centers could essentially never accept a DCD for a medically urgent candidate, and this will cause an increase in waitlist mortality.

• Are there other potential options the committee should consider?

The ASTS suggests that the committee consider requesting that OPO choose to allocate the organs they expect to take more time to allocate first, such as lung or heart, followed by the organ that are quicker to allocate second. This will reduce the need to have so many concurrently accepted offers for liver, which are more than 10-fold higher than lung. Another potential solution is to require only 1 offer be accepted within 8 hours of when the OR time is planned for the first offer, rather than 4-6 hours before the OR time as the committee considered.

ASTS Position: Strongly Oppose

Require Reporting of Patient Safety Events

This proposal markedly broadens the type and number of events mandating reporting to the OPTN within 24 hours of the transplant hospital (TH) becoming aware of them. The policy proposal includes disparate, seemingly unrelated elements. For example, it would require TH reporting of prior living donors being listed for transplant within two years of donation, as well as propose a sweeping number of events and "near-miss" events to be reported, including a series of organ transportation events which are all completely beyond the purview or control of THs. The proposal also requires TH to perform tasks that should be the responsibility of the OPTN or the MPSC such as awareness of any sanction taken by a state medical board or other professional body against a transplant professional working for an OPTN member. It also duplicates the administrative burden and potential sanctions related to already reportable events like CMS "never events." The OPTN should have its own direct line of communication with CMS and not impose dual reporting by TH.

Summary

This proposal would require TH reporting of events that are completely outside the control of the TH and any reasonable QAPI efforts of the TH to mitigate those events. TH do not typically arrange transportation of organs, do not employ ground couriers, pilots, luggage handlers or any of the myriad intermediaries in the transportation chain from donor procurement hospital to receiving transplant hospital. This proposal would impose sweeping mandates on THs and would specifically set in motion an MPSC investigation into these events that are completely outside the scope or purview of the TH or related personnel. These efforts will waste scarce resources and detract from strategic efforts to increase the number of transplants performed, access to transplantation, and the reduction of healthcare disparities. The OPTN should consider engaging OPOs in this effort rather than THs.

We strongly oppose the "Near Miss Event Definition "and its proposed reporting. "Near miss event" analyses are important components of strong transplant quality programs. Studying near misses helps prevent safety events. However, by making near miss events reportable and potentially punishable, programs with strong quality programs risk being flagged more often. We strongly oppose the "Transportation Events" portions of this proposal and recommend the OPTN work with OPOs on these events.

We support the clarification and expansion of reportable events surrounding ABO typing errors or discrepancies, as these events are within the purview of the TH, are critical checkpoints prior to the transplant event, are inextricably linked to adverse outcomes, and have been the source of significant patient safety events.

The element of this variegated proposal that we unequivocally (strongly) support is the modification of living donor reporting requirements under Policy 18.5. This would clarify existing ambiguity by simply stating in policy that reporting is required when any living donor is added to any wait list within two years of living donation.

Because this proposal includes multiple policy elements that are well-intentioned but poorly designed, and which are likely to harm the overall transplant endeavor rather than advance it, we are

forced to stand in opposition to this proposal. We humbly suggest that the MPSC separate the disparate elements of this proposal for clarity of purpose and intent. We would strongly support the living donor portion of this policy proposal as a stand-alone proposal and would likewise support the ABO typing component of this proposal if advanced in isolation.

• Based on the "near miss" definitions considered for incorrect organ or incorrect potential transplant recipient, do you have any concerns with the proposed definition?

Yes. See above.

•Do you agree with requiring reporting for living donors placed on the wait list for any organ within two years after donation?

Yes. We strongly support this portion of the policy proposal and would strongly support this as a stand-alone proposal.

• Do you think the transportation events included in this proposal as required reports are appropriate?

No. This proposal would require TH reporting of events that are completely outside the control of the TH and any reasonable QAPI efforts of the TH to mitigate those events. TH do not typically arrange transportation of organs, do not employ ground couriers, pilots, luggage handlers or any of the myriad intermediaries in the transportation chain from donor procurement hospital to receiving transplant hospital. This proposal would impose sweeping mandates on THs and would specifically set in motion an MPSC investigation into these events that are completely outside the scope or purview of the TH or related personnel. These efforts will waste scarce resources and detract from strategic efforts to increase the number of transplants performed, access to transplantation, and the reduction of healthcare disparities. We must strongly oppose this portion of the proposal.

• Are there other definitions for ABO typing errors or discrepancies that the MPSC should consider?

No.

ASTS Position: Strongly Oppose

ASTS
American Society of Transplant Surgeons

Continuous Distribution of Hearts Concept Paper

1. **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?**

   Oppose. The current proposal does not include objective recipient specific physiologic variables that could further stratify a recipient's clinical condition and waitlist survival when listed for transplant.

2. **Should the Committee create an attribute for post-transplant survival for inclusion in the first version of the continuous distribution of heart allocation framework? Why or why not? What, if any, predictive models should the Committee consider for use?**
   a. Strongly support. We would urge the committee to carefully evaluate all variables and consider the possibility that models that include race as a variable may negatively impact a candidate's post-transplant survival and therefore the candidates composite score (by potentially and inadvertently reducing a candidate's post-transplant survival score), thereby further handicapping already disadvantaged populations. Recipient size should also be considered as an attribute of possible biological disadvantage.
   b. We would also urge the committee to consider the magnitude of effect of a temporary mechanical support variable on both the medical urgency/waitlist survival score and the post-transplant survival score. As the need for temporary mechanical circulatory support may be included in both attributes, we must be careful that the presence of this variable in both attributes does not negate itself (i.e. increase the medical urgency/waitlist survival score with an equal and opposite decrease in the post-transplant survival score).

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?**
   a. Support. The Committee should consider more heavily weighting certain difficult to transplant blood types. We have found that blood type "O" has already shown to be disadvantaged in the lung continuous allocation model and therefore has resulted in an unexpected decrease in transplant of blood type "O" lung allografts.
      i. Letter from OPTN to transplant programs (*OPTN: A Message To All Lung and Heart-Lung Transplant Programs*, 3 Aug. 2023)
      ii. OPTN: Organ Procurement and Transplantation Network, 2023, *Lung Continuous Distribution Three Month Monitoring Report*, https:/optn.transplant.hrsa.gov/media/fzhh1e5r/data_report_lung_committee_cd_07_13_2023.pdf.
   b. The committee should prioritize requesting biostatistician vendors (i.e., SRTR and MIT) to verify the accuracy of their model inputs.
   c. 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.

d. The Committee should use this opportunity to unify the pediatric and adult allocation system such that all offers are open to all recipients. Given the matriculation of many congenital heart disease patients to the adult system, this would allow greater opportunity for this population of patients to share in organ offers they would otherwise not be offered due to their age.

4. **Considering the individual attributes, what information should the Heart Committee use to evaluate success toward the outcome of that specific attribute?**

   Support. We recommend caution against using non-traditional outcomes that would require more onerous data collection.

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?**

   Strongly support. 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 important 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 made a priority for heart continuous distribution.

ASTS Position: Neutral

Update on Continuous Distribution of Livers and Intestines

The ASTS greatly appreciates the work of the liver-intestine committee and we do understand that this is not a policy proposal but rather, it is an ongoing update on the work of the liver committee on continuous distribution. Unlike all of the other organ groups, the Liver Intestine Committee has adopted a major policy change in February of 2020. Therefore, the ASTS is wondering if instead of adopting yet another major policy change, could the committee instead thoroughly examine the current system for recent allocation outcome changes as these may have great commonality with the variables held to the highest importance in continuous distribution? For example, both donor and recipient factors are already considered in the current system. DCD and donors over age 70 (donor factors) are allocated in the 150 nm circle down to MELD 28 (recipient factors) while standard criteria donors are allocated to increasing concentric circle sizes of 150, 250 and 500 for decreasing levels of patient acuity. Donors under age 18 (donor factors) are shared to pediatric candidates (recipient factors) over a 500 nm circle and then nationally before going to adults. While sharing nationally rather than within a specific distance from the donor hospital would be the best from a medical urgency standpoint, this is not feasible for efficient function of the OPTN with our current technology, and so the circles are a balance of both urgency and efficiency.

It seems that the current policy which went live in February of 2020 has already adopted the essential tenants of continuous distribution, especially since post-transplant survival is not possible to incorporate given there are no readily available models which accurately predict post liver transplant survival and therefore won't be included. Additionally, unlike other organs where HLA matching is very important, there are few or no other well-accepted factors to include for candidate biology. The committee lists blood type under this category however, blood group O recipients are only compatible with O (or A2) donors, so if the O donors are allocated to all other blood groups in additional to O, this will create a worsening disparity for type O patients (which is the current problem with lung CAS and why a special public comment cycle is open to address this.)

Rather than working to develop a completely new system, working to optimize the recently adopted system based on careful ongoing analysis of the impact of changes adopted in Feb 2020 (and additional new changes implemented in July 2023), while ensuring any necessary adjustments also remain in line with the principles of continuous distribution, seems aligned with the goals of the OPTN, especially considering the major changes which will be coming under the modernization plan.

The committee will also adopt mathematical optimization, which requires the committee to decide which outcomes they want to optimize and then the system will create a policy model to achieve that. While this seems theoretically favorable, from a practical standpoint, how does the committee actually determine whether increasing the distance required to travel by 25% is or is not acceptable, to achieve a 15% reduction in waitlist mortality? Why not 30% further for 20% fewer deaths, or 28% and 18%? Does the committee have all the information they need, such as whether there are enough planes and how much this additional travel will cost and who will pay, to actually make that decision? In addition, it is actually not possible to provide "equal access to all candidates regardless of their blood type" as stated in Figure 1, unless we are planning to not use a percentage of available blood type AB livers, so that AB

candidates would wait as long as the other blood types. Regarding adding height or body surface area, does the committee think it may be important to determine the impact of MELD 3.0 before considering changes based on height or BSA? Overall, it does seem like developing the rating scales will require a level of omnipotence that will be very difficult for the committee to attain.

The current proposal also provides the results of the values participation exercise, which included responses from more than 1,000 participants, of which approx. 40% were patients/caregivers and approx. 40% were transplant professionals, with the remainder being general public, OPO, or lab professionals. Medically urgent candidates and pediatric candidates were the most favored both in the unweighted and weighted analyses, and the ASTS is fully supportive of these attributes and notes both of these attributes are central to the policy adopted in 2020. The document also notes that experience with lung allocation system has suggested that increased efficiency is needed. However, given an abstract choice such as the example provided in the policy document of 30% increased travel versus saving 15% more lives, most will select saving lives.

• Do you agree with the Committee's decision to not include an attribute for post-transplant survival in the first iteration of continuous distribution?

Yes, the ASTS agrees with this decision. Though we share the strong interest expressed by the transplant patients and families in prioritizing post-transplant survival, we agree with the committee's decision to not include the L-EPTS model into the system due to the noted methodological concerns as well as concern about the predictive performance.

• Do you have any feedback for how geographic equity should be incorporated as an attribute in liver candidate's composite allocation score?

The ASTS agrees that medical urgency is the primary consideration, however national allocation for adult liver allografts is not possible due to logistical concerns.

• Do you have any feedback for ways to increase efficiency in the organ allocation and placement process, especially given the low priority assigned to proximity in the VPE?

The ASTS agrees that increasing the number of candidates to which the system offers livers and increasing the distance traveled will decrease the efficiency of the system of allocation and placement. Given that the Committee just did make a large change that increased both of these parameters, we strongly suggest that they further analyze the impact of this change after gathering more real-world data, and then use this knowledge to provide a more granular assessment of the anticipated impact of further changes.

• Do you agree with the purpose for each attribute outlined in Table 1?

The ASTS agrees with medical urgency and pediatric priority attributes but disagrees with providing equal access regardless of blood type, given this is not actually possible to achieve. The ASTS questions whether adopting a priority for BSA/height should be done now given MELD 3.0 adopted July 2023 will also impact access for candidates according to these attributes; there could be substantial risk to over-prioritize these variables. The ASTS agrees with the remaining attributes of the challenges related to geographic disparity and travel which have already been noted.

• Do you have any feedback on outcome metrics or ways to assign points to candidates for each attribute in the optimization analysis?

As noted above, the major challenge with creating a system of continuous distribution is exactly how to assign points to candidates for each attribute. There is not a scientific way to do this, and it seems it would be an arbitrary choice. The ASTS would again suggest a more thorough and transparent evaluation of the several new allocation changes that have been implemented within the last several years, some only within the last few months, in order to determine if the implemented changes have resulted in their intended consequences in improving desired allocation outcomes, and whether the system would actually benefit from the addition of more complexity.

ASTS Position: Neutral

Ethical Analysis of Normothermic Regional Perfusion White Paper

The Ethical Analysis of Normothermic Regional Perfusion (NRP) paper submitted for public comment by the OPTN Ethics Committee aims to explore and map the relevant ethical considerations to NRP and the ensuing implications for the OPTN and broader transplant community. The main conclusions are that NRP has great potential utility but raises concerns about compliance with the dead donor rule and potential for harm to the donor. Moreover, the paper concludes that authorization should include "disclosure of recirculation through the heart (TA-NRP) and the potential restoration of any cerebral perfusion (TA-NRP and A-NRP), as well as considerations of meaningful differences form other donation approaches."

- The initial description of NRP in the background section says that it is "aimed at improving organ quality by reducing cold ischemic time." This is not accurate. It is aimed at improving quality, but the mechanism is not the reduction of cold ischemic time but rather the immediate warm perfusion of the organs following a prolonged agonal period which allows for organ functional assessment and evaluation. NRP separates two organ damaging events that occur in standard rapid recovery DCD: donor warm ischemic time during which the organs lack perfusion and oxygenation, and cold preservation. Replacing immediate cold preservation with warm perfusion, the organs are immediately oxygenated and given the chance to function and recover from the warm ischemia damage.
- The committee intentionally chose the following terminology to describe NRP: recirculation, restoration of circulatory blood flow, circulatory restoration. The distinction that is drawn between circulation and perfusion is as follows: Circulation is a process involving blood flow in the body through vessels and/or the heart. Perfusion is a technique. The footnote on the choice of language states: "If it is in context of post-circulatory death declaration then circulation may be used to highlight the potential concern of oxygenated blood flowing to the brain." From the footnote, it seems as though circulation is only relevant to TA-NRP because the definition requires blood flow to the heart, but the context provided for the use of the term circulation would apply to both A-NRP and TA-NRP. We believe that one area of need for the entire discussion around NRP is clarification and consistency of the terminology that is used.
- The comparison of TA and A-NRP in the table have different characterizations of what occurs after cannulation of the aorta. For TA-NRP it says that warm perfusion and circulation of oxygenated blood are initiated with an ECMO or bypass machine. In A-NRP, it says normothermic perfusion to the abdominal organs is initiated. In both cases, oxygenated blood perfuses the organs with the assistance of an ECMO or bypass machine. However, in TA-NRP, the donor is reintubated and the lungs are ventilated for gas exchange. Reintubation and ventilation are also used with all rapid recovery lung procedures. It is not, however, used in abdominal-only NRP donor procedures.
- On page 20, the authors note that "spontaneous reversal of asystole has been observed in TA-NRP when cardio-pulmonary bypass was used." This does not make sense as cardio-pulmonary bypass is an intervention, so the reversal of asystole in this scenario is not spontaneous.
- On page 29, the committee notes that donors may be moved to an OPO recovery center. This is not possible with DCD donation as only deceased individuals can be transferred to recovery centers, and DCD donors are not dead at the time of withdrawal of life-sustaining treatments.

What information should be disclosed to potential donors and next of kin regarding NRP, and how should one approach disclosure?

- This question should be studied rather than decided by members of the transplant community. Qualitative research of the public as well as donor families will develop a robust understanding of what information is relevant in decision-making about organ donation and about the acceptability of different procedural aspects.
- Using graphic language to describe how NRP is conducted (e.g., severing the blood vessels to the head, reanimating the body) should be avoided. All organ donation procedures are invasive and involve blood removal, organ removal, and cutting blood vessels so the description should be morally relevant without providing unnecessary or unwanted details.
- When authorization for donation occurs, the OPO may not know if NRP is going to be used so we recommend that authorization for all DCD donation include information about the possibility of using NRP as well as that of using ex-situ machine perfusion (which may also pose ethical concerns particularly with heart donation) so that the family is not approached multiple times for additional authorizations.

Are there any additional ethical considerations or evidence that should be taken into account in the analysis?

- OR team experience. NRP allows for a single procedure that benefits all organs undergoing perfusion which rapid recovery can compromise one organ for the benefit of another organ (e.g., heart rapid recovery requires drainage of blood from the donor to prime the pump which adds to the warm ischemic time and could compromise the ability to utilize organs that have short windows for warm ischemic damage such as the liver). The operative procedure for NRP is more controlled than rapid recovery and likely to provide a better overall experience for operating room teams.
- Resource utilization. NRP uses a single machine and cannulation setup for organ perfusion which ex situ machine perfusion requires a separate device for each organ. This comes at a higher cost as well as increased waste in terms of disposable components needed for each setup. Furthermore, normothermic machine perfusion requires either donor or banked blood to prime the circuit, and if used for multiple organs may require more blood than what is needed during NRP. The ethical analysis should include a value analysis of competing procedures and technologies.
- Expanding the concept of moral distress: While the committee focuses on moral distress of clinicians that are asked to engage in NRP when they believe it is morally wrong, there are also clinicians that believe NRP, or other machine perfusion technology is morally obligatory. If NRP is ethically acceptable based on the dead donor rule and nonmaleficence, and it has greater utility than the alternative options for organ procurement, then it is not only morally acceptable but morally obligatory. For clinicians who believe this and are forced to perform rapid recoveries, they experience moral harm when organs that could have been utilized with NRP are not utilized or when organ transplant recipients have poor outcomes that could have been prevented with NRP.

ASTS Position: Neutral

Efficiency and Utilization in Kidney and Pancreas Continuous Distribution

Regarding the latest iteration of OPTN request for feedback on the *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution*, we continue to be generally supportive of the concept of a continuous allocation system. We are gratified to see this latest expression of the OPTN's commitment to dealing with the innumerable pragmatic operational issues in kidney and pancreas allocation under a CAS, and overall are supportive of the focus on operational items that provide evidence that a transition to a CAS will be actionable and safe. We point out that the allocation system has seen major changes, and consequently disruptions, over the last few years, and we advocate strongly for an operational philosophy in the design of CAS for all organs that specifically aims to avoid massive changes in allocation patterns at the outset. We appreciate the malleability of CAS, and expect that post-implementation monitoring will be vigorous and course corrections frequent, and hope that the fundamental strategic pillar of increasing the number of transplants performed with adequate safety guides future adjustments of the CAS.

We wish to also point out that the extension of allocation of pancreas beyond the local OPO has had detrimental impact on intestine allocation because at times the pancreas intestine allograft (or liver, pancreas and intestine allograft) need to be allocated together. These intestine candidates should show up on the pancreas list with high priority or be a mandatory share due to the inability to transplant these patients when all needed organs are not allocated from the same donor (and this is not a requirement in current allocation). In many cases, only the intestine is offered and therefore a center must decline despite the donor being a good match. In addition, when pancreas and intestine are allocated from the same donor the local team is nearly uniformly given priority when both organs for anatomical reasons are not able to be placed from the same donor into separate recipient candidates. In this case, usually the intestine team is coming from outside the local area and travel at high cost, however CT angiography is not routinely performed and therefore problematic early branching of the SMA, that would preclude transplantation of both organs is not identified prior to the donor operation. Prioritization of the 2 grafts needs to be placed into allocation match runs. This priority appears more appropriate to favor the intestine team as it is difficult to transplant these patients with current allocation and wait times have extended over the past 2 years from approximately 90 days on average to > 2 years. Furthermore, the small number of pancreata that would not be utilized relative to the number of transplanted pancreata would not be significantly altered. Furthermore, the intestine is a rare organ for transplantation and one of the most sensitive to preservation injury and therefore given the restrictions on donors, we recommend the intestine should be given the priority.

Facilitated Pancreas

• *Do you have any feedback specific to facilitated pancreas?*

Yes. See below.

• *Do you support the recommendation of maintaining the 250NM distance for both the qualifying criteria and when facilitated pancreas bypasses are applied?*

Yes

• *Do you support the proposed qualifying criteria (increasing the number of pancreata transplanted from more than 250 NM from 2 to 4)?*

No, we oppose that suggested component. The current facilitated pancreas offer threshold requires that transplant hospitals have performed 2 transplants from outside 250 NM in the previous 2 years. The enormous differences in population and transplant hospital density across the nation make the 250 NM based threshold for facilitated pancreas offers a very different hurdle for transplant hospitals in different regions of the nation. The current threshold of 2 transplants meeting criteria excludes the majority of pancreas programs from consideration for facilitated pancreas offers. Moving the threshold to 4 would exclude an even larger proportion of existing programs. The current threshold of 2 transplants from donors originating >250 NM from the transplant hospital over the prior two years leaves 46 qualifying pancreas programs throughout the nation. The OPTN request for feedback and associated documents provide no rationale for further limiting this number. In the absence of an argument for increasing the threshold, we would advocate that the OPTN maintain the current threshold for the transition to a continuous distribution framework.

ASTS Position: Support