

Meeting Summary
Region 3 Meeting
March 16, 2018

The UNOS Region 3 meeting was held on March 16, 2018 in Atlanta, Georgia. Dr. Tom Pearson, Region 3 Councillor, convened the meeting and welcomed those in attendance. There were 116 individuals in attendance representing 85% of institutional voting members.

Non-Discussion Agenda **Proposals not presented or discussed**

Manipulation of Waitlist Priority in the Organ Allocation System through the Escalation of Medical Therapies (Ethics Committee)

Beginning in 1993, the Ethics Committee (the Committee) developed a series of white papers that are available through the Organ Procurement and Transplantation Network (OPTN) website. A white paper is an authoritative report or guide that informs readers concisely about a complex issue and presents the issuing body's philosophy on the matter. It is meant to help readers understand an issue, solve a problem, or make a decision.

There have been recent reports describing the manipulation of waitlist priority of the organ allocation system in both the medical literature and the lay press. To date, the OPTN and the United Network for Organ Sharing (UNOS) have not offered guidance or established a formal position statement on this issue.

This white paper will define and present an ethical analysis of manipulation or the waitlist priority of the organ allocation system through the use of medically unnecessary interventions that are used to increase a transplant candidate's priority on the waitlist. The white paper will delineate the potential harms to transplant candidates, the wait list as a whole, transplant providers, and transplant hospitals involved in the manipulation of the organ allocation system.

Region 3 vote: 29 support, 0 oppose, 0 abstentions

This white paper was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: June 12, 2018

The white paper is available on the OPTN website:

<https://optn.transplant.hrsa.gov/resources/ethics>

Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB (Operations and Safety Committee)

The OPTN/UNOS Operations and Safety Committee (the Committee) updated the Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB, originally developed by the Committee and approved by the OPTN/UNOS Board of Directors in June 2011.

Changes made include:

- Updated OPTN Policy references
- Amended information about special considerations such as neonates
- Updated additional complementary resources
- Revised structure and addition of key points
- Made language more accessible

Region 3 vote: 29 support, 0 oppose, 0 abstentions

This guidance document was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: June 12, 2018

The guidance document is available on the OPTN website:

<https://optn.transplant.hrsa.gov/resources/guidance/>

Guidance on Requested Deceased Donor Information (Organ Procurement Organization Committee)

The OPTN/UNOS Organ Procurement Organization Committee created this guidance document to address the requested deceased donor information removed from policy as part of a recent public comment proposal. This guidance document is designed to assist members in identifying additional testing and other information needed to best evaluate potential donors.

This guidance document is intended only to provide guidance for OPOs and transplant hospitals during organ placement. The scope and content should reflect collaboration between OPOs and transplant programs, taking into consideration their needs and best practices. This is *not* intended to be a comprehensive list of all information necessary to evaluate organs for all donors.

Region 3 vote: 29 support, 0 oppose, 0 abstentions

This guidance document was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: June 12, 2018

The guidance document is available on the OPTN website:

<https://optn.transplant.hrsa.gov/resources/guidance/>

Review Board Guidance for Hypertrophic and Restrictive Cardiomyopathy Exception Requests (Thoracic Organ Transplantation Committee)

The OPTN/UNOS Board of Directors recently approved the Thoracic Organ Transplantation Committee's (Committee) Proposal to Modify the Adult Heart Allocation System during its December 2016 meeting. During the development of the proposal, the Committee received feedback from the heart transplant community voicing concerns that hypertrophic cardiomyopathy (HCM) and restrictive cardiomyopathy (RCM) candidates may be disadvantaged by the proposed policy. The Committee considered the following issues in HCM and RCM candidates:

- HCM/RCM physiology may not benefit from mechanical circulatory support devices (MCSDs), and the higher statuses are device driven
- A lack of uniform expertise in HCM/RCM physiology results in variability in Regional Review Board (RRB) decisions across the country
- Objectively quantifying the severity of illness is challenging

The Committee acknowledged that some HCM/RCM candidates may have higher mortality and may not be candidates for mechanical support options, but ultimately did not change proposed policy due to lack of objective data to support these assumptions. Instead, the exception and review process will accommodate these candidates, who can apply to the review board (RB) for an exception in any status as their medical urgency and potential for benefit would warrant. The Committee recognized that HCM/RCM expertise may be inconsistent across the RBs, thus potentially making evaluation and award of HCM/RCM exception requests vulnerable to variability. To help mitigate these potential inconsistencies, the Committee created guidance for the RBs with the goal of outlining objective criteria to standardize the evaluation and decision-making of HCM/RCM exception requests.

This proposal aligns with the OPTN strategic goal of improving equity in access to transplant by providing objective criteria to RBs, potentially making evaluation and award of exception

requests for HCM/RCM candidates more consistent, especially for those boards that lack an HCM/RCM expert. In addition, developing standardized exception criteria creates an intelligible pathway for more medically urgent HCM/RCM candidates to obtain access to higher urgency statuses, under which they may be transplanted more quickly, thereby potentially reducing waitlist mortality for those candidates.

Region 3 vote: 29 support, 0 oppose, 0 abstentions

This proposal was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: June 12, 2018

Modification of the Lung Transplant Follow-Up Form (TRF) to Better Characterize Longitudinal Change in Lung Function following Transplantation (Thoracic Organ Transplantation Committee)

The current OPTN/UNOS adult and pediatric lung and heart-lung Transplant Recipient Follow-up form (TRF) collects lung graft function status limited to bronchiolitis obliterans syndrome (BOS). The Thoracic Organ Transplantation Committee (Committee) identified two issues with the way graft function data is collected on the TRF, which limits the utility of this data in the context of chronic lung rejection:

- BOS data collection is outdated, incomplete and inaccurate
- Restrictive allograft syndrome (RAS) is not collected at all

Therefore, the limited data currently collected does not capture all the prognosis possibilities for declining graft function and may not accurately describe the type of rejection a patient is exhibiting. Chronic lung allograft dysfunction (CLAD) is a broader, more contemporary definition of post-transplant lung dysfunction, encompassing both obstructive and restrictive chronic lung rejection. This proposal will modify the adult and pediatric lung and heart-lung TRF forms to align with updated professional definitions. Refining the outcomes data the OPTN collects can better inform future policy.

This proposal aligns with the OPTN strategic goal of improving transplant recipient outcomes by collecting more granular data on lung dysfunction to help inform future policies for improving lung transplant outcomes. In addition, it will more accurately characterize longitudinal change in lung function following transplantation. Finally, examining outcomes other than strictly survival (in particular, quality-of-life measures such as pulmonary function) will be important for patients and for program assessment.

Region 3 vote: 29 support, 0 oppose, 0 abstentions

This proposal was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: Pending implementation and notice to OPTN members

Align VCA Transplant Program Membership Requirements with Requirements of Other Solid Organ Transplant Programs (Vascularized Composite Allograft Transplantation Committee)

In December 2015, the OPTN/UNOS Board of Directors approved changes to the Bylaws to remove the ambiguous term “foreign equivalent” from the transplant program key personnel requirements. Members and the Membership and Professional Standards Committee found it difficult to determine if a board certification or case experience performed outside the United States should be considered equivalent. In lieu of accepting foreign board certification, the Board approved continuing education pathways in order for individuals who were foreign board

certified or U.S. board ineligible to continue to be considered for key personnel positions at solid organ transplant programs. These changes were not made to the membership requirements for key personnel at vascularized composite allograft (VCA) transplant programs due to feedback from professional transplant societies concerned about the impact of such changes on the nascent developmental stage of the VCA transplant field.

The current membership requirements for VCA transplant programs in the OPTN Bylaws include a pathway for non-board certified individuals to qualify as a primary VCA transplant surgeon. However, this pathway will sunset on September 1, 2018. The VCA Committee feels the implications of this sunset would:

- be overly restrictive
- result in membership requirements that were dissimilar to the membership requirements for all other solid organ transplant programs
- prohibit a surgeon who is U.S. board ineligible, but otherwise well qualified by training and experience, to qualify as a primary VCA transplant surgeon

This proposal addresses this gap for surgeons who wish to apply to be a primary VCA transplant surgeon. This proposal is not intended to reduce the rigor of the training and experience requirements for key personal at VCA transplant programs. Rather, it is intended to add an option for these surgeons that is consistent with the of membership requirements for all other solid organ transplant programs.

The Committee feels this proposal is in keeping with Goal 4 of the OPTN Strategic Plan by ensuring consistency between the requirements between key personnel at solid organ and VCA transplant programs. It will also address a problem posed by the increased burden for individuals to qualify as a primary VCA transplant surgeon if the sunset provision is not amended.

Region 3 vote: 29 support, 0 oppose, 0 abstentions

This proposal was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: Pending implementation and notice to OPTN members

Guidance on Optimizing VCA Recovery from Deceased Donors (Vascularized Composite Allograft Transplantation Committee)

Engaging in vascularized composite allograft (VCA) recovery from deceased donors requires a significant amount of planning and development by organ procurement organizations (OPOs) and VCA transplant programs. OPOs currently recovering VCAs have reported as long as a two-year development period for standard operating procedures (SOPs) or protocols and training on the same. To assess the barriers to VCA authorization and recovery, the OPTN/UNOS VCA Committee (Committee) conducted an on-line survey of OPOs in the U.S. The Committee felt barriers identified in this survey likely contribute to low numbers of deceased VCA donors, and further delays in the development of VCA recovery SOPs/protocols at OPOs.

The Committee believes this guidance will address an unmet need for the OPO community. As a result of this proposal, OPOs without experience in VCA recovery will have access to effective practices identified by those OPOs with experience in the field. This guidance also reinforces the concept that OPOs can support VCA transplant programs outside their donation service area (DSA), and potentially even outside their region.

The Committee feels this proposal is in keeping with Goal I of the OPTN Strategic Plan. By increasing VCA awareness to OPOs that have not yet recovered VCAs, there will hopefully be an increase in deceased donors screened for VCA donation and VCA recoveries.

Region 3 vote: 29 support, 0 oppose, 0 abstentions

This guidance document was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: June 12, 2018

The guidance document is available on the OPTN website:

<https://optn.transplant.hrsa.gov/resources/guidance/>

Discussion Agenda

Executive Committee

2018-2021 OPTN Strategic Plan

No comments.

This proposal was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: July 1, 2018

Improving the OPTN/UNOS Committee Structure

In June 2016, the OPTN/UNOS Executive Committee endorsed formation of a two-year working group (“committee governance working group”) to assess the OPTN/UNOS committee governance structure, possible improvements to committee recruitment, selection, and engagement, as well as how to improve committee alignment with the Board of Directors. After endorsing several new changes to improve the committee recruitment process, the Executive Committee is considering a new concept recommended by the committee governance working group with regard to improving the committee governance structure.

The committee governance working group identified the current “one size fits all” structure as needing improvement because it limits opportunity for broader transplant community participation and makes it difficult to incorporate diverse perspectives on committees. In addition, the structure and current methods for collecting public comment from committees, regions, societies, and the general public does not allow the Board of Directors to fully consider the sentiment of particular groups or communities when making policy decisions, as perspectives are offered sporadically throughout the system. In this document, the Executive Committee outlines a proposed new volunteer workforce structure and requests feedback on whether this new concept better incorporates perspectives of different important constituencies (patient, living donor, donor family, transplant professionals), while also maintaining the subject matter expertise.

Region 3 vote: 20 support, 7 oppose, 1 abstention

Region 3 Comments: Although the region approved the proposal, members discussed several concerns and suggestions.

Committees & Expert Councils:

- Members are concerned that the pediatric voice will be diminished without continued regional representation from the Pediatric Committee and believe it will be harder for their voice to be heard at the regional level. A member suggested piloting both a pediatric committee and a pediatric expert council together.
- The existing ad-hoc Disease Transmission Advisory Committee (DTAC) performs a number of functions including reviewing potential disease transmission cases and developing policy proposals. Members want a better understanding of how the DTAC’s

workload/purpose would change as a subgroup of the proposed Operations Committee. There was also a suggestion to create an expert council for infectious disease specialists as well to focus on emerging issues in the field.

- Members would like a better understanding of how the proposed Quality Improvement (MPSC) Committee will address quality improvement within a regulatory committee.
- Members would like clarity on which groups would be included in the “vulnerable populations” part of the proposed Minority Affairs and Vulnerable Populations Expert Council.

Volunteer Staffing:

- Members feel that there is currently a lack of transparency in the existing selection and appointment process for committee member and leadership positions. Members want the selection and appointment process to be transparent in any proposal put forth.
- There was concern that the proposed structure of an expert council would create volunteers who are using the opportunity as a way to build resumes/CVs rather than generating engaged volunteers. Members want to better understand the workload and participation expectations for expert council leadership and volunteers.
- A member suggested that “fresh eyes” are needed to be defensible and clear with our policies and suggested adding non-industry participation as well.

Committee response: The committee governance workgroup is finalizing its recommendations to the Executive Committee. Significant concerns about specific items in the concept paper were received during public comment, but there was general support for the overarching goals of broadening committee engagement, improving intra-Committee communication, and increasing engagement between the Board and committees. Feedback during public comment also indicated an appetite for developing a proof of concept to test some of the items in the concept paper prior to pursuing any changes to committee structure.

The workgroup is recommending a proof of concept be debuted for the Fall 2018 public comment cycle which maintains the original structure and purpose of all committees. It also maintains the ability for all committees to sponsor policy projects. Two interested committees will be engaged as partners in developing an “expert council” of their constituency’s official representatives on other committees (e.g. the patient representative on the Kidney Committee engaging with the Patient Affairs Committee) as well as that constituency’s representatives on the Board of Directors. This “expert council” will be layered over the existing committee, enabling the two groups to share feedback and respond to project ideas and proposals out for public comment. They will meet via regular conference call and the “expert council” layer may be invited to the committee’s regular in-person meeting. Committee leadership is involved with identifying measures of success, engagement activities, touchpoint frequency, their expert council’s charge, and performing the review of the pilot.

The workgroup is also recommending another layer that includes other members of the constituency who are on committees but not the official representative (e.g. an OPO representative on the Liver Committee who is also a recipient) and the pilot committees’ alumni. This third layer would meet online only and would help test tools and methodology to engage an online community in a structured, vetted way.

The proof of concept would last from July 1, 2018-December 30, 2018. Lessons learned will be used to determine future expansions of the proof of concept as the tools continue to be tested.

In spring 2018 public comment, feedback to the concept paper entitled “Improving the OPTN/UNOS committee structure” indicated significant concerns about specific recommendations, but general support for the overarching goals of broadening committee engagement, improving intra-Committee communication, and increasing engagement between the Board and committees. The Executive Committee carefully considered feedback. They discussed forging ahead with a formal proposal based on the concept paper, abandoning the project, or testing a modified version of the proposed structure that addresses concerns raised during public comment. Ultimately, they decided to pursue this latter option.

The proof of concept, which will be tested during the fall public comment cycle, maintains the original structure and purpose of all committees. It also maintains the ability for any committees to sponsor policy projects.

Two committees, Patient Affairs and Transplant Coordinators, are testing a “Constituent Council” structure: a constituency’s official representatives on other committees (e.g. the patient representative on the Kidney Committee) as well as that constituency’s representatives on the Board of Directors will merge with the current roster of members for that committee. This proof of concept also invites other members of the constituency who self-identify as having a patient or clinical transplant coordinator perspective, but do not serve in that official capacity on their home committee (e.g. an OPO representative on the Liver Committee who is also a recipient).

The proof of concept will last from July 1, 2018-December 30, 2018. Lessons learned will be used to determine future expansions of the proof of concept.

Thoracic Organ Transplantation Committee **Broader Distribution of Adult Donor Lungs**

On November 24, 2017, the OPTN/UNOS Executive Committee approved an emergency change to lung allocation policy to remove the donation service area (DSA) as a unit of distribution and instead distribute lungs from adult donors to all lung candidates within 250 nautical miles of the donor. DSA level allocation was also removed from the pediatric donor sequence. Because this change was made on an emergency basis, it must be distributed for public comment within six months of the change, and will expire on November 24, 2018, if no other action is taken.

The Thoracic Organ Transplantation Committee is sponsoring this retroactive public comment proposal, which also includes two additional changes to policy that are required as a consequence of removing the DSA as a unit of distribution from lung allocation policy:

- 1) Modifications to Board-approved heart-lung allocation policy that has not yet been implemented
- 2) Modifications to policy for sensitized lung candidates

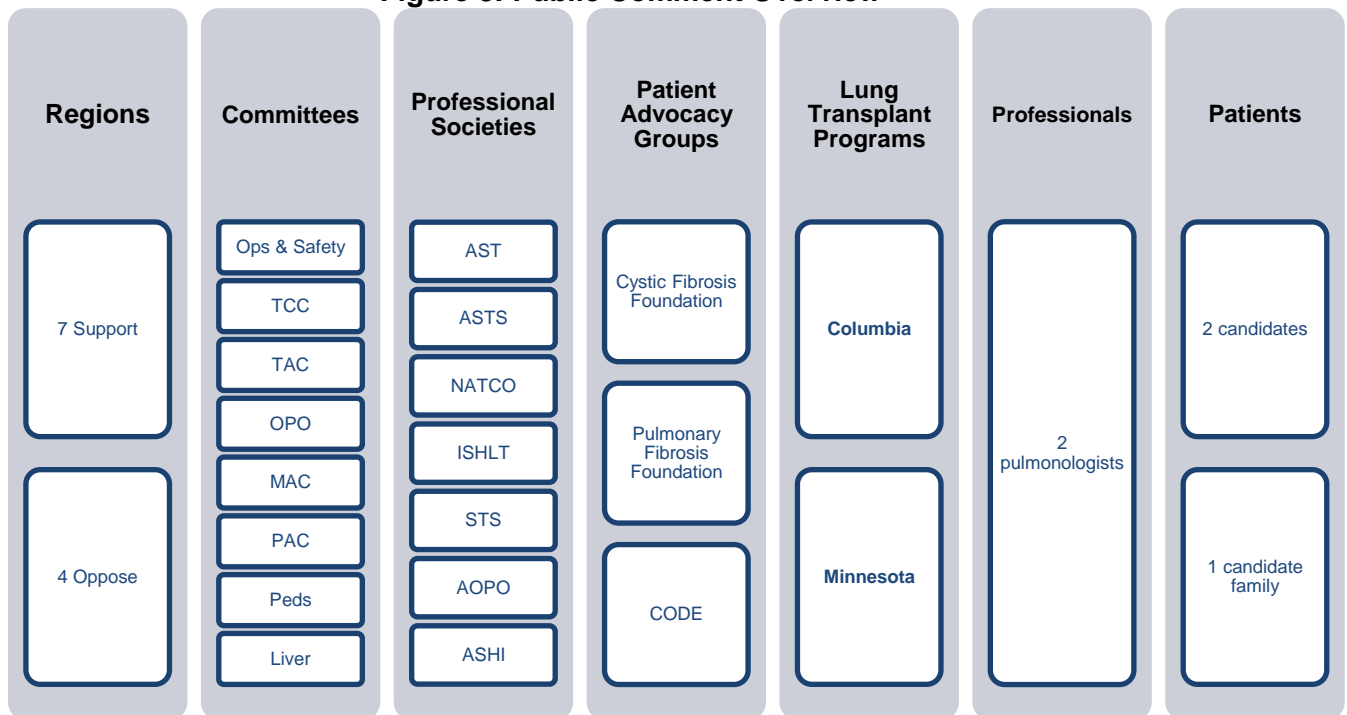
All of these changes will make lung allocation policy more consistent with the OPTN Final Rule, provide more equity in access to transplantation regardless of a candidate’s geography, clarify and make more transparent heart-lung allocation policy, and ensure that heart-lung allocation policy and policy addressing sensitized lung candidates are capable of being implemented in light of the changes to lung distribution.

Region 3 vote: 6 support, 13 oppose, 11 abstentions

Region 3 Comments: The region did not support the proposal. Members feel that the 250 nautical mile circle will transplant sicker patients and mortality and outcomes will shift in the wrong direction. There is also concern that the changes will favor large transplant centers and the Committee needs to assess the impact of the circles over different types of geography (ex. Densely populated cities, coastal areas, etc.). One transplant center noted that they have seen a drop in offers and poorer donor lung quality since the 250 nautical mile circle was implemented. During the thoracic program directors meeting held prior to the regional meeting, members also felt that the TSAM data is insufficient and need to have more information on one year survival, status of lung recipients (in the hospital or LTAC), and impact on costs for transplant centers and OPOs. They are also interested in tracking organ offers to assess the changes in imports and exports based on the DSA.

Committee response: The proposal garnered 34 comments. Overall, there was general support for the concept of broader distribution for lungs. Further, there was support for the Committee to be granted the opportunity to vet alternative solutions through the normal policy development process, thus necessitating an extension of the sunset date.

Figure 8: Public Comment Overview



The Committee sought specific feedback regarding the following questions:

1. Is 250 nautical miles from the donor hospital the appropriate first zone of distribution for lungs procured from donors at least 18 years old?
2. Are the proposed changes to heart-lung allocation policy clear?
3. Which of the options the Committee considered for sensitized candidates do you prefer?

In addition, members were asked to comment on both the immediate and long term budgetary impact of resources that may be required if this proposal is approved. Consequently, this feedback, among other comments, is reflected in the overarching themes, detailed below. The Committee's response and any subsequent changes made post-public comment are elaborated upon within each theme.

1. Feedback regarding whether 250 nautical miles from the donor hospital is the appropriate first zone of distribution for lungs procured from donors at least 18 years old

Feedback regarding whether or not 250 nautical mile was the ideal first unit of distribution varied. There was some consensus for the 250 nautical mile solution, but there was also a fair amount of opposition. Those who supported the interim policy change, including the International Society of Heart and Lung Transplantation (ISHLT), were comfortable because the effect of distributing to 250 nautical miles was similar to distributing to the DSA, and post-implementation data indicated no immediate adverse impact to patients.¹ In addition, supporters felt this change better aligned with the Final Rule than DSA. Those who opposed distributing to 250 nautical miles encouraged the Committee to take the time to consider and analyze other options; the implemented change may not be the optimal solution. This faction was more likely to support distributing lungs even more broadly. Indeed, even among the regions that supported the change, there was support for the Committee to have the time to vet other options.

Patient advocacy groups and the OPTN/UNOS Patient Affairs Committee supported distributing lungs to 500 nautical miles. However, several commenters noted that the implemented change, and any other model of broader distribution, may have unintended consequences (see concerns, cited below). There were several suggestions for alternative solutions, including 125 nautical miles + DSA, and population density models. The Committee noted the modeling indicated a decrease in waitlist mortality with 500 nautical mile sharing, however without the opportunity to evaluate the consequences of other models, the Committee was hesitant to change the first unit of distribution from 250 nautical miles to 500 nautical miles.

In light of the public comment feedback, the Committee considered maintaining the 250 nautical mile solution, increasing the first unit of distribution to 500 nautical mile, or distributing based on some other model, either permanently or as a placeholder while the Committee explored other options (thus extending the sunset date). They reaffirmed that the 250 nautical mile interim policy should not be made permanent as there has not been sufficient time to vet an optimal geographic solution via analyses. In addition, the Committee has not yet had the opportunity to evaluate unintended consequences of the current change, let alone other models. Further, the Committee did not feel it prudent to finalize its policy proposal prior to the complimentary work being completed by the Ad Hoc Committee on Geography.² Indeed, it is likely their recommendations would inform future lung distribution policy. Therefore, they opted not to propose increasing the first unit of distribution to 500 nautical miles or some other model at this time.

The community also expressed other concerns associated with broader distribution of lungs:

- Potential for increased travel to recover organs
- Potential for increased costs associated with increased travel and increased use of ex vivo lung perfusion
- Unknown long-term impact on post-transplant outcomes
- Unknown impact to low volume/small centers

¹ OPTN/UNOS. *Monitoring of the Lung Allocation Change, 4 Month Report Removal of DSA as a Unit of Allocation*. Descriptive Data Request prepared for the OPTN/UNOS Thoracic Organ Transplantation Committee. Presented April 19, 2018.

https://optn.transplant.hrsa.gov/media/2463/20180412_thoracic_committee_report_lung.pdf

² Ad Hoc Committee on Geography. March 20, 2018 Meeting Minutes. Meeting Minutes. https://optn.transplant.hrsa.gov/media/2477/20180320_geography_meetingsummary.pdf

- Unknown impact to specific diagnoses groups

The Committee acknowledged these concerns and will ensure they are considered, should the Committee be given the opportunity to continue work. Ultimately, the Committee voted unanimously to propose maintaining distribution to 250 nautical miles as interim policy and request a two-year extension to allow the Committee ample time to consider alternatives (16-approve, 0-oppose, 0-abstentions).

2. Feedback regarding heart-lung policy

A majority of public comment feedback indicated support for the policy as written. Other feedback included:

- Concern that the policy does not help heart-lung candidates whose need for lungs is more urgent than their need for a heart
- Policy should be revised under a larger multi-organ project
- Heart-lung allocation shouldn't be a manual process by the OPO; a "smart" system should be programmed
- The proposed policy is still too complex

The Committee considered the following options based on public comment feedback:

- No change
- Extend priority to heart-lung candidates/create an exception pathway for heart-lung candidates
- Address via a larger multi-organ project

They acknowledged that ideally, heart-lung policy would be considered under a multi-organ policy project, which might include the "smart" programming suggested by the OPTN/UNOS Operations and Safety Committee. However, making those changes now would be substantive and out of scope at this time.

However, in light of the emergency lung policy changes, and in recognition of the work that was already completed by the Committee under the adult heart allocation policy changes, the group felt it was necessary to move forward with modifications to the policy. The group did feel the changes made to heart-lung policy from the approved-but-not-yet-implemented adult heart allocation policy were more clear and informed by data.³ However, the Committee acknowledged it is still a manual process for OPOs and the variability in how OPOs run matches remains.

Therefore, the Committee felt without the opportunity to look at heart-lung as part of a more holistic multi-organ project or make substantive changes in the form of an exception pathway, they were comfortable with the policy language as it went out for public comment as an interim solution.

The Committee voted unanimously (16-approve, 0-oppose, 0-abstentions) to recommend the policy as written with minor language clarifications.

3. Feedback regarding sensitized candidate policy

³ OPTN Descriptive Data Request, "Heart-Lung Allocation: Death Rates for Heart-Lung, Heart, and Lung Candidates." Prepared for the Thoracic Committee on December 21, 2017.

Finally, the Committee transitioned to the sensitized candidate policy. During development of the proposal, the Subcommittee considered three options:

- Remove the policy altogether
- Permit transplant programs to request an exception from the LRB to prioritize the sensitized candidate
- Modify current policy to permit all transplant programs and OPOs in any geographic area in which the candidate would appear in Zone A to agree to permit the OPO to allocate lungs to the candidate out of sequence

There was limited substantive feedback regarding this portion of the proposal. All regions supported striking the policy. Conversely, The OPTN/UNOS Transplant Administrators Committee, ISHLT, the National Association for Transplant Coordinators (NATCO), an individual transplant coordinator and a candidate family supported the LRB pathway. The OPTN/UNOS Transplant Coordinators Committee supported the current policy with Zone A swapped in for DSA. The OPTN/UNOS Pediatric Transplantation Committee was split between striking the policy and providing access through an LRB pathway. Finally, the OPTN/UNOS Patient Affairs Committee supported providing some option to prioritize these candidates, versus no option.

The Committee considered the feedback. It recognized that sensitized candidates have potential to be disadvantaged because they are less likely to be able to accept offers from donors, and that ideally, the policy could be modified more extensively, based on evidence. However, conceding that a lack of data is a barrier to developing a more robust policy, the Committee debated which of the options initially considered would be most prudent in the short-term.

The group considered the proposed solution that went out for public comment: striking the policy altogether. Public comment was not largely opposed to this option and it is straightforward. There is no information to help define sensitized candidates and there is little evidence that the existing pathway was ever used. This solution might be unlikely to impact many patients. In addition, sensitization does not equate to urgency, so it perpetuates the LAS as the sole driver of prioritization. Striking the policy does not attempt to address a complicated issue without clear solutions. Finally, broader distribution should benefit sensitized candidates to some extent; what they need is access to a greater number of offers, not necessarily higher priority on the match. However, the Committee noted that removing the policy carries some risk because there would be no mechanism for prioritization for sensitized candidates. In addition, it eliminates a pathway that previously existed for a group of candidates that are more challenging to match.

There was strong consensus amongst the Committee that the LRB pathway was not optimal. Although logistically it may be most practical solution, there is not consensus within the lung transplant community around the definition of a sensitized patient. Lung transplant programs have different thresholds of what they are willing to accept as a positive crossmatch, and how many mismatches they are willing to accept. Members also noted that there was variable confidence in virtual HLA crossmatches. In addition, the Committee recognized the need to develop guidelines to help assist the LRB in evaluating sensitized candidate exception requests. This in itself would present the same challenges as developing policy. Further, since guidelines would have to be developed post-implementation of the policy change, as they are required to go out for public comment, the Committee did not favor this option.

Finally, the Committee considered the final option: maintaining policy that would permit allocating lungs out of sequence if the sensitized candidate's transplant program was able to

secure agreements with other lung transplant programs whose candidates might appear ahead of the highly sensitized candidate. They debated four options that met this intent:

Table 1: Sensitized Candidate Policy Options Considered

Option	Timing of agreement	Advantages	Disadvantages
<p>Option 1: Permit transplant programs to get agreements from any program above their candidate on the list to agree to be bypassed, no geographic limitation</p>	<p>At time of match</p>	<ul style="list-style-type: none"> • Provides a pathway for sensitized candidates • Does not prescribe how far down the match run the sensitized candidate appears 	<ul style="list-style-type: none"> • Not practical unless there are only a few candidates ahead of the sensitized candidate on the match run • Difficult to achieve unless the transplant program knows the OPO and the other transplant programs ahead of it pretty well
<p>Option 2: Allow OPO to allocate to sensitized candidate within Zone A if transplant program has gotten agreements from all other transplant programs in Zone A</p>	<p>At time of match</p>	<ul style="list-style-type: none"> • Provides a pathway for sensitized candidates • Most similar to current policy, except replaces DSA with Zone A • Limits the benefit only to candidates in Zone A 	<ul style="list-style-type: none"> • Constantly shifting geography • Difficult to achieve in a timely manner because this would have to happen after the match is generated
<p>Option 3: Allow OPO to allocate to sensitized candidate within Zone A if transplant program has gotten agreements from all other transplant programs within 500 nautical mile of the candidate</p>	<p>Advanced agreement</p>	<ul style="list-style-type: none"> • Provides a pathway for sensitized candidates • Similar concept to current policy • Limits the benefit only to candidates in Zone A • Alleviates the time-sensitive nature of the match by allowing the program to get these agreements in advance 	<ul style="list-style-type: none"> • Difficult to achieve unless the transplant program knows the OPO and the other transplant programs within 500 nautical mile pretty well
<p>Option 4: Policy modeled after</p>	<p>At time of match</p>	<ul style="list-style-type: none"> • Provides a pathway for sensitized candidates • Based on medical judgement 	<ul style="list-style-type: none"> • Not practical unless there are only a few ahead of the candidate on the match run

kidney medical urgency policy ⁴		<ul style="list-style-type: none"> • Not complicated by securing agreements based on set geography • Does not prescribe how far down the match run the sensitized candidate appears 	
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In addition to the disadvantages outlined in **Table 1**, sensitization does not equate to urgency, so allowing candidates with a lower LAS to receive a lung allograft before those who are listed at greater urgency may not be appropriate. In addition, it gives the OPO discretion, which they typically do not want. Finally, all of these options are difficult to monitor.

The Committee debated these concepts. They quickly eliminated options 2 and 3, as the logistic limitations made the solutions impractical. Options 1 and 4 are similar, but the Committee favored broader policy language rather than a very specific policy that prescribes when it is permissible to bypass other candidates on the match. Option 4 is also most similar to *Policy 8.2.A: Exceptions Due to Medical Urgency* for kidneys. The Committee appreciated the importance of modeling its proposed sensitization policy off of concepts and precedent in other OPTN policies. Rather than striking the policy altogether, the Committee ultimately voted on option 4 (8-approve, 3-oppose, 2-abstentions).

The Committee voted to send the proposal to the Board of Directors in June for consideration (16-approve, 0-oppose, 0-abstentions).

The Board amended the proposal to remove the November 24, 2018 expiration date for the 250 nautical mile distribution unit for deceased donor lungs the Board clarified previously approved heart-lung allocation policy that will be implemented in the fall of 2018 by replacing references to the DSA and zones with references to specific allocation classifications The Board adopted changes to the policy for sensitized lung candidates. Effective Date: Policies 1.2, 10.2.A, and 10.4: June 12, 2018 Effective Date: Policy 6.6.F: October 18, 2018

Membership and Professional Standards Committee **Appendix L Revisions**

Appendix L of the OPTN Bylaws details actions that the OPTN, through the Membership and Professional Standards Committee (MPSC) and Board of Directors, may take when OPTN members fail to comply with OPTN obligations. Appendix L also outlines members' rights when the MPSC or Board of Directors is considering taking certain actions. The current Bylaws require the MPSC to engage with members through predetermined steps and timelines. As a result, both the MPSC and the member are sometimes required to interact in ways that do not provide sufficient value. Additionally, the current Bylaws include conflicting requirements, lack consistent and sufficient detail, and are organized confusingly. The proposal improves the OPTN review process and describes the process in a way that is more detailed and easier for members to understand. With a focus on member improvement in response to noncompliance

⁴ Policy 8.2.A Exceptions Due to Medical Urgency. Policy 8 Allocation of Kidneys. Organ Procurement and Transplant Network Policy.

https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_08

with OPTN obligations, the rewrite of Appendix L primarily supports the OPTN strategic goal of promoting living donor and transplant recipient safety.

Region 3 vote: 31 support, 0 oppose, 0 abstentions

Region 3 comments: Members support the proposal. One member suggested that it would be beneficial to require that two MPSC members have content expertise during the informal discussions.

Committee response: The MPSC made some minor clarification and formatting edits to the proposed Bylaws language post-public comment (Exhibit E), but it did not make any changes in direct response to the feedback provided during public comment. The MPSC discussed all the public comment feedback provided in response to this proposal during its March 27 teleconference. The following summarizes the public comments and the MPSC's response:

Regional Meeting Comments

- All 11 OPTN/UNOS regions unanimously supported the proposal. Discussion at the regional meetings yielded a few specific comments and recommendations for the MPSC to consider. The MPSC expressed its appreciation for the support provided at the regional meetings, and responded to the additional considerations individually:
 - At the Region 3 meeting, members suggested it would be beneficial to require that two MPSC members have content expertise during informal discussions.

MPSC Response: Subject matter experts are commonly present on the MPSC, and the MPSC will always work to include experts on all of its reviews. Informal discussions are intended to be information gathering conversations among peers. The MPSC is concerned that this perspective may be lost if larger panels are needed to conduct the informal discussion, and with the inclusion of additional experts outside of the MPSC. Nothing in the proposal prohibits the MPSC from obtaining additional expertise for informal discussions if necessary, and the MPSC has done so in the past, even when not required by the Bylaws. However, the MPSC felt requiring at least two subject matter experts for every informal discussion may limit the MPSC's ability to quickly hold a discussion with a member for a seemingly straightforward issue, such as clarifying the MPSC's concerns described in a letter or further explaining why the MPSC requested specific information. With this perspective, and for the sake of maintaining member confidentiality, the MPSC did not support Bylaws changes that may potentially require prematurely asking experts outside the committee to interact with members during informal discussions. The proposal continues to require at least two subject matter experts participate in interviews and hearings.

Following the public comment period, the MPSC did make a number of minor changes for formatting and to further clarify some of the proposed language. This list of changes is included as **Exhibit E**. The Committee reviewed these changes during its April 17 teleconference, and then unanimously supported a resolution to approve the Bylaws changes offered in the Appendix L proposal, as provided in the meeting materials and discussed during the teleconference, for the Board of Directors' consideration at its June 2018 meeting (23 support, 0 oppose, 0 abstentions).

This proposal was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: June 12, 2018

Ad Hoc Disease Transmission Advisory Committee

Clarify Informed Consent Policy for Transmittable Conditions (Discussion Agenda)

Current OPTN Policy requiring specific pre-transplant informed consent due to potential disease transmission is vague leading to varying interpretations. The Membership and Professional Standards Committee (MPSC) sent a memo to the Ad Hoc Disease Transmission Advisory Committee (DTAC) in April 2017 requesting further clarifications. The policy phrase “known medical condition” has led to questions about application in practice. A broad interpretation of this policy would include requiring a specific informed consent for any positive serology, culture, or other donor test result which would be cumbersome without adding benefit to the patient.

Epstein-Barr virus (EBV), cytomegalovirus (CMV), and culture results were mentioned as examples. The MPSC did not believe that many, if any; adult programs would complete a specific informed consent for EBV or CMV mismatches, as they are very common and would not impact using an organ except under unusual circumstances. Applying this policy to require specific informed consent prior to surgery for those serologies or other donor culture results may not be reasonable and leads to undue burden on the center.

Current and previous DTAC leadership has consistently maintained that the policy was not meant to include CMV and EBV mismatches as they are part of the regular business of transplant and are quite frequent. DTAC expects that these would be included as part of routine pre-transplant education. Due to the issues with language interpretation, the DTAC proposes changes to this policy.

This proposal would specify conditions requiring specific informed consent prior to transplant. The Committee has decided to tie the conditions that would require specific consent to existing Policy 5.3.B Infectious Disease Screening Criteria. This policy specifies organ specific preferences that can be made in Waitlist made for individual candidates on whether organ offers will be received from donors who have tested positive for certain transmittable conditions. Currently, this policy includes CMV for intestines only, as well as hepatitis B (HBV) core antibody and Nucleic Acid Test (NAT), hepatitis C (HCV) antibody and NAT for heart, intestine, kidney, liver, lung, pancreas, heart-lung, and kidney-pancreas listings. Organs from HIV positive donors may only be recovered and transplanted according to Final Rule requirements.

Currently, use is only permissible for kidney and liver transplantation. Consent required for these organs is covered by Policy 15.7.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs.

Linking pre-transplant organ offer informed consent to candidate screening establishes a principle and specificity. It will also then incorporate changes that might occur over time to the screening policy that would be consistent from listing through transplant. These changes also address the growing use of positive organs for conditions such as HCV as effective treatments have become available. The proposal does not change required informed consent for US Public Health Service increased risk organs.

Region 3 vote: 8 support, 15 oppose, 2 abstentions

Region 3 Comments: One member strongly expressed the opinion that the OPTN should not be “in the business of consent writing.” Transplant centers should determine which conditions require consent and OPTN policy needs to be less specific. For example, one member noted

that in their practice they see more post-transplant complications with EBV and CMV than hepatitis B or C. One of the intestinal programs in the region thinks that the CMV requirement for intestine should be removed because that is a clinical decision based on a number of recipient factors. They also noted there is a difference between isolated intestine and multi-visceral transplants involving an intestine.

Additionally, the manner in which consent is documented should be left to the transplant centers to decide. Members do not want to obtain the patient's signature for consent.

Committee response: This proposal was changed in response to public comment. The DTAC met by teleconference on March 13, 2018 and for their in-person meeting on March 29, 2018 in Richmond, Virginia to discuss public comment and consider post public comment revisions.

Public Comment Summary

During the public comment period (January 23 – March 23, 2018), this policy proposal received 22 comments on the OPTN website. DTAC presented the proposal to nine committees: Ethics, Kidney, Liver and Intestines, MPSC, PAC, Operations and Safety, Pediatrics, Thoracic, and Vascularized Composite Allograft. All Committees were supportive of the proposal. Nine of eleven regions supported the proposal. Regions 2, 9, and 10 had unanimous support. Four professional societies, ASTS, AST, American Society for Histocompatibility and Immunogenetics (ASHI), and North American Transplant Coordinators Organization (NATCO), all submitted comments in support of the proposal.

Region 3 did not support the proposal. Region 8 was split (6-8-8). Two individuals commented on the proposal and expressed concerns. All comments will be detailed below according to themes that emerged through public comment.

The Committee received feedback on the two specific questions posed to the community as part of the proposal:

1. Should informed consent policy include an actual patient signature or is discussion and medical record documentation sufficient?
2. Do you have any concerns or comments about the list of conditions in the current candidate screening (Policy 5.3.B Infectious Disease Screening Criteria) and re-execute the match (5.5.B Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results) policies?

The Committee also received feedback on the following additional topics:

1. Support to clarify policy
2. Timing of informed consent
3. Importance of pre-transplant education and best practices
4. Patient centric materials
5. Risk proportion needs balance
6. Frustration with PHS increased risk guideline requirements

Feedback Question 1: Signature and Documentation Requirements

The DTAC asked for specific feedback on two questions. The first question was whether a signature should be required for informed consent. Current policy requires documentation of the discussion and informed consent. It does not specify that a signature is required. The majority of respondents did not believe that a signature should be required in policy. Obtaining informed consent after organ offer and before transplant is often done in a phone call when the organ

offer is made. Obtaining a signature might not be practical due to the timing. Some respondents requested that policy be silent on this issue, however, the DTAC believes that the minimum requirement must be in policy to reduce transplant community confusion and to establish the baseline for monitoring. The ASTS and the PAC favored obtaining a patient signature. After considering these comments, the DTAC decided to leave policy as is which requires discussion and documentation. Policy is the minimum requirement and transplant programs can obtain signatures if they choose. Table 2 below summarizes responses to the feedback question.

Table 2: Summary of public comment responses: Is signature needed for informed consent?

	Patient Signature Required	Documentation Without Patient Signature	Other suggestions
Regions		4 total (3, 7, 8, 10)	<ul style="list-style-type: none"> • Either but do not specify in policy (2) • Let transplant program decide (3)
Committees	Patient Affairs (except 1 member)	Pediatrics Thoracic	<ul style="list-style-type: none"> • Mirror increased risk process (Kidney) • Do not specify in policy (Liver) • No strong preference (MPSC)
Professional Organizations	ASTS	NATCO	<ul style="list-style-type: none"> • No consensus do not specify in policy (AST)
General Public	1 individual		

Feedback Question 2: Specific Conditions

The second feedback question DTAC asked was for concerns or comments about the list of conditions in the current candidate screening and re-execute the match OPTN Policies. The issue of whether CMV screening is still clinically relevant for intestine candidates has been anecdotally raised during other projects. In addition, screening for hepatitis B surface antigen (HBsAg) has not been included historically in candidate screening due to small numbers and lack of use. As treatments have emerged and NAT testing helps differentiate past exposure versus active viremia, use of organs with positive results for HCV has been increasing. Between 2013 and 2018, the number of HCV positive deceased donors with at least one organ transplanted rose from 361 to 775 and the proportion rose from 4.4% to 7.5% of all deceased donors⁵. While it has been more common to transplant positive donor organs into positive recipients, there are programs that are now using HCV antibody positive/NAT negative (Ab+/NAT-) organs for negative recipients. Given these changing trends in transplantation since 2007 when programming for candidate screening started, and 2015 when policies were last amended, the DTAC requested feedback on specific conditions used for candidate screening (Policy 5.3.B Infectious Disease Screening Criteria) and re-executing the match (5.5.B Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results) Policies. Based on public comment, the DTAC decided not to make changes to those policies at this time. The feedback, however, was used to shape the proposed informed consent policy. Table 3 below summarizes public comment on this question.

⁵ Data obtained from the OPTN database on May 3, 2018; data subject to change based on future data submission or correction.

**Table 3: Summary of public comment responses:
Do conditions for candidate screening and re-execute the match need to change?**

	Yes	Yes	No	Other
	Add	Delete		
Regions		CMV 5 total (1,3,8,9,11) Hepatitis C Ab+/NAT- 1 total (9)	1 total (2)	<ul style="list-style-type: none"> • Living list outside policy (7) • Not enough conditions (8)
Committees	EBV for Pediatrics CMV for all organs (Patient Affairs)	CMV (Liver and Intestines Operations and Safety Pediatrics) Hepatitis B Core or Hepatitis C Ab+/NAT- (Thoracic)	Kidney MPSC	<ul style="list-style-type: none"> • Living list outside policy (MPSC)
Professional Organizations	CMV for all organs (AST Kidney Community of Practice)		AST ASTS NATCO	
General Public	CMV for all organs/ (2 individuals)			

Region 11 supported the proposal with an amendment to remove CMV (intestines only) from informed consent requirements. Region 3 felt that the OPTN should not be making policy regarding informed consent and that transplant hospitals should develop their own informed consent policies. Region 8 was split (6-8-8) due to disagreements over what specific conditions should require informed consent and a general sentiment that more conditions should be in informed consent requirements. Both individuals who submitted comments felt that informed consent for CMV should be required for all organs due to serious sequelae that can happen.

Due to scope of the debate and the changes made post public comment, the summary of Committee discussions will be outlined in a separate section below.

Support to clarify policy

In general, the transplant community was highly supportive of simplifying and clarifying the policy. The challenge of defining “known medical condition” that can be transmitted according to “medical judgment” was acknowledged. The DTAC, along with multiple audiences, discussed conditions warranting informed consent. The discussions took into account recent data regarding: risk of disease transmission, availability of effective prophylactic and treatment strategies, organ shortage, organ utilization, risk of organ discard, and mortality on the waiting list. These discussions led to better understanding that there were no perfect answers and where to draw the line is not obvious. The Committee intends for this policy to be a minimum standard. Transplant hospitals should obtain informed consent when needed according to their

internal policies, state laws, and to be compliant with the CMS CoPs if they are a Medicare or Medicaid provider.

Timing of informed consent

Some commenters felt that the timing could be better clarified in policy. There is the general informed consent that applies to all candidates (or potential candidates) that must be completed before transplant. Based on the request, the DTAC proposed to change the timing clause here to read “any time prior to” as opposed to “before”. There are other additional circumstances that require informed consent prior to transplant such as when a donor meets criteria for being PHS increased risk. This additional consent requirement is specific to a potential transplant recipient (defined in OPTN Policy as a candidate appearing on a match run). Because this requirement is based on an identified donor, the timing must be logically after organ offer. Current policy language uses the term “before transplant”. This language will be clarified to state, “after organ offer but before transplant”.

A concern is that the community might still misinterpret policy and for example obtain consent during the evaluation period for using a PHS increased risk donor and believe that they have completed the requirement. The error would be not realizing that consent currently is and will still be required for these type of donors (increased risk) after organ offer yet prior to transplant for both deceased and living donors. DTAC does plan to develop and provide significant education to the community to help dispel any misperceptions.

Importance of pre-transplant education and best practices

The importance of conducting a thorough general informed consent and providing candidate education throughout the process was suggested. The Committee will be working with the UNOS Professional Education department to develop education on this topic. The DTAC moved general consent to the beginning of the policy to emphasize its importance as well as be in chronological order. DTAC believes that prior to listing or during the evaluation process is the best time to have an educated and comprehensible informed consent. The Committee believes this is when the likelihood of being offered an organ positive for CMV or EBV should be discussed as the majority of transplants performed are from donors positive for one or both conditions. Regardless of the proposal outcome, the DTAC will serve as a subject matter expert (SME) to help develop professional education materials on this topic.

Patient centric materials

Several members have asked for checklists or standard information that can be given to candidates in order to help with the informed consent process. Commenters identified the need for materials that are patient centric with appropriate health literacy and cultural competency incorporated in their development. The DTAC is checking on an effort started with AST to develop patient materials related to increased risk. The hope is that this effort could help meet this need.

Risk proportion needs balance

Several transplant professionals, including the ASTS representative on the informed consent work group, raised the concern that we are overemphasizing certain risks without providing appropriate balance. Some risks are heavily regulated in mandated informed consent (e.g. increased risk) while others such as the “number of sclerosing glomeruli” on a kidney are not. There is concern that too much emphasis on obtaining informed consent for certain risks compared to the risk of dying on the waitlist leads to unnecessary patient fear and organ turn downs. A balanced approach to risk will be included in professional education efforts. The DTAC is aware of this concern. They put some risk perspective in the [guidance document](#)

“Understanding the Risk of Transmission of HIV, Hepatitis B, and Hepatitis C from U.S. PHS Increased Risk Donors” published last year addressing use of increased risk organs.

Frustration with PHS increased risk guideline requirements

Several commenters raised specific frustration with the PHS increased risk guideline designation and OPTN informed consent requirements suggesting again that they do not balance the risk of refusing a transplant. It is feared that some tenets in the increased risk definition might be causing undue concern for candidates and leading to organ discard. The relevancy of the concern is growing as now one-quarter of all deceased donors fall within the increased risk definition and therefore must be consented to receive the organ. OPTN data from 2017 show that 2,704 out of 10,286 (26%) deceased donors were classified as increased risk.⁶

The DTAC has worked to publish more information about concerns related to organs from donors with intravenous drug use (IVDU). From data available, these donors appear to be most likely to transmit HIV, HBV, or HCV. While this is of continued concern due to the growing opioid epidemic and subsequent increase in donors with this type of history, the converse consideration of relatively good organ quality due to the younger age of most IVDU and availability of treatments for HCV is not heard as often. The risk of using these organs might be perceived as greater than the actual data indicate. Furthermore, other risks, such as the risk of dying on the waitlist, might not be considered in appropriate perspective given the emphasis on PHS increased risk. Member concerns have been shared with the CDC ex-officio DTAC member. The PHS includes CDC who develops and publishes the guideline. The OPTN is not the author of and cannot change the guideline. The OPTN, however, is bound within the Final Rule to be consistent with CDC guidelines for donor testing and recipient follow up and thus parts of the PHS increased risk guideline have been incorporated into OPTN policy.

Post Public Comment Changes for Specific Conditions and Other Considerations

CMV

Based on public comment, DTAC leadership proposed eliminating CMV from the requirements. Contradictory responses were raised during public comment period; while a few comments favored consent for CMV, and even extending it to ALL organ types, most responses opposed having consent being part of an OPTN/UNOS policy. The DTAC concluded that a robust discussion about CMV should take place initially at the time of listing for transplant if possible. The proposed policy includes the expectation that discussions about conditions such as CMV will happen during the general informed consent process. An educational initiative is planned to promote these discussions at a time when then the patient can ask questions and receive answers outside of the pressured time of organ offer.

The feedback received from the Liver and Intestines Committee, as well as the Pediatric Committee, weighed heavily in making this recommended change. These groups have the greatest concerns for their constituencies since currently it is only required for intestinal transplants. Accordingly, it was felt that CMV should be removed from the informed consent requirement for intestinal transplants at the time of organ offer. These groups also questioned the necessity of having CMV as part of candidate screening and re-executing the match run; however Region 11 felt strongly that CMV screening was still applicable even if removed from the consent policy.

⁶ United Network for Organ Sharing Research Department. What do the Numbers Say? OPTN/UNOS Descriptive Data Analyses. Prepared for the DTAC Full Committee. March 29, 2018.

To determine the impact, current data were reviewed. In 2017, there were 108 intestine donors and 44 of them were CMV positive.

Because of the small number and resources required for IT programming changes, the DTAC did not want to propose changes for candidate screening and re-execute the match policies with this proposed action.

HBV and HCV

The DTAC remained cognizant of the need to be consistent with CDC recommendations as per the Final Rule. The PHS increased risk guideline recommendation 14 states: "When organs from HBV- or HCV- infected donors will be used, the transplant center team primarily responsible for the patient's care should have an informed consent discussion with the transplant candidate, or medical decision maker, prior to transplantation regarding the risks related to disease transmission." Accordingly, it was felt that HBV and HCV should be included in the informed consent policy.

Excluding only CMV for intestines would likely be confusing if the policy were tied to candidate screening and re-execute the match policies. Furthermore, the Committee decided that the policy did not need to match as candidate screening might be a larger set of conditions as it exists for both efficiency and safety reasons. It was decided to return to listing the conditions in the policy that would require informed consent.

DTAC members had a lengthy discussion as to whether anti-HBc and anti-HCV (HBV and HCV antibody tests, respectively) should be included in the age of NAT which indicates active infection. The factors that were included in the discussion included: risk of disease transmission, available effective prophylactic and treatment strategies, organ shortage, organ utilization, risk of organ discard, and mortality in the waitlist. Recent single center cohort studies and the 2017 AST HCV Consensus Conference stated that organs from donors who were HCV Ab+/NAT- confer a low risk of transmission as these results indicate past but not active infection. Furthermore, the available new therapies for HCV are highly effective in solid organ transplantation.

When DTAC studied several cases where unexpected transmission occurred in HCV Ab+/NAT- donors it turned out that all of these donors were PHS increased risk due to IVDU with a cause of death related to active drug use and overdose. The risk of disease transmission is likely to be related to their risk for acquisition of a new HCV infection. These cases likely represent donor HCV re-infection during the eclipse period of NAT testing. Although NAT is highly sensitive, it does not detect HCV until 3-5 days after infection. Candidates electing to accept these organs would be consenting for increased risk due to being increased risk (IVDU). To date, all cases of HCV transmission from HCV Ab+/NAT- donors have been from PHS increased risk donors with IVDU and other risk factors.

The Committee also debated whether to include anti-HBc as a positive test indicative of HBV infection. In some cases, HBV can remain dormant in the liver and become reactivated. The Committee discussed the availability of vaccination and prophylaxis as the strategy to mitigate this low risk. DTAC believes that the HBV results should be considered as part of an individual recipient/organ donor quality discussion, given that the majority of transplants pose essentially no recipient risk. In addition, as with CMV, recipients can be given prophylaxis to prevent disease. The proposed general informed consent requirement addresses this issue by adding the clause that centers need to inform candidates that test results can impact post-transplant management (e.g. need to give prophylaxis). Enforcing consent on centers using HBVcAb+

(yet HBsAg and NAT negative) donors particularly for non-liver recipients, when the documented risk of transmission under those circumstances is very low, may actually result in more discards. After much debate and based on the above considerations, the Committee decided on not including the antibody tests for HBV and HCV in the informed consent requirements. The proposal will include positive tests for HBsAg, HBV NAT, and HCV NAT as these represent active viremia.

The DTAC did consider the PHS increased risk guideline definition of what positive tests define infection in the donor. The PHS guideline uses the term “presumed infected” and includes any donor with a positive test for antibody and/or NAT results. For HBV, this includes anti-HBc, HBsAg, and/or NAT. For HCV, this includes anti-HCV and/or NAT. OPTN Policy must be consistent with but not necessarily identical to the recommendations according to the Final Rule. For example, in current policies, the OPTN requires post-transplant testing for HIV, HBV, and HCV after use of an increased risk donor organ. These policies do not specify timing or test type while the PHS increased risk guideline is more specific. After the DTAC had agreed upon the concept for the policy, the UNOS/OPTN general legal counsel and Chief Medical Officer were consulted. They agreed that the DTAC definition using HBV and HCV NAT results, as well as HBsAg, but not including antibody tests would be sufficiently consistent with the PHS increased risk guideline and therefore meet the OPTN obligation in the Final Rule.

Informed Consent Cross-Reference in Re-Executing the Match Policy

Once the DTAC agreed upon the concept to limit informed consent requirements to test that equate to active viremia, the Committee discussed an existing cross reference in Policy 5.5.B: Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results to Policy 15.3.A: Donors with Additional Risk Identified Pre-transplant. When a candidate has accepted an organ with a pending result that then is found to be positive, the candidate who has accepted the organ has the right to continue with the acceptance and transplant once informed and consented about the positive result. The proposed conditions in informed consent policy would not be an exact match to those that trigger a new match run if certain positive results become available.

Data were reviewed. In 2017, there were 69 donors who met the potential re-execute the match criteria where a match was run prior to having results but subsequent positive results became available and at least one organ was still transplanted. Of the 69 donors, 14 donors had at least one organ accepted at the time the positive results became known. Only three recipients had indicated on candidate screening that they did not want that type of positive organ (1= HBcAb, 2 = HCV Ab)⁷. In these cases, the positive results did not change the outcome. These three recipients continued with acceptance and transplantation of these organs. The other recipients had indicated that they would accept positive organs on the candidate screening.

The revised proposed policy would not require result disclosure or informed consent to those undergoing a match re-run, although transplant centers could have internal policies to do this. The revised proposed policy would not require result disclosure or informed consent although transplant centers could have internal policies to do so. The number of recipients for whom this cross-reference might apply is small (n =20) and the DTAC believes that most users will primarily use Policy 15.3 as their reference. This positive CMV or antibody results should be handled similarly to how EBV and CMV will be handled. It is not known at the time of listing if patients had the discussion with their providers about what type of organ would be accepted. In

⁷ Data obtained from the OPTN database on April 16, 2018; data subject to change based on future data submission or correction.

addition, a significant amount of time may have passed (e.g. 6 years for one of the three who received a kidney) and therefore the medical rationale might have changed (e.g. patient's health worsening and cannot wait for other offers). Transplant hospitals will be required to obtain informed consent from candidates accepting actively infected HBV or HCV NAT positive donor organs.

The post public comment changes in summation include:

- Requiring informed consent for a smaller subset of positive tests that indicate active disease outlined in Table 4 below.
- Clarifying timing language for both the general informed consent and the informed consent required for certain conditions after organ offer
- Other minor edits for clarity and brevity

Table 4: Post Public Comment Changes for Informed Consent of Transmittable Disease

If donor is positive for (test name below), then informed consent is required after organ offer and prior to transplant	Public Comment Tie to candidate screening and re-execute the match policy conditions	Final Post PC Proposal Delete anti-HBc and anti-HCV. Tests do not indicate active viremia.
Anti-HBc (HBV core antibody)	Yes	No
HBsAg	No	Yes
HBV NAT	Yes	Yes
Anti-HCV (HCV antibody)	Yes	No
HCV NAT	Yes	Yes
CMV Intestines (INT) only	Yes	No

The DTAC voted unanimously (15-0) at their April 24, 2018 teleconference to send the proposed policy to the OPTN/UNOS Board of Directors for consideration at their June 2018 meeting.

This proposal was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: Pending implementation and notice to OPTN members.

Operations and Safety Committee

Extra Vessels: Reducing Reporting Burdens and Clarifying Policies (Consent Agenda)

This proposal changes requirements when extra vessels are shared among transplant hospitals. Members will no longer need to submit a justification to the Membership and Professional Standards Committee (MPSC). Instead, they will report the sharing in the existing extra vessels TIEDI reporting system. The justification requirement is no longer needed as no associated policy violations have been identified and it creates unnecessary burden. Reporting sharing in TIEDI is already occurring which assures tracking capabilities. IT programming will allow OPOs to view extra vessel dispositions from donors that they recovered.

This proposal also changes extra vessels labeling requirements for infectious disease results. The proposal narrows infectious disease labelling from “all” to only “HIV, hepatitis B (HBV), and hepatitis C (HCV)” results. This will facilitate synching test results and test names between DonorNet, TransNet, and the label that currently have inconsistencies. A TransNet barcode will be added to the label to allow for scanning and accessing all infectious disease results available in DonorNet. This will also allow for more efficient and timely response if future policy change requirements for infectious disease testing.

This proposal also aligns policy language with the Final Rule that states that vessels (including extra vessels) are considered part of the organ with which they are recovered and subject to applicable requirements. Some current policies need clarifications, exclusions, or deletions to fit within this logic and framework.

Region 3 vote: 24 support, 0 oppose, 0 abstentions
No comments.

Committee response: There were changes made to the proposal in response to public comment. During the public comment period (January 23 – March 23, 2018), this policy proposal received 18 comments on the OPTN website. Comments included input and feedback from OPTN/UNOS Committees, professional societies, and regions. The Operations and Safety Committee held two webinars for other OPTN/UNOS Committees that were interested in the proposal. The proposal was also presented during a national webinar open to the public. Three committees provided feedback on the OPTN website (Membership and Professional Standards Committee (MPSC), Ad Hoc Disease Transmission Advisory Committee (DTAC), and Organ Procurement Organization (OPO) Committee). The DTAC provided recommendations to the Committee during the development of the proposal. They support the proposal as written as does the OPO Committee. The MPSC supported the proposal but did voice concerns regarding the difficulties in training OR staff in new technologies. In addition, five professional societies provided support for this proposal moving forward to the OPTN/UNOS Board of Directors. These include the American Society for Histocompatibility and Immunogenetics (ASHI), Association of Organ Procurement Organizations (AOPO), North American Transplant Coordinators Organization (NATCO), American Society of Transplant Surgeons (ASTS), and American Society of Transplantation (AST). All eleven regions discussed the proposal. Every region unanimously approved the proposal.

The Operations and Safety Committee asked for specific feedback on what additional infectious disease testing is conducted due to donor travel history or other local protocols but not mandated by national policy so that these tests can be considered as possible optional additions in DonorNet. DTAC, AST, and Region 2 provided feedback that highlighted testing for Strongyloides at a number of OPOs. Given that many OPOs perform testing for this infectious disease, Committee members agreed that changes in DonorNet were valuable for ease-of-use and applicability. As such, Strongyloides will be added to the DonorNet Infectious Disease Screening tab. While it is not a policy requirement to perform donor Strongyloides testing, the addition will make entering and finding results for this test easily accessible.

Several other themes emerged from public comment:

1. The implementation of the extra vessels barcode and associated technological and training barriers that affect transplant hospitals
2. Improving communications on extra vessels
3. Revisiting policies and potential new policies

Implementation of the extra vessels barcode

The MPSC supported the proposal but raised concerns over the implementation of the extra vessels storage barcode. In particular, the MPSC expects significant technology and training barriers in the use of this barcode. Feedback provided by Region 11 stated that operating room staff may struggle using the barcode, especially since many operating room staff may not be familiar with transplant medicine and procedures. Furthermore, the MPSC stated that difficulties may arise during implementation in transplant hospitals. These difficulties include limited availability of compatible barcode scanners; lack of ability to relabel with TransNet; lack of routine practice due to infrequent extra vessels use after storage or sharing; and requiring major process changes at transplant hospitals.

Upon reviewing this feedback, Committee members noted that no new requirements were being placed on transplant hospitals for the use of TransNet. The barcode is being added simply as an enhancement, not a requirement. In addition, this policy proposal will change prior OPTN Policy stating that all infectious diseases must be verified before transplanting extra vessels into a recipient. As a result of these changes, only HIV, HBV, HCV will be required, decreasing the verification burden. Finally, there are three options for viewing test results: paper, DonorNet, or scanning the barcode. Transplant hospitals will be able to choose their preferred method of viewing results to complete the basic requirements for examining HIV, HBV, and HCV results to determine storage ability or verification. The barcode scan is an enhancement that will assist with accessing real-time up to date results for all infectious diseases that are entered in DonorNet.

The Committee, however, is aware of the realities that operating room staff face in a fast-paced, high-pressure environment. The Committee also recognizes that operating room hospital staff must adhere to many protocols and procedures and that they may not be familiar with transplant specific processes. Additional functionality available with the barcode scan could create short-term difficulties during implementation. Nevertheless, Committee members believe that adding barcodes as an enhancement to extra vessels storage and usage will both increase patient safety as well as provide transplant hospitals with cutting-edge options for efficiency. The Committee is committed to working with member organizations to provide proper outreach and educational communications for the process of implementation if transplant hospitals opt to utilize extra vessels barcodes. The use of TransNet and accessing infectious disease results available through DonorNet is voluntary not required.

Improving communications on extra vessels

There were several suggestions directed at improving communications by OPTN/UNOS Committee members, professional societies, and regions. These suggestions include the following:

- Adding policy language requiring transplant hospitals to notify OPOs if extra vessels are used in a secondary recipient to ensure communication of additional donor information and potential disease transmissions (OPO Committee)
- Including information regarding extra vessels in Potential Donor Derived Disease Transmission Event (PDDTE) notifications (AST)
- Including both the UNOS ID and the corresponding match ID on TransNet labels, given that scanning capabilities are not always available (Region 6)
- Notifying OPOs when extra vessels are shared via a TransNet alert (Region 7)
- Managing new information post-transplant for stored donor vessels (Region 8)

Committee members carefully considered all these communication suggestions. OPOs will be given access to the OPTN extra vessels reporting system within TIEDI. This will facilitate

communication and the ability of the OPO to know the disposition of extra vessels that they have recovered. The information can be shared or entered on the PDDTE as available. The issue with transplant hospital's needing a match ID to access information in DonorNet is known and solutions are being considered within the broader UNOS IT departments. The bar code will be the first step in providing more up to date information regarding the donor testing status. It might be possible in the future to add additional information (e.g. other test results such as cultures).

The Committee discussed the Region 1 concern and suggestion. Current OPTN data is silent on this pathway although nearly all (99%) of extra vessels dispositions are reported to the OPTN since the new reporting system in TIEDI was implemented in 2015. Committee members agreed that a data request is warranted to gain insight into the occurrence of transplant hospitals requesting that an OPO provide extra vessels for a planned living donor procedure. An OPTN data request will be developed. After reviewing available data and patterns of this occurrence, the Committee will formulate next steps.

Revisiting policies and potential new policies

Other public commenters mentioned areas where current policies should be revised or new policies should be considered.

- Since OPTN policy prohibits programs from storing vessels positive for HBV, HCV, and HIV, look at requirements to verify all infectious disease testing results of the extra vessels and all infectious disease testing results of the recipient prior to transplant (Region 7)
- Why ban storing of HCV positive extra vessels-Use of HCV positive organs growing and treatment available (Region 8)
- Considering pathways for documenting events when transplant hospitals request extra vessels from OPOs for living donor procedures (Region 1)
- Modify the label to reflect that recovery date means when the donor entered the OR (Region 2)

Comments were provided which questioned the ban on storing HCV-positive extra vessels, specifically given the increase in available treatments (Region 8). The Committee appreciates and is aware of the increased usage of positive HCV extra vessels, but at this time, no changes were made to OPTN Policy. As such, HIV, HBV, and HCV are not allowed to be stored with the exception of HBV-core positive extra vessels. Since OPTN Policy prohibits transplant hospitals from storing extra vessels positive for the aforementioned infectious diseases, Region 7 requested insight into requirements to verify all infectious disease testing results of the extra vessels and all infectious disease testing results of the recipient prior to transplant. In an effort to further clarify policy, the Committee removed recipient infectious disease results verification as it gives the false impression that donor positive extra vessels can be stored and transplanted within positive recipients. It also did not make sense to keep this since the verification requirements will be limited to the HIV, HBV, or HCV versus "all". Further clarifications includes changing policy label infectious disease names to match label names (Anti-HBcAb to anti-HBc). Region 2 voiced concern on the subject of recovery date. Currently, there is no definition for recovery date in OPTN Policy. The only definition is in help documentation in DonorNet that states that the recovery date is the day that the donor entered the operating room. This can get confusing as the cross-clamp date can vary if recovery goes past midnight. In fact data suggest that there are approximately 7 percent of cases where recovery date and cross clamp date do not match. This has a downstream impact on when the extra vessels expire. OPTN policy requires that extra vessels be used or destroyed within 14 days of the recovery date. Policy

violations may be incurred since cross clamp time can potentially be a different date than entry into the operating room. The other confounding factor is that TransNet is a point of care labeling system. Labels are printed in real time as is the best practice to avoid labeling mix ups. The current date automatically populates into the extra vessels label and must be manually changed if the current recovery date was a day earlier (before midnight).

Region 2 had suggested modifying the label to read “time donor entered OR” rather than “recovery date” to avoid this confusion. Committee members agreed that the lack of clarity regarding recovery date warrants policy changes. However, the substantive changes necessary to clarify recovery date and the potential impacts on existing data will require a new round of public comment. In the new public comment proposal, recovery date will potentially be defined as cross clamp date. This proposed change to define recovery date as cross clamp date can work within the current system. Furthermore, OSC consulted with the OPO Committee and the Data Advisory Committee (DAC) leadership. They support pursuing policy changes on defining recovery date as cross clamp date. The Operations and Safety Committee will continue to pursue this potential policy change for the next round of public comment.

The Operations and Safety Committee met for their in-person meeting on April 11, 2018 in Richmond, Virginia. They agreed to the following proposal language changes post public comment:

- Addition of prohibition of sharing to extra vessels that have not yet had completed HIV testing for the emergency use of organs not yet tested. Once testing is complete then regular policies apply.
- Further consolidation of extra vessels verification requirements. Movement of verification sections currently in Policy 16 to verification sections in Policy 5 for ease of use. Removal of requirement to verify recipient infectious disease results.
- Made all label names consistent with DonorNet. Change DonorNet and extra vessels label requirements for hepatitis B core antigen testing to anti-HBc for proper nomenclature and to be consistent with CDC terminology.
- Changed “may” to “must” to further clarify that living donor extra vessels are allowed for use only in the living donor recipient
- Other minor edits for style, consistency, and clarity

They voted unanimously (17 in favor-0 opposed) to send the policy proposal to the OPTN/UNOS Board of Directors for consideration at their June 2018 meeting.

This proposal was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: September 1, 2018

Organ Procurement Organization Committee

Expedited Organ Placement Concept Paper

This concept paper was not on the agenda for the Board meeting. The committee plans to develop a proposal for spring 2019 public comment.

Pancreas Transplantation Committee

Change Waiting Time Criteria for Kidney-Pancreas Candidates (Discussion Agenda)

A section of the kidney pancreas (KP) waiting time criteria limits accrual to candidates on insulin that have either a C-peptide ≤ 2 ng/mL or a C-peptide > 2 ng/mL and a body mass index (BMI) below or equal to the maximum (30 kg/m²).

The Pancreas Committee (Committee) analysis and review of current evidence indicates that this waiting time criterion represents an unnecessary and arbitrary restriction to certain candidates' access to transplantation.

The waiting time criterion was included in the 2014 Pancreas Allocation System (PAS) because of concerns about outcomes for high BMI Type 2 candidates (who are identified by having a high C-peptide) and the possible impact of the new PAS on kidney alone transplants. However, Type 2 high BMI pancreas candidates can be transplanted successfully and show comparable outcomes to other simultaneous pancreas kidney (SPK) recipients. Additionally, Type 2 candidates with high BMIs have consistently represented a very small proportion of all KP transplants, unlikely to have any impact on kidney alone transplants.

The KP waiting time criterion arbitrarily restricts waiting time for Type 2 high BMI candidates while allowing Type 1 high BMI candidates to continue wait time accrual and have greater access to transplant. Evidence gathered by the Committee suggests this restriction for Type 2 candidates is inappropriate because Type 1 and Type 2 KP outcomes are similar for those recipients with high BMIs.

In Type 2 candidates transplanted prior to PAS, outcomes are similar in recipients with a BMI \geq 30 and BMI < 30. Finally, the Committee identified an inequity in the KP waiting time criterion: minorities including African Americans, Asian Americans and Hispanics are more likely to be Type 2 candidates registered for a KP transplant. These populations are also more likely to have a higher BMI within the Type 2 candidate list, indicating that the current policy creates an inequity in restricting minority populations' access to transplant.

Removing the KP waiting time criterion and maximum allowable BMI would provide certain candidates access to kidney and pancreas transplantation based on center best practices and clinical evidence rather than an arbitrary BMI criterion. In 2015, 25% of pancreata recovered for transplant were discarded. Changing KP waiting time criteria may lead to an increase in the number of transplants by enhancing access for candidates currently prevented from accruing waiting time and reducing the pancreas discard rate. This is in alignment with the OPTN first strategic goal. It may also reduce an inequity in access to transplant, in alignment with the OPTN second strategic goal.

Region 3 vote: 5 support, 15 oppose, 1 abstention

Region 3 Comments: Members did not support the proposal as written due to concerns about the impact on the kidney-alone waiting list. There is a large number of type 2 diabetics and eliminating the BMI threshold requirement may drastically increase the number of kidney-pancreas candidates and open the gates to gaming (e.g. listing kidney patients for kidney-pancreas in an effort to receive a kidney transplant more quickly). Members noted that they would support increasing the maximum allowable BMI in a more incremental approach, but would need additional data to determine the appropriate increase.

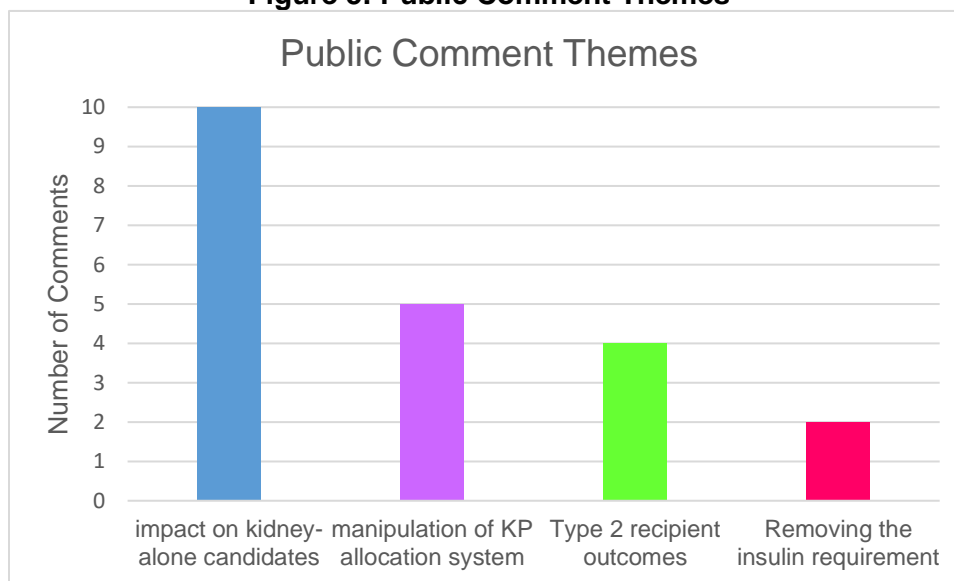
Committee response: This proposal was distributed for public comment during a 60-day period from January 22 through March 23, 2018. Overall, a majority of commenters supported the proposal. Eight regions supported the proposal and three opposed it. The OPTN/UNOS Operations and Safety Committee supported the proposal, as did the OPTN/UNOS Minority Affairs Committee (MAC). The Kidney Committee did not support the proposal. All of the professional organizations that reviewed the proposal – American Society of Transplant Surgeons (ASTS), American Society of Transplantation (AST), American Society for Histocompatibility and Immunogenetics (ASHI), The Organization for Transplant Professionals (NATCO), International Pancreas and Islet Transplant Association (IPITA) – supported it. AST

and NATCO, in their comments, noted that the Committee should closely monitor the impact of the change. The Committee carefully considered each theme and concern from public comment. Besides the concerns that the Committee responds to below, the proposal also received positive feedback indicating support for the solution offered by the Committee: in particular, support for removing a clinically unnecessary limitation on waiting time accrual.

Figure 5 shows the most common concerns and comments raised during public comment:

1. Impact on kidney-alone candidates
2. Manipulating the KP allocation system
3. Type 2 recipient outcomes
4. Removing the insulin requirement

Figure 5: Public Comment Themes



Below is a review of each public comment theme.

1. *Impact on kidney-alone candidates*

The Kidney Committee, MAC, and several regions expressed concern that removing the restriction for C-peptide > 2, high BMI candidates could lead to an increase in Type 2 SPK transplants that decreases the number of offers to local kidney-alone candidates. In particular, concern was expressed about the potential impact on pediatric candidates and kidney-alone candidates with an EPTS < 20. If Type 2 high BMI KP candidates receive more kidney offers, healthier kidney-alone candidates may wait longer for a transplant. Given the large Type 2 diabetic population, several commenters suggested raising the maximum BMI instead of eliminating it, then monitoring the impact of this change before removing the maximum altogether. Some commenters felt that eliminating the maximum BMI was too drastic given the potential impact on the kidney-alone population.

Committee Response:

The Committee carefully considered the potential impact on the kidney-alone population by looking at the number of Type 2 high BMI candidates that were transplanted before the waiting time criterion restricting their access was put into place in 2014. On average, there

were less than 9 transplants each year of Type 2 SPK recipients with BMIs > 30.8 After public comment, the Committee requested data on the distribution of BMIs for both Type 1 and Type 2 SPK recipients in the pre-PAS era (Figure 6).

Figure 6: Adult KP Recipient BMI at Listing, 2004-2014

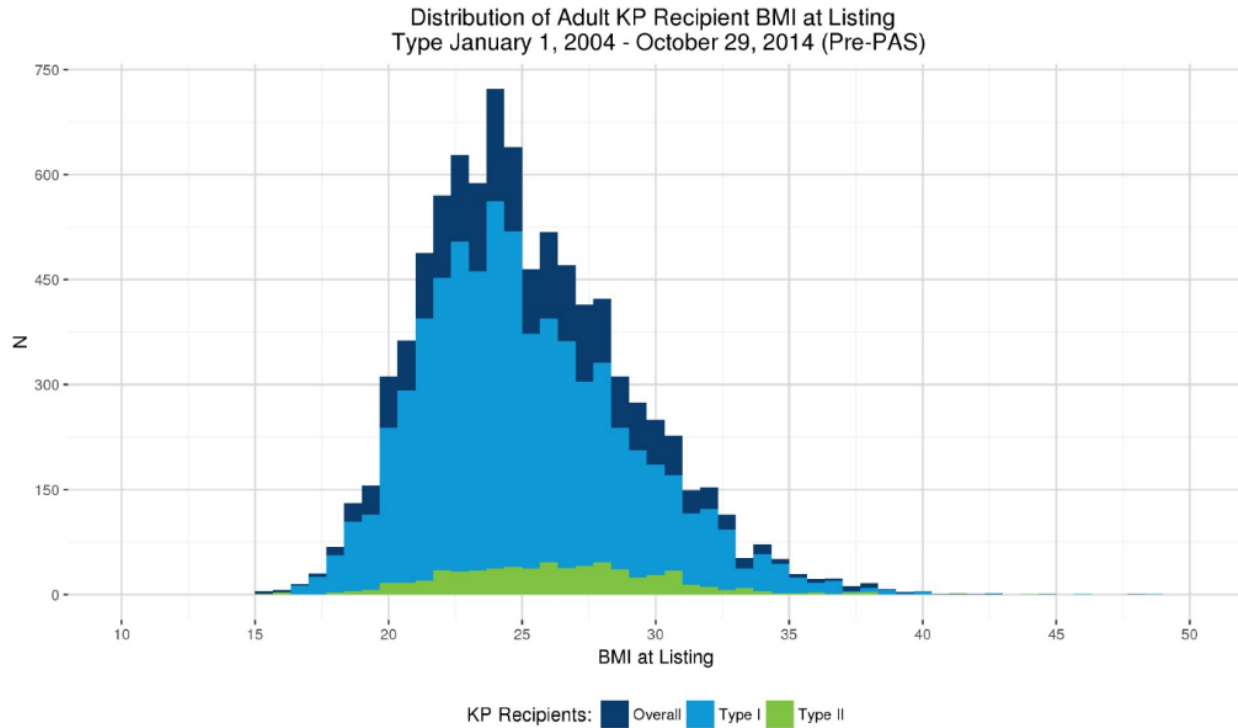


Figure 6 shows that the Type 2 transplanted SPK population is not significantly different than the distribution of the Type 1 transplanted SPK population from 2004 to 2014. The graph shows that there were very few Type 2 diabetic patients transplanted who had a BMI > 30 before there were any restrictions on waiting time accrual. The graph also shows, however, that there are many more high BMI Type 1 patients getting SPK transplants than Type 2 patients getting SPKs at all. This highlights that most high BMI candidates can get transplanted without any restriction on their waiting time, and the low number of high BMI Type 2 candidates getting transplanted pre-PAS supports the Committee's position that the change to KP waiting time is unlikely to have a significant impact on kidney-alone populations.

The Committee also considered that the proposed solution to eliminate the BMI restriction received the support of 8 of 11 regions, all organizations that considered the proposal (AST, ASTS, NATCO, IPITA, ASHI), and two of three OPTN/UNOS committees. The Committee agreed that the few Type 2 high BMI SPK candidates should be able to accrue waiting time if considered suitable for transplant by their programs. In response to the concerns that were raised, the Committee supports monitoring kidney-alone post-transplant outcomes for patient and graft survival, as well as pre vs. post-policy trends in organ offers to pediatric kidney-alone candidates as part of the implementation of this proposal.

⁸ Ibid.

2. *Concern about manipulating the KP allocation system*

Some commenters expressed concern that programs could manipulate the KP transplant allocation system by accepting a KP for a Type 2 high BMI KP candidate, decline the pancreas but keep the kidney and transplant it into the candidate. Kidney-alone candidates have longer waiting times, so Type 2 high BMI candidates on the kidney waiting list could be listed for a KP to get a kidney sooner.

Committee Response:

The Committee carefully considered this concern and has requested data to examine whether this type of manipulation may occur. However, the method of KP and kidney allocation indicates that this behavior is extremely unlikely. If a program accepts a KP for a candidate, then discovers the pancreas is not viable for transplant, the program must alert the OPO. The OPO decides whether the kidney stays at the center or not. Depending on the cold ischemia time, the OPO may ask that the program send the kidney back. If the cold ischemia time is too long such that additional travel would make the organ unviable, the OPO may accept the program transplanting it into the original candidate. Thus, the program risks damaging its relationship with its local OPO if it repeatedly accepts a kidney-pancreas only to reject the pancreas very late in the process. Also, a program attempting to game the system does not get to decide what to do with the kidney; it is up to the host OPO to further allocate the organ according to Policy 5.9 Released Organs.

There is no evidence the Committee is aware of indicating this type of manipulation occurs now. The Committee will examine many programs actually transplant just the kidney after accepting both the kidney and pancreas to see how widespread the opportunity for gaming is. However, the Committee recognizes and affirms that KP programs often have legitimate clinical reasons for determining a pancreas is not viable upon examination. Therefore, data indicating that programs sometimes reject the pancreas is in itself not evidence of gaming. The Committee looks forward to sharing the analysis currently being performed with the Board once it is completed in May.

The risk incurred by the program by this type of behavior, in potentially damaging its relationship with its local OPO, other transplant programs, the OPTN and the broader transplant community, indicates this behavior is unlikely to occur. However, the Committee considered these concerns in its decision to reinstate insulin usage as a requirement for KP waiting time criteria. See Public Comment Theme 3 – Require insulin usage – for further discussion.

3. *Type 2 recipient outcomes*

Although the Committee identified substantial evidence indicating that Type 2 recipients with higher BMIs can have similarly positive outcomes to other SPK recipients, certain commenters still felt concern that transplanting organs in Type 2 high BMI candidates would not be the best utilization of the organs.

Committee Response:

The Committee reviewed substantial literature and performed data analyses to determine whether Type 2 outcomes or high BMI outcomes suffer compared to other SPK recipients. Figures 2 and 3 in this proposal indicate that Type 2 candidates with a BMI above 30 can have comparable kidney and pancreas graft outcomes. The Committee acknowledges that a candidate's BMI is certainly a factor in determining whether the transplant would be successful, but this is true for candidates with C-peptide < 2 as well. Many factors affect

whether a candidate would be appropriate for transplant, including BMI, but BMI does not serve as an absolute contraindication for transplant. Factors such as age can be a more significant factor than BMI for predicting technical failures,⁹ yet KP waiting time provides no restriction on age to accrue waiting time (nor would that be appropriate).

In addition, implementation of the pancreas graft failure definition on February 28, 2018 will ensure that programs are reviewed on their pancreas graft outcomes going forward.¹⁰ This serves as a disincentive for programs to transplant candidates that may be clinically more susceptible to post-transplant complications or poor graft outcomes.

4. *Require insulin usage*

Certain reviewers of the KP waiting time proposal questioned the public comment proposal's change to remove the requirement for a candidate to be on insulin in order to accrue waiting time. For these commenters, being on insulin represented a baseline requirement for a candidate receiving KP offers, and should be reinstated in the waiting time criteria.

Committee Response:

The Committee originally considered whether to remove the insulin usage requirement before public comment, and concluded it was appropriate to remove it because certain candidates may not currently be on insulin but still require a KP transplant. These cases are rare but do occur.¹¹ Post-public comment, however, the Committee considered adding insulin usage back in as a requirement for KP waiting time. The Committee acknowledged the concerns about having candidates not on insulin accruing waiting time. The Committee also recognized that adding insulin usage to the KP waiting time criteria may address concerns with manipulation as well.

Public comment themes included concerns about removing insulin usage as a requirement and concerns about manipulating the allocation system. If the Committee reinstated insulin as a requirement in the KP waiting time criteria, it would be responding to both of these themes. Demonstrating that candidates are on insulin would provide evidence that the candidate does indeed need the pancreas as well as the kidney, lessening fears of manipulation. Including this criteria increases the evidence that the patient needs an SPK transplant. The Committee agreed that adding insulin back in as a requirement for KP waiting time accrual would be appropriate.

Modifications Considered

Change Table 11-1

In addition to the original proposal to remove the 3rd KP waiting time criterion, the Committee considered modifying the table in policy to change the percent of active KP candidate. See Figure 7 for the table:

⁹ Laftavi, 2017.

¹⁰ OPTN/UNOS, Proposal for the Definition of Pancreas Graft Failure, 2014.

¹¹ Curry, 2016.

Figure 7: Table 11-1

Table 11-1: Maximum Allowable BMI

If the percent of active kidney-pancreas candidates that meet criterion 3.b:	Then the OPTN Contractor will:
Is greater than 15% nationally	Reduce the maximum allowable BMI by 2 kg/m ²
Is less than 10% nationally	Increase the maximum allowable BMI by 2 kg/m ²

The Committee discussed increasing the percentage of active KP candidates that can meet criterion 3.b (on insulin and having a C-peptide level > 2 but a BMI < 30) before the maximum allowable BMI is reduced. However, no Committee members supported keeping the adjustable BMI and modifying the table to change the percentage of KP candidates that meet the criteria. This option was considered confusing and perpetuating a complicated and non-transparent policy.

Fixed BMI

Some commenters felt that a more cautious approach would be to gradually raise the maximum BMI instead of removing the requirement altogether. The Committee considered raising the maximum allowable BMI instead of eliminating it before sending the proposal out for public comment in January. The Committee decided against this option since it would have less of an impact and would still leave in place a policy that, in the Committee's opinion, was arbitrary and unfair by allowing Type 1 and not Type 2 high BMI candidates to accrue waiting time.

After public comment, the Committee reconsidered modifying the maximum allowable BMI instead of eliminating it altogether. In particular, the Committee considered making the BMI a fixed number. Currently, the BMI may fluctuate every 6 months depending on the percentage of active KP candidates that have C-peptide levels > 2 and BMI below or equal to the maximum according to *Policy 11.3.B Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old*. The Committee discussed how this system is very confusing for the community in that members of the community may not know what the current BMI is, since policy does not specify the value. There could be scenarios where eligible candidates may not realize they are able to accrue waiting time, and their programs do not list them for a KP transplant.

The Committee felt a fixed BMI would be an improvement on the current system, in which the BMI can fluctuate and programs may not know what constitutes current eligibility for high C-peptide candidates. However, a significant portion of the Committee agreed that a fixed BMI would not adequately address the issues identified by the Committee of inequity and fairness. Raising the maximum BMI to a fixed number would leave an unfair restriction on waiting time accrual for certain candidates, a restriction that is not based on scientific consensus or equity considerations. As Figure 6 shows, the number of high BMI Type 1 recipients greatly outnumbered high BMI Type 2 recipients from 2004 to 2014.

After careful review and discussion, the Committee agreed that a BMI restriction on Type 2 candidates accruing waiting time would be inappropriate to include in policy.

Reinstate Insulin Requirement

The Committee acknowledged the concerns expressed during public comment regarding candidates not on insulin accruing waiting time. Most Committee members supported at least having a history of insulin use as a requirement in the KP waiting time criteria. However, doing so might mean modification to TIEDI® forms, which often requires additional administrative steps prior to implementation. In a straw poll to assess support for either keeping or removing the insulin requirement, a large majority of Committee members supported keeping the requirement as a helpful compromise that may address several concerns raised in the public comment themes.

Post-Public Comment Changes

Given the near-unanimous support for adding back in the insulin requirement, the Committee discussed two main options for modifying the KP waiting time criteria:

1. Require insulin but remove the BMI requirement and references to the maximum BMI. This alternative is identical to the original proposal except it puts insulin usage back as a requirement for KP waiting time accrual.
2. Require insulin and change the BMI requirement so candidates with C-peptide levels > 2 would have to meet a fixed BMI threshold. The BMI would no longer fluctuate, and all candidates with C-peptide levels > 2 would have to meet this BMI requirement.

Ultimately, Committee members unanimously agreed to send option 1 to the Board. Committee members agreed that it would be appropriate to require KP candidates to be on insulin in order to accrue waiting time, since this would demonstrate the candidate's need for a pancreas transplant and lessen any perception of manipulation of the KP allocation system by programs that wanted the kidney but not the pancreas. Committee members felt that any number chosen for the fixed BMI threshold would still be arbitrary, and agreed that it was inappropriate to require a certain BMI just for candidates with C-peptide levels > 2. This alternative is closest to the solution that went out for public comment, which received support from all of the organizations that reviewed it, as well as 8 of 11 regions.

This proposal was approved during the June 2018 OPTN/UNOS Board of Directors meeting.

Effective date: Pending programming and notice to OPTN members