MEETING SUMMARY
Region 1 Meeting
March 6, 2017

The UNOS Region 1 meeting was held on March 6, 2017 in Worcester, MA. Dr. Heung Bae Kim, Region 1 Councillor, convened the meeting and welcomed those in attendance. There were 86 individuals in attendance representing 89 percent of institutional voting members.

Regional Discussion Session

- Alex Glazier, from New England Donor Services, presented an updated on the affiliation between the LifeChoice and New England Organ Bank OPOs.
- Matt Moss, from New England Donor Services, presented information about the UNOS Pilot on Direct EMR Donor Referrals.
- Drs. Melissa Yeung and Indira Guleria, from Brigham & Women's Hospital, led a discussion about HLA protocols in Region 1. The session included a review of protocols for virtual versus physical crossmatching and A2/A2B to B kidney eligibility. A robust discussion was held, in particular, regarding logistics of physical crossmatching (when to request it, when not to request it, and what the OPOs responsibilities are).
- Brian Shepard presented information about UNOS Labs.

OPTN/UNOS Update

Stuart Sweet, MD, OPTN/UNOS President, provided the OPTN/UNOS Update which included the following information:

- More than 33,600 US organ transplants in 2016
    - This is a new record
    - 20% increase in transplants over 5 years
- COIIN
    - Update on initial cohort
    - Overview of two-year timeline
- Expediting the offer process: utility v. choice
    - To what extent is the community willing to limit our range of choices on individual organ offers in order to prevent discards and increase the number of transplants?
    - Preview of OPO Committee proposal: Improving the Efficiency of Organ Allocation
- Liver Distribution Update
    - Key stakeholders with diverse viewpoints gathered at a meeting in Miami to discuss principles related to geographic disparity and liver distribution
    - How the Committee will use new supply/demand metrics to generate heat maps and determine geographic variability by DSA/region
    - Liver Distribution options under consideration by the Committee for fall 2017 public comment
    - Liver Committee Work Plan: Enhancing Liver Distribution, NLRB, HCC
- 2017 Board of Directors Election
    - 2017 OPTN/UNOS President: Yolanda Becker, MD, University of Chicago Medical Center
    - Vice President/President-Elect: Sue Dunn, RN, BSN, MBA, Donor Alliance, Inc.
- Call for nominations: 2018-2019 Board of Directors
    - Goals for 2018-2019 Board: improve diversity for a better overall balance in skill sets and professions, minority and gender representation, and patient/donor backgrounds

    - Positions Open on 2018-2019 Board
- UNOS Labs: bringing behavioral science to the matching system
    - Mock Offer Simulation System: pursuing a “near real-world” offer decision-making environment
    - Recruiting participants to contribute to the study by responding to mock organ offers
- UNet Data Portal: Available Visualizations and Reports
    - Overview of monthly reports available to members
    - Report of Organ Offers (ROO) updated weekly and available in Tableau and Excel
    - Other available reports in “My Data Files”: ABO Validation and Outcomes of Transplanted Organs
    - New reports coming soon: data submission compliance (CMS and OPTN), US waiting list by zip code of residence, donors recovered with fields included in SRTR OPO reports
- New UNOS Benchmark Report
    - Benchmark reports are organ-specific
- UNOS Data and Quality services
    - Customized dashboards for OPOs and transplant centers
    - Market impact analyses for institutions considering organizational changes
    - Customized min-primers, data boot camp trainings, international consulting/training seminars
    - Data coordinating contracts for clinical trials
    - Registry development/management for regional/national collaboratives
    - Consulting opportunities
- 2016 Financial Results
    - 2016 OPTN Expenses
    - Registration fees provided 88.5% of funding
    - Federal appropriations provided 11.5% of funding
- FY 2017 finances
    - Registration Fee Increase as of October 1, 2016 from $957 to $979

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

Rewrite of Article II: Board of Directors (Executive Committee)
The OPTN/UNOS Executive Committee is currently reviewing the structure and recruitment process for the OPTN/UNOS Board of Directors. As part of that review, the Executive Committee has identified improvements that are needed in the Bylaws governing the structure and operations of the Board of
Directors, the Executive Committee, and the Nominating Committee. The goal of this proposal is to improve transparency about the process for nominating and electing the Board of Directors, filling Director vacancies, and removing voting Directors. The majority of the changes in the proposal seek to better organize and add clarity to Article II: Board of Directors and move current sections within the Article to sections more appropriate for the topic.
Region 1 Vote – 10 yes, 0 no, 2 abstentions
This proposal was approved during the June 2017 OPTN/UNOS Board of Directors meeting.
Effective date: September 1, 2017

Histocompatibility Laboratory Bylaws and Policies Guidance Document (Histocompatibility Committee)
The OPTN/UNOS Histocompatibility Committee created this guidance document in order to provide additional information or clarification for the OPTN/UNOS bylaws and policies. This guidance document is designed to assist OPTN Members with interpreting the bylaws and policies governing histocompatibility laboratories and histocompatibility testing of donors and candidates.
This guidance document is intended only to provide guidance for labs on certain aspects of histocompatibility testing and written agreements. The guidance given for testing is not intended to overrule the clinical needs of a patient. Additionally, the scope and content of written agreements should reflect collaboration between laboratories and transplant programs, taking into consideration their needs and laboratory best practices.

This project was developed during the histocompatibility bylaws and policies rewrite. During that time the committee decided that several sections of bylaws and policies were better suited as a guidance document. In total, 28 sections of policy fell into this category. The committee reviewed those sections, and decided to omit certain sections that referenced out of date components of histocompatibility testing, or because they related to testing standards better governed by lab accrediting agencies like ASHI or CAP.
Region 1 Vote – 10 yes, 0 no, 2 abstentions
This guidance document was approved during the June 2017 OPTN/UNOS Board of Directors meeting.
Effective date: June 6, 2017
The guidance document is available on the OPTN website: https://optn.transplant.hrsa.gov/resources/guidance/policy-and-bylaws-guidance-for-labs/

Discussion Agenda

Liver and Intestinal Organ Transplantation Committee

National Liver Review Board (Policy and Exception Score Assignments)
When the calculated MELD or PELD score does not reflect a liver candidate's disease severity, the transplant program may request an exception score. Currently there is not a national system that provides equitable access to transplant for liver candidates whose calculated MELD or PELD score does not accurately reflect the severity of their disease. Instead, each region has its own review board that evaluates exception requests submitted by the liver transplant programs in its region. Most regions have adopted independent criteria used to request and approve exceptions, commonly referred to as “regional agreements.” Some have theorized that regional agreements may contribute to regional differences in exception submission and award practices, even among regions with similar organ availability and candidate demographics. In November 2013, the OPTN/UNOS Board of Directors charged the Liver and Intestinal Organ Transplantation Committee with developing a conceptual plan and timeline for the implementation of a National Liver Review Board (NLRB). In January 2016, the Liver Committee distributed the proposed structure of the NLRB for public comment. This proposal includes refinements to the structure, plus the proposed manner of assigning exception points to candidates based on their diagnosis.
Region 1 Vote – 7 yes, 2 no, 7 abstentions
Region 1 Comments:
The region supports the structure and points proposal for the National Liver Review Board, but had the following comments and concerns.

• Concern was raised over the prospect of centers not volunteering staff to participate on the review boards. This system relies on volunteer participation, and cannot be successful without buy-in from most centers. Some feel that participation should be mandatory.

• Along these lines, the region generally opposes what is perceived as "punishment" for review board participants who do not complete cases in a seven day timeframe. The committee must encourage volunteerism in this system, and the language in the proposal concerning individuals and programs being suspended/terminated from participating on the review board is not productive and opposes the review board's reliance on volunteer participation. The committee should consider language that is less punitive.

• The proposal lacks clarity on the randomization of assigning cases; will reviewers be assigned cases from their own DSA? Their own region?

• There was discussion about the six month re-calculation of MMaT, and whether the proposal's plan is appropriate to allow candidates to retain a higher score until their extension, in the event that the MMaT decreases. Some noted that this could disadvantage patients with exceptions that come in new under an adjusted, lower MMaT in comparison with candidates with existing exception scores that haven't been adjusted down. However, the region was unable to reach consensus on this concern. Similar concerns were raised regarding the grandfathering of existing score exceptions at the time of the policy's implementation, that patients with standing exceptions may be advantaged over patients with scores under the new system that have the same condition but could have lower scores. Again, consensus about the region's level of concern could not be reached.

Committee Response:

In response to public comment feedback, the Committee made changes to the originally proposed policy changes, and voted (9-approve, 4-oppose, 0-abstentions) to send the modified proposal to the OPTN/UNOS Board of Directors for consideration during its June 2017 meeting.

Post-public Comment Changes

180 day update to exception scores

In the public comment proposal, the policy stated that at each 180 day update, if the re-calculated median MELD at transplant (MMaT) increased, candidates with existing standardized scores would be assigned the increased score to match the re-calculated MMat. However, if the MMaT decreased at the 180 day update, candidates with existing standardized scores would not be assigned the new re-calculated MMaT until the candidate was due for an extension. The Committee's reasoning for this policy was that they didn't want a candidate's exception MELD score to change in a matter of days. For example, a candidate could be provided a MMaT exception score the day prior to the 180 day update, and following the update, have a different MELD exception score. Shortly, after voting on this policy, the Committee identified an issue with their reasoning.

The problem with the policy as proposed in public comment, relates to the scenario of candidates with similar clinical characteristics having different MELD exception scores depending on their timing around the 180 day update. For example, if a candidate received a MELD exception score of 28 based on the MMaT 1 day prior to the 180 day update, and at the update the MMaT fell to 27, this candidate would retain their MELD exception score of 28 for 89 days (until the time of their next extension). So in this scenario, a candidate provided a MELD exception score a day after the 180 day update would be

disadvantaged although they could have similar clinical characteristics and the only difference would be their timing around the 6 month update. The Committee agreed that the only equitable policy regarding the 180 day update was that all candidates with existing standardized score exceptions will be assigned a score to match the re-calculated MMaT.

Based on this conclusion, the Committee presented this change during the regional meetings and asked the community to provide feedback. In the regions that supported the proposal, there was support from the community that all existing MELD exception candidates would receive the re-calculated MMaT exception score at the 180 day update. The post-public comment modification to the policy language reflects this sentiment of the Committee and regions.

Exclusion of nationally shared livers from the MMaT calculation

During public comment, a region voted an amendment stating the MMaT calculation should not include transplants resulting from national allocations. The idea behind this amendment is that nationally shared livers are often utilized in low-MELD candidates. Therefore, the use of nationally shared livers in low-MELD candidates will lower the MMaT in the DSA. In a scenario where one center in a DSA is aggressive in this practice, the MMaT score for exception candidates in the DSA will be effected by these transplants, even if other centers do not transplant nationally shared livers at the same rate. The region commented that the resulting effect on the MMaT score for exception candidates in the DSA may discourage the use of nationally shared livers.

During the Committee's discussion of this comment, the Committee strongly agreed they did not want to propose a policy that would discourage utilization of nationally shared livers. The majority of the Committee questioned whether excluding these transplants would have an impact on the MMaT in the DSAs, due to the lower percentage of nationally shared transplants compared to local and regionally allocated livers. Regardless, the Committee agreed to exclude transplants resulting from nationally shared livers in the MMaT calculation. Subsequent analysis performed by UNOS showed that 10 out of 52 DSAs experienced a change in their MMaT by excluding nationally shared livers. The amount of change ranged from -0.5 to +2.5.

Removal of language referencing prior scoring

During public comment the Committee identified existing policy language that referenced HCC exception candidates receiving a MELD or PELD equivalent to a 10 percentage point increase in the candidate's mortality risk every three months. This is policy language that will be removed with the adoption of the proposed change to a fixed score based on the MMaT in the candidate's DSA.

This proposal was approved during the June 2017 OPTN/UNOS Board of Directors meeting.
Effective date: Pending programming and notice to OPTN members

Liver Review Board: Guidance Documents

Medical urgency for liver allocation is determined either by the MELD or PELD score, or by the assignment of a status (1A or 1B). The scores and statuses are intended to reflect the candidate's disease severity, or the risk of 3-month mortality without access to liver transplant. However, for some the risk of death without access to liver transplant or the complications of the liver disease are not accurately predicted by the statuses or the MELD or PELD score. In these instances, the liver transplant program may request exceptions.

Most OPTN/UNOS regions have adopted independent criteria used to request and approve exceptions, commonly referred to as "regional agreements." These regional agreements may contribute to regional differences in exception submission and award practices, even among regions with similar organ availability and candidate demographics.

The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee (hereafter, the Committee) is pursuing the establishment of a National Liver Review Board (NLRB) to promote consistent, evidence-based review of exception requests. In support of this project, the Committee has developed guidance for specific clinical situations for use by the NLRB to evaluate common exceptional case requests for adult candidates, pediatric candidates, and candidates with hepatocellular carcinoma (HCC). This supplements existing national guidance and replaces the regional agreements. Review board members and transplant centers should consult this resource when considering submitting exception requests.

Region 1 Vote – 7 yes, 1 no, 7 abstentions

This guidance document was approved during the June 2017 OPTN/UNOS Board of Directors meeting.

The guidance document is available on the OPTN website:
https://optn.transplant.hrsa.gov/resources/guidance/liver-review-board-guidance/

Kidney Transplantation Committee

Improving Allocation of En Bloc Kidneys

Kidney transplantation is the preferred treatment for end stage renal disease (ESRD), yet demand far exceeds supply. There are currently 99,158 candidates waiting for a kidney transplant, but only 15,631 kidney transplants have occurred to date. One strategy to increasing the donor pool is transplanting both kidneys, including the vena cava and aorta, from a very small pediatric donor en bloc into a single recipient. However, there are several challenges to allocating en bloc kidneys:

- There is currently no OPTN policy regarding how to allocate en bloc kidneys
- Candidates are currently screened off match runs for en bloc kidneys as the KDPI implemented does not incorporate transplant type (single vs. en bloc)

This is the Kidney Committee's first attempt to address these issues.

Region 1 Vote – 8 yes, 5 no, 3 abstentions

Region 1 Comments:

Support for this proposal is largely split in Region 1, although a majority of members do support it. The region voiced the following comments and concerns.

• The region strongly supports an exception to OPTN/UNOS policy 5.9 (Released Organs) in the case of split en bloc kidneys. The importing transplant center should be permitted to "back up" the second kidney at their own center, rather than release it to the host OPO. This would prevent unnecessary and significant cold time from accruing on an organ that will already be difficult to place. One member noted – and others agreed – that small kidneys such as these cannot be pumped. Typically, pumping an organ is practiced to mitigate substantial cold time. Without this option, it is particularly critical for these kidneys to be transplanted as quickly as possible, and this will be jeopardized by releasing them.

• It was additionally noted that requiring one kidney of a split en bloc to be released might create disincentive to split. If centers are not permitted to keep both kidneys, they might well choose to transplant an en bloc they would otherwise split due to the concern of a split second kidney

being lost to cold time. This behavior would only serve to decrease the number of transplants, which would be in contradiction of the proposal's goal.

• There was much discussion concerning the 15 kg threshold for mandatory en bloc allocation. Some members feel that this cutoff is far too high, and that a large proportion of kidneys in the 7 kg – 15 kg range are suitable to be split. However, other members noted that 15 kg is already closer to a standard reference point for some OPOs when determining how to allocate small kidneys, and that transplant centers will still have the option to split kidneys under the proposed policy. The general feeling is that the mandatory cutoff could realistically be anywhere from 10-15 kg, but there is no consensus in the region as to what the exact figure should be.

• There is no consensus in the region regarding what the discretionary range for optional en bloc allocation should be (the proposal suggests 15 kg – 25 kg), or whether there should be a discretionary range at all.

• Members discussed whether weight is the most appropriate indicator of kidney function, and whether it should serve as the mechanism for determining whether a kidney is allocated en bloc or not. One member suggested that height would be a more accurate marker. However, others deferred to the committee's rationale for selecting weight over other criteria. The consensus in Region 1 is that weight should remain the mechanism for determining allocation.

• One member suggests allocating en bloc kidneys according to OPTN/UNOS policy 8.5.H (donors with KDPI scores greater than 20% but less than 35%). This, however, is not a consensus of the region.

• The region feels that there should be risk adjustment for en bloc kidney transplants in the same way that high KDPI kidney transplants will now be excluded from outcomes monitoring. Transplanting en bloc kidneys is a challenging procedure with its own set of unique risks, and UNOS needs to encourage more transplant centers to broaden their practice to include en bloc transplants. Risk aversion to en bloc kidneys is still very much a problem, and if this proposal aims to increase the number of these types of transplants, then UNOS needs to also consider ways to encourage more centers to perform them.

Committee Response:

This proposal represents the work of a diverse group of kidney transplant professionals, including representatives from both high-volume and low-volume en bloc kidney programs, OPO staff, pediatric specialists and transplant program administrative personnel. The response to the proposal was generally favorable, with various recommendations suggested. Table 4 summarizes the diversity of respondents and the overall level of support. Eight regions, two Committees, two individuals and all societies supported a majority of the proposal. Three regions opposed the proposal and six Committees were neutral:

Table 4: Public Comment Overview

Regions	Committees	Societies	Individuals
	Minority Affairs	AST	

Regions	Committees	Societies	Individuals
8 Approved	Pediatric		2
	OPO	ASTS	
	Transplant administrators		
3 Opposed	Transplant coordinators	AOPO	
	Operations & Safety		
	MPSC	NATCO	
	Patient Affairs	ANNA	

The proposal garnered 26 comments. The Committee requested specific feedback from the community regarding whether the weight threshold for mandatory en bloc kidney allocation should be increased (from less than 15 kg to 20 kg, 25 kg or other) and the option for OPOs to allocate kidneys from donors 15 to 25 kg as singles or en bloc be removed. Consequently, this feedback, among other suggestions, 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 or sub-theme.

<u>Releasing second kidney from a split en bloc unit according to Policy 5.9 Released Organs</u>

Concern regarding releasing the second kidney split from an en bloc unit (hereafter, referred to as the "second kidney") back to the OPO for reallocation was one of the most prolific themes, and several sub-themes were identified. The community strongly suggested the Committee consider allowing the receiving center to keep the second kidney, or at least keep it within the DSA or region. The community was very concerned the second kidney would be vulnerable to increased cold ischemic time and at high risk of being discarded. The Committee also heard that programs will be disincentivized to split the en bloc unit if they have to release the second kidney back to the pool. There were a few comments that the Committee should consider adding a timeframe for OPO's attempting to allocate the second kidney; if it couldn't be re-allocated within that designated timeframe, it could be released back to the original receiving center. Two regions questioned whether it was appropriate to include special consent for these kidneys or require programs to comply with Policy 5.3.C Informed Consent for Kidneys Based on KDPI Greater than 85%, as some, not all, reflect a KDPI score of 85 or greater. There were also a few concerns that this provision could lead to gaming, meaning a receiving center could start accepting a lot of en bloc units knowing that it is permissible to split the unit. Members noted that a center was unlikely to accept a kidney split by another center, making that kidney difficult to place. Finally, there were

several comments supporting the proposal as written (to release the second kidney according to Policy 5.9 Released Organs).

The workgroup discussed this feedback at length. They reviewed options to keep the requirement, eliminate the provision, or consider modeling language after Policy 9.8.A Open Variance for Segmental Liver Transplantation. Modeling language after Policy 9.8.A is not ideal because it lacks transparency; making such a change would be a significant modification post-public comment. Therefore, workgroup members felt this was not a fair option. They also quickly dismissed eliminating the requirement. In 2016, the OPTN/UNOS Board of Directors approved changes that aligned several conflicting kidney allocation policies that addressed what to do with a kidney that could not be transplanted into the originally intended recipient. These changes made Policy 5.9: Released Organs the prevailing policy. This policy not only applies to kidneys, but all organs. Eliminating the requirement from the proposed en bloc language would introduce inconsistency those policy changes aimed to correct. Although the community did not favor this provision, both the workgroup and Committee were comfortable with it. Ultimately, they opted to leave this requirement unchanged. The workgroup agreed with UNOS' belief that this is the most fair, transparent option to allocation. Writing more prescriptive policy language would likely look very similar to the effect of Policy 5.9. Finally, keeping this provision maintains consistency throughout policy with regard to how to handle situations in which a deceased donor organ cannot be transplanted into the original recipient.

One of the challenges the workgroup acknowledged was the lack of data to help mitigate concerns for keeping this requirement. The OPTN cannot track the instances an en bloc unit is split, nor discards given the current limitations of the system that programming would address if this policy is approved The Committee will ensure that appropriate metrics are included in the monitoring plan to capture how many en bloc units are split, as well as the number of discards (of en blocs or the second kidney) so that if over time it looks like something should be changed, the Committee will have data to support those changes.

<u>Weight threshold for mandatory en bloc kidney allocation</u>

The community largely concurred with the Committee's proposed weight threshold of less than 15 kg for mandatory en bloc kidney allocation. However, there was some variation across regions. Some regions suggested raising the weight threshold from 15 kg to 20 kg. One region even suggested raising the threshold to 25 kg. These regions cited OPTN data showing that there are kidneys being transplanted en bloc from donors as high as 25 kg, and even higher. Other regions felt the threshold should be decreased to less than 10 kg, or within the range of 10 to 15 kg. These commentators felt decreasing the weight threshold was appropriate for two reasons: first, their recommendations reflected their current center practice. Some programs are comfortable splitting en bloc units from donors as small as 10 kg (or even less) and with acceptable outcomes. Second, these members were concerned that mandating allocation of en bloc kidneys from donors of higher weights could reduce an opportunity to implant as singles. In addition, one Committee felt that increasing the weight range would slow down allocation: by increasing the threshold, more programs may opt in to receive offers, but only ever intend to accept kidneys from the larger donors. More people opting in equals less

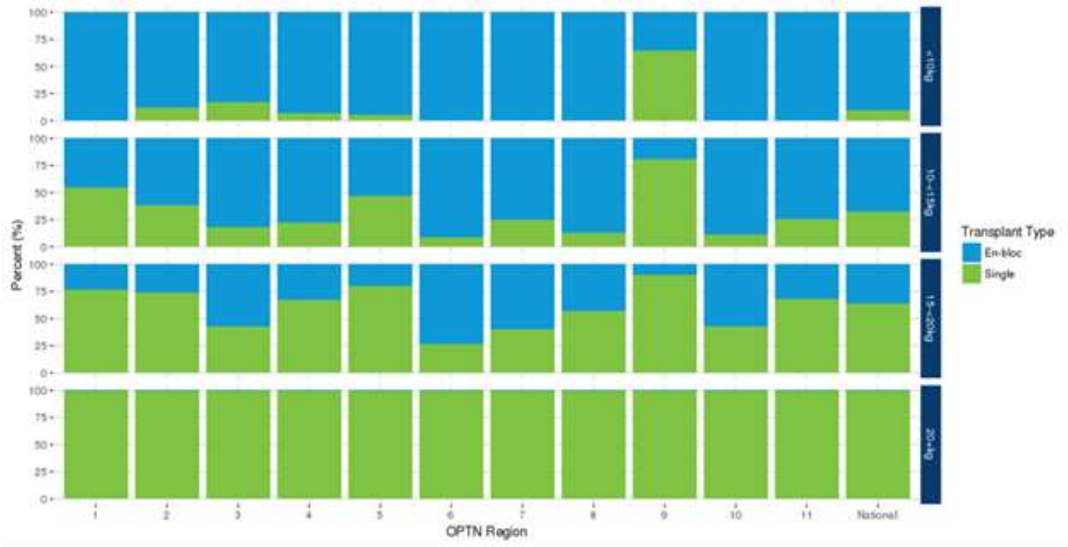
effective facilitated placement because the OPO has to go through a longer list. Finally, increasing the weight threshold may increase the instances of splitting kidneys. The provision to reallocate the second kidney from a split en bloc unit was not popular during public comment.

The workgroup deliberated over this feedback. Although there was consensus for the less than 15 kg weight threshold during public comment, some members of the workgroup were concerned that programs transplanting kidneys en bloc from donors greater than or equal to 15 kg would be disadvantaged by the explicit cut-off, especially as the workgroup agreed to eliminate the optional provision for OPOs to allocate kidneys from donors greater than or equal to 15 kg. If the workgroup set the threshold at less than 15 kg, these programs would never see en bloc offers, unless they changed practice.

To assuage these concerns, the workgroup requested more granular data on en bloc transplant counts (versus single kidney transplants) by region and donor weight categories. UNOS provided a descriptive data analyses for deceased donor kidney transplants between 2010-2015 to analyze the number (percent) by kidney transplant type (single vs. en-bloc), donor weight (<10kg, 10-<15kg, 15-<20kg, 20+kg) and OPTN Region.

(See next page)

Figure 6: Percent En bloc by Region and Donor Weight



Source: Wilk, "En-bloc Deceased Donor Kidney Transplants by Region/Center and Donor Weight," 2017.

Data shows that all OPTN regions (except 9), and nationally, had more en bloc versus single deceased donor kidney transplants with donor weights less than 10 kg and at least 10 but less than 15 kg. Across most OPTN regions (7 out of 11), and nationally, a higher percent of transplants were single vs. en bloc for donor weights at least 15 but less than 20 kg. A higher percent of transplants were single vs. en bloc for donor weights greater than or equal to 20 kg for all OPTN regions. Absolute data on number of

potentially discarded or unrecovered kidneys in each of these classifications or potential donor organs in each subgroup is unknown.

This data confirmed the workgroup's concerns. It demonstrates there are several regions that may be disadvantaged by mandating the weight threshold for en bloc kidney allocation be less than 15 kg because they are transplanting kidneys from donors 15 to 20 kg en bloc about 50 percent of the time (one region is doing more en bloc than single transplants with kidneys from donors in that weight range). Furthermore, the Maluf study demonstrates a similar pattern: 28 percent of all en bloc kidney transplants analyzed in that study were procured from donors weighing more than 14 kg. The workgroup wanted to accommodate programs currently doing en bloc transplants with kidneys from donors in the at least 15 but less than 20 kg weight range. It is important to clarify the workgroup's original intent: it was not to increase the number of transplants by forcing programs that currently do no or few en bloc kidney transplants to now perform them. The intent was to facilitate procuring kidneys from an underutilized donor pool and get those kidneys to centers who are comfortable using them, primarily as en blocs, but also as singles.

Therefore, the workgroup opted to raise the weight threshold to less than 20 kg. There is currently no consensus regarding when en bloc kidneys should be split for transplantation into two recipients to maximize utility without compromising graft outcomes; rather it is typically based on the surgeon's discretion. Setting the threshold at 20 kg provides the most flexibility in that it allows the programs who want to transplant kidneys from heavier donors the ability to do so, while allowing programs who are comfortable splitting those kidneys to split. The workgroup acknowledged these are small numbers and conceded that once data is available, the Committee will be able to make changes if warranted.

<u>Recommendation to remove the option to allocate en bloc/single from donors 15 to 25 kg</u>

While not as strong as the two previous themes, there was consensus to eliminate this option. The original intent was to accommodate current practice across the various service areas and not to dictate medical practice. However, both OPOs and transplant programs felt that it did not provide explicit direction to OPOs on how and when to allocated organs from donors in that weight range and could lead to confusion.

It became apparent that once this option was removed, policy provided no explicit direction on how to allocate kidneys greater than or equal to 20 kg. UNOS staff was uncomfortable with this ambiguity and advised the Committee to add clarifying language. The Committee considered two options. The first option was the least flexible, in that it would mandate all kidneys from donors greater than or equal to 20 kg to be allocated individually, according to deceased donor's KDPI in allocation Tables 8-5 through 8-8. This option is explicit and tells OPOs exactly what to do with kidneys from donors greater than or equal to 20 kg, but it does not accommodate a large donor/small kidney situation.

The second option allows for more discretion. The proposed language indicates that if an OPO procures both kidneys from a single deceased donor greater than or equal to 20 kg, they may do any of the following:

- Offer each kidney individually according to the deceased donor's KDPI in revised allocation Tables 8-5 through 8-8
- Offer both kidneys according to Policy 8.6.B: Double Kidney Allocation
- Offer both kidneys en bloc according to Policy 8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%

These are the options OPOs currently have, and this language simply codifies current practice. In essence, this is the status quo. It provides direction, but is not explicit and still puts the OPO in the role of decision-maker. Although the community favored more explicit direction, ultimately the Committee opted for the more flexible option for more difficult to place kidneys.

With these options, it may seem that the weight threshold is somewhat arbitrary. However, this justifies the workgroup's desire to raise the mandatory weight threshold to 20 kg in an effort to accommodate programs transplanting kidneys en bloc from donors at least 15 but less than 20 kg. If the Committee kept the weight threshold at less than 15 kg for mandatory en bloc kidney allocation, OPOs would not be mandated to allocate kidneys from donors at least 15 but less than 20 kg as en bloc to programs who currently accept those organs as en bloc. They would have the option to, but it is not required. This potentially could disadvantage specific patient populations that may benefit from en bloc kidneys from a slightly heavier donor.

Other criteria to drive allocation of en bloc kidneys

The community was predominantly silent regarding the actual criteria that will drive en bloc kidney allocation. However, there were a few suggestions of other criteria that could be used in place of or in addition to donor weight: donor height and kidney size. A single commenter suggested donor height; there was slightly more consensus around kidney size. Although the workgroup had considered kidney size, they chose weight as this donor characteristic is readily available prior to organ recovery and is a significant predictor of organ recovery from small pediatric donors. OPOs also favored this criterion. The Committee considered public comment feedback but ultimately decided to keep donor weight as the determining criterion in allocating kidneys en bloc.

KDPI and risk adjustment

The Committee did not receive many comments regarding their proposal to mask the KDPI score in DonorNet to mitigate the artificially high KDPI scores of en bloc kidneys. A single commenter felt omitting the KDPI takes away predictive information from coordinators and surgeons to consider when evaluating offers, but others from that region agreed that masking the KDPI is an appropriate compromise, as en bloc KDPI scores are too skewed to serve as a meaningful data point. There were two commenters that suggested a risk adjustment for en bloc kidney transplants in the same way that high KDPI kidney transplants will be excluded from outcomes monitoring.

Committee leadership discussed this feedback with SRTR. SRTR advised that in their program specific reports (PSRs), the KDPI equation is used exactly how it is programmed in UNetSM to estimate the risk

of graft failure, i.e. without the en bloc coefficient. Currently, small donor en bloc kidneys reflect a relatively high KDPI score. The higher the KDPI of an organ, the higher its estimated risk of graft failure. However, this may not be an accurate reflection of the true risk for en bloc transplants. Furthermore, the PSRs include "procedure type" as a factor: for example, left kidney, right kidney, double kidney, or en bloc kidney. In the 1-year deceased donor graft survival models as of April 2017, there is no extra risk (or reduction of risk) associated with procedure type, aside from a very small protective effect for using the left kidney. The risk-adjustment model (i.e., outcomes calculations) will not harm or reward programs for completing en bloc transplants because both KDRI and en bloc are included in the model and can capture the potential effect of en bloc on one-year post-transplant outcomes. Committee leadership were satisfied with this explanation and did not have any concerns.

The Board declined to approve this proposal during the June 2017 OPTN/UNOS Board of Directors meeting.

This proposal has been modified and is going out for a second round of public comment in fall 2017.

Concept paper: Improving Allocation of Double Kidneys

Though dual kidney transplantation has been shown to provide a substantial survival advantage over single kidney transplantation, in particular from deceased donors with high KDPI values, currently only about 1% (approximately 100 per year) of kidney transplants are duals, and this low rate has further decreased under KAS. With discard rates for high KDPI kidneys at or above 50%, expanding the prevalence of dual kidney transplantation may be a way to increase the number of kidney transplants by reducing the number of discards.

Current policy and programming in UNet surrounding dual kidney allocation are suboptimal and need revision in order to possibly expand the use of dual kidney transplantation.
For example, some elements of the current policy are ambiguous ("rising creatinine"), and UNet currently does not take into account single vs. dual usage when calculating the KDPI. These policy and programming limitations were not addressed as part of the new KAS that was implemented on December 4, 2014.

This is the Kidney Committee's first attempt at addressing this issue.

No vote

This concept paper has been developed into a proposal and is going out for public comment in fall 2017.