The UNOS Region 8 meeting was held on March 10, 2017 in Kansas City, MO. Dr. Christie Thomas, Region 8 Councillor, convened the meeting and welcomed those in attendance. There were 77 individuals in attendance representing 86 percent of institutional voting members.

**Regional Discussion Session**

- Joanne Oxman, Representative to the Living Donor Committee, led a discussion about living donation. Members discussed challenges in living donation including evaluation and costs for donors that are unable to travel to the recipient's center. Members also suggested best practices and resources, including a Transplant Mentors Program at Gift of Life which can connect potential donors to other actual living donors.

- Jennifer Prinz, OPO Chair, led a discussion about systems optimization. Members were concerned about reducing the time limits from 1 hour to 30 minutes. With regards to functionality, members would like to know the number of centers that have entered a provisional yes for the other candidates ahead of their candidate on the match run. There were also comments about the challenges of transporting organs and missed flights, especially in smaller cities like those in Region 8.

- Christie Thomas, Councillor, presented information on drug overdose. Members were interested in knowing the number of people actually dying from drug overdose to determine if these people were underutilized. Members would like more information and guidance to assess the actual risk to patients which would also help determine whether the potential donor pool was underutilized. There was interest in learning how to extend the viability of the organs of these potential donors. Members also wanted to know the breakdown in type of organs used in Region 8 (e.g. # of hearts, kidneys, etc.)

**OPTN/UNOS Update**

David Klassen, MD, UNOS Chief Medical Officer, 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

- COIN
  - 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
  o 2017 OPTN/UNOS President: Yolanda Becker, MD, University of Chicago Medical Center
  o Vice President/President-Elect: Sue Dunn, RN, BSN, MBA, Donor Alliance, Inc.
• Call for nominations: 2018-2019 Board of Directors
  o 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
  o Positions Open on 2018-2019 Board
• UNOS Labs: bringing behavioral science to the matching system
  o Mock Offer Simulation System: pursuing a “near real-world” offer decision-making environment
  o Recruiting participants to contribute to the study by responding to mock organ offers
• UNet Data Portal: Available Visualizations and Reports
  o Overview of monthly reports available to members
  o Report of Organ Offers (ROO) updated weekly and available in Tableau and Excel
  o Other available reports in “My Data Files”: ABO Validation and Outcomes of Transplanted Organs
  o 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
  o Benchmark reports are organ-specific
• UNOS Data and Quality services
  o Customized dashboards for OPOs and transplant centers
  o Market impact analyses for institutions considering organizational changes
  o Customized min-primers, data boot camp trainings, international consulting/training seminars
  o Data coordinating contracts for clinical trials
  o Registry development/management for regional/national collaboratives
  o Consulting opportunities
• 2016 Financial Results
  o 2016 OPTN Expenses
  o Registration fees provided 88.5% of funding
  o Federal appropriations provided 11.5% of funding
• FY 2017 finances
  o 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 8 Vote – 22 yes, 0 no, 0 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 8 Vote – 22 yes, 0 no, 0 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 8 Vote – 18 yes, 1 no, 2 abstentions**

**Region 8 Comments:**
Members generally supported the proposal, but had the following comments on the proposal:

- If the policy will require NLRB members to vote on requests within 7 days of receipt, members would like the ability to use their mobile devices to review and vote on requests.
- A few members said that reducing exception points by 3 from median meld at transplant (MMaT-3) seems like a minor adjustment that will not level the playing field. They felt that MMaT-5 would be better. However, others felt that MMaT-3 was appropriate and that MMaT-5 might be too big of a shift at this time.
- One member commented that making it more difficult for cancer exceptions will incentivize centers to try alternatives like resection.

**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 +2.5.1

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.

Response to Other Public Comment

The proposal also received additional feedback that did not prompt post-public comment modifications.

Exception scores based on MMaT in the Region versus DSA

The Committee discussed the feedback on the geographic unit used for the MMaT calculation. 3 of the 11 regions opposed the proposal and commented that the MMaT calculation be based on transplants in the Region, not the DSA as proposed in public comment. A concern raised by the use of the DSA for the MMaT calculation is the idea that with the smaller geographical unit, candidates may experience larger fluctuations in their MELD score at every 180 day update. The Committee discussed this concern and acknowledged that it would be ideal to use a larger geographic unit for the MMaT calculation, either the region or perhaps a national MMaT. However, with the current disparities in MMaT across the country, there are several regions with significant variation in MMaT among the region’s DSAs. Because of this, providing a MMaT score based on the region could be viewed as disadvantaging candidates in high MELD DSAs. This is significant because the DSA is the initial unit of liver allocation within each classification in policy, therefore an exception candidate’s MELD score should reflect the environment of their respective DSA.

The majority of regions (7 out of 11) supported the proposal as written, that the MMaT score calculation would be based on the candidate’s DSA. The professional transplant societies, AST, ASTS, and NATCO also issued public comment in support of the proposal as written in public

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1 OPTN/UNOS Descriptive Data Request. Prepared for the OPTN/UNOS Liver & Intestinal Organ Transplantation Committee Conference Call, April 20, 2017.
comment. Based on the majority of support from the community, in addition to the Committee’s initial intent, the Committee voted (9-approve, 4-oppose, 0-abstentions) to send the originally proposed policy basing the MMaT on the DSA, to the OPTN/UNOS Board of Directors for consideration during its June 2017 meeting.

Exception scores based on MMaT by blood type

During the regional meetings, several regions commented that the MMaT exception scores should be blood type specific. This concern is based on the idea that certain blood types may be disadvantaged by providing one score that includes all blood types. The Committee originally considered this idea during the early stages of the project’s development. The concern at that time for the committee was that several DSAs would not have enough yearly transplants for certain blood types to reach statistical significance for a MMaT calculation. The proposed policy states that if there were fewer than 10 transplants in the DSA in the previous year, the MMaT will be calculated for the region where the candidate is registered. By providing a score based on individual blood types, it is likely that candidates in some DSAs would receive the MMaT in the region due to low numbers of transplants in certain blood types.

To address this concern, UNOS staff performed an analysis looking at the MMaT by blood type across the DSAs. The consensus within the Committee after reviewing the data was that there was little variation among blood type within the DSAs and that the variation was not significant enough to change the proposed policy. Based on this rationale, in addition to the broad support from the majority of the regions (7 out of 11) an professional societies (AST, ASTS, and NATCO), the Committee voted (9-approve, 4-oppose, 0-abstentions) to send the originally proposed policy that includes all blood types in the MMaT calculation, to the OPTN/UNOS Board of Directors for consideration during its June 2017 meeting.

Timing of implementation with a future broader sharing proposal

The Committee discussed the relationship between this NLRB proposal and the redistribution project and whether the NLRB proposal, if approved by the Board, should be implemented as soon as it can be programmed, or whether it should wait until a broader sharing proposal is approved. The Committee weighed the benefits of programming the NLRB immediately, which include that this proposal, once implemented, will make access to liver transplants more equitable and standardized nationwide due to the new review board guidelines and standardized manner of assigning exception scores. Additionally, the Committee determined that awaiting the approval of the broader sharing proposal is too risky, as it is unclear how the next proposal will be received in public comment and when it will likely be sent to the Board for approval. Ultimately, the Committee voted to send a resolution to the Board of Directors that the NLRB be implemented pending programming and communication to members. Implementation of the NLRB will not be contingent on the approval and/or implementation of a redistribution proposal.

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

Effective date: Pending programming and notice to OPTN members

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2 OPTN/UNOS Descriptive Data Request, Median Allocation MELD Score at Transplant by DSA within Region and Recipient Blood Type. Prepared for OPTN/UNOS Liver & Intestinal Organ Transplantation Committee Conference Call, April 20, 2017.
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 8 Vote – 19 yes, 0 no, 2 abstentions

Region 8 Comments:
Members generally supported the proposal and offered the following comments on the proposal:

- There was a comment that pediatric candidates with HCC should be awarded exception points similar to pediatric candidates with hepatoblastoma.
- Both adult and pediatric patients with hepatic epithelioid hemangioendothelioma should get exception points.
- Liver transplant candidates with a failed shunt should be added as an exception for Budd Chiari.
- It would be helpful to have the positive and negative values for alpha-fetoprotein levels in candidates provided to the review board members.
- Suggestion to remove hepatopulmonary syndrome because they do not have the same mortality on the waiting list.
- There have been excellent results for treating neuroendocrine tumors and should use this treatment.
- Suggestion to require/request molecular markers for adenomas.

Committee Response:
During the public comment period, the Committee made changes to the originally proposed guidance, and voted (14-Approve, 0-oppose, 0-abstentions) to send the modified proposal to the OPTN/UNOS Board of Directors for consideration during its June 2017 meeting.

HCC Guidance Document

In the public comment proposal, the Committee included guidance regarding contraindications for Hepatocellular Carcinoma (HCC) exception requests. This included language stating that an exception may be appropriate for patients with macro-vascular invasion of branch portal vein, and ruptured HCC. Following public comment, the committee clarified this guidance by specifying primary portal vein branch invasion. The use of “primary” is more in line with appropriate clinical terminology. Within this section of guidance, the Committee also clarified
that patients should remain stable for a prolonged (minimum of 12 months) interval after treatment.

Following a recommendation by the MELD Enhancements and Exceptions Subcommittee, the Committee has added additional guidance regarding the six month delay for HCC candidates that have recurrent tumor following resection. The Committee discussed this topic and ultimately feel that it is appropriate that candidates who presented with T2 HCC, who underwent complete resection and subsequently developed T1 (biopsy proven) tumor recurrence, should be considered for a MELD score exception without a six month delay period. The Committee concluded that candidates that pursue resection in contrast to transplant, and subsequently recur, should be considered for deviation from the normal 6 month delay. This guidance will serve as a resource for NLRB reviewers assigned to the HCC specialty board to use when reviewing cases that meet this clinical situation.

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 8 Vote – 17 yes, 2 no, 1 abstention
Region 8 Comments:
Members generally supported the proposal, but raised concerns about how costs would be charged for en bloc kidneys especially if the kidneys were later split and transplanted into two recipients. Members would like some clarity on how the SAC would be applied. Although some members noted that that it is standard practice for OPOs to charge one SAC for an en bloc when transplanted into one recipient, they would like to refer this matter to AOPO. One member noted that allocating the second kidney from a split kidney will be difficult and suggested changing the policy to allow for the accepting center to keep both kidneys if they are split. This will help minimize cold time and may incentivize splitting for 15-25 kg donors. A member noted that they liked having the option of allocating the 15-25 kg donor kidneys as en bloc or singly because the number of arteries may vary.

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

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<th>Regions</th>
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<th>Societies</th>
<th>Individuals</th>
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<td>8 Approved</td>
<td>Minority Affairs</td>
<td>AST</td>
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<td>Transplant administrators</td>
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<td>3 Opposed</td>
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<td>Operations &amp; Safety</td>
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<td>Patient Affairs</td>
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*American Nephrology Nurses Association

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.

Releasing second kidney from a split en bloc unit according to Policy 5.9 Released Organs

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.

Finally, although there were just two comments regarding requiring informed consent, the workgroup discussed whether Policy 5.3.C should apply to en bloc kidneys. This issue did not come up during the development of the proposal. Although a majority of en bloc kidneys have a KDPI score of 50-85%, there are some that have a score of 85 percent or greater (Table 1). However, as previously mentioned, these scores are inflated, and will be masked to the program upon receiving offers. If a program decides to split an en bloc unit and releases the second kidney to the OPO to re-allocate, the KDPI score will be revealed when a new match is run, allocating the second kidney according to the deceased donor’s KDPI score. If that score is greater than 85 percent, only candidates who have previously consented according to Policy 5.3.C to receive offers for kidneys with a KDPI greater than 85 percent will appear on the new match run. One workgroup member suggested making reference to this within the proposed en bloc policy language, but a majority of the group did not feel strongly about adding this language.

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Weight threshold for mandatory en bloc kidney allocation

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.4

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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.\(^5\) 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.\(^6\) 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

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\(^5\) Maluf, 2704.

acknowledged these are small numbers and conceded that once data is available, the Committee will be able to make changes if warranted.

Recommendation to remove the option to allocate en bloc/single from donors 15 to 25 kg
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. 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.

Financial implications
Finally, there were three comments regarding the financial implications of this proposal. The Transplant Administrators Committee asked if the Committee considered the financial impact to transplant programs. The Committee confirmed it had deliberated this, and acknowledged that facilitated placement might increase travel costs for high volume en bloc transplant programs who felt the need to send their own procurement team to retrieve organs from areas that may lack the surgical expertise for this specific recovery procedure. The OPO representative on the workgroup did not feel the current practice of charging one acquisition fee for en bloc kidneys will change in light of this proposal. This question was put forth to several other OPOs and they confirmed the same. One region pointed out that the allocation of UNOS resources to implement this project is large given the small number of en bloc kidney transplants nationally.

The Committee voted unanimously to approve the en bloc policy as amended and to send to the OPTN Board of Directors in June 2017 for consideration (19-yes, 0-no, 0-abstentions). The Board declined to approve this proposal during the June 2017 OPTN/UNOS Board of Directors meeting. This proposal has been modified and is 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 out for public comment in fall 2017.