

OPTN/UNOS Kidney Transplantation Committee
Meeting Minutes
October 15, 2018
Chicago, IL

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Introduction

The Kidney Transplantation Committee met in Chicago, IL on 10/15/2018 to discuss the following agenda items:

1. Clarifying Maintenance Dialysis Language Update
2. UNOS Research Orientation
3. Pancreas In-Person Meeting KP Update
4. Liver Committee Geography Proposal Update
5. Paused Projects Discussion
6. Geography Allocation System Discussion

The following is a summary of the Committee's discussions.

1. Clarifying Maintenance Dialysis Language Update

The Living Donor Committee has an active project: Clarifying Maintenance Dialysis Language

Summary of Discussion:

The Committee heard an update from the chair of the Living Donor Committee on their project, Clarifying Maintenance Dialysis Language. The goal of the project is to bridge consistent terminology across policies and associated forms while increasing clarity without altering or increasing reporting for centers. The Living Donor Committee's proposal is to simplify the policy language and make it uniform, which will enhance consistent reporting and data collection.

There were a number of questions regarding frequency of dialysis, and patients who are not on dialysis but are low Estimated Glomerular Filtration Rate (eGFR). There was clarification the policy in question is for maintenance dialysis reporting for a living donor, not listing a patient. Committee members agreed with not wanting to add burdens to transplant programs, but also agree the cutoff should not just be dialysis and suggest an eGFR threshold "or" dialysis which would give more granularity into the path of these donors. The Living Donor Committee plans to submit a data request to start looking at the follow up data that has been submitted to understand what is happening among the donor community. The primary goal of the current language change proposal is to clarify the distinction between acute vs. long-term dialysis treatment. If the form itself is to be changed, it will require approval from the Office of Management and Budget (OMB).

The suggestion was also made for the Living Donor Committee to tackle long-term improvements as the current two year reporting structure is tedious and difficult. The limitations of the current structure are recognized and there are projects under the Health Resources and Services Administration (HRSA) which will look at long-term follow up of donors that will potentially take the responsibility off of the transplant programs.

The Committee supports the clarification language.

Next Steps:

The Living Donor Committee Chair will bring feedback from the Kidney Committee back for further deliberation, with the hopes that the proposal will be ready for the spring public comment cycle.

2. UNOS Research Orientation

Summary of Discussion:

UNOS staff presented a UNOS Research Department Orientation to the committee members. The presenter explained the purpose and responsibilities of the Research Department and the Research Analyst position for the Committee and its projects. As part of the committee support structure, the Research Department provides analyses in support of the policy change initiatives and for monitoring the change post-implementation. Other roles of the department are fulfilling data requests, scientific research, and database activities. Another important item was the process of requesting data as a Committee:

- Data requests should be made through the process of committee discussion – and not by individual committee members.
- Results of the analysis are presented at a future meeting or conference call.
- Manuscripts based on the committee activities must be reviewed by HRSA prior to submission.

There were no questions from the Committee

3. Pancreas In-Person Meeting KP Update

Summary of Discussion:

UNOS staff presented an update on the recent committee meeting. The Pancreas Committee is considering altering geography decisions to be different from the Kidney Transplantation Committee based on characteristics for pancreas that are different from kidney after looking at factors such as efficiency, cost, differing cold ischemia time, etc. In fact, they believe pancreas allocation choices may have more similarities with liver.

Next Steps:

The Pancreas Committee and the Kidney Committee will evaluate potential changes once Scientific Registry for Transplant Recipients (SRTR) modeling comes back.

4. Liver Committee Geography Proposal Update

Summary of Discussion:

The Chair of the Liver and Intestine (Liver) Transplantation Committee presented an update on the special public comment period. The Liver Committee has proposed two new models, Broader 2-Circle Sharing (B2C) and Acuity Circles. The Liver Committee supports the B2C model at a threshold of 32 MELD/PELD to replace the regional priority model. The Liver Transplantation Committee is asking the community which model is preferred as well as what the sharing threshold and size of circles should be.

The Committee members asked questions for clarification on what to recommend to patients who want to multi-list (list at more than one transplant program). It was advised this could be complicated. Since there would be no more region/DSA structure, the patient would have to list outside of the circle to get offers from other donor hospitals. The Liver Committee Chair was asked to elaborate on how modeling helped to inform the committee's recommendation. The Liver Committee Chair expressed the modeling was exceptionally helpful and produced positive results for the B2C model.

There was concern if the modeling would have any effect on kidney allocation. The Liver Committee Chair advised the Simultaneous Liver-Kidney Transplant policy would need to be changed, but other potential effects on kidney patients are not known at this point.

The Committee requested clarification on the pediatric prioritization in the proposed model, and whether there is an age or size cutoff. It was explained there are two different types of pediatric donors, under 12 years of age and 12-18 years of age. The term "Pediatric Donors" includes both groups.

There were questions regarding how the new modeling improves the differences in wait time and mortality rates, and how the allocation system will change results for those regions with low mortality rates. The Liver Committee also modeled waitlist mortality which was improved in both models, especially the acuity model. The Liver Committee Chair also made the point the policy is not designed to increase transplants, but is intended to improve equity through changing geographical units of allocation.

Next Steps:

The Committee will await the results of public comment.

5. Paused Projects Discussion

Data Summary:

The Committee has a number of paused projects: Kidney Allocation System (KAS) Review Project, Kidney Paired Donation (KPD) Deceased Donor Chains, and KPD Repairs

Summary of Discussion:

UNOS staff gave an update on paused committee projects.

Kidney Allocation System (KAS) Review Project

UNOS staff gave an update on the Kidney Allocation System (KAS) review project. Subcommittees of the Kidney and Pediatric committees were formed for the project. Currently for all KAS Kidney Donor Risk Index (KDPI) sequences, highly sensitized candidates are at the top of the match. In reviewing KAS, it was discovered transplants to high Calculated Panel Reactive Antibodies (CPRA) patients increased dramatically. Additional post-KAS analyses have revealed:

- Not all 100% CPRA candidates are the same.
- While KAS was successful in increasing access to CPRA 100% candidates overall, some of the very highly sensitized candidates (i.e. CPRA 99.99%) did not receive as much access as some in the lower end (i.e. CPRA 99.5%)The workgroup did submit a data request before the project was put on hold.
- Transplant rate is 35 times higher for CPRA 99.5-99.6 vs. CPRA 99.99+
- Offer rate for CPRA 99.5-99.6 candidates is 55 times higher than for CPRA 99.99+ candidates, but still much lower than CPRA<50% candidates
- Post-KAS differences in median waiting time (MWT) based on precise CPRA value are profound: half a year for patients with CPRA just rounding to 100%, versus 10+ years for CPRA 99.99%+ patients, a 20-fold difference.

Right before the project was put on hold, the workgroup did submit a data request for two additional reports before any alterations to the KAS are proposed:

- Demographics (blood type, ethnicity) of kidney alone waiting list candidates/transplant recipients by granular CPRA and pre/post-KAS years and

- Median KDPI of transplanted kidneys by granular CPRA and age group (pediatric versus adult) by pre/post-KAS years

There was concern among the Committee members that putting highly sensitized candidates at the top of the list is not reflective of the concept of longevity matching. The Committee was reminded that longevity matching was only for a subset of patients (EPTS 0-20% and KDPI 0-20%). The point was also made that as the Committee moves toward a new distribution model, the allocation points will have to be redefined in general and the focus should not be on where we are but where we are going.

The Pediatric workgroup reviewed KAS data as well. Under KAS currently, pediatrics are prioritized for highest quality kidneys. While the number of pediatric transplants did not change, the percentage did because of an increase in transplants overall. The overall national listing was down slightly, but there was some regional variability with pediatric listing practices. The subgroup submitted additional data requests:

- Demographics of pediatric kidney alone transplant recipients (ethnicity, ABO, CPRA, HLAm, KDPI, KDPI by donor weight) by pre/post-KAS years
- Number/% of pediatric kidney alone candidates and pediatric kidney alone transplant recipients by granular CPRA and pre/post-KAS years
- Waiting list mortality for pediatric kidney candidates by pediatric age group (0-5, 6-10, 11-17) for the 3rd year post-KAS (12/4/2016 – 12/3/2017)
- Demographics (age, ethnicity, ABO, CPRA, HLAm, mean KDPI) of all kidney alone transplant recipients of pediatric (<18) donor kidneys by pre/post-KAS years, overall and by pediatric donor age groups (0-5, 6-10, 11-17)

It was suggested as the Committee moves forward with a new allocation model, new sequences will be determined based on the allocation model chosen. The Committee proposed new sequencing which would move prior living donors and pediatrics above 0-ABDRmm. The proposal idea received full committee support.

KPD Deceased Donor Chains

The Chair gave an update on this project which had been placed on hold. The workgroup concepts went out for Public Comment and received support in different degrees, with list exchange receiving the most support. When the project is picked back up, the workgroup may pursue a pilot project.

KPD Repairs

The Chair gave a brief update on this project which was also placed on hold. When this project is picked back up the workgroup will review feedback from the Policy Oversight Committee before determining Next Steps.

6. Geography Allocation System Discussion

Summary of Discussion:

UNOS staff gave an overview to the Committee of the proposed frameworks for organ distribution and informed committee members that decisions made during the meeting are simply for the modeling request. No final decisions about frameworks or variations will be made until modeling can be considered. The Chair reiterated the discussion is not to build consensus but to build a value system as a group. The Chair prepared a number of discussion questions:

Do you support broader sharing?

The Committee agreed they do support broader sharing as long as it helps improve waiting time and mortality and does not create disparities in access. Considerations must be made for equity, efficiency and the recognition of limited resources for small or medium sized transplant programs.

Which framework do you support and why (borderless/continuous, mathematically optimized districts, concentric circles)?

The majority of Committee members support the borderless/continuous framework. These Committee members felt this framework allowed for more flexibility for future options while also being easier to explain to patients.

Which kidney proposal do you prefer and why (Circles or Hybrid Model)?

Nearly all Committee members prefer the hybrid model.

Do you favor steep priority point curves or shallow proximity point curves?

The majority of Committee members favor the shallow proximity point curve as it will give less emphasis to proximity and more toward waiting time. There was also concern that adding proximity points may go against the concept of KAS and the Final Rule. The Committee would also not want patients to be disadvantaged based on where they choose to be listed.

What about multiple transplant programs in a small geographic area – will the hybrid solution/continuous distribution allocate fairly to patients (longest waiting times, sensitized, etc.)? In other words, transplant programs are worried but is that what we should be worried about?

Discussion ensued among the Committee members. One member raised the question if the framework needs to be “one size fits all” nationwide, or if different parts of the country could have different frameworks depending on criteria. The Chair suggested creating a proposed framework, getting some modeling and making adjustments as needed. In order to create a proposed framework the Committee needs an idea of where they want to go as a committee with emphasis on patients, not transplant programs.

Concerns about cold ischemia time (CIT), delayed graft function (DGF), cost? Is it real, perceived or somewhere in between?

The Committee did raise concerns about the increase in the discard rate with potentially longer travel times. However, with kidneys already traveling longer distances than other organs, some committee members believe the complication of more travel does not come from CIT or DGF but more from cost of transport.

The Committee also discussed the importance of more education for the transplant community surrounding the allocation discussions and potential changes. The message and education is very important to the success of the new frameworks and it must be understandable to the community as a whole.

Upcoming Meeting(s)

- November 19, 2018 Teleconference
- December 12, 2018 Teleconference