OPTN/UNOS Kidney Transplantation Committee Meeting Summary February 29, 2016 Conference Call

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Discussions of the full committee on February 29, 2016 are summarized below. All committee meeting summaries are available at http://optn.transplant.hrsa.gov/.

Committee Projects

1. Simultaneous Liver-Kidney Allocation (SLK) Project

The intent of the SLK project is to provide medical eligibility criteria to allocate a kidney with a liver from the same donor and create a "safety net" for liver recipients that do not receive a kidney at the time of their liver transplant but later experience renal failure. In December 2016, the Committee voted to distribute a SLK proposal for public comment beginning in January 2016. During this same conference call, the Committee requested supplementary data on (1) the estimated percentage of current SLK recipients that would not qualify under the new medical eligibility criteria, (2) the expected volume of use of potential safety net, and (3) the differences in likelihood of not regaining kidney function by different degrees of medical eligibility criteria. The Committee reviewed the requested analysis. Highlights from the analysis include:

- At least 19% of previous SLK recipients would not have qualified under the
 proposed medical eligibility criteria. UNOS staff believe that this is an
 underestimate because UNet does not collect the exact data proposed in the
 chronic kidney disease medical eligibility category. The analysis used an
 approximation using the best available data.
- For liver-alone recipients, about 2.5% of 48,000 recipients over an 8.5 year time period went on to develop ESRD within a year of the liver transplant (about 140 a year). However, only 31% were actually listed during that time frame.
- The percentage of liver recipients that developed ESRD decreased as the eGFR increased.

Implemented Committee Projects

2. Revising the Kidney Allocation System (KAS)

The Kidney Committee reviewed initial data on the first 12 months post-KAS implementation. This data is also being presented at the regional meetings. The complete analysis will be presented to the Kidney Committee at its April 18th in-person meeting in Chicago. Committee members noted the following after reviewing the data:

- Committee members would like to better understand the reason for the decline in 0-ABDR mismatches.
- Although the analysis provided showed that pediatric transplants have rebounded after an initial decrease, committee members noted that there may still be a perception that pediatric transplants are decreasing. The Kidney Committee will continue to monitor this population.
- Delayed graph function rates increased from 24% to 30%, but this number may be driven by the bolus effect of transplanting patients with a lot of dialysis time.

The six-month survival rate for the cohort reviewed (4-5 months of post-KAS recipients) is over 95%. A committee member noted that while the differences in delayed graft function (DGF) and graft survival rates are not statistically significant pre- and post- KAS, it is having a significant financial impact. The Medicare margin is being eroded because the transplant center applies a length-of-stay modifier for reimbursement when there are longer lengths of stay.

Review of Public Comment Proposals

3. Performance Metrics Concept Paper (Membership and Professional Standards Committee)

The Membership and Professional Standards Committee (MPSC) has developed a concept paper to discuss ways to adjust the OPTN outcomes metrics in order to increase the number of transplants. The work group that created this paper was charged with evaluating different ways to decrease the perceived disincentives created by the current outcome metrics. This concept paper limited its focus on kidney transplants since there is a significant amount of data already available. Currently, some centers do not accept transplantable kidneys because they fear that using kidneys with a high risk of failure will cause their program to be identified for a MPSC outcome review. The work group concentrated on developing criteria for these situations since many patients could be transplanted with currently discarded kidneys and enjoy a better survival rate and a higher quality of life than they would remaining on the list. The concept paper focuses on changing how programs are identified for MPSC outcomes review. A high risk kidney transplant is defined as a transplant involving a recipient with an EPTS score greater than 80 using a kidney from a donor with a KDPI of 85 or greater. Programs would not be flagged for review by the MPSC based on outcomes in high-risk kidney transplants. The MPSC would monitor the national one-year graft and patient survival rate and those higher-risk transplants to make sure that the survival rates were not dropping below an acceptable level and to determine appropriate thresholds for minimum survival to be used in the future. The work group will consider a similar process for other organs once they have made significant progress on the kidney recommendations.

The Kidney Committee generally supports the idea of decreasing the perceived disincentives created by current outcome metrics. During the presentation, committee members gave the following feedback:

Did the MPSC assess other KDPI cut off points to see the percentage of transplants and programs who were flagged but would not be flagged? The MPSC first looked at the characteristics of the kidneys that were being discarded and one of the already used cut points is 85 because that requires a separate notation of informed consent. The MPSC believed it would be easier to use already defined variables that would capture the discards: donor age, whether the kidneys were pumped or not pumped, and biopsy results. However, biopsy results are highly variable in their interpretation and when they are performed. The MPSC also did not want to cause an unintended consequence of pumping kidneys that were not pumped or not pumping kidneys that would be pumped because the inclusion/exclusion for pumping is still nebulous and dependent on centers. What seemed to stratify an increasing number of discarded kidneys was a rising KDPI which is already defined for all programs. The MPSC initially just looked at the graft characteristics and wanted to allow transplant centers to pick the recipient that follows their algorithm now but discussion really brought up that the risk adjustment, currently, does not fully capture all the recipient characteristics. The MPSC then looked for a

readily usable, across the board definition and settled on the EPTS and KDPI but realize it does not capture the entire universe.

A committee member noted that ultimately the proposed changes would affect a small percentage of transplants performed. The committee member suggested using either EPTS or KDPI rather than the two combined. For example, the KDPI may not matter if a candidate has an EPTS of 100 or vice versa because these would generally be considered high risk transplants. Additionally, setting the KDPI at 80 or 75 would have a bigger impact on a greater number of transplants.

A committee member suggested separating DCD kidneys as an isolated variable.

A committee member suggested applying a multiplier to the EPTS and KDPI scores rather than using the proposed score cut off. For example, a high KDPI kidney (e.g. KDPI of 95%) will always be riskier no matter the EPTS of the recipient.

A committee member voiced concerns about the potential for gaming the system with recipients whose scores are in the 70s. The member suggested relaxing the flagging criteria and assessing if more people can be transplanted without making the outcomes worse. The MPSC has another subcommittee working in on a six-month timeline to develop a way to rapidly change transplant practice. This focus of this group is to change flagging criteria to allow centers to use more organs for more recipients without the perceived penalty.

4. Adding HLA DQA1 Unacceptable Antigen Equivalences Table (Histocompatibility Committee)

The Chair of the Histocompatibility Committee presented this proposal. Based on this presentation, the Kidney Committee supports this proposal. The committee members did not have any questions about the proposal.

Upcoming Meetings

- March 21, 2016
- April 18, 2016
- May 16, 2016
- June 20, 2016