OPTN/UNOS Kidney Transplantation Committee
Meeting Summary
April 7, 2014
Chicago, Illinois

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Discussions of the full committee on April 7, 2014 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at http://optn.transplant.hrsa.gov.

Committee Projects

1. State of Kidney Paired Donation (KPD) Report

Dr. Aeder, Chair of the KPD Workgroup presented updated data on the OPTN KPD program, including the number of programs participating, trends in match run eligible candidates and donors, number of transplants, etc. Dr. Aeder explained that the program has been operating as a pilot since 2010. The OPTN created the pilot in order to test the benefits of a national system and use the information gained to improve on any problems and develop a national program. The program has matured over the years and is now ready to become a permanent program. The Committee voted 20-Y, 0-N, 0-A to recommend that the Board of Directors lift the pilot label.

2. KPD Candidate Prioritization Points

Dr. Aeder presented the Committee with policy language specifying prioritization points and the waiting time reinstatement process for candidates in the OPTN KPD program. UNOS staff explained that this proposal was released for public comment in March 2012 but not sent directly to the Board subsequent to public comment because the Committee wanted to address some of the comments received and look at additional options for prioritizing candidates in the program. However, the policy language presented represents how the OPTN KPD system is currently programmed and, since one of the key elements to the OPTN KPD program is transparency and having a prioritization points policy has been deemed especially important for the program to become permanent, the workgroup recommended that the Committee move forward with Board approval. Dr. Aeder added that the workgroup has formed a Design Optimization and Algorithm subcommittee (DOAS) to suggest programming improvements for prioritizing KPD candidates in the future. That subcommittee is hoping to make recommendations for future policy changes in fall 2014 or spring 2015.

The Committee voted 20-Y, 0-N, 0-A to recommend that the policy be approved by the Board of Directors at its June 2014 meeting.

3. Deadlines for Match Response and Crossmatching in the KPD Program

Dr. Aeder presented several recommended changes to the Operational Guidelines governing programs participating in the OPTN KPD program. The problem the working

group is trying to address is that there are currently no deadlines for transplant programs in potential exchanges to respond to offers and report crossmatch results. This leads to inefficiencies in the overall program and prevents donors and candidates from accessing other exchanges and transplant opportunities. For this reason, the KPD workgroup requested that the Committee approve several new deadlines for preliminary exchanges to match offers, reporting crossmatch results, and indicating refusals after preliminary acceptance. One member asked whether the deadlines were business or calendar days. The Committee amended the language to be clear that the deadlines for each new requirement were intended to be business days, with the exception of the deadlines for performing a crossmatch and reporting the results (deadline set at 13 calendar days) and the deadline for reporting a final acceptance or refusal (set at 13 calendar days). The Committee also requested that the language be amended to require that the program 'make available' donor records rather than 'ship' them, so that records could be sent electronically. The Committee adopted these changes. The Committee voted 20-Y, 0-N, 0-A to adopt the following new standards into the Operational Guidelines:

- For any KPD exchange, each of the transplant hospitals receiving the match offer must report a preliminary response to the OPTN Contractor within 2 business days of receiving the offer or the exchange will be automatically terminated.
- The KPD matched donor transplant hospital must provide the matched candidate's transplant hospital the name and location of where the crossmatch kit is to be sent within 1 business day of receiving the notification of exchange acceptance. If this information is not provided to the matched candidate's transplant hospital within 1 business day of receiving notification of exchange acceptance, the exchange will be terminated.
- The KPD candidate's transplant hospital must perform a crossmatch and report the results of the crossmatch to the OPTN Contractor and the matched donor's transplant hospital within 13 days of receiving notification of the exchange acceptance. If the results of the crossmatch are not reported to the OPTN Contractor within 13 days of notification of exchange acceptance, the exchange will be terminated.
- The transplant hospital registering the potential donor in KPD must make all of the donor records accessible to the matched candidate's transplant hospital within 2 business days of receiving the notification of exchange acceptance. If the donor records are not made available within 2 business days of receiving the notification of exchange acceptance, the exchange will be terminated. The donor records must include any updated serology and NAT testing results, and must indicate whether the donor is increased risk according to the PHS Guidelines.
- The matched candidate's transplant hospital must review the donor records and report a final acceptance or refusal to the OPTN Contractor within 13 days of notification of exchange acceptance. If the matched candidate's transplant hospital does not report an acceptance or refusal to the OPTN contractor within the timeframe, the exchange will be terminated.
- The deadlines can be postponed for Guidelines h.iii, h.iv and h.v if all transplant hospitals in the exchange consent. The transplant hospital requesting the extension must submit the request in writing to the OPTN Contractor explaining the reason for the request and providing an updated date by which the transplant hospital will perform. The OPTN Contractor will notify all of the transplant hospitals in the exchange of the request.

- Upon receipt of the request for extension, the transplant hospitals in the exchange will have 1 business day to respond to the request for extension. If all other transplant hospitals in the exchange agree to the extension, it will be granted and the exchange will not be terminated. If any of the transplant hospitals in the exchange fail to respond to the request for extension within 1 business day of receiving the request, the request will not be granted. If the extension request is submitted before the deadline defined by the guidelines, the exchange will not terminate until the resolution of the extension request.

4. Simultaneous Liver Kidney (SLK) Allocation

The Committee continued discussion on simultaneous liver kidney allocation. UNOS staff presented data requested by the Committee in August 2013. Specifically, the Committee requested data on the following:

- Clinical information for SLK recipients at time of transplant for transplants performed since 2005, including percent on dialysis, time on dialysis (<6 months, 6+ months), creatinine values, primary diagnoses for kidney and liver transplants, donor quality (KDPI), MELD by creatinine, and sensitization level (PRA/CPRA).
- Number of listings for kidney after liver transplant for each year since 2005 by Region and DSA; and distribution of time between the liver and subsequent kidney listings including the proportion with kidney listings within certain time period (e.g., within one and three years) after the liver transplants, stratified by primary kidney diagnosis (CNI nephrotoxicity, hepatorenal syndrome, hypertensive nehrosclerosis, type 2 diabetes, other) and exposure to dialysis prior to the liver transplants.
- Number of kidney transplants after liver transplants each year since 2005 by Region and DSA; and distribution of time between the liver and subsequent kidney transplant including the proportion with kidney transplants within certain time period (e.g., one and three years) after the liver transplants, separately for deceased and living donor transplants, and stratified by primary kidney diagnosis (CNI nephrotoxicity, hepatorenal syndrome, hypertensive nehrosclerosis, type 2 diabetes, other) and exposure to dialysis prior to the liver transplants.
- 25th and 50th percentiles of times to transplant for registrations waiting for kidney after liver and for registrations waiting for kidney with no previous liver transplants by blood type. Explore the feasibility of computing percentiles of time to transplant for each blood type, by Region and DSA (feasibility may be limited by sample size).

The results were summarized as follows:

- Among 3,431 SLK recipients during 1/1/05-6/30/13, 510 (15%) did not receive pre-transplant dialysis and had a serum creatinine of <2.5 mg/dl at transplant, which would suggest that some of these patients may not have needed a kidney.
- Of the 510 SLK recipients with no pre-transplant dialysis and a serum creatinine of <2.5 mg/dl, 237 (46%) received a KDPI <35% kidney, which suggests that kidneys utilized in SLK transplants also tended to have a lower KDPI scores.
- Since pediatric kidney candidates are prioritized to receive kidneys from donors with age<35 (KDPI<35 in the new allocation system), SLK transplants in which

the kidney was not needed may disproportionately affect pediatric access to kidneys.

- On average, 200 patients were listed per year for a kidney transplant during 1/1/05-6/30/13 after a solitary liver transplant; the median time to listing for these patients was about 9 years for those with a kidney diagnosis of CNI nephrotoxicity, 6.5 years for hypertensive nephrosclerosis, 5 years for type 2 diabetes, and 11 months for hepatorenal syndrome; additionally, only 19% were listed within a year of the liver transplant.
- On average, there were 120 kidney transplants (including both deceased and living donor) performed per year during 1/1/05-6/30/13 after a solitary liver transplant; the median time to kidney transplant was 10 years for those with a kidney diagnosis of CNI nephrotoxicity, 7 years for hypertensive nephrosclerosis, 6 years for type 2 diabetes, and 2 years for hepatorenal syndrome; additionally, only 9% were transplanted within a year of the liver transplant.
- The 25th percentile of times to deceased donor kidney transplant tended to be lower for registrations added to the waiting list during 2003-2008 after a previous liver transplant as compared to those added to the waiting list during the same time period without a previous liver transplant.

5. Addressing Geographic Disparities in Deceased Donor Kidney Allocation

The Committee continued discussion on a metric to be used to assess geographic disparity in deceased kidney donor allocation. The Geographic Disparities Subcommittee met in February and March to review results of data requested at the August 2013 in-person meeting. The subcommittee presented the results of the data review and the decisions made thus far at the April in-person committee meeting.

The subcommittee reviewed the following data by (deidentified) DSA:

- Offer rate per 100 active patient years
- Transplant rate per 100 active patient years
- Supply/demand ratio (where supply reflects quality of organs and demand represents waiting list population)
- Median time to transplant (competing risks method)

In addition, offers, transplants, and “supply” were calculated for three different donor groups:

- All deceased kidney donors
- Deceased kidney donors with KDPI greater than or equal to 85%
- Deceased donors with KDPI greater than or equal to 85% and non-DCD

The subcommittee also reviewed data to determine whether to use an incident (newly listed) or prevalent (entire list) patient population to define the denominators of the offer rate, transplant rate, and supply to demand ratios. As a result of assessing changes to both the numerators and denominators of these ratios, the subcommittee considered six different types of transplant rates, six different types of offer rates, and twelve different types of supply v. demand metrics, for a total of 24 different metrics. In addition, the Committee reviewed an analysis of the median (and 25th percentile) times to transplant by DSA.

In addition to quantifying the degree of DSA-to-DSA variability by each of the 24 ratios, the correlation between each metric and all others was evaluated to determine which choices –e.g., changes to numerator vs. changes to denominator—would have a larger effect on the optimization modeling to be used for determining new districts. If two metrics are highly correlated, the decision of which one to use would have relatively little impact compared to the choice between two metrics that are weakly correlated or uncorrelated.

The following key findings were reported:

- There is huge variation in access to kidneys across DSAs for all of these metrics.
- The results suggest that case-mix differences (e.g., DSA's with higher proportion of sensitized candidates) may explain at least some of this variability, in particular in offer and transplant rates.
- It is often impossible to estimate median times to transplant due to fewer than 50% of candidates being transplanted in certain DSAs as well as competing risks (e.g., removal from the waiting list for death and other reasons).
- Excluding lower quality kidney donors had very little impact on the rank ordering of DSA's by either offer rates, transplant rates, or supply-to-demand ratios.
- The following decisions are expected to have a much larger impact on the development of new districts based on mathematical optimization:
    - Including all or only recently listed patients (incident v. prevalent waiting list)
    - Including all or only active patients
    - The class of metric to use (offer rates, transplant rates vs. supply-to-demand ratios)

Committee Projects Pending Implementation

6. Revised Kidney Allocation System (KAS)

UNOS staff provided an overview of the educational offerings and tools that have been provided to the transplant community thus far, the plan for educational offerings for the remainder of the year, and key programming implementation dates. The Committee discussed a list of frequently asked questions. The majority of the conversation focused on how programs will update, confirm, and document a patient's dialysis start, the tools that will be provided for talking to patients about KDPI criteria, and whether it is good medical practice for programs to select independent donor screening criteria other than KDPI.

<u>Next steps</u>

- UNOS will hold a KAS webinar on April 24, 2014 on resources for processes and protocols that programs need to put in place in advance of KAS implementation.
- The first major IT implementation date is May 27, 2014. On this day, the EPTS and other critical data fields will be available in UNet℠.
- The Committee members requested a data element that would be helpful in talking to patients about KDPI.

Other Significant Items

7. Update from the SRTR on Program Specific Reports (PSRs) and the Kidney Model Rebuild Process

SRTR staff provided the Committee with an update on the Transplant Program-Specific Reports (PSRs) and, in particular, the kidney model rebuild process. Members of the Committee were pleased to learn that the SRTR is planning to eventually include observed and expected post-transplant survival outcomes for certain multi-organ combinations in the reports, particularly because outcomes for simultaneous liver kidney (SLK) are expected to be included.

The Committee members expressed significant concerns with the SRTR's presentation of a new 5-tier rating system for post-transplant performance ratings, because the new model uses labels and terminology that may be misleading in terms of the quality of the transplant program.

Upcoming Meeting(s)

- May 19, 2014
- June 30, 2014