

OPTN Kidney Transplantation Committee

Meeting Summary

May 23, 2022

Conference Call

Martha Pavlakis, MD, Chair

Jim Kim, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 5/23/2022 to discuss the following agenda items:

1. Policy Oversight Committee Update
2. Dual and En Bloc Kidney Post-Implementation Monitoring Report
3. Kidney Paired Donation (KPD) Policy Update Project

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

1. Policy Oversight Committee Update

The Vice Chair presented an update from the Policy Oversight Committee (POC).

Presentation Summary:

POC is currently working to define project benefit and develop a method to rate various attributes. Some attributes discussed have been number of patients affected, level of impact to those patients, and vulnerable populations affected. The goal is to create a more objective measure to evaluate a project's potential impact to the community and considering its sequencing and prioritization. The POC's ultimate goal is to maximize benefit given the available resources.

As part of the prioritization and sequencing that the POC does, one consideration is how much capacity each committee has to take on more work, but also how much capacity the OPTN staff have to actually implement the planned changes. This capacity, in terms of staff hours, has been fairly constant for quite a while, and the POC has identified a need to increase this capacity. More of the projects involve significant resources to implement, and the work remains important to the community. The POC is currently working with the Finance Committee to request an increase in the available resources for implementing committee work in the next OPTN budget cycle. Capacity, budget, prioritization, and sequencing considerations will result in a shift in committee work:

- More discussions about scope earlier on in projects
- Information technology (IT) Staff more actively involved in discussing potential options for system solutions earlier in projects
- Some projects may not move as quickly until implementation capacity can be increased

Summary of discussion:

The Chair remarked that, instead of thinking of the POC as a hurdle to cross in order to proceed with a project, it's important to remember that the POC provides good feedback, coordination, and allocates resources needed to complete these projects.

There were no additional questions or comments.

2. Dual and En Bloc Kidney Post-Implementation Monitoring Report

Staff presented the Two-Year Post-Implementation Monitoring Report for the Dual and En Bloc Kidney Allocation policy updates.

Presentation Summary:

Changes to dual and en bloc kidney allocation were implemented on September 5, 2019. These changes allowed donors with a kidney donor profile index (KDPI) 35-100 percent to be offered as single or dual, and required that donors weighing less than 18 kg must be offered en bloc before being offered singly. Centers must opt in at the registration level to receive dual or en bloc offers for their patients.

Cohorts:

- Pre-Policy: September 5, 2017 – September 4, 2019
- Post-Policy: September 5, 2019 – September 4, 2020
- Graft and Patient Survival Analyses
 - Pre-Policy: September 5, 2017 – September 4, 2019
 - Post-Policy: September 5, 2019 – December 31, 2020

Dual Kidney

- The number of dual kidney transplants increased from September 2013 to September 2019, and then dropped to 90 transplants in the first year post-implementation. The number of dual kidney transplants increased to 108 in the second year post-implementation
- There was an increased percentage of dual kidney transplants using kidneys from donors with KDPI 86-100 percent after implementation
 - Pre-policy, 47 percent of dual kidney transplants were from donors with KDPI 86-100 percent, which increased to 57 percent post-policy
 - The percentage of dual kidney transplants using kidneys from donors with KDPI 35-85 percent decreased from 52 percent to 39 percent
- There were two pre-policy and eight post-policy dual kidney transplants from donors with KDPI 0-34 percent
- The cold ischemic time (CIT) for dual kidney transplants dropped post-policy, from a pre-policy median cold time of 22 hours to a post-policy median cold time of 20 hours
- One year graft survival for dual kidney recipients decreased from 94 percent to 89 percent after the policy was implemented; but these changes were not statistically significant
 - One year graft survival also decreased for single kidney transplants from 94 percent to 93 percent
- One year patient survival for dual kidney recipients decreased from 99 percent to 93 percent in the post-policy, though it was not statistically significant
 - One year patient survival for single kidney recipients decreased in the first policy from 97 percent to 95 percent
- There was little change in donor disposition post-implementation, with around two percent of donors used for dual kidney transplants in both the pre- and post-policy eras
- Over the course of the post-policy cohort, the percentage of centers and registrations opted in did increase.
 - At the end of August 2021, 47 percent of active kidney registrations were opted in to receive dual kidney offers at 157 programs
 - Around 20 percent of programs have performed a dual kidney transplant in the post-policy era

- 16 donors had both kidneys accepted as a dual and later split and transplanted singly
 - In four instances, the second kidney was not transplanted
 - The remaining 12 donors had the second kidney transplanted into a different recipient
 - In six cases, the second kidney was transplanted in the same program
- 44.44 percent of dual kidney grafts were accepted at a single kidney classification and 55.56 percent at a dual kidney classification
 - Single kidney classifications come before dual kidney classifications on the match run, which may explain the decrease in cold ischemic time post-policy

En Bloc Kidneys

- En bloc transplants dropped to 178 transplants in the first year post-implementation, and then increased to 208 in the second year post-implementation
 - This change may be attributable to the introduction of the 18 kg weight threshold for determining which donors must be allocated en bloc
 - The number of donors weighing less than 18kg dropped from 593 in the pre-policy era to 549 in the post-policy era
- The distribution of donor weight for kidney transplants changed in post-policy, with median donor weight remaining around 11.5 kg but the 75th percentile decreasing from 15kg pre-policy to 14.5kg post-policy
- No increase in the proportion of en bloc kidneys going to pediatric candidates
 - Proportion of en bloc transplants to recipients 18 to 34 years old increased substantially, from 14 percent pre-policy to 40 percent post-policy
- The proportion of en bloc transplants going to recipients with EPTS 0-20 percent increased from 26 percent pre-policy to 77 percent post-policy
- One year graft survival for en bloc recipients remained around 93 percent, while one year graft survival for single kidney transplants decreased from 94 percent to 93 percent
- One year post-transplant patient survival for en bloc kidney transplant recipients increased from 96 percent to 99 percent in the first policy; this change was not statistically significant
 - One year patient survival for single kidney recipients decreased in the post-policy era from 97 percent to 95 percent
- The proportion of donors less than 18kg used in en bloc transplants increased from 56 percent in the pre-policy to 64 percent in the post-policy
 - The percentage of donors less than 18kg with at least one kidney transplanted singly decreased from 19 percent to 11 percent in the post-policy era
 - The percent of donors with neither kidney transplants remained around 23 percent
- The discard rates increase for donors less than 18kg from .15 in the pre-policy to .18 in the post-policy era; this change was not statistically significant
 - The change was more pronounced for donors weighing between 12 and 18kg, but still not statistically significant
- The percentage of centers and registrations opting into receive en bloc offers increased over time
 - At the end of August 2021, 59 percent of active kidney registrations were opted into receiving en bloc offers at 180 centers
 - About 90 centers performed en bloc transplants from September 5, 2019 to March 28, 2020
- There were 65 incidences of kidneys accepted en bloc that resulted in a single kidney transplant
 - In 6 of these incidences, the second kidney was not transplanted

- Of the remaining 59 kidneys, 46 were allocated and transplanted to a recipient at the same program as the original accepting candidate

Conclusion

- Dual Kidney
 - Decrease in volume
 - Cold ischemic time decreased, likely due to being allocated to a single kidney offer classification
 - Splits were rare
 - One year post-transplant patient and graft survival outcomes did not significantly change
 - Many centers opted to receive offers, few performed transplants
- En Bloc
 - Decrease in volume, but increase to pre-policy levels in the last year
 - More transplants to young adult (aged 18-34 and 35-49 years) and low EPTS recipients, but not to pediatrics
 - One year post-transplant patient and graft survival outcomes did not significantly change
 - Discard rates did not differ for donors less than 18 kg
 - Many centers opted to receive offers, few performed transplants

Summary of discussion:

One attendee remarked that some metrics decreased in the post-policy era, and pointed out that the COVID-19 pandemic is likely a confounding factor. The attendee noted that, particularly at the beginning of the pandemic, transplant programs as a whole become significantly more conservative.

The attendee commented on the en bloc data point that showed many programs and registrations opted to receive en bloc offers, but many fewer actually performed en bloc kidney transplants. The attendee wondered if controlling for hypertension as the candidate's primary etiology would provide more insight, as smaller pediatric kidneys are much less likely to perform well in recipients with significant hypertension. The Chair pointed out that this differential might already happen at the transplant center at time of registration, and asked if the attendee was suggesting that the offer comes through and its determined later on that the patient is not a good candidate for en bloc offers, particularly if they are on blood pressure medications. The attendee confirmed this, and explained that this could come down to efficiency or accuracy in how patients are listed. The attendee explained that the transplant staff who input data and manage candidate listing may not necessarily be the same as the staff taking organ call. The nephrologist or surgeons looking at these offers with respect to the candidate information in real time may not communicate directly with the coordinator listing the candidate. If the coordinator who listed the candidate didn't make the distinction that this candidate should not receive en bloc offers, the physician or surgeon is the one who catches that later on, when the candidate receives an en bloc offer. The attendee added that this could be the physician taking call changing their mind about a candidate's en bloc eligibility at the last minute or simply a lack of efficiency and improper candidate data entry during registration. The Chair agreed.

The Vice Chair asked if there was any data available on cold ischemic time for en bloc transplants, and wondered if the comparatively larger number of centers open to receiving offers than performing en bloc transplants has impacted the ability to allocate efficiently. The Vice Chair added that, for dual kidney allocation, the cold ischemic time decreased even with more centers receiving offers than

performing transplants. Staff shared that, for en bloc kidney transplants, the median cold time increased slightly from 16.5 hours to 17.5 hours, and that the overall range increased.

For dual, one member asked if the KDPI used in the report was adjusted to account for the recipient receiving both kidneys, instead of a single kidney. The member explained that KDPI is a single kidney outcome measure, and that the data may be more informative if it took into account the fact that the kidneys are offered and transplanted together. The Vice Chair agreed that the current KDPI in policy is an inaccurate predictor for dual kidney allocation. The Vice Chair noted that KDPI is not masked when allocating dual kidneys, and pointed out that, many years ago, expanded criteria donor (ECD) kidneys allocated as dual utilized the standard criteria donor match run algorithm. The Vice Chair explained that the idea was that the overall renal function of two ECD kidneys would be similar to that of a standard criteria donor.

A member remarked that there were at least 30 percent of dual kidney donors where at least one kidney was not transplanted across the broad range of KDPI 35 to 100 percent. The member asked if this data could be broken down into smaller KDPI spectrums, to see the effect on utilization as KDPI increases. Staff noted that this information is not included in the report, but can be looked into.

One member commented that it would be helpful to have data on the biopsy findings for these kidneys which were not transplanted. The member acknowledged that the Committee currently has a project addressing biopsy data collection going to the Board of Directors in June. An attendee responded that it's unlikely for biopsies to be performed on en bloc pediatric kidneys.

3. Kidney Paired Donation (KPD) Policy Update Project

Staff presented the Update Kidney Paired Donation Policy project, recommended to the Committee by the OPTN KPD Workgroup. The Committee voted unanimously to approve sending this project to August 2022 Public Comment.

Presentation summary:

The KPD Workgroup reviewed existing KPD policies and is recommending minor modifications to clarify language, align with other OPTN policies, and bring deadlines and administrative policies up to date with current practices.

The KPD Workgroup solicited feedback from relevant stakeholder Committees, including Kidney, Histocompatibility, Living Donor, Patient Affairs, Transplant Coordinators, and Transplant Administrators Committees.

The proposal addresses the strategic goal to increase the number of transplants, by increasing the consistency and clarity of administrative requirements in the OPTN KPD system and increasing the efficiency of listing and transplanting candidates.

The Workgroup is recommending changes to 9 KPD policies:

- 1.2: Definitions (Bridge Donor)
 - Update language to be inclusive of Bridge Donor options
- 13.3: Informed Consent for KPD Candidates
 - Include specification that these policies apply to candidates in any KPD program
- 13.4: Informed Consent for KPD
 - Include specification that these policies apply to donors in any KPD program
- 13.4.C: Additional Requirements for KPD Donors
 - Expand financial risk language to align with that in OPTN Living Donor Policy
- 13.4.D: Additional Requirements for Non-Directed Donors

- Cross reference with 14.6.B: Placement of Non-Directed Living Donor Organs to clarify that 13.4.D applies to non-directed donors entering KPD programs only
- 13.4.E: Additional Requirements for Bridge Donors
 - Simplify language, to ensure the program has explicit conversations with the bridge donor on expectations and informing the donor they have the options to determine how long they are willing to wait
 - Emphasize the bridge donor may determine and revise the estimated amount of time they are willing to be a bridge donor
- 13.7.G: Waiting Time Reinstatement
 - Minor language change, to align with kidney waiting time reinstatement Policy 3.6.B.i: Non-function of a Transplanted Kidney
- 13.11.A: Requesting a Deadline Extension for a KPD Exchange
 - Update policy such that a non-response by any transplant program in the exchange defaults to an approval of the request
- 13.11: Receiving and Accepting KPD Match Offers
 - Updated timelines recommended, to improve efficiency:
 - Within 2 business days of receiving match offer: report preliminary response
 - Within 3 business days of receiving match offer:
 - Agreement on contents in crossmatch kit, donor instruction, address for blood sample transport
 - Report agreed upon date of crossmatch to the OPTN
 - Make donor records accessible to candidate's transplant hospital, including serologic/nucleic acid testing (NAT) results, Public Health Service (PHS) risk criteria, and any additional records requested
 - Within 10 business days of receiving match offer:
 - Report to the OPTN the results of the crossmatch
 - Review the donor's records and confirm acceptance or report refusal of match offer to OPTN
 - Within 60 calendar days of receiving match offer: matched donor kidney recovery and matched candidate transplant

Summary of discussion:

The Vice Chair remarked that this proposal seems straightforward. The Chair agreed, and thanked the Committee members who participated in the KPD Workgroup for their efforts.

Staff remarked that the KPD Workgroup has also identified other areas for improvement that could become more substantial proposals to further modernize the OPTN KPD Pilot Program (OPTN KPDP) and improve efficiency. Some of these items could require more resources than simple policy updates, and the KPD Workgroup will continue working. This proposal to clean up and update policy language will help improve the efficiency of the program.

VOTE: The Committee unanimously supported sending the Update OPTN KPD Policy proposal to Public Comment in August 2022. There was no opposition or abstentions.

Upcoming Meetings

- June 24, 2022 - Teleconference

Attendance

- **Committee Members**
 - Martha Pavlakis
 - Jim Kim
 - Amy Evenson
 - Asif Sharfuddin
 - Stephen Almond
 - Bea Concepcion
 - Caroline Jadlowiec
 - Elliot Grodstein
 - Kristen Adams
 - Precious McCowan
 - Sanjeev Akkina
 - Erica Simonich
 - Vince Casingal
- **HRSA Representatives**
 - Jim Bowman
 - Raelene Skerda
- **SRTR Staff**
 - Bryn Thompson
 - Grace Lyden
- **UNOS Staff**
 - Lindsay Larkin
 - Kayla Temple
 - Katrina Gauntt
 - Ruthanne Leishman
 - Lauren Motley
 - Jennifer Musick
 - Jesse Cox
 - Stryker-Ann Vosteen
- **Other Attendees**
 - Jason Rolls