

**OPTN Kidney Transplantation Committee
Kidney Paired Donation Workgroup
Meeting Summary
August 4, 2022
Conference Call**

Marion Charlton, RN, SRN, CCTC, Chair

Introduction

The Kidney Paired Donation (KPD) Workgroup (the Workgroup) met via teleconference on 08/04/2022 to discuss the following agenda items:

1. Welcome and Announcements
2. Workgroup Member Introductions
3. Overview of the OPTN KPD Program and Workgroup
4. State of the OPTN KPD: 10 Year Report

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

1. Welcome and Announcements

The Workgroup Chair welcomed the Workgroup, and staff shared that the August 2022 OPTN Public Comment period opened the day before and that the KPD Workgroup's *Update Kidney Paired Donation Policy* proposal is currently out for public comment.

Summary of discussion:

There were no questions or comments.

2. Workgroup Member Introductions

The Workgroup members, HRSA representatives, and supporting staff introduced themselves.

Summary of discussion:

There were no questions or comments.

3. Overview of the OPTN KPD Program and Workgroup

Staff gave an overview of the OPTN KPD Program and its operations, as well as a brief history of the Workgroup and the Workgroup's most recent projects.

Presentation summary:

The OPTN KPD Workgroup formed in 2004, and worked for several years to develop the program's framework, including releasing a request for information for optimization. In 2009, the National Organ Transplant Act (NOTA) was amended by the Charlie Norwood Act, which declared KPD exempt from the "valuable considerations" clause, which had prevented exchange of human organs. The OPTN KPD Pilot Program (OPTN KPDPP) became operational in 2010, with 4 coordinating centers, and was integrated into the OPTN Computer System in 2011. The KPD Workgroup began moving the operational guidelines to policy in 2012, and eventually removed the Operational Guidelines in 2021.

The OPTN KPDPP is open to all transplant hospitals meeting requirements of kidney transplant programs that perform living donor recovery or a partnering hospital. The transplant hospital must notify the OPTN in writing if the transplant hospital decides to participate in the OPTN KPD program.

The OPTN KPD is part of the OPTN, and is subject to the same governing processes. The Kidney Committee is the KPD Workgroup's sponsoring committee. The KPD Advisory Council advises on education and non-policy improvements, and recommends potential policy changes to the Workgroup.

The OPTN KPDPP is operated by United Network for Organ Sharing (UNOS) staff, who run weekly match runs in the KPD system and perform repairs as needed to 3-way, 2-way, and chain exchanges. All offers are sent via email to match hospitals.

The typical KPD exchange timeline begins with a weekly match run to identify potential exchanges, from which the OPTN Computer System will send match offer emails to all centers involved in the exchange. The programs in the exchange have two business days from time of match offer to report a preliminary acceptances. The programs have four business days from time of match offer to share donor medical records with the matched candidate hospital, arrange preliminary crossmatches, and connect with recipients and check their insurances. The programs have fifteen business days from time of match offer to review donor medical records and clear the donor, report crossmatch results, begin financial contractors, and confirm final acceptance or report a refusal.

Data on the KPD system is available in the OPTN Computer System, and professional resources and patient resources and toolkits are available on the OPTN site.

The KPD Workgroup's last policy change was the *Update OPTN KPDPP Priority Points* project, which was approved by the Board of Directors in 2016. In October 2021, the KPD Operational Guidelines were removed, after recommendation by the KPD Workgroup to the Kidney Transplantation Committee. The Workgroup performed a holistic review of OPTN KPD Policy, and released several recommended changes as a public comment proposal, *Update Kidney Paired Donation Policy*. This proposal includes updates to several administrative policies and processes, as well as clarifications and alignments of informed consent policies. The Workgroup also identified several other potential projects of various sizes, from smaller modifications, larger modifications, and data-related modifications.

Summary of discussion:

The Workgroup had no questions or comments.

4. State of the OPTN KPDPP: 10 Year Report

Staff presented the 10 year report on the OPTN KPDPP.

Presentation summary:

The OPTN KPDPP is a national KPD system open to all OPTN –approved living donor kidney transplant programs. The vision of the KPDPP is that every kidney transplant candidate with an incompatibility but willing and approved living donor receives a living donor kidney transplant. A review on the decennial impact the KPDPP has had on the kidney transplant community provides guidance in further improving to the program and reflecting on the benefit of the program to the OPTN.

All candidates, donors, and transplant hospitals participating in the KPDPP between its initialization in October 2010 and December 31, 2020. The match run was executed on a mostly weekly basis from October 27, 2010, until March of 2020 when the program transition to a bi-weekly cadence in match runs due to the impacts of the COVID-19 pandemic. The match run algorithm searches for 2-way, 3-way, and chain exchanges for all candidate-donor pairs. Chain exchanges begin with a non-directed living

donor (NDD) and end with either a donation to a candidate on the waitlist (closed chain) or a bridge donor who goes on to start another chain (open chain).

Two year unadjusted post-transplant patient and graft survival were assessed using Kaplan-Meier methodology. The cohort for survival analyses was limited to transplants before January 1, 2019 in order to allow all recipients to reach two years of follow-up.

In the last 10 years, 159 kidney programs have agreed at some point in time to participate in the KPDPP, and 32 living donor kidney transplant programs have entered at least one candidate/donor pair throughout this time. Participation in the pilot program increase through the mid-2010s, and then leveled off. KPDPP activity came to a sudden halt as the COVID-19 pandemic hit the country in March of 2020. By the end of 2020, 50 centers were participating per month.

33 percent of the total number of match run-eligible candidates entered are accounted for by 9 centers. At least half of participating centers have entered at least 13 eligible candidates. The average number of candidates added since the inception of the program was 249 candidates per year.

Participation in a match run increased steadily through 2015, and then dropped in January of 2016 when a new policy for histocompatibility that required additional donor/candidate human leukocyte antigen (HLA) requirements were enacted. Many candidates and donors who did not fulfill all the HLA requirements became ineligible until this information was updated in the KPD system. Participation remained fairly stable between 2016 and 2017 following the drop, and then decreased again in March of 2020 due to the impacts of the COVID-19 pandemic, but seemed to rebound by the end of the year. The participation of NDD and bridge donors remained between zero and four in the last five years.

Since 2010, a total of 4,210 match offers have been sent to participating programs. In the last few years, offers per month remained between 5 and 65 offers sent by the program. The match success rate was variable in the early years of the OPTN KPDPP. The first three years of KPDPP yielded less than 30 transplants, so variation is expected. As KPDPP became more established, the match success rate began to decline from 12.3 percent in 2013 to 5.2 percent in 2015. Following the implementation of the histocompatibility policy in January 2016, the match success rate jumped back up to 10.7 percent in 2016 and stay in that range until 2020. In August 2018, the KPDPP began sending weekly email reminders to centers to review donor pre-selects, which may have led to the 12.2 percent match success rate in 2019.

Approximately half of the matches found in the KPDPP have been from 3-way exchanges, and 2-way exchanges account for 18 percent of matches. Chains, initiated by a NDD and sometimes extended by a bridge donor, account for 32 percent of matches.

Distribution of age when comparing candidates and recipients is relatively consistent across age groups, as for comparing potential donors to actual donors. The distribution of race and ethnicity is consistent across groups when comparing candidates and recipients and potential donors and actual donors.

Across blood groups, there are inconsistencies. While blood type O accounts for 61 percent of candidates, it represents only 42 percent of transplants. 32 percent of participating potential donors are blood type O compared to 45 percent of actual donors. The KPDPP has tried to balance blood types through policy by providing more prioritization points to donors of B, A, or AB blood types. Distribution by calculated panel reactive antibodies (CPRA) is uneven for highly sensitized candidates, and patients with a CPRA of 98 percent or greater account for 21 percent of candidates and 6 percent of transplants.

Through December 31, 2020, the KPDPP has facilitated 366 transplants. The number of annual KPDPP transplants peaked in 2013 with 52 transplants, and remained relatively high through 2019, despite a drop in the number of candidate and donor pairs from 2018 to 2019.

The majority of candidates (63.2 percent) who entered the program have been transplanted either through the KPDPP program, deceased donation, other KPD program, or living donation. In total, 11.4 percent of candidates were transplanted through the KPDPP.

Half of KPDPP transplant recipients spend less than 6 months in the program. However, there is a lot of variability in time to transplant, with some patients waiting over 3 years in the KPDPP before being transplanted. With the exception of 2020, the median time to transplant has varied between 60 and 91 days. This time lag was primarily due to logistics, such as sending samples for testing, performing crossmatches, financial complexities, and scheduling OR dates, but it was also affected by acute changes in a candidate's or a donor's health.

OPTN KPDPP recipient two-year patient and graft survival were compared with patient and graft survival for other paired donation recipients, other living donation recipients, and deceased donor kidney-alone recipients. OPTN KPDPP recipients had a 96.4 percent survival rate, which was close to other paired donation survival rates (97.8 percent) and living donor transplant survival rates (97.9 percent). While it is above the deceased donor transplant survival estimates, the confidence interval for OPTN KPDPP encompasses the deceased donor estimates.

The two-year graft survival estimate for OPTN KPDPP recipients is 93.4 percent. It is lower than other paired donation (95.6 percent) and other living donors (96.1 percent), and higher than that for deceased donor transplant (90.6 percent). Given that the OPTN KPDPP has the smallest sample size, it has the most unreliable estimate and widest confidence interval.

Summary of discussion:

The Chair asked how incompatibility is defined, and if that definition included blood type or chronological incompatibility. Staff explained that chronologic incompatibility was not included, but that incompatibility can be any kind of incompatibility as far as blood type or HLA matching or size. Staff shared that the KPD Workgroup previously defined incompatibility after the Charlie Norwood Act was passed and defined KPD as exchange between biologically incompatible. The KPD Workgroup defined biologically incompatible as any pair where the recipient would require immunosuppression after transplant.

The Chair asked if the candidate pool waiting greater than three years were considered highly sensitized. Staff noted that they would need to double check that, but that it is highly likely that those candidates waiting several years in the KPD program are highly sensitized.

Staff encouraged the Workgroup to look through the State of KPD report, as this data can inform the Workgroup in developing and prioritizing projects.

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
 - Marion Charlton
 - Vineeta Kumar
 - Erica Seasor
 - Camille Rockett
 - Sanjeev Akkina
 - Sergio Manzano
- **HRSA Staff**
 - James Bowman
 - Marilyn Levi
 - Raelene Skerda
- **UNOS Staff**
 - Kayla Temple
 - Lindsay Larkin
 - Hannah Brown
 - Meghan McDermott
 - Megan Oley
 - Keighly Bradbrook
 - Katrina Gauntt
 - Ruthanne Leishman
 - Lauren Mauk
 - Stryker-Ann Vosteen