OPTN Kidney Transplantation Committee
Meeting Summary
June 22, 2023
Teleconference

Martha Pavlakis, MD, Chair
Jim Kim, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 6/22/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. 2-Year Monitoring Report: *Removal of Donor Service Area (DSA) and Region from Kidney Allocation Policy*
3. Farewell to Departing Members

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

1. Welcome and Announcements

Committee Leadership welcomed the Committee members.

Staff updated the Committee on the OPTN Minority Affairs Committee's new project to remove the race variable and hepatitis C (HCV) variable from the Kidney Donor Profile Index (KDPI) calculation. The OPTN Minority Affairs Committee will be validating the refitting of the KDPI calculation with SRTR analysis. This project was approved by the Policy Oversight Committee earlier in June, and the OPTN Minority Affairs Committee aims to put out their proposal for public comment in January of 2024. The OPTN Minority Affairs Committee is forming a workgroup with representation from OPTN Kidney and Patient Affairs Committees, as well as representation from the National Kidney Foundation and the American Society of Nephrologists.

Summary of discussion:

There were no questions or comments.

2. 2-Year Monitoring Report: *Removal of DSA and Region from Kidney Allocation Policy*

Staff presented the results of the two year monitoring report for the *Removal of DSA and Region from Kidney Allocation* policy change.

Presentation summary:

The *Removal of DSA and Region from Kidney Allocation* policy change was implemented on March 15, 2021 alongside other efforts, with the main policy change involving replacing DSA and region with a 250 nautical mile (NM) circle. This policy change also added proximity points based on distance between listing center and donor hospital, and increased prioritization for pediatric candidates within 250NM of the donor hospital. Three other policy changes involved defining medical urgency for kidney candidates, setting Sea-Tac airport as the donor hospital for any kidneys recovered in Alaska, and providing options for OPOs when kidneys are released by the originally accepting transplant hospital. Two goals of these

policy changes were to increase equity in access to transplant, and minimize the negative impact of broader sharing on organ utilization and system efficiency.

The pre-policy cohort for this monitoring report was from March 16, 2019 to March 14, 2021; the post-policy cohort was March 15, 2021 – March 14, 2023. The report covered metrics regarding equity in access to transplant, geography, efficiency allocation and utilization, and post-transplant outcomes.

Equity in Access to Transplant

In the pre-policy era, there were 34,479 transplants, and there was an increase in post policy to 38,823 transplants. Transplant rates, or the number of waiting list removals due to the number of deceased donor kidney transplant, divided by the total amount of time on the waiting list in active status for registrations ever waiting during the study period. There was a significant increase in the transplant rate of all patients in the post policy era, with the rate increasing from 29.85 in the pre-policy era to 38.6 transplants per 100 active patient years in the post-policy era.

For all pediatric age groups at listing, there was a statistically significant increase in the post-policy era, with the largest change seen in patients aged 12-17 at listing, going from 142 to 229 transplants per 100 active patient years. For the adult age groups, there was also a statistically significant increase in transplant rates post policy.

There was a significant increase in the transplant rate for all race and ethnicity groups post-implementation, with the largest increase for black, non-Hispanic candidates, with their transplant rate going from 29.14 to 40.2 transplants per 100 active patient years.

For all calculated panel reactive antibody score (CPRA) groups except “unknown CPRA at listing,” there was a statistically significant increase in transplant rate, with the most drastic increase seen in registrations with CPRA 80 to 97%. Those candidates saw an increase from 36.69 transplants per 100 active patient years to 66.32 in the post-policy era.

There is a slight increase in the distribution of dialysis time at listing, with the median increase by 0.06 years, which is realistically not a huge increase. There was a statistically significant increase in transplant rates across all groups organized by dialysis time, with the largest increase in transplant rate for candidates with 3 or more years of time on dialysis. Candidates with 3 or more years of dialysis time saw an increase in transplant rate from 64.93 to 94.91 transplants per 100 active patient years.

Geography

In the post-policy era, Kidneys are traveling further, with a smaller peak in the distribution of distance from donor hospital at the lower nautical mile distances. The median distance increased from 71 to 120 nautical miles in the post-policy era. In the post-policy era, there was an increase in the proportion of transplants occurring within 250 NM, increasing from 78.74% of transplants in the pre-policy era to 84.53% of transplants occurring within 250 NM of the donor hospital in the post-policy era.

The proportion of transplants using kidneys in the same DSA decreased from about 70 percent to about 40 percent. There was an increase in the proportion of transplants that were “regional” or “national” shares.

There was an increase in the number of transplants for all regions except for regions 2 and 8, where the number of transplants decreased slightly. In region 2, there were about 15 less transplants in the post-policy era, which was a roughly 0.4% decrease compared to the pre-policy era. In region 8, there was about 146 less transplants in the post-policy era, which was a 6% decrease.

The number of transplants increased in 35 DSAs, and decreased in 21 DSAs. The number of transplants increased in 145 centers, and decreased in 94 transplant centers. The number of transplants increased in 27 states and decreased in 21 of them. There are no active kidney transplant programs in Alaska, Idaho, Montana, and Wyoming.

Efficient Allocation and Utilization

Looking at the distribution of cold ischemic time in hours, there was a slight increase in cold ischemic time in the post-policy era. The median cold time in the pre-policy era was 17.2 hours, which increased to 19.5 in the post-policy era. In the pre-policy era, 29.24% of transplants experienced delayed graft function (DGF). This increased in the post-policy era by 3.65 percent, up to 32.9% of transplants experiencing DGF.

Pre-policy there were 23,407 deceased kidney donors recovered; in the post-policy era, there were 27,926 deceased kidney donors recovered. This was an increase of 4419 donors.

Non-use is defined as the number of deceased donor kidneys recovered for the purpose of transplant but not transplanted, divided by the total number of kidneys recovered for transplant. There was an increase in non-use rate from pre-policy to post-policy, by about 4.9 percent. The 35-85 percent KDPI kidneys saw a 4.7 percent increase in non use rates, while there was a 5.1 percent increase in non-use rates for kidneys with KDPI 86 to 100 percent. There was an increase in non-use rates for lower KDPI kidneys, though it is not as drastic.

In looking at the distribution of sequence number of final acceptor of kidney matches, kidneys were accepted further down the match run in the post-policy era than in the pre-policy era. For kidneys in the pre-policy era, the median sequence number of acceptance was 9, and in the post-policy era the median sequence number was 18.

In looking at the distribution of hours from first offer to cross clamp of kidney match runs, defining offer from the time of first electronic offer to time of cross clamp. There was a slight increase in the amount of time between first offer and cross clamp, with a median of 23.37 hours in the pre-policy era increasing to a median of 25.9 hours in the post-policy era. In the pre-policy era, there were 3430 matches where cross clamp occurred before any offer was sent, and in the post-policy era, there were 1409 matches where the cross clamp occurred before any offers were sent.

Offers per active patient year for kidney match runs, defining offer rates as the number of offers from kidney match runs divided by the total amount of time in active status for kidney registrations ever waiting during the study period. This looks only at match runs with a final acceptance, and does not include any offers after the final acceptance. Looking at the offers, the offer rate almost doubled, from 88.92 offers per active patient year in the pre-policy era to 165.34 offers per active patient year in the post-policy era.

Acceptance rates were defined as number of offers with a final acceptance divided by the total number of offers from Kidney match runs. The acceptance rate pre-policy was 3.6 acceptances per 1000 offers, and this decreased to 2.25 acceptances per 1000 offers in the post-policy era.

Post-Transplant Outcomes

Post-transplant patient and death-censored graft survival were calculated using a Kaplan-Meier survival estimates and then, due to insufficient follow up and concerns about informative censoring, this report only looks at survival for deceased donor kidney transplants from March 16, 2019 through February 28, 2022. There was no statistically significant difference in one-year post-transplant patient survival between the two eras, with survival rate 95.6 percent in the pre-policy era and 95.7 percent in the post-

policy era. In looking at one-year post-transplant graft survival rates, there was no statistically significant difference between the pre and post policy eras. The graft survival rate in pre-policy era was 93.3 percent, and in the post-era it was 93.1 percent, with no statistically significant difference.

Conclusion:

There were notable increases in transplant rate for several sub-populations, including:

- Pediatric candidates
- Black, Hispanic, and Asian candidates
- Candidates with a CPRA 80-97 percent
- Candidates with 3 or more years of dialysis time at listing

Changes in transplant volume varied across the country, with an increase in a majority of states, DSAs, and transplant programs. There was also an increase in all regions, except for Region 2 and Region 8.

Deceased donor kidneys traveled farther, although a majority are staying within 250 NM. Kidneys are less likely to be transplanted within the same DSA of recovery as compared to pre-policy, although 40.11 percent of transplants stayed within the same DSA. Non-use of kidneys has increased by 4.9 percent overall. Median cold ischemic time and rate of delayed graft function has also increased.

Summary of Discussion:

One member pointed to the distribution of sequence number of final acceptor for kidney match runs, noting that it appeared there were more data points pre-policy than post-policy, as the area of the curve is much smaller post-policy. Staff explained that this distribution is based on density, which shows how likely a value is to fall in that area – the higher area or taller curve in the pre-policy era indicates that those sequence numbers are more likely to fall in that area. Staff explained that the curve shown for post-policy sequence number of final acceptor is lower because it's less likely to see a final acceptance in the earlier sequence numbers in the post-policy era. Staff noted that there were 22,220 match runs in the pre-policy era, and 21,984 match runs in the post. There was a decrease of about 300 match runs.

A member remarked that it would be unlikely to see statistically significant differences in 1 year outcomes, and that 1 year graft survival is a low standard. The member continued that the standard of measurement for long term outcomes needs to be higher than 1 year graft survival. Another member agreed that the trends in cold ischemic time and delayed graft function were concerning, and that the current graft and patient survival metrics are not entirely sufficient to mitigate the concerns for long term outcomes.

One member noted that the increase in non-use is also concerning, and that this will need to be explained and understood. Another member commented that it is hard to understand if the rate of increase is due to the policy, or the result of OPOs becoming more aggressive in the donors they pursue. The member continued that many have seen their local OPOs pursue more medically complex donors in an effort to increase the number of kidneys procured, particularly with incoming changes in how CMS regulates and monitors OPO performance. The member pointed out that the median donor age has increased sharply in the last 2 or 3 years, and that the increase in non-use rate may in part be due to OPOs procuring kidneys from donors that are highly unlikely to perform well as a graft. The member added that not every kidney procured is acceptable for transplant. A member commented that there are likely several reasons behind the trends in non-use rate, and that it will be important for the public to understand the new system does not account solely for the non-use rate.

One member commented that the increase in cold ischemic time indicates a problem, and that it would be helpful to see the cold ischemic time stratified by KDPI. The member remarked that they would

expect the differences pre- and post- policy in cold ischemic time magnified for high KDPI kidneys. The member commented that the current allocation system is not efficiently allocating high KDPI kidneys to a potential recipient that would accept it quickly enough. The member noted that there are a lot of components to allocating high KDPI kidneys efficiently, and that there are a lot of aspects that are more modifiable. The member remarked that there are behavioral things that can be done to optimize the environment for organ acceptance, which are relevant to every organ. The member pointed out that high KDPI kidneys should not be offered out at 2AM, as every coordinator receiving the offer will just provisionally accept the offer without reviewing it until the kidney has been clamped. The member continued that at this point, the program receiving the offer will need to make a decision quickly and the cold ischemic time will likely already be high, and the program will end up needing to decline the organ. The member continued that people who take organ call can likely best contribute to how the environment can be optimized for organ acceptance, but that the OPTN should address this issue overall. Another member agreed. One member remarked that decision fatigue and other psychological factors are real concepts that play a major role in offer evaluation acceptance. The member continued that the overall allocation system should be re-evaluated with these psychological principles, as there are major efficiency gains that could be reaped from relatively simple changes. The member explained that timing of donor organ recoveries or pumping kidneys at the donor hospital as opposed to during transplant. The member shared that they believe these kinds of efficiencies are responsible for a large chunk of the non-use rate.

One member described an offer from a donor with recurrent stage 4 cancer, which had been considered cured, but that there were other medical considerations. The member commented that transplanting a kidney from a donor with these characteristics is very risky, and that it's unlikely that most transplant programs would consider such an offer. The member continued that the metrics and goals presented to OPOs and transplant programs are not appropriately aligned, as OPOs are asked to procure as many organs as possible, while programs are responsible for transplanting aggressively while protecting their patients. The member continued that OPOs and transplant program should be better aligned, to ensure OPO resources are appropriately manage and conserved by not recovering organs that programs cannot effectively or safely transplant. The member continued that this practice inflates rates of non-use. Another member agreed.

A member asked if there was any supplemental data regarding the increase in non-use rate. Staff remarked that the monitoring data does not, at a surface level, provide much insight on the reasons for the increase in non-use rate, but that this is being explored. The member asked if the increase in the number of donors has lead to post-policy increases, or is it that the policy is generally redistributing the organs available, or both. Staff noted that it is difficult to tell, particularly as the data includes COVID, changes in OPO metrics, and other considerations, and that the pre- and post-policy comparison is not sufficient enough to answer that question. Staff continued that the literature has shown there has been an increase in donor age, donors with higher creatinine, and also more donors in general, which will contribute to this data. One member pointed out that the non-use rate has increased for kidneys across all KDPIs, so there are likely other factors at play.

The Vice Chair remarked that it will be important to evaluate more data to better understand what is driving the increases in transplants and in the non-use rate. The Vice Chair remarked that it is encouraging that there has been an increase in transplants, and that the one year outcomes have been the same. The Vice Chair posited that the increase in non-use could potentially be due to programs needing to work with more OPOs and vice versa. The Vice Chair also noted that the increase in cold time and median distance are concerning, but that it is interesting to see that the was a greater proportion of transplants occurring within 250 nautical miles of the donor hospital. The Vice Chair continued that it's

likely it's not more organs flying, just that it's programs having to work with more OPOs. The Vice Chair added that efficiency has many components, including allocation efficiency. The Vice Chair continued that OPOs have a responsibility to determine whether the donor kidneys will be safe and appropriate for transplant, and when allocating, OPOs and the system should be working to optimize conditions for acceptance.

The Vice Chair pointed to the increase in the number of offers with fewer acceptances, with the number of offers per active patient year nearly doubling. The Vice Chair added that this could explain the increase in non-use, as transplant programs are accepting less. Staff explained that the offers per active patient year only include offers on match runs with a final acceptance.

An SRTR representative remarked that almost all the metrics improved, particularly with equity. The SRTR representative remarked that an increase of 1 hour in cold ischemic time won't influence most people's decision to take a kidney, and that the relative increase in number of nautical miles traveled wasn't likely enough to alter the decision making process. The SRTR representative explained that the reason kidneys are being declined that are transplantable is because they are being offered to the wrong patient. The SRTR representative continued that a patient with 7 years of waiting time is not the best candidate for a medically complex kidney, but that there are other patients at their program who might be a better match. The STR representative explained that it is important to get the right kidney to the right patient in a more efficient way.

A member wondered how the number of kidney donors recovered by policy era would look broken out by year, and whether an inflection point would be evident for when the updated CMS requirements for OPOs went into effect.

One member asked if the refusal codes and non-use reason codes have been updated or are currently under evaluation. Staff explained that the OPTN Data Advisory Committee is currently evaluating the "discard reason" field in the OPTN Computer system.

An SRTR representative asked how there were more donors, more transplants, but fewer match runs with a final acceptance. Staff explained that there was a smaller number of final acceptances. One member pointed out that there should be at least one match run per donor. Staff clarified that there are occasionally multiple match runs for a donor, depending on changes in donor information or released organ match runs. The Vice Chair remarked that, for the most part, each donor is likely at least one match run. Staff explained the distribution of sequence number of the final acceptor for kidney match runs, noting that this figure is based on kernel density, which is based on probability. In the pre-policy era, the sequence number of the final acceptor was more likely to occur lower on the match run, and in the post-policy era, the acceptances were further down the match run and thus less likely to be accepted in the earlier part of the match run.

In looking at number of transplants by center, an SRTR representative asked if this data included kidney transplants performed as part of a multi-organ transplant. Staff explained that this does included kidney transplants performed as part of a multi-organ transplant. The SRTR representative explained that the pre-policy data suggested that geography and proximity to a program that performs multi-organ transplants may affect the transplant rates and behaviors at individual programs. The SRTR representative explained that this could help explain the changes in transplant numbers and rates by center.

3. Farewell to Departing Members

Staff and the Committee thanked the departing members of the Committee for their service, dedication, and contribution to the OPTN.

Summary of discussion:

The Committee members thanked each other and Staff.

Upcoming Meetings

- July 17, 2023 – Conference Call

Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Arpita Basu
  - Asif Sharfuddin
  - Chandrasekar Santhanakrishnan
  - Bea Concepcion
  - Elliot Grodstein
  - Jason Rolls
  - Kristen Adams
  - Marian Charlton
  - Marilee Clites
  - Patrick Gee
  - Peter Lalli
  - Precious McCowan
  - Stephen Almond
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Grace Lyden
  - Peter Stock
- **UNOS Staff**
  - Lindsay Larkin
  - Thomas Dolan
  - Keighly Bradbrook
  - Kieran McMahon
  - Kayla Temple
  - Ben Wolford
  - Elena Liberatore
  - Kaitlin Swanner
  - Krissy Laurie
  - Lauren Mauk
  - Lauren Motley
  - Mariah Huber
  - Rebecca Fitz Marino
  - Ross Walton
  - Sara Moriarty
  - Ruthanne Leishman
- **Other**
  - Caitlin Peterson
  - Dave Weimer
  - John Lunz
  - Namrata Jain

- Aparna Sharma
- Leighann Burgess