OPTN Kidney Transplantation Committee
Meeting Summary
February 21, 2024
Teleconference

Jim Kim, MD, Chair
Arpita Basu, MD, Vice Chair

Introduction

The Kidney Transplantation Committee met via teleconference on 02/21/2024 to discuss the following agenda items:

1. Welcome and Objectives
2. Recap Continuous Distribution and Efficiency Focus
3. Continuous Distribution Modeling Update
4. Task Force Update
5. Literature Review: Overview and Key Take-Aways
6. Introduction: Defining "Hard to Place"
7. Data Results: Kidney Non-Use and "Hard to Place"
8. Defining "Hard to Place" Break-Out Groups and Report Out
9. Committee Discussions: Defining "Hard to Place" and Considerations
10. Lung Allocation Efficiency Proposal
11. Ad Hoc Multi-Organ Transplantation Committee's *Modify Effect of Acceptance* Proposal
12. Ad Hoc Multi-Organ Transplantation Committee's *Concepts for Modifying Multi-Organ Policies* Paper
13. Discussion: Life Expectancy and Mortality Risk for Chronic Kidney Disease (CKD) Patients on Dialysis and with Transplant
14. Minority Affairs Committee's *Refit Kidney Donor Profile Index (KDPI) without Race and HCV* proposal

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

1. Welcome and Objectives

The Chair and Vice Chair welcomed the Committee and other attendees, and staff reviewed the agenda, objectives, and ground rules for the meeting.

Summary of Discussion:

There were no questions or comments.

2. Recap Continuous Distribution and Efficiency Focus

Staff provided a recap of the Committee's efforts to develop a continuous distribution allocation framework as well as the Committee's pivot towards efficiency and utilization-focused efforts.

Presentation Summary:

The initial goal of the Kidney and Pancreas Continuous Distribution project was to transition the current classification system into a continuous distribution framework. The underlying ethical principles of this

framework are equity, utility, transparency, and autonomy. The Committee's focus in this framework emphasizes sustainable equitable allocation, reducing waste and promoting placement efficiency, understandability, and shared decision-making.

With increasing trends in out-of-sequence allocation and non-use, the Board asked the Committee to begin shifting the focus of Continuous Distribution towards improving utility and non-use, addressing:

- Reducing non-use and non-utilization of kidneys
- Reducing out of sequence allocation of kidneys
- Consideration of expedited placement pathways for kidneys at high risk of non-use

Prior to the Board Resolution, the Committee had discussed and finalized 11 attributes and related rating scales across the 5 major goals of allocation – medical urgency, post-transplant survival, candidate biology, patient access, and placement efficiency. The Committee has submitted and reviewed two Organ Allocation Simulator (OASim) modeling requests, including optimized policy scenarios, and undertaken intensive optimization work with Massachusetts Institute of Technology (MIT) partners, including refinement of weights and rating scale shapes. This work involved significant Committee discussion to determine modeling goals for each attribute. The Committee also considered and discussed several other aspects of Kidney allocation in a continuous distribution framework, including review boards and updated definitions of kidney medical urgency, dual and en-bloc kidney allocation, removing the requirement for Organ Center allocation of "national" kidneys and updating the Kidney Minimum Acceptance Criteria Screening Tool (KiMAC) and released organ allocation.

With the passing of the Board resolution in September, the Committee began working to pivot towards addressing non-use, allocations out of sequence, and expedited kidney placement. The Committee's pivot has been in alignment with the initiation of the Expeditious Task Force. This has involved focused efforts towards understanding and addressing non-use of kidneys:

- Data and literature review to understand potential drivers of non-use and scope
- Consensus building efforts to define "hard to place" kidneys across multiple contexts
- Collaboration, coordination, and alignment with the OPTN Task Force on Efficiency across Committee efforts
- The Scientific Registry of Transplant Recipients (SRTR) and Massachusetts Institute of Technology (MIT) have ongoing efforts investigating options to expand efficiency-related metrics to evaluate potential continuous distribution policies

In October, the Committee reviewed an update on MIT Optimization, including consideration of elevated simulated travel distances for pediatric recipients and an updated Calculated Panel Reactive Antibody (CPRA) rating scale to address access for patients with a CPRA greater than 99.9 percent. The Committee's goals were largely met by the re-optimized policies, with pediatric travel distance, equalizing access across CPRA groups, and efficiency and utilization identified for improvement The Committee also discussed several ideas, concepts, focus areas, and pain points regarding system efficiency, which were sent to the Task Force for consideration.

In December and January, the Committee discussed and refined several key research questions related to non-use, including topics such as:

- Defining "hard to place" and "at risk of non-use"
- Aligning patient risk tolerance and organ risk
- Impacts of travel logistics, allocation order, and cold ischemic time on non-use
- Impacts of evaluation and information sharing practices, such as biopsy

The Committee also finalized a preliminary data request and received literature assignments, encompassing topics such as identifying predictors of non-use; drivers and solutions; patient voice and preference; and transportation, biopsy, and information sharing.

Looking ahead, the Committee will aim release a Committee Update Paper for the Summer 2024 Public Comment cycle, detailing the Committee's pivot towards greater efficiency and utilization focus, including non-use data and literature review, discussions relating to defining "hard to place," discussions relating to expedited placement, and coordination with the Task Force and discussions related to drivers, pain points, and focus areas of non-use. The Committee will also form an Expedited Placement Subcommittee to discuss expedited kidney allocation. This Subcommittee will align and communicate with the Task Force on expedited placement and related variances.

Summary of Discussion:

The Committee had no questions or comments.

3. Continuous Distribution Modeling Update

Staff shared a brief update on the progress of MIT and Scientific Registry of Transplant Recipients' (SRTR) efforts to model non-use, and the Committee discussed a formal request to SRTR to update kidney allocation models to incorporate non-use and efficiency related questions.

Presentation Summary:

Both MIT and SRTR teams are working to incorporate non-use and non-utilization into the allocation simulation models. To facilitate this work, the Committee will discuss a preliminary formal request to the SRTR to incorporate non-use into an allocation simulation model. Leading up to the use of these models, the Committee will return to discussions of continuous distribution attributes, specifically related to incorporating greater efficiency.

In preparation for Kidney and Pancreas utilization modeling, the OPTN Kidney and Pancreas Committees are asked to submit an initial request to SRTR to prepare the simulation models. This request will be specific only to asking the SRTR to prepare simulation models to include utilization/non-use and utilization related research questions.

There are three possible outcomes to this request. The first potential outcome is that the SRTR determines they are unable to adequately model utilization across policy changes; if this is the case, the SRTR and the Committee will need to attempt to answer this question outside of simulation. Another outcome could be that SRTR able to adequately model utilization changes, but with downstream consequences to the ability to answer other research questions for the simulations; if this is the case, the Committee will need to determine the trade-off is worthwhile. Finally, the final potential outcome could be that the SRTR is able to adequately model utilization metrics without meaningful impact to the reliability of other research questions.

Summary of Discussion:

An SRTR representative shared that the simulation utilizes all the patients on the waiting list and donors from that time period, then models and compares current policy to potential new policies to understand which candidates are transplanted with which kidneys, and from this, predicting graft and patient survival. The SRTR representative continued that this request would include all kidneys recovered for transplant from the time period, not just those kidneys that were transplanted. The SRTR representative explained that the Committee can provide efficiency research questions that the SRTR can use in building the model, such that the SRTR can determine which questions may be answered by the model and which will need to be answered in other ways.

The Vice Chair asked if, in the event the SRTR cannot model utilization metrics, whether the Committee will be provided with reasonings or missing data points. An SRTR representative explained that the deliverable associated with this request includes reports around utilization, sub-models required to build the simulation, how they are built, and how each sub-model was selected to answer the Committee's questions. The SRTR representative continued that this report will also describe operational validation showing that the model is able to replicate historical behavior. The SRTR representative added that, if utilization cannot be modeled, the report will provide the reasoning.

One member asked how the SRTR is going to determine which kidneys were not used and for what reason. An SRTR representative explained that the model of utilization within the simulation may not get down to the level of detail in regard to specific reasons for why an organ was not used. A member remarked that this level of detail would be important to understanding changes in utilization and non-use. Another SRTR representative added the model could potentially describe, with a particular policy, whether the kidney non-use rate increases or decreases. The SRTR representative continued that the simulation may utilize models developed from offer acceptance patterns, to understand how allocation order can impact an organ's odds of acceptance and transplant. The SRTR representative noted that there is a lot of nuance here, particularly as one program's decline is another program's transplant. The SRTR representative added that it can be hard to pinpoint reason for non-use, particularly as it is possible an organ may have been used if it was offered to a different center, or at a different time.

A member asked how the SRTR plans to model non-use, and if it will be a granular model. An SRTR representative explained that the model will be based on all relevant historical data related to non-use, evaluating a counterfactual for a particular historical timeframe. Another SRTR representative continued that this request will help inform the nuances and details of how the model is built and its capabilities, particularly as there are many ways to model these questions.

The Vice Chair asked if the historical data will be broken up based on eras or years, noting that program practices and behaviors can shift over time, particularly as some programs become more and less aggressive in offer acceptance practices. An SRTR representative explained that this is the kind of question that the SRTR will need to answer as the model is being built, but that the model will utilize a more recent cohort, similar to previous modeling requests. Another SRTR representative added that generally, kidney simulations utilize 1 year of data, which is typically sufficient to understand impact of the policy.

A member asked if there will be multiple models necessary to account for the spectrum of kidneys, particularly in considering KDPI. The member continued that the model could potentially help differentiate policies that may be more beneficial to placing higher KDPI or medically complex kidneys. An SRTR representative noted that this is something the SRTR has considered and added that this is where understanding the Committee and the community's research questions for the model is important. The SRTR representative explained that, as an example, the SRTR could potentially create models specific to certain types of kidneys if needed. The SRTR representative explained that the SRTR does this for things like offer acceptance, which varies for adults and pediatric patients, in order to improve accuracy of the model.

One member asked how filters will affect the model. An SRTR representative explained that this depends on the time period that is ultimately used in the simulation. The SRTR representative noted that previous modeling requests utilized March 15, 2021 through March 15, 2022, and that this time period only includes about 2 months of offer filters. In these requests, offer filters were not considered. The SRTR representative continued that, if more recent eras are going to be utilized, the model will need to consider the widespread use of filters and incorporate the filters and programs' filter settings. The SRTR representative that a program's filter settings historically would be the same in the model.

A member asked if life expectancy of the recipient will be accounted for in the model, and if so, how. The member continued that higher KDPI and more medically complex kidneys would be more likely to be transplanted into older recipients, and that these acceptance decisions would likely to some degree reflect the life expectancy of the recipient. The SRTR representative explained that currently, recipient life expectancy is not utilized in the models beyond EPTS 0-20 matching. Another SRTR representative explained that these models do account for candidate factors and noted that programs tend to be more likely to accept higher KDPI kidneys for older recipients. The SRTR representative continued that these candidate factors would capture the potential survival.

Staff presented a set of draft research questions, noting that this request is regarding modeling capabilities, as opposed to modeling results.

Presentation Summary:

The following draft non-use related research questions were developed from previous Committee conversations regarding non-use research and modeling questions:

This request will be specific only to asking the SRTR to prepare simulation models to include utilization/non-use and utilization related research questions:

- Primary Research Question: How do the proposed policies impact utilization and non-use of deceased donor kidneys?
    - Including breakdown of non-use by KDPI, etc.
- Secondary Research Questions:
    - How do the proposed policies impact timing and sequence number at acceptance?
        - Is there an increase in organs accepted after sequence 100?
    - How do the proposed policies impact the demographics of candidates who accept high KDPI and "hard to place" organs?
    - How do the proposed policies impact waitlist mortality, transplant outcomes, etc.?
    - How do the proposed policies impact cold ischemic time?

Summary of discussion:

The Vice Chair suggested the inclusion of trends in non-use for certain OPOs and centers. Staff asked if that could be evaluated historically, as opposed to through a model. Staff explained that a standard data request could describe trends in non-use and allocation out of sequence, including where allocation of out of sequence is taking place and which areas are accepting these organs. The Vice Chair agreed. An SRTR representative recommended including consideration of timing, noting that some OPOs begin allocation out of sequence once the organ reaches a specific cold time, to ensure the organ is placed. The Vice Chair remarked that there are certain OPOs that have this data and their own internal protocols for aggressive placement when an organ begins accumulating a critical mass of cold ischemic time. Another member agreed that OPOs likely keep their own version of that data to justify the out of sequence allocations. Staff remarked that there are data sets for match runs that have been flagged for out of sequence allocation, as well as data related to tracking bypass codes that may have been used in allocating a kidney out of sequence. Staff continued that this data is being validated and compared, to ensure the quality of the data. A member added that it is important to capture the attributes of kidneys that are being allocated out of sequence, noting that if this matches those kidneys that are not used, it could help to understand which kidneys may require an alternate allocation pathway.

The Chair remarked that comparing organs that were not used in 2019 versus 2021 is difficult, particularly as so much has changed in the transplant and healthcare fields in the last several years. The Chair continued that historically, the SRTR has explained that behavior can't be modeled, but that non-

use is highly dependent on behavior. The Chair continued that it is hard to quantify and understand how much of the increase in non-use is due to general expansion of the donor pool, COVID and related lags in resources and behaviors, or other factors. The Chair noted that different cohorts should be evaluated to understand whether the types of organs not being used before are not being used now.

A member shared that when their OPO allocates out of sequence, they use the Recovery and Usage Map (RUM) report to understand which programs may accept the kidney. The member continued that the centers not appearing on the RUM report have not previously accepted a kidney with those specific criteria, even though those programs still appear on the match run. The member continued that the data is available and should be incorporated into the models in terms of offer acceptance patterns. The member shared that more than 80 percent of kidneys allocated this way are placed, as opposed to about a 23 percent transplant rate of these organs previously.

Staff explained that addressing non-use will require a combination of evaluating historical data and simulation. Staff continued that these questions will guide the model so the Committee can understand whether adjustments to the allocation algorithm and potential tools can be expected to have positive impacts to reducing non-use. Staff noted that the question being posed to the Committee today is what modeling results the Committee would need to feel comfortable that the potential allocation proposals achieve the Committee's goals. Staff continued that the Committee should also outline these goals, noting that these could be reduced cold ischemic time, lower non-use rates for certain types of kidneys, and so on.

A member recommended that the match runs should also incorporate RUM data based on program's actual acceptance practices to reduce inefficiency in allocation. The member noted that these programs end up declining the organ offers and increasing cold ischemic time. Staff noted that this is an example of how the allocation algorithm could be adjusted to address non-use, but that these models are hoping to measure how the algorithms are performing. Staff continued asked which questions the Committees would want answered to make sure that such an adjustment would achieve what the Committee set out to achieve in terms of efficiency and non-use.

A member asked if the Committee is being asked to determine if the model has measured the system well. An SRTR representative explained that the SRTR will determine whether the models are adequate in taking on the request. The SRTR representative asked the Committee what they would hope to see in a modeling report to determine if the allocation system is more efficient, has achieved reduced non-use, and so on. The SRTR representative continued that the Committee is being asked to prioritize research goals. A member responded that the main outcome of interest is non-use, but that there are critical aspects in the nuances of how that is simulated. The member continued that median sequence number at acceptance and cold ischemic time are good metrics to include.

The Chair pointed out that programs are held to new metrics, and that these metrics contribute to non-use, particularly as programs are less likely to take riskier organs while they are held to specific graft survival metrics. The Chair added that it would be more helpful to predict outcomes from using these non-used kidneys, and how that will impact programs' graft survival metrics, down to an individual program level. The Chair continued that if programs could understand the outcomes of kidneys that are not currently used now but are similar to kidneys that were transplanted 5 years ago, then programs may feel more comfortable that the outcomes of these organs are good and may be more likely to accept and transplant them. Another member agreed. The member explained that programs are measured on waitlist mortality, post-transplant survival, and organ acceptance behavior. The member continued that looking at the opportunity cost of passing up an offer, then that is a patient who may pass away on the waitlist. The member explained that post-transplant survival in terms of transplant program metrics is only measured to a year. An SRTR representative confirmed this, and noted that the

MPSC looks at one year, but that the SRTR also shares other reports on 3-year post-transplant survival and other outcomes as well. The SRTR representative continued that it sounds like the Committee would like to include post-transplant patient and allograft survival in the simulation, to understand potential interactions in efficiency and utilization. A member agreed, recommending that the simulation be able to show whether one policy is able to provide a greater number of years of survival. The member continued that median survival on dialysis is predictable, as well as median survival with a transplant, and that the model could potentially include a goal related to increasing the number of life years saved. An SRTR representative asked if this question would relate time of listing to removal from the list as well. The member pointed out that HRSA currently plans to ask transplant programs to begin collecting data on patients who were evaluated for transplant but ultimately not listed, but noted for now, that the earliest available data is at time of listing.

One member recommended evaluating data based on kidney decline reasons could provide more information regarding the concerns programs have with certain organs, particularly if another center accepted the organ further down the match run. The member remarked that the literature available has dug into organ and donor specific characteristics to understand organ non-use, and that it could be helpful for programs to have more accurate information on outcomes for certain organs. An SRTR representative remarked that this could potentially be addressed outside of simulation, with recent historical data being evaluated to understand why these organs are being declined or potentially investigating cases where one kidney from a donor is transplanted, and the other is not transplanted.

One member asked if the SRTR is able to model projected estimated glomerular filtration rate (eGFR) for a kidney recipient 3 years post-transplant. The member continued that this could help provide insight into whether a policy with decreased non-use provided benefits to patients' renal function. The member noted that there are significant morbidities associated with low renal function, and that relisting should be avoided if possible. An SRTR representative shared that the SRTR has not historically included eGFR in simulation models, particularly because eGFR is variable and dependent on many factors, including nephron mass. The SRTR representative continued that there is limited data regarding recipient creatinine.

A member explained that there is a survival benefit for patients in accepting a higher KDPI kidney when the patient has less time on dialysis, as opposed to waiting longer on dialysis for a lower KDPI kidney. The member continued that this is relatively true unless there is a drastic difference in organ quality. The member added that opportunity cost should also be considered, particularly if a candidate is relisted for transplant. The member explained that having the data to show that higher KDPI kidneys can provide survival benefit, particularly for candidates with less time on dialysis, will help programs become more comfortable accepting and transplanting higher KDPI kidneys. An SRTR representative explained that there was analysis done on this, and that this kind of analysis can be performed outside of a simulation modeling. The Chair agreed that this should be investigated, noting that life years gained in receiving a more marginal kidney earlier in a patient's time on dialysis may provide a greater overall survival benefit for a patient. The Chair continued that education, particularly related to patient education, is critical. The Chair remarked that patient choice is important here as well, as some patients may prefer to wait longer for a lower KDPI graft, while others may prefer to get off of dialysis as quickly as possible. The Chair remarked that programs have expected outcomes calculated for them based on different patient and donor risk factors, and asked if this could be used to predict potential graft loss for those organs that are not used based on who may an appropriate candidate for such organs. The Chair wondered how many of the non-used organs would have resulted in graft loss versus number of life years gained from those organs. The Chair continued that this could potentially illustrate to programs and patients the benefit of increasing utilization of these organs. An SRTR representative agreed, noting

that potentially the Donor Data and Matching System could instead present expected graft survival and expected patient survival with the transplant versus on dialysis when an offer is made, in order to support the offer making decision. The SRTR representative continued that these are models the SRTR could make and that could be incorporated into the Donor Data and Matching System, and offered that this could be impactful to addressing non-use. A member agreed, noting that there are limitations to KDPI. The member offered that rather than simply presenting KDPI and EPTS, the system could find a way to quantify whether the patient will see maximum benefit from accepting the organ versus waiting longer for another offer.

4. Task Force Update

A Committee member who also serves as a representative on the OPTN Expeditious Task Force (the Task Force) provided an update on the Task Force's recent efforts and discussions.

Presentation Summary:

The transplant industry is experiencing record growth, with a higher volume of organs to allocate and transplant requiring updates across the industry. Organ non-use and non-utilization rates present opportunity for improvement, ensuring all possible donated organs are allocated instills trust in the transplantation system and honors donor family gifts of life. Healthcare as an industry is changing, including transplantation, particularly as improved data sharing and new technology allows for streamlined processes to expedite how decisions are made in providing care, especially in the transplant process. Organ transplantation is at a critical inflection point, and there is an opportunity to modernize the transplant system, drastically increase the number of successful transplants, and give more patients a second chance at life with gifts from donors and their families.

The Task Force has three main pillars: Growth, Efficiency, and Use and Utilization. Growth focuses on saving more patient lives by increasing the number of successful deceased donor organ transplants. Efficiency focuses on updating processes to match each organ with the best patient as efficiently as possible. Use and Utilization focuses on honoring the precious gifts from donors and donor families by increasing the use of deceased donor organs. Pursuit of these pillars depends on ensuring equity and safety for all patients.

The Task Force is utilizing a patient centered approach, with the aim to improve patient experiences. This includes standardization, to bring clarity and help patients and families know what to expect in their transplant journeys; streamlined processes to reduce donor case times, late declines, and to drive more reliable transplant outcomes for patients; and optimization, including a framework for allocating hard to place organs in order to expedite decisions, lower non-use rates, and increase the number of transplants.

The Task Force currently represents partners from across the transplant community, including donor families, community advocates, medical professionals, patients and families, OPO staff, and OPTN Board and Committee members.

The Task Force kicked off with a two-day workshop in October, holding a larger virtual meeting in November as well as multiple smaller Bold Aims Workgroups meetings in November and December. The Task Force had additional two-day workshops in December and January, as well as another virtual meeting in January.

The Task Force's initial initiatives include:

- Design rescue pathway variance protocols
- Design studies to better understand non-use and non-utilization

- Evaluate OPTN bylaws/policies that may be barriers to utilization and efficiency
- Host a community event to address challenges in utilization and efficiency
- Secure commitments for growth and support for initiatives

The Task Force is also considering designing a multi-pronged study, including:

- Novel data analytics to understand drivers of non-use, such as:
    - Donor and organ clinical characteristics analysis
    - Aggregated offer acceptance patterns
- Expert panel evaluation simulation
    - Engaging surgeons directly to understand, based on a sample, which non-used organs could have been transplanted, and how; which and how many were truly non-transplantable
- Qualitative/attitudinal research
    - Prospective collection of narratives to understand how organs go un-used and why some organs remain un-accepted

The Task Force is also beginning to focus on removing disincentives or obstacles to achieving the Task Force's bold aims. The Task Force is soliciting feedback on what OPTN policies may create obstacles to growth, utilization, or efficiency, and what additional OPTN policies could create incentives to growth, utilization, or efficiency.

The Task Force is also working on developing a new community event and is seeking feedback on what kind of event would best help to identify potential solutions and/or improvement projects and engage the community in collaborative problem-solving activities. The Task Force is considering the following potential topics: transportation, perfusion, payers, donation after cardiac death (DCD) donor transplantation, and donation and allocation processes. In the meantime, the Task Force has been a presence at several current community events, including OPTN regional meetings; webinars for the public, patients, and other interested groups in late spring; and transplant community conferences.

Looking ahead, the Task Force will continue messaging its Bold Aim widely and frequently to better understand barriers, invite collaboration, and secure commitments. The Task Force is also rallying the community to commit to piloting the most promising concepts to strengthen the organ donation and transplant system.

Summary of discussion:

One member remarked that it is important for the Task Force to also collaborate with the payers and insurance carriers, noting that these organizations make transplant fiscally viable. The member continued that buy-in from these groups is critical, particularly as non-use conversations relate to more marginal, riskier organs that may have higher associated costs, particularly with longer length of stays for patients. The member continued that payers may not understand or approve longer length of stays for patients, and that it is important for payers to understand that it is both in their interest and patients' interest for patients to receive a transplant and get off of dialysis. The presenting member agreed, noting that transplant programs have to maintain some profit margin in order to continue operating. The member shared that the Task Force has been trying to bring the Center for Medicaid Services (CMS) into discussions, and that there has been talk about reaching out directly to private payers and insurance carriers.

5. Literature Review: Overview and Key Take-Aways

The Committee shared key take-aways from the literature review.

Guiding questions:

- What were key take-aways you found in the literature?
- How could these key take-aways be applied to a continuous distribution allocation framework?
- How could these key take-aways be applied to an expedited placement framework?

Summary of discussion:

One member discussed White et al.'s "Impact of the new fast track kidney allocation scheme for declined kidneys in the United Kingdom," sharing that the United Kingdom's (UK) fast track kidney allocation scheme involves making simultaneous offers to centers who have opted into receiving such offers. [1] The member continued that, after 45 minutes, the organ is allocated to the highest priority candidate for whom the offer has been accepted according to the original match run. The member remarked that this scheme was effective particularly in only offering the kidneys to programs that would have accepted those kidneys based on the specific organ characteristics and findings. The member emphasized that the strongest aspect of this framework includes ensuring the offers are only sent to programs that are willing to accept them, offering simultaneously to reduce cold time, and returning to the match run to ensure the organs are still allocated as equitably as possible to the highest priority candidate at the program that would accept the organ. The member shared that this study found the fast track scheme reduced cold ischemic time and increased kidney transplant rates. Another member agreed, noting that it was interesting to see how the UK fast track scheme defined when an organ could be allocated via the fast track scheme. The member shared that the UK fast track scheme defined "at risk of non-use" as 6 hours of cold ischemic time or 5 programs having declined it. The member noted that these thresholds are decisive and effective, though the UK is smaller than the United States (US) in terms of population and geography.

A member shared that the Lentine et al.'s article found a wide range in OPO biopsy practices.[2] The member remarked that there are now OPTN Policy requirements for biopsy performance, and shared that their OPO has seen an increase in kidney placement since the implementation of this policy, but that neighboring OPOs have seen a decline in kidney acceptance. The member shared that this OPO is no longer able to place similar kidneys that had been placed before the *Establish Minimum Criteria to Require Kidney Biopsy* policy was implemented. The member shared that the UK and European transplant systems perform fewer procurement biopsies and noted that it may not be necessary for the United States transplant system to perform as many biopsies as it does currently.

One member shared that Mehrotra et al.'s article "Physician and patient acceptance of policies to reduce kidney discard" found that both patients and providers generally supported increased transplantation and more effective allocation of higher KDPI kidneys.[3] The member added that this article also discussed questions regarding waiting time reinstatement for recipients of high KDPI organs who experience graft failure within 1 year of transplant. The member remarked that there are novel, consensus-backed ways to approach reducing non-use while ensuring patient buy in.

A member discussed the Mankowski et al.'s article "Accelerating Kidney Allocation: Simultaneously Expiring Offers," noting that this was based on the original Kidney Allocation System utilizing donor

[1] White, et al. (2015). Impact of the new fast track kidney allocation scheme for declined kidneys in the United Kingdom. *Clin Transplant, 29(10),* 872-881. https://pubmed.ncbi.nlm.nih.gov/26094680/
[2] Lentine, et al. (2019). Variation in use of procurement biopsies and its implications for discard of deceased donor kidneys recovered for transplantation. Am J Transplant, 19 (8), 2241-2251. https://pubmed.ncbi.nlm.nih.gov/30809941/
[3] Mehrotra, et al. (2020). Physician and patient acceptance of policies to reduce kidney discard. Clin Transplant, 34(11). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7929781/

service area and regions.[4] The member shared that, rather than sequentially offering, the article models a method of offering where multiple programs receive the offer at once, in "batches." The member remarked that this article made sense from a general system perspective, but that from a program and surgeon perspective, there are concerns with such a concept, particularly in terms of increasing offer volume. The member shared that the authors found minimal difference regionally, but that larger offer "batches" nationally resulted in increased acceptance rates and decreased cold ischemic times. The member added that the authors modeled increased workload to the centers and concluded that there was minimal increase in program workload. The member disagreed with this conclusion, noting that programs would then need to call patients with these offers and perform virtual crossmatches, and that increased offer volume could greatly increase workload for programs. The member continued that simultaneously offer making would have negative impacts to programs, particularly smaller programs, and could end up reducing program willingness to thoroughly review offers and accept more marginal organs. The member recommended that increased efficiency in the system would be better realized by more efficient and predictive filtration. The member expressed support for mandatory offer filters, with some malleability for programs to adapt and change behavior to become more aggressive with time.

One member remarked that, looking through several articles, the factors contributing to increased risk of non-use are consistent and well known. The member continued that understanding how these factors interact with each other could help understand potential outcomes and risk of non-use. The member remarked that cold ischemic time, high KDPI, and glomerulosclerosis appear consistently across the articles. The member remarked that there should be a mechanism to measure and recognize this limitation. An SRTR representative agreed, noting the information related to predicting potential graft outcomes should be available at time of offer, not just as a model. The member responded, noting that incorporating such data into the OPTN Donor Data and Matching system would help in the short term, but that over time, the programs should become consistent in the information used to accept an organ. The member remarked that there is a risk in expedited placement if programs are not able to demonstrate growth and change in accepting more marginal organs. The member continued that expedited placement pathways utilizing a smaller list of programs based on historical acceptance behavior will need to accommodate shifting program practices.

A member commented that transportation limitations was also a theme, remarking that there are certain organs that a program cannot accept because there is no way for the organ to travel quickly enough.

The Vice Chair discussed the King et al.'s article, remarking that it is difficult to balance efficiency and equity, particularly in placing hard to place organs, with a single policy.[5] The Vice Chair continued that it may not be feasible to achieve equity among hard to place organs, but that this may be what is necessary to ensure the organs are placed and transplanted. The Vice Chair noted that it is important to focus offering more medically complex kidneys to programs that will accept them.

One member shared that, amongst the articles investigating increased risk of non-use, there were many consistent organ and donor characteristics associated with increased risk of non-use or allocation out of sequence. The member added that these characteristics are also shown in the data request the Committee submitted. The member remarked that the models described in these articles could potentially be updated to include more contemporary data, which could help highlight whether and how

[4] Mankowski, et al. (2019). Accelerating kidney allocation: Simultaneously expiring offers. Am J Transplant, 19(11), 3071-3078. https://pubmed.ncbi.nlm.nih.gov/31012528/

[5] King, et al. (2022). Deceased donor kidneys allocated out of sequence by organ procurement. Am J Transplant, 22(5), 1372-1381. https://pubmed.ncbi.nlm.nih.gov/35000284/

practices have changed. The Chair agreed that it would be interesting to utilize these models using current data, particularly as it relates to current practices and the circles-based allocation.

The Chair remarked that originally, the initial goal of the Continuous Distribution of Kidneys effort was to transition the kidney allocation system with minimal changes, but that with the recent Board of Directors resolution, the Continuous Distribution system will need to improve efficiency and non-use as well. The Chair continued that these articles provide critical information, but that the Committee will need to determine which elements should be incorporated into the Continuous Distribution system and how. The Chair described Stewart et al.'s article "Diagnosing the decades-long rise in the deceased donor kidney discard rate in the United States," noting that controlling for donor and organ factors, that the non-use rate would have been very similar.[6] The Chair continued that it is hard to tell whether there is a shift in the organs that were not being used before and if those organs continue to not be used now. The Chair added that it may be that OPOs are recovering organs from more medically complex donors, but that it is hard to tell whether and why programs are not transplanting organs now that may have been transplanted previously, and if the outcomes of those transplants are favorable. The Chair continued that answering these questions would provide more information from a transplant program and patient perspective in whether patients are comfortable with particular outcomes.

A member wondered how much the increased political pressure to increase transplant by increasing organ recovery, even from more medically complex donors, has contributed to increased non-use, particularly in the context of transplant program and OPO metrics. The member added that there are some programs that may not take potentially riskier organs for fear of impact to outcomes metrics, and asked if these metrics are risk-adjusted. An SRTR representative confirmed that transplant program outcome metrics are risk-adjusted to incentivize programs to accept those kidneys for appropriate patients. The member asked how that information is communicated to the patient when the offer is presented to them, particularly for a medically complex organ offer. The SRTR representative remarked that transplant program metrics available to patients are risk-adjusted, and that the offer-specific conversations happen on a doctor and patient level and may vary based on the clinical information for both the patient and the donor and the patient's goals for transplant. One member remarked that there is an overwhelming amount of information available to patients, and that it can be difficult for patients to navigate and discern. The member continued that it would be helpful for there to be a simple, consolidated, and standardized educational material. For kidneys, this information could provide patients information on risks and potential outcomes of accepting a higher KDPI kidney for transplant, versus risks and potential outcomes for remaining on dialysis. Another member asked if the timing of offer – such as day or night – has an impact to these conversations with patients. The member remarked that offer timing is shown to have relevance for clinicians and could well have relevance for patients as well in terms of risk tolerance. A member responded that Cohen et al. (2019) found a higher rate of non-use and decline when the organ was offered over weekends.[7] The member added that these authors also found other factors associated with non-use that were not related to donor quality, such as donor height and increased market competition.

A member shared that Narvaez et al. (2018) found that timing of offer can increase risk of non-use, particularly as clinicians on call may be less equipped to thoroughly review and evaluate an offer at

[6] Stewart, et al. (2017). Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. Transplantation, 101(3), 575-587. https://pubmed.ncbi.nlm.nih.gov/27764031/

[7] Cohen, et al. (2019). Kidney allograft offers: Predictors of turndown and the impact of late organ acceptance on allograft survival. Am J Transplant, 18(2), 391-401. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5790617/

night.[8] The member continued that this could be true for patients as well. The member remarked that one article found many potential predictors of non-use lose their statistical significance when the authors included more detailed clinical factors. The member explained that this type of detailed anatomical and pathology data may not be available at time of offer for a variety of reasons. The member remarked that it could be beneficial to incorporate more detailed clinical kidney-specific information data collection in the OPTN Donor Data and Matching System. The member offered that Stewart et al. (2022) explored more efficient allocation methods, including systems of allocation that require patients to opt into waiting longer for an organ with greater expected longevity or accepting an organ with lower expected longevity sooner.[9]

One member shared that Cohen et al. (2019) found that decline codes do not necessarily align with organ quality and characteristics. The member commented that there is discrepancy between the reported refusal and non-use reason codes and donor characteristics, and that it is important to ensure granular refusal reasons are available and accurately reported.[10] Another member agreed, noting that refusal codes are important to understanding non-use and how to reduce it. The member pointed out that it can be difficult for surgeons to code individual patients out throughout the match run using more accurate codes, particularly in the middle of the night. The member offered that potentially, surgeons could decline organs and provide a free text reason, which potentially artificial intelligence could rapidly review, consolidate, and categorize.

A member asked if there is an opportunity from an OPO perspective to address offer timing concerns, particularly related to late night and weekend offers. Another member responded that there is little room for adjustments in timing for OPOs, particularly as this could delay organ recovery times and OPOs are beholden to both donor family and donor hospital time and resource constraints. The member continued that most family complaints relate to timing, particularly in cases with cardiothoracic donors where there is a lot of donor management to optimize the organs.

One member asked if there has been any research done on whether third party offer call has contributed to increased non-use, as opposed to surgeons or coordinators taking the offer. The member remarked that surgeons and coordinators may be reviewing based on individual patient information, but that third party transplant coordinators do not have access to patient information and only have a list of decline criteria on behalf of the program. The member continued that third party offer call use may have changed or reduced program aggressiveness and system efficiency, particularly by creating more barriers between the offer and final decision makers. Staff shared that the OPTN Operations and Safety Committee did have a data request related to how often a "provisional yes" becomes a decline based on whether the initial responder is from the program itself or a third party offer call or screening service. Staff shared that there was not a large increase in the "provisional yes-decline" rate, thought across the board, about 75 percent of provisional yes responses end up becoming a decline. Staff commented that this contributes to the perception that "provisional yes" does not signal a lot of intent to accept. Staff shared that there is only about a 3 or 4 percent increase in "provisional yes-decline," and that this trend was similar to the "provisional yes-decline" rate for if the initial offer came in at night as opposed to the daytime. Staff remarked that there was minimal impact from nighttime offers and third party offer call services in terms of frequency of "provisional yes" responses later becoming a decline. Staff remarked

[8] Narvaez, et al. (2018). Hard-to-place kidney offers: Donor and system level predictors of discard. *Am J Transplant, 18(11)*, 2708-2718. Accessed at https://pubmed.ncbi.nlm.nih.gov/29498197/

[9] Stewart, et al. (2022). Oversimplification and Misplaced Blame Will Not Solve the Complex Kidney Underutilization Problem. Kidney360, 3(12), 2143-2147. Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9802557/

[10] Cohen, et al. (2019). Kidney allograft offers: Predictors of turndown and the impact of late organ acceptance on allograft survival. Am J Transplant, 18(2), 391-401. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5790617/

that this could look different if non-use or another outcome was investigated, as opposed to provisional yes to decline. A member remarked that the decision to use a third party offer call service can be tough for transplant programs – there are benefits to having a more alert shift worker take the call, but the offer decision is so nuanced that many surgeons may not be comfortable passing it off to a non-clinician. The member continued that offer filters could overtake the role of the third-party screen service with more nuanced clinical filters. Another member shared that many programs use third party offer call or screening services to weed out absolute or immediate declines, and then in the daylight hours, programs will go back through their offers to determine whether they are truly interested in accepting. The member shared that "provisional yes" does not signal strong interest, and that their OPO does not consider a "provisional yes" a strong back-up to an acceptance until having talked to the program and received verbal confirmation that they would be prepared to accept. The member shared that some programs will input a provisional yes without having had a surgeon review the offer at all.

6. Introduction: Defining "Hard to Place"

Staff introduced the background, rationale, and goals for the Committee's discussions on defining "hard to place."

Presentation summary:

In September of 2023, the OPTN Board of Directors (BOD) asked the Committee to "consider an expedited placement pathways for kidneys at high risk of non-use"

The objective of this discussion is to develop a preliminary, evidence-based definition for "kidneys at risk of non-use"

- For our purposes, this label is being used interchangeably with "hard to place" kidneys
- Preliminary – the Committee will be able to modify and tweak this definition as needed, for a variety of purposes that such a definition will be used for
- Evidence based – draw upon your knowledge and discussions of literature and data in consideration of this definition, as well sharing your expertise

The rationale for the definition of "hard to place" is to provide a greater standard in defining "hard to place" and kidneys "at (increased) risk of non-use"

- Previously, support in public comment for standardizing a definition of "hard to place" kidneys
- Helps to identify which kidneys may become hard to place, or else may benefit from or require an expedited allocation pathway

The approach for this discussion will include review of the most up-to-date data on non-use and relevant demographics, which are the results from January's data request. The Committee will then break out into Virtual and In-Person groups, with specific focus on pre- and post-cross clamp characteristics and considerations.

Summary of discussion:

There were no questions or comments.

7. Data Results: Kidney Non-Use and "Hard to Place"

Staff presented the results of the Committee's January Data Request regarding descriptive characteristics of kidney non-use.

Presentation summary:

Parts 1 and 2 of this data report utilize a cohort representing all deceased kidney donors recovered in the United States between January 1, 2014 and September 30, 2023, and describes into distributions of donors over time, as well as non-use rates by donor characteristics in 2022. Part 3 of this data report utilizes a cohort of all matches run for deceased kidney donors from January 1, 2023 to September 30, 2023, and describes the percentage of offers sent by sequence number and donor characteristics.

Part 1: National Trends in Deceased Donors Recovered, Kidneys Recovered, and Transplants

The number of kidneys recovered, the number of kidneys transplanted, and the number of kidneys recovered and not used for transplant have increased every year from 2017 to 2022.

The non-use rate of deceased donor kidneys recovered in the United States is described as the number of kidneys recovered but not used for transplant divided by the number of kidneys recovered for the purposes of transplant. The non-use rate increased between 2014 and 2016, and then decreased from 2016 to 2017. The non-use rate increased steadily from 2017 to 2020, after which the non-use rate increased more sharply. From 2014 to 2019, the non-use rate fluctuated around 19-20 percent. The number of kidneys recovered has increased most sharply, particularly between 2019 and 2022. During this time period, there were many policy changes and external factors influencing including the COVID-19 pandemic, new CMS regulations for OPOs, changes to dual kidney policy, changes to PHS increased risk factors, and the implementation of circles-based kidney distribution (KAS-250). In 2023 the non-use rate was 27.2 percent in the first 9 months, which is the highest in the cohort.

The non-use rate of deceased donor kidneys by recovery rate and KDPI groups shows that KDPI 86-100 percent and KDPI 35-85 percent groups had greater variability in non-use rate over time. Over time, the largest increase in non-use rate occurs for these two groups. Looking at KDPI groups more granularly, the highest and most variable non-use rates occur for organs with KDPI 60 and higher. From 2014 to 2023, KDPI 60-69 percent kidneys had non-use rates between 21-30 percent; KDPI 70-79 had non-use rates hovering between 30-40 percent; KDPI 80-89 percent had non-use rates between about 40 and 55 percent, and KDPI 90-100 percent had non-use rates between about 60 and 80 percent.

Part 2: Donor Characteristics Over Time and by Non-Use Status in 2022

The percent of donors aged 50 or greater has increased over the last decade; in 2014 donors aged 50-64 years old were 27 percent of all donors recovered, and 65 years or greater were 5.5 percent, with about 32.5 percent of all donors older than 50 years. In 2023, donors aged 50-64 were 33 percent, and donor aged 65 or greater were about 8 percent, accounting for 41 percent of all donors recovered being more than 50 years old. In general, the donor population is older now than before. In looking at non-use rates from 2022, the non-use rate was 43.89 percent for donors aged 50-64 and 70.03 percent for donors aged 65 and older.

In the last decade, the percentage of donors with a history of cancer has not significantly increased over time. From 2014 to 2018, the percentage of donors with a history of cancer was about 2.8 to 3.2 percent, and in 2023 it was up to 3.8 percent. In 2022, the non-use rate is higher for donors with a history of cancer at 47.43 percent, compared to a non-use rate of 25.76 percent for donors without a history of cancer. Donors with an unknown history of cancer in 2022 had a non-use rate of 32.44 percent.

From 2014 on, the percentage of donors with a history of hypertension has increased over time, accounting for about 30.5 percent of donors in 2014 and increasing to 37 percent of donors in 2023. In 2022, the non-use rate was higher for donors with a history of hypertension (45.24 percent) compared to donors without a history of hypertension (15.85 percent). In 2022, the non-use rate for donors with an unknown history of hypertension.

From 2014, the percent of donors with a duration of diabetes greater than 5 years has increased by about 2 percent over the last decade to about 7 percent of donors in 2023. In looking at 2022 non-use rates, there is a discrepancy between donors with a duration of diabetes greater than 5 years (61.15 percent non-use rate) compared to donors without a duration of diabetes greater than 5 years (23.68 percent). Donors with an unknown duration of diabetes had a non-use rate of 56.01 percent, and donors with an unknown diabetes history had a non-use rate of 30.71 percent.

The percentage of donation after cardiac death (DCD) donors over time has increased significantly from 2014 to 2023. In 2014, about 16.5 percent of donors were DCD, and in 2023, DCD donors accounted for 36.3 percent of donors. In 2022, non-use rate was slightly higher for DCD donors, at 33.87 percent for DCD donors compared to 23.06 percent for non-DCD donors.

From 2014 on, the percentage of donors with anoxia as cause of death has increased over time. In 2014, anoxia, cerebrovascular stroke, and head trauma were relatively evenly distributed across the donor population. In 2023, anoxia is the cause of death for more than half of donors, at 50.1 percent. Cardiovascular stroke as cause of death is included in the KDPI calculation. 2022 non-use rates for donors by cause of death saw the highest non-use rates for donors with cerebrovascular stroke as cause of death (40.74 percent), compared to anoxia (24.52 percent), head trauma (14.74 percent), CNS tumor (28.72 percent), and other (34.3 percent). Although anoxia has become the most frequent cause of death, it is the second lowest in terms of non-use rate by causes of death.

Percent of kidneys pumped has increased over time, from 2014 to 2023. In 2023, there were more kidneys pumped (52.8 percent) than not pumped. In 2022, non-use rate was highest for pumped kidneys (31.23 percent) compared to kidneys that were not pumped (22.71 percent).

The proportion of kidneys biopsied stayed about the same over time. From 2014 to 2017, there was a slight decrease in 2015, but generally the percentage of kidneys biopsied did not change significantly. From 2018 to 2019, there is a slight increase; from 2019 to 2023, the percentage of kidneys biopsied has not changed significantly. The highest incidence of biopsy occurred in 2021, at 59.8 percent of all kidneys biopsied. The percentage of kidneys biopsied has remained in the 58-59 percent range. Although percentages are not changing, the OPTN as a whole is recovering more donors, and so the absolute volume of kidneys being biopsied are increasing. 2022 non-use rates differed significantly for kidneys that were biopsied (40.2 percent non-use rates) compared to kidneys that were not biopsied (7.5 percent).

From 2014, the reasons for non-use over time has increasingly become “no recipient located – list exhausted,” accounting for the reason for the majority (more than 60 percent) of non-used kidneys between 2021 and 2023.

Part 3: Match Run Characteristics and Analysis

This analysis evaluated matches to understand characteristics of hard to place organs, utilizing only match runs where the organs were transplanted. This analysis asked if there are donor characteristics that result in allocation further down the match. This analysis examines the percent of offers sent up to a sequence number. Considering all of the offers sent out in a time period, this analysis examines what percent of offers were sent by sequence number 1, versus sequence number 50, and so on until the maximum sequence number. If there are donor populations allocated quickly (with a smaller number of offers), then the 50 percent of offers would have been sent out at a low sequence number. On the other hand, for harder to place donor characteristics, the median number of offers sent may be reached at a much later sequence number. This analysis may be affected by multiple factors, particularly as there are donor characteristics that result in longer match runs (such as biological compatibility). There is also

screening criteria in place for individual candidates, which can affect the length of the match run and the number of offers required to allocate the organ.

For example, in looking at donors split out by blood type, AB donors have a lower sequence number at 100 percent of offers than type O donors, as there are fewer candidates listed who are compatible with AB donors. Differences in match characteristics by ABO are likely mostly driven by biological compatibility.

In looking at mechanism of death, drowning, natural causes, and seizure often required more offers in order to allocate these organs. These types of match runs reached 50 percent of offers at around sequence 2000, while other causes of death were at around 1000 or below. These mechanisms of death may correlate with more offers required in order to place these organs.

In looking at donor region of recovery, there were two outlier regions. Regions 6 and 8 reached 50 percent of offers sent out at around sequence 2500; comparing that to Regions 5 and 7, which reached 50 percent of offers sent out at around sequence 1300. These results may be indicative of organs needing to travel further from Regions 6 and 8.

Conclusion:

Deceased kidney donors over time have gotten older, more likely to be DCD, more likely to have a history of hypertension, and more likely to have a longer history of diabetes. Organs recovered have seen increases in biopsy and in being pumped. It is important to keep in mind that the data displays these characteristics individually, but that practically, these characteristics interact with each other. A majority of organs recovered and not used for transplant cite the reason as "no recipient located – list exhausted." Donor mechanism of death and region of recovery may affect how many offers are needed to find a transplant recipient.

Summary of discussion:

The Chair remarked that these characteristics interact with each other, and that it would be helpful to be able to cross reference the characteristics, such as pump and biopsy data. The Chair continued that typically, an organ is being biopsied because there is clinical cause for concern, and that is why those kidneys may not be transplanted as frequently.

One member pointed out that it is important to keep in mind that there are kidneys at high risk of non-use that are transplanted but never function. The member continued that it is important to understand that reducing non-use is important, but that some organs are not safe or appropriate for transplant and should not be transplanted, no matter the cold ischemia time. Staff responded that, on a similar note, the OPTN Expeditious Task Force has also been asking what the graft failure and delayed graft function rates look like among kidneys allocated out of sequence. Staff shared that this analysis is underway and is specific to kidneys allocated out of sequence, but that this analysis could potentially be expanded to understand the larger question posed by the member.

A member remarked that cancer type and how old the cancer is can have an impact, as can type of stroke, particularly in terms of evaluating clinical risk of a potential graft. The member explained that a cerebral aneurysm is a very different underlying pathophysiology than an inclusive stroke. The member remarked that cancer and stroke are likely still relatively small contributors to risk of non-use. The member pointed out that "natural cause of death" is vague and somewhat meaningless in distinguishing between different causes of death. The member continued that "natural cause of death" should be broken out into separate, more distinctive categories. Staff shared that there are currently potential efforts to align mechanism and cause of death data with more traditional death records within the OPTN Data Advisory Committee.

One member expressed interest in the geographic data, noting that regions 6 and 8 are comparatively less dense populations and geographically large regions, although these regions are not far from highly populated states. The member asked if anyone from regions 6 or 8 have thoughts on why these regions tend to need to allocate so much further down the list. Another member shared that some of the OPOs in that area only have one transplant center in their donor service area or within 250 nautical miles, and if that program is not aggressive, the OPO may need to allocate further down the match run or to programs further away. One member shared that there may be less transplant program competition in the area, and so programs may feel less inclined to accept offers for more marginal donors. The Chair wondered, in broader geographic regions, whether having a limited number of centers within 250 nautical miles of the donor hospital results in a greater number of declines as OPOs begin to offer to programs outside of 250 NM but within 500 NM, who can see a significant number of declines representing the decision making of only a few surgeons and clinicians. A member remarked that the OPTN Expeditious Task Force has discussed potentially blinding programs to sequence number, so that programs couldn't see other programs' behavior and decline decisions or understand their patient's priority.

8. Defining "Hard to Place" Break-Out Groups and Report Out

The Committee broke out into two groups to discuss potential definitions and characteristics of "hard to place" kidneys, and then came back together to share and discuss group determinations.

Summary of discussion:

The Vice Chair presented on behalf of the virtual break out group, sharing that this group discussed whether all kidneys are appropriate for transplant and what the scope of the definition should be, including whether the definition should capture all kidneys that are hard to place versus having more narrow boundaries.

The Vice Chair added that, in discussing a pre-clamp definition, the virtual group agreed that a high KDRI is a good identifier for "hard to place" kidneys that are at higher risk of non-use. From this, the virtual group discussed whether individual factors in the KDRI calculation should be evaluated differently than others, but there was consensus that the overall score is more beneficial. One member shared that their program uses donor admission proteinuria as a potential characteristic, and the virtual group discussed whether this indicator alone is appropriate, or if this indicator is more meaningful for donors with specific characteristics, such as longstanding chronic kidney disease, hypertension, and diabetes. The virtual group agreed that a proteinuria cut off of urine albumin-to-creatinine (UACR) ratio of 30 mg/g or greater is an appropriate threshold, and that proteinuria should be considered in context with kidney biopsy results to determine if that organ will be hard to place. The virtual group also noted that some programs examine the donor's hospital course and management to understand potential risk to graft function. The Vice Chair continued that it is unclear which details could be incorporated into a definition, and how. The Vice Chair shared that the virtual group discussed long term cocaine use, but there was limited data relating to graft outcomes for donors with long term cocaine use.

In considering logistical factors, the virtual group agreed that distance from the recipient and flight and transportation availability were the greatest factors. The virtual group agreed that these factors, combined with KDPI 50-85 percent kidneys, may benefit most from a definition of hard to place. The Vice Chair continued that the virtual group discussed potential breaking a definition up into KDPI groups, particularly low, medium, and high KDPI. The virtual groups remarked that the medium and low KDPI kidneys may have a higher chance of being transplanted, and so this definition could incorporate more post-clamp factors, while higher KDPI kidneys are less likely to be used and may require a definition

incorporating more pre-clamp factors. The virtual group remarked that expedited placement may be required earlier for high KDPI kidneys in order to maximize use.

The Vice Chair shared that the virtual group discussed that smaller, lower volume programs will continue to struggle to accept kidneys at higher risk of non-use and higher risk of graft failure, particularly as each individual transplant makes up for a larger proportion of the transplant programs' outcomes. The Vice Chair remarked that it would be impactful to help mitigate the risk of accepting higher-risk organs for these programs.

The in-person break out group discussed both pre- and post-clamp indicators of increased risk of non-use. The in-person group agreed that there may be a potential need for expedited placement prior to organ recovery, and that in this case, a kidney should be able to meet the definition of "hard to place" based on pre-clamp information alone. In considering post-clamp characteristics, the in-person group expressed a preference for system and timing factors, similar to the UK and European models of fast-tracking kidney allocation, such as declines from a certain number of candidates and centers. The in-person group agreed that OPTN data should be evaluated to determine where that threshold should lie, and that this may require a follow up data request. The in-person group also discussed a cold ischemic time threshold, agreeing on a 6-hour threshold. The in-person group discussed whether the cold ischemic time threshold should be adjusted for time of day, noting that geography would also impact how critical time of day is, particularly with respect to how close the nearest airport is to the donor hospital, the size of that airport, cargo hours, and other transportation limitations. The in-person group agreed that this level of granularity may be more confusing than helpful and determined that a simpler cold ischemic time threshold is more appropriate, allowing for greater OPO discretion and nuance in determining when to switch allocation to an expedited allocation pathway.

The in-person group discussed pump use, anatomy, biopsy and glomerulosclerosis, and how this information is helpful in determining which programs may accept an organ. The in-person group also discussed how filtering can be improved in terms of both post-clamp and pre-clamp risk indicators.

Similar to the virtual group, the in-person group also discussed transplant program metrics, and how improved risk adjustment, as well as how programs can better understand risk-adjustment, specifically in regard to which factors are most impactful. The in-person break out group discussed metrics as a potential way to encourage programs to be more open to accepting potentially higher risk organs.

9. Committee Discussions: Defining "Hard to Place" and Considerations

Staff provided an overview of the Committee's previous discussions and break out group report outs, and the Committee continued "hard to place" discussions.

Summary of discussion:

One member remarked that proteinuria may require more nuance, particularly as many urinalysis samples are taken after catheters are placed and thus are difficult to interpret in terms of proteinuria. The member continued that there typically isn't significant additional urinalysis and proteinuria testing on deceased donors.

The Chair discussed the concept of a certain number of programs or candidates having declined and noted that this would potentially need to vary based on geography and population density. The Chair proposed a certain percentage of the match run as a trigger for a definition of "hard to place." The Chair remarked that simple sequence number may not be adequate, considering that there are regions of the country where one transplant program may account for the first 100 candidates on the match run, and that a decline from one center for the first 100 candidates should not be considered the same as a decline for 100 candidates from 15 or 20 centers. The Chair recommended that the Committee evaluate

match run data to identify thresholds for number of centers having declined before an OPO initiates out of sequence allocation. The Chair added that total number of centers declined is preferable to number of candidate declines, as this includes center acceptance practices and its variation, versus number of candidates and their individual clinical considerations. Staff asked if a program decline for one candidate is sufficient to be considered one center decline, or would it be necessary for the program to have declined on behalf of all the program's candidates on the match run. The Chair remarked that potentially there is a certain percentage or number of declines per center that should be considered, as one decline, particularly at the top of the match run, may be more reflective of individual candidate considerations as opposed to risk aversion in a program's offer acceptance practices. The Chair continued that the goal of this data would be to understand which donors are at risk of non-use, and up to a certain sequence, there would be a certain number of center declines with a certain number of patients per center that have turned the offer down. The Chair remarked that only one patient declined per center may be too loose of a definition of center decline, but that with hard to place kidneys, it would be expected that allocation would reach a higher sequence number capturing more patients per center having turned the offer down. The Chair remarked that the definition of "hard to place" or else an expedited placement pathway trigger could be multifaceted, including match run thresholds and cold ischemic time thresholds.

The Chair remarked that programs may make offer decline decisions on behalf of a patient based on clinical judgement, without the patient's awareness. The Chair noted that patients necessarily place trust in their transplant programs and care teams, and asked how much information becomes too much information and overwhelms a patient, particularly in terms of offers and offer decision making. The Chair then asked the Committee, in considering policy solutions, how to best reconcile different patient perspectives on how much waiting time is acceptable. The Chair pointed out that patients who are older and have been on dialysis longer likely has a different perspective than a pre-dialysis patient who has just been listed, but that there is significant variation between patient transplant goals and expectations. A member responded that this variation should be considered on an individual basis, and that programs should work with each patient individually to understand their transplant goals. The member shared that patients need more education regarding the entire dialysis to post-transplant process. Another member agreed, noting that some patients are not aware of how the listing process works, including consenting for high KDPI kidneys. The member shared that their program recommended opting out of receiving high KDPI and waiting longer for a graft with longer potential graft life. The member noted that it is likely there is great variation in how programs manage high KDPI consent and patient donor selection. The member agreed that these preferences should be determined on an individual basis, and the programs should understand a patient's individual transplant goals. The member added that patients who have been on dialysis for extended periods of time may wish to receive a transplant faster. The Chair agreed, noting that it is important for patients to understand that getting transplanted earlier or faster may mean that the kidney may not function as well, or for as long as another graft may. The Chair remarked that the "hard to place" kidneys may be considered potentially lower longevity grafts, and that it will be important for patients to understand an individual graft's potential risks.

A member asked the Committee how they would define a "perfect kidney," noting that it was their understanding the biggest impact to graft function and longevity is how a recipient manages treatment afterwards. The Chair responded that this looks different for each patient and from each surgeon, but that typically, a "perfect kidney" maximizes a patient's benefit from transplant. The Chair continued that, if a patient's goal is to get off of dialysis as soon as possible, the definition of an appropriate kidney for transplant may be broader. The Chair continued that clinicians may also consider impact to program metrics, noting that patient risk tolerance has to be balanced with impact to program metrics and

programs' ability to provide care for other patients. The Vice Chair agreed but noted that different geographic regions have varying patient populations with different needs. The Vice Chair explained that, in their region, there are many patients with the misunderstanding that kidneys with hepatitis C or hepatitis B are poor quality kidneys, and that the educational needs of these patients differ from educational needs of other patients. The Vice Chair continued that there should be standardized, widely available education around PHS increased risk and high KDPI kidneys. The Vice Chair added that the "perfect kidney" is the kidney that the patient receives that meets their goals and which lasts the patient's lifetime. A member agreed, noting that there has been literature to show that the longer patients remain on dialysis, the higher their risk of waitlist mortality. The member continued that transplant care teams should be having more conversations about the opportunity cost and risk of remaining on dialysis to wait for a higher quality kidney. Other Committee members agreed, noting that it's not just availability of the material, but care teams having direct conversations with patients to ensure understanding. A member pointed out that literature has shown that there is a point at which a patient with significant dialysis time has a higher chance of mortality on dialysis than receiving a transplant, and that it is important for patients to understand these risks over time.

One member remarked that the LDOs do not always objectively portray the risks and benefits of transplant as a treatment option to dialysis patients. The member continued that the OPTN and dialysis centers need to be on the same page and using the same language. The member shared that patients are required to self-advocate to a high degree in order to access transplant while receiving dialysis, particularly from for-profit dialysis centers. The member explained that dialysis centers profit from patients remaining on dialysis. The Chair remarked that this is an important consideration, particularly that many types of stakeholders are not aligned. The Chair continued that these stakeholders should be aligned across a common goal.

The Chair remarked that potentially, the new approach to Continuous Distribution should incorporate a multi-step approach, where portions of the project are separated into individual proposals. The Chair continued that a Committee consensus definition of "hard to place" will provide a solid foundation for the Committee to come back to in considering a more efficient continuous distribution allocation system. The Chair remarked that it is important for the transplant system to transplant the right organ with the right patient, and an expedited placement framework based on a consensus definition of "hard to place" can help improve efficiency prior to the implementation of continuous distribution.

A member remarked that there are a number of individual clinical factors currently being considered in the development of the "hard to place" definition, at least based on what is known prior to cross clamp. The member commented that it may be helpful to have the SRTR and statistical analysis to understand to what degree each of these characteristics matter. The member continued that it would be worthwhile to develop a statistical scoring system, and that potentially this work could be validated or used to validate across other predictive scoring systems. The member asked if the Committee should choose factors that may be important and request the SRTR to determine relative relevance in a statistical model. Staff noted that data is limited regarding some characteristics, such as proteinuria, and shared that the results of the January data request describe recent data regarding many of the other characteristics. Staff asked if the member was imagining a calculator that could be used to quantify the risk of non-use, from which the Committee could determine a threshold of sufficient risk. The member suggested the Committee develop a preliminary list of characteristics, such as DCD, high KDPI, and degree of glomerulosclerosis, and then statistical analysis can be done to determine how these factors were represented in historic cohorts of donor kidneys that were not used, and from there determine thresholds for factors selected. The member continued that a scoring system could stem naturally from this. Another member pointed out that these criteria also interact with each other, and that a donor

who meets multiple criteria may have increased likelihood of non-use. The member referenced Mohan et al (2018), noting that there was a higher odds ratio of non-use as a donor met more characteristics. Another member agreed.[11]

One member asked if the "hard to place" kidney allocation process should consider patient education. The Chair remarked that it may be more effective to focus on donor factors in determining what makes an organ "hard to place," but that patient education and patient preference should be incorporated into allocation of a "hard to place" kidneys. The Chair added that patients have the option to decline any organ for any reason, and that it is important for patients to feel comfortable and certain of accepting an organ offer, including for "hard to place" kidneys.

One member commented that the UK and European models of expedited placement utilize simple triggers to determine which kidneys are eligible for expedited placement. The member recommended that the definition of "hard to place" adopt a similar simple, understandable framework utilizing basic donor characteristics. The Chair agreed, noting that the European system also utilizes two different allocation frameworks – a standard pathway, and a higher risk pathway for higher risk recipients. The Chair continued that this program gives patients the opportunity to opt into the higher risk program, which allows these patients to access transplant more quickly with potentially higher risk organs. The Chair continued that in some cases, patients had significantly reduced waiting times with limited impact to post-transplant outcomes. The Chair remarked that it is important for this system to be opt-in, so that patients have a choice in their path to transplant. Another member agreed, noting that additional tools could help clinicians have explicit conversations with patients about quantified risk. The member gave an example that the organ being offered may have some estimated or projected graft life, based on the graft life of similar organs in most cases. The member continued that it is possible to capture the reduction in risk of mortality and morbidity compared to dialysis.

The Committee expressed agreement with the preliminary characteristics below and agreed to continue pursuing more data to determine allocation-based thresholds and understand how these characteristics interact with each other.

<u>Preliminary characteristics:</u>

Clinical Indicators:

- Combination of multiple characteristics → more characteristics equals more risk, greater than the sum of its parts
    - High Kidney Donor Risk Index (KDRI), which includes multiple associated factors
    - Donor admission proteinuria
    - Biopsy, pump, and anatomy factors
- Cold ischemic time greater than 6 hours, noting interaction with distance

Allocation indicators:

- Number of candidate or center declines (or sequence number of allocation)
    - May need additional data to determine appropriate thresholds
        - Percentage of candidates who have declined, or percentage of centers declined
        - Certain proportion of a center's potential candidates, or a certain number of candidates the center has declined for

[11] Mohan, et al. (2018). Factors leading to the discard of deceased donor kidneys in the United States. Kidney Int., 94(1), 187-198. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6015528/

- Cold ischemic time greater than 6 hours, noting interaction with distance and flight availability

10. OPTN Lung Transplantation Committee: *Promote Efficiency of Lung Allocation* Proposal

The Committee received a presentation and provided feedback on the *Promote Efficiency of Lung Allocation* proposal.

Presentation summary:

The purpose of this proposal is to add new data collection to aid evaluation of lung offers; provide an overview of lung offer filters (implemented January 31, 2024); and request feedback on other potential system enhancements, such as "bypass bilateral and other lung" button if only single lung is available or the option to opt in to offers from isolated areas beyond specified maximum recovery distance.

Lung offer filters were implemented on January 31, 2024. Lung transplant programs can build program-level filters based on donor type (donation after brain death (DBD)/DCD), distance, donor age less than, and donor age greater than. Candidates can be excluded from program-level filters using these criteria: candidate age less than, CPRA exceeds, candidate blood type, candidate match score is less than, and candidate match score exceeds.

Other potential system enhancements include a "bypass bilateral and other lung" button is only a single lung is available. Lung transplant programs are required to indicate lung(s) and laterality needed for each candidate. If the OPO only has a single lung available, this button would bypass all candidates on the match who either need bilateral lungs or the other lung. Currently, OPOs must manually bypass these programs, or the program must decline.

The Lung Committee is also considering providing an option for programs to opt in to offers from geographically isolated areas. Currently, lung transplant programs enter "maximum recovery distance" for each candidate. If programs want to accept offers from areas like Hawaii, Alaska, and Puerto Rico, they may need to set this distance very broadly and may receive excess offers from great distances. The "opt in" approach would allow them to receive offers from those areas while setting a shorter "maximum recovery distance." For example, a lung transplant program in Seattle, Washington could indicate the following in screening criteria and offer filters:

- Donor acceptance criteria – maximum recovery distance of 500 NM
- Program indicates it will accept offers from isolated areas:
    - Hawaii: Honolulu (2326 NM away)
    - Alaska: Juneau (790 NM away)
- Offer filters: donor is DCD and distance greater than 300 NM

In this example, the candidate would not appear on a match run for a donor recovered in Las Vegas (about 870 NM away) but would appear on a match for a donor in Honolulu (2300 NM away).

The Lung Committee is also considering policy approaches to improving efficiency in allocation. Sea-Tac Airport in Seattle, Washington is currently used as the location of the donor hospital for the following organs if procured in Alaska, as Alaska has donor hospitals but no transplant programs:

- Kidney
- Kidney-Pancreas
- Pancreas
- Pancreas islets
- Liver
- Intestine

- Liver-intestine

This rule does not currently apply for lung, heart, or vascularized composite allografts.

Questions for consideration:

- Do you think the proposed system enhancement would help reduce unwanted organ offers?
- Do you think this system enhancement would promote utilization of donor organs from more geographically isolated areas like Alaska, Hawaii, and Puerto Rico?

Summary of discussion:

One member commented that allocating kidneys from Alaskan donor hospitals as if they were located at the Seattle-Tacoma (Sea-Tac) airport significantly improved and simplified allocation of those organs. The member continued that it would make sense to replicate something similar for thoracic organs. The member added that Alaska to Seattle is still a greater distance, and that it can be difficult to make this work with more medically complex organs, such as livers from DCD donors. The member recommended that offer filters include the capability for programs to make multi-factorial filters for specific geographically isolated areas, such that programs could potentially implement a filter for DCD livers from Alaska, for example. The member added that this would be important for allowing programs to maximize efficiency gains from screening, allowing them to avoid certain types of organs from geographically isolated areas while still receiving other offers from these areas.

Another member noted that advanced filtering for organs from geographically isolated areas could benefit OPOs attempting to allocate these organs, allowing them to send offers to programs that will accept the organs sooner. The member explained that there may be specific programs and surgeons that may be willing to accept organs from much further away, but that it can be difficult to reach those patients on a match run.

Staff thanked the Committee for their feedback, noting that there are many potential ways to operationalize these concepts, and that the OPTN Lung Committee had considered policy pathways, specific utilities in the OPTN Waitlist System, and similar options. Staff shared that the OPTN Lung Committee will also specifically reach out to OPOs in geographically isolated areas to gather feedback.

11. Ad Hoc Multi-Organ Transplantation Committee: *Modify Effect of Acceptance* Proposal

The Committee received a presentation and provided feedback on the Ad Hoc Multi-Organ Transplantation Committee's *Modify Effect of Acceptance* Proposal.

Presentation summary:

The purpose of the proposed policy is to clarify when a single organ offer acceptance takes priority over a required multi-organ transplant (MOT) share. This proposal will clarify that when a primary single organ is declined after an organ has been accepted, the OPO is not required to allocate to required MOT shares since a second organ is no longer available.

January 2023 concept paper requested input on a variety of topics, including organ offer acceptance and required shares. OPTN Policy 5.6.D: *Effect of Acceptance* states that when an organ has been accepted by a transplant program, that offer is binding. However, OPOs may not finalize acceptance of organs in case there is a late organ offer refusal and an MOT candidate is on the match run. This change will allow OPOs to move forward with placing single organs. The OPO will not be required to allocate to the required MOT shares if a second organ is no longer available.

Consider the following MOT allocation example. The heart, liver, and lungs are all accepted as individual organs, and both kidneys have been accepted by other candidates. The OPO then receives notification

that the heart candidate can no longer accept the organ. The next candidate on the heart match run is a qualifying heart-kidney candidate. Current policy requires the OPO to offer the kidney along with the heart, but the kidneys have been placed and are no longer available.

The proposed policy would clarify that the OPO is not expected to offer the kidney along with the heart to the next qualifying heart-kidney candidate since the kidneys have already been allocated with a primary acceptance. However, the primary organ should still be offered to the candidate, the case the program is willing to accept the primary organ without the secondary organ.

OPOs and transplant hospitals may need to evaluate their internal policies and procedures to account for this clarification.

The Lung Committee is considering the following policy language, with new language underlined:

> Policy 5.6.D: Effect of Acceptance: When a transplant hospital accepts an OPO's organ offer without conditions, this acceptance binds the transplant hospital and OPO unless they mutually agree on an alternative allocation of the organ.
>
> <u>If an organ has been accepted by a transplant program, that organ is no longer available for subsequent offers, including those according to *Policy 5.10: Allocation of Multi-Organ Combinations.*</u>

Questions for consideration:

- Should a specific timeframe be included in the policy language?
    - For example, if an organ has been accepted by a transplant program and the donor recovery has been scheduled.
- Do patients and donor families support the concept that accepted organs take priority over required multi-organ shares?

<u>Summary of discussion:</u>

One member noted that as written, the policy would require the formal acceptance of the kidney as opposed to a provisional yes. Staff clarified that the Multi-Organ Committee's policy language refers to "offer acceptance," which has a specific definition in OPTN policy.

A member remarked that the policy language does not provide adequate clarity to allow OPOs to maintain their primary offers to single organ candidates when another offer is declined, and the subsequent candidate is a multi-organ candidate requiring an organ that has already been offered as primary to a single organ candidate. The member commented that the thoracic or liver center may feel that a kidney is not placed until it has left the OPO, and a kidney program may not feel comfortable formally accepting ahead of receiving post-clamp information. The member added that it would be difficult in most cases to know which kidney a program is being offered, and if the program has choice, which kidney they would accept prior to cross clamp. The member asked whether this policy would still hold in a scenario where it's a multi-organ candidate that has declined first. Staff confirmed this, noting that this policy language refers to organs, and that it does not matter if the initial acceptance was for a multi-organ or a single organ candidate. Staff continued that this policy aims to clarify that, if the organ was accepted, it is not available to be offered to the required multi-organ shares.

Staff noted that the OPTN Multi-Organ Transplantation Committee (OPTN MOT Committee) considered a specific time frame, specifically where OPOs would no longer be bound by multi-organ shares if the organ recovery date and time has been set. However, the MOT Committee noted that organ recovery time is a shifting target and decided to move forward with a policy based on acceptance.

The Chair noted that thoracic organs and livers are typically accepted based on pre-recovery information, while kidneys are not typically fully allocated until post-recovery information is available. The Chair added that hearts, livers, and lungs are also typically recovered by a program's own recovery team. The Chair continued that even though kidneys are not fully allocated until after recovery, it would not be appropriate to withdraw a primary offer to a kidney-alone candidate.

One member pointed out that most programs will bring patients in prior to recovery, particularly if the program is not waiting for biopsy results. Another member pointed out that heart donors are typically young and healthy, and that there would not be a ton of post-recovery information necessary to confirm kidney acceptance. The member continued that kidney transplant programs should be able to commit to young healthy donors earlier in the allocation processes. The Chair countered that this policy would still apply with liver kidneys, and that some liver donors can be older, while some heart donors can be in their 40s or 50s. The Chair added that acute kidney injury should also be considered. The Chair added that biopsy results may be relevant to back up kidney programs if the multi-organ acceptance falls through.

Staff asked the Committee if programs will bring patients into the hospital while the match run still has a provisional yes, as opposed to an acceptance. A member explained that their program tries to keep patients at home for convenience, but there may be situations where a patient will need more time to come in or additional evaluation, requiring the patient to come to the hospital earlier in the process.

Staff asked the Committee if it would provide more clarity for the language to specify that an OPO cannot withdraw a primary offer to allocate a multi-organ combination. One member agreed. Staff noted OPTN Policy does not current define primary offers, but that this could be done to better define the appropriate sequence of allocation. One member asked if the primary offer would be the first two kidney patients on the match run. Staff shared that typically, the primary offer is the final, official offer, such that a program deciding to accept the offer, accepts the organ and thus has the responsibility to transplant the organ into the patient they have accepted it for.

A member offered that maybe it should be left up to OPO discretion, particularly as OPOs may know based on their allocation discussions how serious each center is about accepting the offer. The member added that if the OPO knows the center is serious enough about the offer to have called their patient, the OPO should be honor bound not to withdraw that offer to allocate the kidney with the heart. On the other hand, if the center is less seriously considering the offer, the OPO would be able to offer the kidney with the heart. The Chair remarked that currently, there is OPO variation in determining whether to withdraw the single-organ offer. The Chair continued that this proposal aims to eliminate that variation between OPOs and provide clarity for both OPOs and transplant centers in multi-organ and single organ allocation rules. Staff agreed, noting that this proposal aims to also address situations where late turn downs result in late-allocation of multi-organ offers, so that an OPO is not penalized for moving forward with allocation of single-organ offers that have already been made and accepted. Staff explained that currently, OPTN Policy is explicit on when OPOs are required to offer multi-organ combinations and when multi-organ allocation is permissible. A member further explained that the current structure of multi-organ policy delays allocation and increases the disruption caused by late declines.

One member offered a potential solution, such that only a threshold of kidney patients. The member explained that if a heart-only acceptance falls through and the next patient is a heart-kidney patient, those kidney patients in the threshold could potentially have priority over the heart kidney.

One member asked if heart and lung currently have safety net kidney priority, and the Chair confirmed that OPTN policy includes heart-kidney and lung-kidney safety net. The Chair noted that, during those

discussions, there was pushback from the thoracic transplantation community out of concern that certain heart or lung patients who do not qualify for heart-kidney or lung-kidney priority may not survive long enough to benefit from safety net priority on a kidney match run. The Chair noted that further discussion questioned if those patients were stable enough to receive multi-organ transplant.

One member remarked that there should be a way to confirm commitment to acceptance above just a provisional yes, but less than a final acceptance. Another member agreed, pointing out that programs can't enter a final acceptance ahead of recovery, particularly when considering choice of left or right kidney. The member noted that there should still be some way to ensure stronger commitment from the kidney programs than a provisional yes. The Chair noted that the system is not currently built to allow for kidney acceptance prior to OR, particularly in considering choice of left or right kidney. Currently, the OPTN Donor Data and Matching System requires the user to determine which kidney is being accepted, which makes it difficult to enter an acceptance ahead of recovery, when, typically, choice of left or right is made based on relative anatomy and visualization of the organs. Another member agreed, noting that only the OPO and the accepting center will be aware in the situation of the program's level of intent to accept the organ. A member remarked that there isn't a straightforward way to establish that commitment in the current system without leaving it up to OPO discretion. The Chair noted that it would be hard to distinguish greater level of commitment from programs anyway, particularly as programs may still decline for anatomy concerns even if the patient is worked up and preparing for surgery. A member remarked that OPOs should not be obligated to withdraw primary offers from single-kidney patients when the patients are in the hospital preparing for transplant surgery. The Chair agreed, adding that the organ should stay with that patient for whom a program plans to accept it.

One member pointed out that there is a level of acceptance between provisional yes and final acceptance that could be considered a "provisional yes plus." Another member recommended building out the OPTN Donor Data and Matching System to include data collection to indicate whether the program has performed a virtual crossmatch and other evaluation elements. The Chair considered that there may be system programming necessary to ensure it's clear that the kidney is already allocated.

A member remarked that it would be particularly disappointing for a primary offer to highly sensitized candidates to be withdrawn to offer a multi-organ combination.

12. Ad Hoc Multi-Organ Transplantation Committee: *Concepts for Modifying Multi-Organ Policies* Concept Paper

The Committee received a presentation and provided feedback on the Ad Hoc Multi-Organ Transplantation Committee's *Concepts for Modifying Multi-Organ Policies* concept paper.

Presentation summary:

The purpose of this concept paper is to request feedback from the community to inform future policy proposals. The Multi-Organ Transplantation Committee's goal is to establish an updated framework for Kidney multi-organ allocation.

The previous January 2023 concept paper requested input on the following:

- Kidney alone vs kidney multi-organ candidates
- Offering kidneys to candidates of equal priority
- Organ offer acceptance and required shares
- Balancing direction vs. flexibility for organ procurement organizations

Previously, the community has expressed support for promoting priority for specific groups relative to kidney multi-organ candidates, including pediatric, highly sensitized, medically urgent, and prior living

donor kidney candidates. The community also discussed the multi-organ status of kidney with pancreas candidates and requested better guidance for OPOs during multi-organ allocation.

The Multi-Organ Transplantation Committee has reviewed a significant amount of data regarding deceased donor transplants, specifically between March 15, 2021 and December 31, 2022. In this time period, a kidney with KDPI 0-34 percent was allocated to kidney alone candidates 41 percent of the time, compared to 90 percent of kidney-pancreas (KP) candidates, 79 percent of heart-kidney candidates, 70 percent of other kidney multi-organ candidates, and 60 percent of liver-kidney candidates. Comparatively, because KDPI is annually mapped to a reference population of deceased donors in the United States with a kidney recovered for the purpose of transplantation in the prior calendar year, about 34 percent of donors each year would be expected to have kidneys with KDPI between 0-34 percent.

The Multi-Organ Committee also reviewed donors who donated both kidneys by recipient type, including whether kidneys were placed with multi-organ candidates, kidney-pancreas candidates, or kidney-alone candidates. This data utilized the same cohort period between March 15, 2021 and December 31, 2022. For 82 percent of donors from whom both kidneys were transplanted, both kidneys went to kidney-alone recipients. The remaining 18 percent of donors where both kidneys were placed can be broken down as follows:

- 37 percent of these donors had 1 kidney placed with a KP recipient and the other placed with a kidney alone recipient
- 51 percent of donors had 1 kidney placed with a multi-organ recipient and the other kidney placed with a kidney alone recipient
- 8 percent of donors had 1 kidney placed with a multi-organ recipient and the other kidney placed with a KP recipient
- 3 percent of donors had both kidneys placed with multi-organ recipients
- Less than 1 percent of donors had both kidneys placed with a KP recipient
    - These donors were en bloc donors

In looking at placement of kidneys by KDPI when both kidneys are transplanted, for the same cohort period:

- For 0-34 percent KDPI donors:
    - 70 percent of the time, both kidneys went to kidney alone recipients
    - 13 percent of the time, one kidney went to a kidney alone recipient, and the other to a KP recipient
    - 13 percent of the time, one kidney went to a kidney alone recipient, and the other to a multi-organ recipient
    - 3 percent of the time, one kidney went to a multi-organ recipient and the other to a KP recipient
    - 1 percent of the time, both kidneys went to multi-organ recipients
- For 35-85 percent KDPI donors:
    - 91 percent of the time, both kidneys went to kidney alone recipients
    - 1 percent of the time, one kidney went to a kidney alone recipient, and the other to a KP recipient
    - 7 percent of the time, one kidney went to a kidney alone recipient, and the other to a multi-organ recipient
    - Less than 1 percent of the time, one kidney went to a KP recipient, and the other to a multi-organ recipient

    - Less than 1 percent of the time, both kidneys went to a multi-organ recipient
    - Less than 1 percent of the time, both kidneys went to a KP recipient
- For donors KDPI 86-100 percent:
    - 99 percent of the time, both kidneys went to kidney alone recipients
    - 1 percent of the time, one kidney went to a kidney alone, and the other went to a multi-organ recipient

The Multi-Organ Transplantation Committee is requesting additional feedback from the community on the following:

- Multi-organ vs. single kidney offers:
    - How should MOT candidates be prioritized when there is only one kidney available?
    - Do patients and donor family members support efforts to improve access to transplant for kidney alone candidates, even if it means that candidates registered for multiple organs may need to wait longer for a suitable donor?
    - Should kidney-pancreas (KP) candidates be considered multi-organ candidates and be prioritized among other multi-organ combinations?
        - Previous feedback expressed concern with this approach as it might disadvantage pancreas candidates
        - Previous recommendation to treat kidney-pancreas candidates more similarly to kidney candidates
    - Do more kidneys need to be made available for kidney-pancreas and kidney alone candidates or should the focus be on making more kidneys available for kidney-alone candidates?
    - When both kidneys are available from a donor with a kidney donor profile index (KDPI) between 0-34 percent:
        - Should one kidney be allocated to MOT including kidney-pancreas (KP) and the second kidney to kidney alone?
            - Using data from the March 15, 2021-December 31, 2022 cohort, this would result in about 150 additional kidneys to kidney alone candidates
        - Should one kidney be allocated to MOT and the second kidney to KP or kidney alone?
            - Using data from the same cohort, this would result in about 30 additional kidneys to kidney alone or kidney-pancreas candidates
        - What are the potential impacts to KP and pediatric candidates?
            - Significant impact for pediatric kidney candidates, given small number on the waiting list (about 310 candidates)
- Policy guidance for OPOs
    - Should policy direct the order in which OPOs allocate organs? If so, how should expected waitlist mortality or graft survival be incorporated into the prioritization of candidates across different match runs?
    - What additional policy or system considerations would OPOs need to follow a match run order directed by policy?
    - Do patients and donor family members support efforts to promote more consistency in how organ allocation is managed by OPOs across the country?

<u>Summary of discussion:</u>

One member remarked that it makes sense that multi-organ recipients have access to low KDPI kidneys, particularly as thoracic and liver donors are typically lower KDPI donors to begin with. The member added that this still raises questions regarding equity in access.

The Chair noted that it is encouraging to see that the data shows a much smaller percentage of donors where both kidneys are allocated only to multi-organ combinations. The Chair remarked that there is fear in the kidney transplant community that kidney patients may be disadvantaged by so many organs going to multi-organ or kidney-pancreas patients, but the data shows that at least one kidney is allocated to kidney patients the majority of the time. Staff noted that there has been an increase in multi-organ transplantation, but there has also been an increase in kidney-alone transplantation, and that the kidney-alone transplantation has grown more rapidly than multi-organ transplantation. Staff asked the Committee if there is still more opportunity to provide access for highly sensitized kidney and pediatric kidney candidates. The Chair offered that safety net kidney priority may also affect this, questioning whether safety net kidney candidates may receive too much priority.

The Chair remarked that kidney-pancreas patients should not be considered multi-organ patients, and instead should be considered kidney patients, given that they must meet the same waiting time qualification requirements to be listed for a KP. The Chair added that the kidney follows the other organ in most multi-organ combinations, but that it is rare for pancreas to be transplanted alone. The Chair also pointed out that multi-organ transplantation has increased, while kidney-pancreas transplantation has decreased, and that the best way to increase utilization of pancreata is to allocate the kidney with the pancreas as well.

One member remarked that, as a pediatric program, their program typically accepts all low KDPI kidney offers, and rarely declines without an extreme anatomy concern. The member added that it is not uncommon for multi-organ programs in their area to accept and later turn these kidneys down, without a clear reason, and that their program then receives the offer without having had the opportunity to prepare the patient for transplant ahead of recovery. The member continued that many in the community feel that pediatric kidney alone patients should have priority over multi-organ adult patients, adding that there is no metric to look at the benefits a pediatric patient receives from transplant compared to an adult. The member continued that the adult has already had the opportunity to complete puberty and live a good portion of their life healthy, while pediatric candidates have not yet had that opportunity. The member shared that morbidity and mortality statistics for pediatric candidates on dialysis are significantly higher compared to those patients' cohorts, and that this difference is reduced dramatically when these patients receive a transplant. The member noted that it is acceptable to consider kidney-pancreas as kidney patients, instead of as multi-organ patients.

13. Discussion: Life Expectancy and Mortality Risk for Chronic Kidney Disease (CKD) Patients on Dialysis and with Transplant

A member shared data illustrating the Expected Remaining Lifetime of patients on dialysis, with a transplant, and the general public, by age group and gender. The Committee briefly discussed this data.

Presentation Summary:

The presented data shows that expected remaining lifetime is higher for the general population compared to patients on dialysis and with transplant. This gap is largest for the 0-14 age group and becomes increasingly smaller across older age groups. Expected remaining lifetime is much higher for patients who have received a transplant over patients remaining on dialysis; while this gap becomes smaller over time, there remains a significant gap between transplant recipients and dialysis patients across all age groups. Expected remaining lifetime is more than double for patients who have received a transplant over patients still on dialysis, and this remains true across age groups.

Summary of discussion:

A member remarked that even in patients in their late 70s, transplanted patients expected survival more closely resembles the general population than those on dialysis. The member concluded that there is significant survival benefit with a transplant for patients in any age group.

14. OPTN Minority Affairs Committee: *Refit KDPI without Race and HCV* Proposal

The Vice Chair of the OPTN Minority Affairs Committee (MAC) presented the *Refit KDPI without Race and HCV* proposal, and the Committee provided feedback.

Presentation summary:

The purpose of this proposal is to remove race and hepatitis C virus (HCV) from the KDPI calculation, such that the calculation better reflects the likelihood of graft failure for kidneys from African American/Black and HCV-positive deceased donors.

This proposal will refit the KDRI model without race and HCV and re-map it to the KDPI scale. The KDPI is a measure that combines deceased donor factors to summarize the quality of deceased donor kidneys into a single number. Transplant professionals use the KDPI to help them make informed decisions about donor organ suitability for their candidates. The KDRI is an estimate of the relative risk of post-transplant kidney graft failure and is translated into a KDPI percentile from 0-100% for the purposes of OPTN allocation. Lower KDPI scores are associated with longer estimated function, while higher KDPI scores are associated with shorter estimated function.

The race and HCV variables equivocally increase the KDPI of kidneys from African American/Black and HCV-positive deceased donors, making these kidneys appear less suitable for transplant. Race is a poor proxy for human genetic variation, as it is a social construct that lacks biological meaning. Excluding race from the KDPI calculation has no impact on the calculation's predictive ability. It is postulated that it is not race, but the presence of APOL1 gene 1 and gene 2 that confers a worse kidney allograft outcome. HCV has become less relevant as contemporary HCV treatments are highly effective.

Member Actions: the OPTN Computer System will need to be updated with the refit KDPI calculator. Kidney transplant programs and OPOs will need to be familiar with changes to the OPTN KDPI calculator. The KDRI will continue to map to 100 percent and the number of donors in each KDPI sequence will be roughly the same. While the number of donors in each KDPI sequence will remain consistent, changing how donors are categorized by KDPI will impact donor candidate matching.

Questions for consideration:

- Do community members support the removal of race and HCV variables from the KDPI calculation? Why or why not?
- Do transplant professionals believe this policy change will impact acceptance behavior when using KDPI to assess deceased donor kidneys for transplant? Why or why not?
- Do patients and donor families support the proposed solution? Why or why not?

Summary of discussion:

One member thanked the Minority Affairs Committee Chair for the presentation and the Minority Affairs Committee's work on this proposal. The member expressed support for the proposal.

The Chair expressed support for the proposal. The Chair commented that KDPI is a somewhat crude marker for suitability and longevity of an organ, and that this is a step towards refining KDPI. The Chair asked if the Minority Affairs Committee has looked at previous data to understand how refitting the KDPI would have changed allocation, and how KDPI would have looked previously without race and HCV

variables. The Chair of the OPTN Minority Affairs Committee explained that SRTR and the OPTN Research support team have worked to understand how refitting KDPI will reorganize certain donors. The Chair of the OPTN Minority Affairs Committee continued that HCV has a somewhat nominal effect on acceptable, particularly as there are effective treatments available for HCV. The Chair of the OPTN Minority Affairs Committee continued shared that the difference in KDPI with the removal of the HCV variable is less than 10 percent. The Chair of the Minority Affairs Committee explained that, in looking at distribution of high KDPI by race, there is a disproportionate proportion of African American donors in the "high KDPI" category. If KDPI was taken as a percentile of organ quality, it would be expected that each race would be equally represented. When the race variable is removed from KDPI, the distribution of race among high KDPI donors is much more equally proportional. The Chair of the Minority Affairs Committee commented that this shows that KDPI is a more accurate, relevant metric when considering quality of organs across racial groups. The Chair of the Minority Affairs Committee added that in some instances, the difference in KDPI for a Black and non-Black donor, holding all else equal, was as much as 20 percentage points. The Chair of the Minority Affairs Committee noted that, after refitting, the KDPI of some organs may increase, but that this will ultimately reflect a more accurate and appropriate KDPI.

One member shared that they had put in their own information, and also found about a 20-point difference when African American was selected. The member shared that this is a drastic difference, particularly in the context of biracial or multi-racial donors. The member added that the inclusion of a race variable in KDPI makes it difficult to maintain integrity that race is not a factor in allocation while a variable like this is in place, particularly when talking to donor families. The member expressed support for the proposal. The Chair of the Minority Affairs Committee agreed, noting that the work of the OPTN was founded on the trust of the community, and the trust that the general public places on the system to utilize the gifts given. The Chair of the Minority Affairs Committee agreed that race should not matter, and that risk associated with race should be further broken down to reflect the actual clinical risk factor, such as genes or medical conditions. The Chair of the MAC added that medical comorbidities and clinical information should what is used to determine the suitability of transplantation and longevity of a particular graft, and that race is not a biological difference.

A member expressed support for the proposal, and asked if there were other changes made in refitting the KDPI calculation. The Chair of the Minority Affairs Committee explained that the Minority Affairs Committee only considered the removal of two variables, and that the KDPI will continue to include height, weight, age, hypertension, diabetes, cerebrovascular accident as cause of death, serum creatinine, and DCD. The Chair of the Minority Affairs Committee continued that the KDPI is a logarithmic calculation, and removing some variables will distribute the other variables more uniformly. The Kidney Committee Chair added that the other KDPI factors will not have a proportional increase, and some factors may become more impactful than others. The Chair of the Minority Affairs Committee shared that the Minority Affairs Committee will continue meeting with SRTR to discuss how the variables will refit to more accurately represent organ longevity.

Upcoming Meetings

- March 18, 2024

Attendance

- **Committee Members**
  - Jim Kim
  - Arpita Basu
  - Martha Pavlakis
  - Aparna Sharma
  - Charles Strom
  - Eloise Salmon
  - Jason Rolls
  - Chandrasekar Santhanakrishnan
  - Sanjeev Akkina
  - Curtis Warfield
  - Patrick Gee
  - Tania Houle
  - Leigh Ann Burgess
  - Marian Charlton
  - John Lunz
  - Stephen Almond
  - Kristen Adams
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Grace Lyden
  - Ajay Israni
  - Jodi Smith
  - Jon Miller
  - Tim Weaver
- **UNOS Staff**
  - Kayla Temple
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Thomas Dolan
  - Carlos Martinez
  - Linwood Butler
  - Alison Wilhelm
  - Joann White
  - James Alcorn
  - Kelley Poff
  - Kimberly Uccellini
  - Lauren Motley
  - Nick Wood
  - Sarah Roache
  - Susan Tlusty
  - Viktoria Filatova
- **Other Attendees**

- Oscar Serrano