

OPTN Kidney Transplantation Committee

Meeting Summary

August 26, 2024

Teleconference

Jim Kim MD, Chair

Arpita Basu, MD, Vice Chair

Introduction

The OPTN Kidney Transplantation Committee (the Committee) met via teleconference on 8/26/2024 to discuss the following agenda items:

1. OPTN Expeditious Task Force Update
2. Post-Implementation Monitoring Report: 1-Year Minimum Criteria to Require Biopsy
3. Post-Implementation Monitoring Report: 6-Month Standardize Biopsy Reporting and Data Collection

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

1. OPTN Expeditious Task Force Update

OPTN Contractor Staff presented a brief update on the OPTN Expeditious Task Force's (the Task Force) first expedited placement protocol.

Presentation summary:

The Task Force's Rescue Pathways Workgroup is working to initiate the first expedited placement variance protocol, also known as "Rescue Pathways Protocol 1: Accelerated Placement of Hard to Place Kidneys." This initial protocol will test the allocation variance process. The protocol will also:

- Limit participation to no more than 5 Organ Procurement Organizations (OPOs)
- Limit eligible organs to those at greatest risk for non-use
- Protect highest priority candidates' ability to receive offers
- Provide an opportunity for programs that do not routinely access these offers to increase acceptance

It is anticipated that this first test will produce findings that may need to be further tested. The Rescue Pathways Workgroup acknowledges the potential limitations of reporting and analysis with small sample sizes.

28 OPOs submitted interest in participating in the first protocol; 5 of these OPOs were selected with consideration for geography, volume, allocation, and non-use rates.

Transplant program invitations are being sent and will be based on geography and opportunity to test protocol. Transplant programs participating in the program should commit to increased use of KDPI 75-100 kidneys. These programs are responsible for identifying appropriate patients and ensuring readiness. These programs will work closely with identified OPOs and the Expeditious Task Force. In selecting transplant programs, the Rescue Allocation Pathways Workgroup chose to:

- Prioritize proximity to OPO

- Select enough transplant centers to account for OPO donor volume
- Exclude children's-only programs
- Consider hospitals with various histories of accepting high KDPI kidneys
- Over-invite, to account for a portion of transplant programs that will opt out of participation

The Task Force's Rescue Allocation Pathway Workgroup's efforts to test expedited kidney allocation protocols will support the Kidney Committee's efforts to develop a kidney expedited placement policy.

The Rescue Allocation Pathways Workgroup and Task Force developed the expedited placement variance, allowing protocols to be tested in real time before implementation as a finalized policy. This Workgroup also reviews, modifies, submits, and monitors protocols within the variance.

The Kidney Expedited Placement Workgroup recently performed a literature review to identify core components of successful expedited placement policies and is currently developing a protocol for consideration and testing by the Rescue Allocation Pathways Workgroup. This Workgroup maintains awareness of protocols and ultimately works towards developing an expedited placement policy. This Workgroup will also discuss and consider expedited placement in the context of continuous distribution, including systems requirements.

Summary of discussion:

One member asked if there was a timeline for implementing the first rescue allocation pathways protocol. OPTN Contractor Staff responded that the Rescue Allocation Pathways Workgroup has identified and begun preparing five OPOs and is currently working to send out invitations to identified transplant programs. The Rescue Allocation Pathways Workgroup is aiming to finalize commitment from these programs within a few weeks of this invitation and complete onboarding and orientation steps for all OPO and transplant program participants. The Rescue Allocation Pathways Workgroup is hoping to initiate the protocol on September 19th, and the protocol will not run longer than 6 months. OPTN Contractor Staff explained that the Rescue Allocation Pathways Workgroup or Executive Committee may make the decision to stop the protocol earlier, if necessary, based on monitoring markers or if sufficient data has been gathered.

The Chair expressed support for a joint meeting with the Kidney Expedited Placement Workgroup and the Rescue Allocation Pathways Workgroup, noting that the significant overlap between scope and work. The Chair asked if the protocol includes any programming changes with respect to notifications, provisional yes, and data collection. OPTN Contractor Staff responded that OPOs will use a protocol-specific bypass code, and that the Rescue Allocation Pathways Workgroup is developing a detailed instruction document for OPOs and transplant centers in how this protocol will be operationalized and data collected in order to support monitoring and evaluation. OPTN Contractor Staff added that there will not be additional programming to support the protocol at this time, but that the protocol outlines specific timelines for OPO notification to transplant programs in terms of pre- and post-recovery notification and information sharing. The protocol will also utilize a secondary match run, to track acceptances within the protocol and analyze that data. The Chair remarked that participation in the protocol will be voluntary for transplant programs and noted previous discussion and emphasis on transparency and equity. The Chair asked if programs not participating will be notified if the protocol bypasses them. OPTN Contractor Staff explained that invitations to join the protocol are based on objective criteria, including nautical miles, to ensure increased transparency. OPTN Contractor Staff added that the Rescue Allocation Pathways Workgroup plans to share the list of participating programs and OPOs. OPTN Contractor Staff also noted that this protocol does ensure equity guardrails, including applying only to the highest KDPI kidneys (75 percent or higher), and that standard allocation will take precedence for high priority candidates represented by the first many classifications.

One member noted that this is the only protocol that has been put out thus far, and that this protocol has not been implemented yet. OPTN Contractor Staff confirmed this, noting that the process to establish the first protocol has been resource intensive, but that hopefully subsequent protocols can move more quickly, with established processes in place. OPTN Contractor Staff explained that this protocol will also test how the protocols themselves are run and may need to update processes to improve clarity or efficiency.

2. 1-Year Post-Implementation Monitoring Report: Establish Minimum Kidney Donor Criteria to Require Biopsy

The Committee reviewed the 1-year post-implementation monitoring report for the *Establish Minimum Kidney Donor Criteria to Require Biopsy* policy.

Presentation summary:

This policy established minimum kidney donor criteria to require biopsy, including any donors 18 years of age or older who meet at least one of the following criteria:

- Anuria, or a urine output of less than 100ml in 24 hours during current hospital admission or in the course of donor management
- Donor has received hemodialysis or other renal replacement therapy during current hospital admission or in the course of donor management
- History of diabetes, or HbA1c of 6.5 or greater during donor evaluation or management
- Kidney donor profile index (KDPI) greater than 85 percent at time of original match run
- Donor age 60 years or older
- Donor age 50-59 years, and meets at least two of the following criteria:
 - History of hypertension
 - Manner of death: cerebrovascular accident (CVA)
 - Terminal serum creatinine greater than or equal to 1.5 mg/dl

This monitoring report is limited, due to limitations in data collection in the OPTN Donor Data and Matching system, particularly regarding anuria and use of dialysis.

The monitoring report utilized all adult deceased kidney donors recovered in the United States between September 6, 2021 and September 5, 2023. The policy eras were defined as:

- Pre-policy: September 6, 2021 to September 5, 2022
- Post-policy: September 6, 2022 to September 5, 2023

There was little to no change in the percent of donors biopsied between the pre- and post-policy eras. There was a total of 12,682 donors in the pre-policy era; 8,098 were biopsied (63.85%) and 4,584 (36.15%) were not biopsied. There were 14,368 total donors in the post-policy era, 9,082 (63.22%) of which were biopsied and 5,285 (36.78%) were not biopsied.

There was about a 3 percent increase in non-use rate for biopsied donors from the pre- to post-policy era. For biopsied donors in the pre-policy era, there was a 38.59 percent non-use rate (6,219 kidneys recovered but not transplanted out of 16,115 kidneys recovered). For biopsied donors in the post-policy era, there was a non-use rate of 41.88 percent (7,565 kidneys recovered but not transplanted out of 18,062 kidneys recovered). For non-biopsied donors in the pre-policy era, there was a 7.16 percent non-use rate, compared to a 6.13 percent non-use rate in the post-policy era. The total non-use rate was 27.23 percent in the pre-policy era, and 28.72 percent in the post-policy era.

There was little to no change in delayed graft function status overall and by biopsy status. For biopsied kidneys, delayed graft function rates were 40.06 percent in the pre-policy era and 40.91 percent in the post-policy era. For non-biopsied kidneys, delayed graft function rates were 26.63 percent in the pre-policy era and 26.73 percent in the post-policy era. Overall delayed graft function rates were 24.06 percent in the pre-policy era and 34.20 percent in the post-policy era.

There was a 5 percent increase in biopsy for donors who met the minimum criteria compared to the pre-policy era. There was about a 5 percent decrease in biopsy for donors who did *not* meet the minimum criteria. Overall rates of biopsy across donors changed little, at 36.15 percent in the pre-policy era and 36.78 percent in the post-policy era.

There was a 10 percent increase in non-use rate for donors who meet minimum criteria but are not biopsied; from 35.47 percent in the pre-policy era to 44.31 percent in the post-policy era. There was little to no change in non-use rate for donors who met minimum criteria and were biopsied between the pre- and post-policy eras. There was a very small change in the non-use rate for donors who met minimum criteria, from 54.27 percent in the pre-policy era and 55.77 percent in the post-policy era.

There was a slight decrease in delayed graft function for donors who met minimum criteria but were not biopsied, from 38.95 percent in the pre-policy era to 31.89 percent in the post-policy era. For donors who met criteria and were biopsied, delayed graft function rates were 39.05 percent in the pre-policy era and 38.91 percent in the post-policy era. For kidneys from donors who did not meet criteria but were biopsied, delayed graft function rates were 40.55 percent in the pre-policy era and 42.28 percent in the post-policy era. For kidneys from donors who did not meet criteria and were not biopsied, delayed graft function was 25.90 percent in the pre-policy and 26.62 percent in the post-policy era.

KDPI

All KDPI groups saw decreases in percent biopsied, except for donors with KDPI 86-100 percent. This decrease was most dramatic for donors with KDPI 21-34 percent, from 46.06 percent in the pre-policy era to 39.63 percent in the post-policy era. For kidneys within KDPI 86-100 percent, biopsy rates increased slightly from 95.79 percent in the pre-policy era to 97.61 percent in the post-policy era.

There was a slight increase in non-use rates for donors with high KDPI. For KDPI 86-100 percent donors who were biopsied, there was an increase in non-use rate from 73.3 percent in the pre-policy era to 75.1 percent in the post-policy era. For KDPI 86-100 percent donors who were not biopsied, which represents a very small sample size, non-use rates increased from 71.1 percent in the pre-policy era to 91.1 percent in the post-policy era. Non-use rates decreased for KDPI 35-85 percent kidneys that were not biopsied, from 13.8 percent pre-policy to 11.2 percent post-policy.

There were slight increases in delayed graft function for kidneys from donors who were 0-20 percent KDPI and biopsied, from 31.08 percent pre-policy to 36.55 percent post-policy. There were also slight increases in delayed graft function for donors with KDPI 86-100 who were not biopsied, from 37.14 percent pre-policy to 44.44 percent post-policy.

Donor Age

There was a slight decrease in the percentage of donors under the age of 60 being biopsied. Specifically, biopsy rates decreased from 34.76 percent to 30.59 percent for donors aged 18-24; from 59.89 percent to 55.36 percent for donors aged 35-49, and from 83.63 percent to 82.49 percent for donors aged 50-59. For donors aged 60 or older, the percentage of donors biopsied increased from 94.06 percent to 97.76 percent.

There were slight increases in non-use rates for donors over the age of 60, from 60.5 percent to 64 percent. For donors aged 60 or older who were biopsied, the non-use rate increased from 60.9 percent to 63.6 percent. For donors aged 60 or older who were not biopsied, the non-use rate increased from 54.7 percent to 82.2 percent.

There were slight increases in delayed graft function for biopsied donors under the age of 50. For donors aged 18-34 who were biopsied, delayed graft function increased from 41.29 percent in the pre-policy era to 43.67 percent in the post-policy era. For donors aged 35-49 who were biopsied, delayed graft function increased from 39.33 percent to 42.02 percent in the post-policy era. For donors aged 18-34 who were not biopsied, delayed graft function remained similar, from 21.39 percent pre-policy to 21.64 percent post-policy. For donors aged 35-49 who were not biopsied, delayed graft function rates were 30.07 percent in both the pre- and post-policy eras.

In considering biopsy monitoring based on recovering OPO, as compared to the pre-policy era:

- 23 of 56 OPOs (about 41 percent) biopsied donors more frequently
- 37 of 56 OPOs (about 66 percent) saw non-use rates increase for biopsied donors
- 34 of 56 OPOs (about 60 percent) saw non-use rates increase for all donors
- 32 of 56 OPOs (about 57 percent) saw an increase in delayed graft function for biopsied donors
- 27 of 56 OPOs (about 48 percent) saw an increase in delayed graft function for all donors

In conclusion, there has not been a drastic increase in the percentage of biopsied donors. There were small shifts in the type and characteristics of donors that have been biopsied. Non-use has increased, although due to the shifting landscape of donors being recovered and biopsied, there is not sufficient evidence to suggest biopsy status alone has increased non-use rates.

Summary of discussion:

One member expressed support for caution in interpreting this analysis, noting that conclusions about non-use should not be made on the basis on biopsy practice alone. The member noted that there were slightly higher delayed graft function rates in lower KDPI donors, adding that most of these donors should not be biopsied. The member continued that there are some valid reasons for such donors to be biopsied, but that it would be more helpful to understand why younger and lower KDPI donors are being biopsied. The member posed that some of these cases may be due to addressing valid concerns, while others may be a result of an overly generous biopsy policy. OPTN Contractor Staff noted that data for biopsy reason is limited, but that that OPOs have pointed to programs requesting biopsy, though this in itself is not a clinical rationale. The member remarked that there are more anuric donors and donors on continuous renal replacement therapy (CRRT) in recent years, and that biopsy can be important to ensuring there is no acute damage or necrosis. The member noted that this could explain some trends in biopsy practices. The member added that concerns related to extended cold ischemic times and delayed graft function should be addressed by understanding why donors that do not meet criteria are biopsied.

The Chair noted that there is limited data in the OPTN Donor Data and Matching System with respect to anuria and donors, but asked if there was a way of knowing how many donors would have met that criterion. OPTN Contractor Staff noted that there is currently no data collection regarding use of CRRT, and that urine output data is often missing for most donors, and inconsistently collected and reported for others.

The Chair remarked that it is encouraging to see that there is not really an increase in the proportion of biopsies, particularly when that was one of the biggest concerns during public comment for this proposal.

3. 6-Month Post-Implementation Monitoring Report: Standardize Kidney Biopsy Reporting and Data Collection

The Committee reviewed the 6-month post-implementation monitoring report for the *Standardize Kidney Biopsy Reporting and Data Collection* policy.

Presentation summary:

The *Standardize Kidney Biopsy Reporting and Data Collection* policy was implemented on September 14, 2023. This policy established or redefined several different data collection fields, including:

- Biopsy type
- Tissue preparation technique
- Number of glomeruli
- Number of globally sclerotic glomeruli
- Percent globally sclerotic glomeruli
- Interstitial fibrosis and tubular atrophy (IFTA)
- Vascular disease
- Arteriolar hyalinosis
- Cortical necrosis
- Fibrin thrombi

The cohort for this monitoring report includes all deceased donor kidneys recovered in the US for the purposes of transplantation between March 18, 2023, and March 12, 2024. Policy eras defined pre-policy as March 18, 2023, to September 13, 2023, and the post-policy as September 14, 2023, to March 12, 2024. The monitoring analysis is limited by the fact that many of these data elements did not exist prior to implementation.

Between these eras, there was a 6 percent increase in the percentage of kidneys biopsied, from 64.61 percent to 58.72 percent.

Wedge biopsy was the most frequent biopsy type in each era, accounting for 90.61 percent of biopsies pre-policy and 91.59 percent post-policy. Needle biopsies accounted for 8.99 percent of biopsies pre-policy and 8.41 percent post-policy.

There was no change in the distribution of the number of glomeruli observed, with a median of 55 in the pre- and post-policy era. There was similarly little to no change in the distribution of percent glomerulosclerosis, with a median of 8 percent in the pre- and post-policy eras.

Post-policy distributions

In the post-policy era, frozen section was the most common tissue preparation technique, with 90.43 percent of biopsies using frozen sections and only 9.57 percent using formalin-fixed paraffin-embedded (FFPE) sections.

92.12 percent of biopsied kidneys had an IFTA of 25 percent or less, and 61.76 percent of biopsied kidneys had an IFTA of 5 percent or less. 4.94 percent of biopsied kidneys had an IFTA score between 26-50 percent, and 1.04 percent had an IFTA greater than 50 percent. 1.90 percent of biopsied kidneys had an “unknown” IFTA score reported.

The majority (57.48 percent) of biopsied kidneys showed no sign of vascular disease. 28.62 percent had mild vascular diseases, and 8.61 percent had moderate vascular disease. 2.04 percent had severe vascular disease, and 3.26 percent had “unknown” reported for vascular disease.

The majority (72.84 percent) of biopsied kidneys showed no sign of arteriolar hyalinosis, and 19.24 percent of biopsied kidneys showed mild to moderate (1 arteriole) arteriolar hyalinosis. 4.04 percent of biopsied kidneys showed moderate to severe arteriolar hyalinosis, and 1.09 percent showed severe/multiple or circumferential hyalinosis. 2.79 percent of kidneys had unknown reported for arteriolar hyalinosis.

The vast majority (95.54 percent) of biopsied kidneys were absent for cortical necrosis; 1.53 percent of biopsied kidneys showed present cortical necrosis. 2.93 percent of biopsied kidneys had reported “unknown” cortical necrosis.

The vast majority of biopsied kidneys were absent for fibrin thrombi (93.18 percent), and 3.40 percent of biopsied kidneys had present fibrin thrombi report. 3.43 percent of biopsied kidneys had “unknown” fibrin thrombi reported.

Summary of discussion:

One member remarked that it’s interesting to see the percentage of frozen section and FFPE sample types and noted that it would be potentially useful to know what level of experience the pathologists performing the biopsy have. The member explained that often, OPOs may only have access to the on-call pathologist who may or may not have experience with kidney, and particularly frozen deceased donor kidney, biopsies. The member continued that this variation in pathologist experience can impact the reliability of the biopsies themselves. The member added that OPOs have countered this to a degree by uploading images of the kidney biopsy slides so that evaluation programs can look as well. OPTN Contractor Staff noted that currently, there is no way to determine the pathologists’ experience level based on currently reported data in the OPTN Donor Data and Matching System.

A representative from the Scientific Registry of Transplant Recipients (SRTR) noted that a great proportion of those biopsy results indicate normal findings. One member agreed. The SRTR Representative asked if the monitoring reporting investigated non-use related to specific pathological findings. The SRTR Representative explained that they receive offers with high cold ischemic time with normal biopsy findings, and that it would be important to ensure such offers are accepted before such high cold times accrue. The SRTR representative asked if the monitoring report included any data on non-use for kidneys with normal biopsy findings. OPTN Contractor Staff noted that this is not included in the current monitoring report but could be added to subsequent monitoring for this policy. The SRTR Representative continued that many programs indicate they will accept pending biopsy results, and then turn the organ down once normal biopsy results are posted anyway, and that this scenario should be prevented and avoided.

One member asked what definition of “normal biopsy results” should be used here, asking if “normal biopsy” would include negative or mild results across all parameters. The SRTR representative continued that there have been multiple studies that indicate biopsies may result in non-use, and that the reality may be that those programs were not likely to accept those organs regardless of biopsy results. Another member agreed.

A member expressed frustration with the required biopsy policy, sharing that they are often willing to accept certain organs without a biopsy, only to find the OPO has biopsied it anyway. The member noted that biopsy sampling practices can be over aggressive, with larger samples removed from the organs.

One member offered that “normal biopsy” results could be defined as glomerulosclerosis less than 10 percent, and all other findings “absent” or “mild,” with the exception of acute tubular necrosis, which the member noted should not impact the biopsy read. Others agreed. Another member offered that less than 5 or 10 percent glomerulosclerosis, and similarly less than 10 percent for vascular changes should

be considered. The member explained that it is unlikely for a donor kidney to have such low glomerulosclerosis, no IFTA, and no vascular changes. The member suggested that the definition of “normal” biopsy results should be a little more lenient.

OPTN Contractor Staff agreed that the subsequent report could evaluate non-use rate at each variable level, and include overall non-use rate for “normal” and “non-normal” biopsy results.

Upcoming Meetings

September 16, 2024

October 8, 2024 – Detroit, MI

Attendance

- **Committee Members**
 - Jim Kim
 - Curtis Warfield
 - Eloise Salmon
 - Jason Rolls
 - John Lunz
 - Kristen Adams
 - Leigh Ann Burgess
 - Marc Melcher
 - Patrick Gee
 - Prince Anand
 - Tania Houle
 - Toni L. Bowling
- **HRSA Representatives**
 - James Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
 - Grace Lyden
 - Jon Miller
 - Peter Stock
- **UNOS Staff**
 - Kayla Temple
 - Shandie Covington
 - Thomas Dolan
 - Beth Overacre
 - Houlder Hudgins
 - Lauren Motley
 - Sarah Booker