

## **OPTN Organ Procurement Organization Committee**

### **Meeting Summary**

**November 10, 2021**

### **Conference Call**

**Kurt Shutterly, RN, CPTC, Committee Chair**

**PJ Geraghty, MBA, CPTC, Vice Chair**

#### **Introduction**

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 11/10/2021 to discuss the following agenda items:

1. Biopsy Best Practices Project Update
2. Redefine Provisional Yes Project Update
3. Mandatory Usage of Offer Filters Project Update

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

#### **1. Biopsy Best Practices Project Update**

The Committee received an update on the OPTN Kidney Transplantation Committee's Biopsy Best Practices Workgroup and provided feedback on their projects, *Establish Minimum Donor Criteria to Require Biopsy and Standardize Pathology Reporting and Data Collection*.

##### Data summary (as applicable):

The Policy Oversight Committee's Biopsy Standards Workgroup identified several key areas for improvement in Kidney Biopsy Practices:

- Absence of established minimum set of criteria appropriate to initiate kidney biopsy
- Inconsistencies in quality of biopsy analyses is a major hurdle to greater allocation efficiency, with discrepancies between post-procurement and final pathology reports common, lack of organ-specific experience, and some transplant surgeons performing their own biopsies, slowing efficiency

The Workgroup has developed a set of donor criteria to require biopsy, which the OPTN Kidney Committee will review on November 15, 2021.:

- Anuria, as indicated by no urine output for at least 6 consecutive hours
- Renal replacement therapy received during current hospital admission or in course of donor management
- History of diabetes, or HbA1c of 6.5 or greater during donor evaluation or management
- KDPI > 85% at time of match run
- Excluding Pediatric Donors
- Donor age 60 or older
- Donor age 50-59 and at least two risk factors
- Hypertension
- Manner of death: Cerebrovascular Accident (CVA)
- Terminal creatinine  $\geq$  1.5

The Biopsy Best Practices Workgroup reviewed OPTN data in the development of these criteria. Biopsy rates increase with increasing donor KDPI and age, and biopsy rates were significantly higher for donors with a history of diabetes and those who met the expanded criteria (ECD). Per the data, about 28% of donors recovered in 2019 would qualify for biopsy under the proposed criteria. Of those 28% of donors, 90% were biopsied. Less than half of the deceased donor kidney biopsies performed in 2019 would qualify as required kidney biopsies under the proposed criteria.

The Workgroup has decided to pursue a policy proposal requiring host OPOs to perform kidney biopsy for donors meeting this minimum criteria.

The Workgroup also developed a standardized pathology report, with specific biopsy parameters and response options:

- Biopsy type – Wedge or Core Needle
- Tissue Preparation Technique – Frozen Section or Formalin-Fixed Paraffin-Embedded Section (FFPE)
- Number of Glomeruli – numeric field response
- Number of Globally Sclerotic Glomeruli – numeric field response
- Percent Globally Sclerotic Glomeruli – numeric field response
- Nodular Mesangial Glomerulosclerosis – absent, present, or unknown
- Interstitial Fibrosis and Tubular Atrophy (IFTA) - <5 percent, 5-10 percent, 11-25 percent, 26-50 percent, or >50 percent
- Vascular Disease (Percent Luminal Narrowing of the Most Severely Involved Vessel) – None (<10 percent), Mild (10-25 percent), Moderate (26-50 percent), Severe (>50 percent)
- Cortical Necrosis – absent, present with numeric percentage field response
- Fibrin Thrombi – absent, present with numeric percentage field response
- Other Comment open text field

The Workgroup has decided to propose updates to both DonorNet and the Deceased Donor Registration (DDR) to align biopsy data collection and standardize reporting per these parameters. Potential programming will include cascading data and automated calculations, which can alleviate data burden on OPOs.

#### Summary of discussion:

A member asked if projects will propose policy language regarding unnecessary biopsies, and what happens if a center requests a biopsy outside of these criteria. Staff responded that this proposal would require biopsy only for those donors meeting criteria, and that OPOs could still choose to perform biopsy on donor kidneys outside of the criteria on their own, or at the request of the transplant center. Another member shared that the criteria were developed with the intention to minimize the number of biopsies done. The member continued that discussions through the development of the criteria included factors like amphetamine use, or ethylene glycol toxicity, but the Biopsy Best Practices Workgroup decided to focus on common situations over niche cases where biopsy is indicated. The member concluded that not every biopsy outside of the criteria is unnecessary, and it's not efficient or practical to protocol every instance where a biopsy is indicated.

One member asked about creatinine as a criterion. Staff shared that the Biopsy Best Practices Workgroup discussed creatinine thresholds and trends extensively in regards to acute kidney injury (AKI), but ultimately decided that it was out of scope and impractical to define creatinine trends and thresholds for AKI. Another member commented that elevated creatinine can have different indications

across donor types, such as younger donors and older donors. The member shared that this is an instance where an OPO could decide to perform or a transplant center could request a biopsy.

The Chair expressed approval of both projects, and remarked that this policy will provide substance to OPOs case for refusing to perform unnecessary biopsies requested by transplant centers. The Chair asked if the OPO would be able to not perform a required biopsy at the request of the accepting transplant center. Staff shared that the Biopsy Best Practices Workgroup discussed instances where, if a biopsy couldn't be performed, documentation could reflect why. Another member remarked that the Workgroup discussed these instances, and agreed that if an accepting surgeon didn't want to biopsy, there shouldn't be any obligation to biopsy. The member pointed out that the goal was to establish a set of guidelines to require OPOs to biopsy, such that a biopsy couldn't be refused for not meeting OPO criteria. A member shared that if the primary transplant center requests no biopsy and later turn it down, the OPO is in a difficult position to reallocate that kidney without biopsy information. The member added that in broader sharing, this will become increasingly difficult.

A member strongly suggested including language to allow an OPO to provide documentation if a biopsy cannot be performed. The member shared that pathology services are not consistently available, particularly at community hospitals where pathology services are contracted out. The member continued that transplant hospitals do not always have the bandwidth to pick up cases, and that it can be very difficult to ensure pathology services. The member remarked that having to perform a biopsy on a 30 year old donor with a relatively new history of diabetes, for example, just to meet policy when pathology services are already inaccessible would be an undue burden, and such a provision would allow OPOs to avoid policy violation. Another member agreed, and shared that the Biopsy Best Practices Workgroup did discuss this.

One member commented that these criteria are fairly conservative compared to many biopsies performed. The member shared that for east coast OPOs working with upwards of 90 kidney transplant centers, there is a lot of biopsy and pump criteria to consider, and standardization will be very helpful. The member suggested including language related to transplant centers performing their own biopsies and rejecting for those results, which often forces OPOs to reallocate kidneys with significant cold time. Staff responded that some of this thinking parallels the rationale for the standardization of biopsy reporting project, which aims to reducing inconsistencies in analyses across the board and hopefully reduce the need for transplant surgeons to perform their own biopsies.

A member asked what timeframe the anuria criterion would apply to, and staff remarked that this had not been discussed but will be brought to the OPTN Kidney Committee when voting.

One member pointed out that biopsy quality varies significantly with sampling quality, particularly as indicated by the number of glomeruli visualized. The member recommended establishing a minimum number of glomeruli to qualify a biopsy as a reliable and sufficient sample. Staff remarked that the Biopsy Best Practices Workgroup did discuss this and utilized the top parameters (biopsy type, tissue preparation technique, and number of glomeruli visualized) to trigger thinking regarding the external factors affecting how reliable biopsy information is. The member remarked that their OPO utilizes a minimum of 20 glomeruli, but that the central pathology lab will still issue a report with 6 glomeruli. The member continued that many people evaluating the biopsy report don't pay attention to that number or don't recognize so few glomeruli as a non-representative sample.

## **2. Redefine Provisional Yes Project Update**

The Workgroup received an update on the Redefine Provisional Yes Project.

### Data summary:

Purpose: Improve processes to increase the efficiency of organ offer, review, and acceptance system and reduce overall organ allocation time, including:

- Redefine provisional yes and associated member responsibilities
- Limit number of organ offers
- Modify organ offer time limits with system enforcement
- Modify organ offer notifications

Workgroups discussions thus far have included identifying challenges related to provisional yes, reviewing current policy and demos related to provisional yes, and identifying policy modifications focused on defining and outlining specific expectations of members pre- and post-recovery of organs.

Potential policy ideas have included defining and outlining expectations of transplant programs, including:

- Transplant programs must confirm candidate availability for transplant
- Transplant programs must evaluate organ offers to see if the offer immediately meets any of their internal refusal reasons
- Transplant programs must assess histocompatibility
- Transplant programs must assess whether the candidate has had a recent COVID-19 exposure

Redefining Provisional Yes recommendations have included a tiered approach within provisional yes, with Tier 1 as a primary offer, Tier 2 as a back-up offer, and a third tier. Policy would include defining and outlining requirements of each tier, and clarifying requirements of primary and back-up offers. These expectations and requirements include:

- Tier I
  - Transplant programs must evaluate organ offers to see if the offer immediately meets any of their internal refusal reasons
  - Transplant programs must assess candidate's medical suitability
  - Transplant program notifies OPO of any additional information needed
  - Transplant programs must assess histocompatibility
  - Transplant programs must confirm candidate availability for transplant
- Tier II
  - Transplant programs must evaluate organ offers to see if the offer immediately meets any of their internal refusal reasons
  - Transplant programs must assess candidate's medical suitability
  - Transplant program notifies OPO of any additional information needed
- Tier III
  - Transplant programs must evaluate organ offers to see if the offer immediately meets any of their internal refusal reasons
  - Program will be notified if they are close to receiving offer – will then move to Tier II (follow additional criteria/requirements once moved up on match run to that tier)

Several programming components have also been discussed, specifically push notifications or alerts to indicate that the transplant program has reviewed the offer and if any additional information is needed to make a final decision, transplant programs being able to see where they fall on the match run, and offers that are a part of multi-organ transplantations.

### Summary of discussion:

A representative from the Redefine Provisional Yes Workgroup pointed out that the meaning of a Provisional Yes has changed from its original intended meaning, and ostensibly indicates that transplant center won't decline yet. The representative continued that the Redefine Provisional Yes Workgroup aims to break up Provisional Yes into tiers, so that programs receiving an offer have different levels of evaluation required depending on their place on the match run and the priority of their offer. For example, those primary and first back up offers will need to more fully review the offer and potentially notify the recipient. Those centers with less immediate back up offers can be notified without needing to significantly review an offer yet. The representative commented that this will reduce undue organ offer evaluation burden on transplant centers, and likewise, centers inputting provisional yes far down the list won't require the OPO to wait for evaluate.

A member expressed approval for the Redefine Provisional Yes project, and noted that this will be particularly helpful when allocating abdominal organs, which often requires offering to several dozens of candidates. The member asked if there was consideration for sequence based tiers, particularly when an organ rarely goes to the primary recipient. The member also asked if tier two would obligate a transplant center to confirm a patient's availability for transplant. The representative shared that the Redefine Provisional Yes Workgroup hasn't yet defined which number in the allocation sequence is appropriate, but has determined that organ type and quality will play a large role. The representative continued that most feel that a tier one offer would indicate notifying the recipient, and asked whether notifying the recipient would be appropriate in tier two.

One member asked if a transplant center would be required to perform a crossmatch to assess histocompatibility. The representative clarified that this wouldn't require a physical crossmatch, but whatever a program would want, whether that be acceptance based on a virtual or physical. The representative continued that tier one implies that a center could get whatever kind of crossmatch they want, virtual or physical. The member shared that their region's histocompatibility lab doesn't believe virtual crossmatches meet the national standard, and so the transplant center can never rely on a virtual solely. The member continued that their transplant center has an understanding with the OPO, particularly for marginal and donation after circulatory death (DCD) donors, that the OPO will provide the transplant center with all of the information before the center performs a crossmatch. The member remarked that physical crossmatches cost 1000 dollars a patient, and that requiring a crossmatch for higher kidney donor profile index (KDPI) kidney donors would be extremely expensive for a transplant center. The member cautioned against such a requirement, which could lead a center to code out for many kidneys that are probably not great but potential could be.

The Chair asked how many centers or recipients could fall in a tier one offer. The representative shared that the Redefine Provisional Yes Workgroup hasn't yet determined exactly what the tier thresholds should be, but that organ quality and type will be influential. A KDPI 2 percent kidney probably only needs to be offered to a few programs before acceptance, while a KDPI 99 percent kidney would likely need many more offers in tier one, as many centers will likely turn it down. The Chair remarked that too many centers in the top tiers could result in the current use of Provisional Yes, but that each tier will need a sufficient number of centers to remain efficient. The Chair expressed support for the project.

### **3. Mandatory Usage of Offer Filters Project Update**

The Committee received an update on the Mandatory Usage of Offer Filters project.

#### Data summary:

The purpose of this project is to mandate the use of offer filters based on identified criteria in policy. The project approach will involve a review of monitoring report of the nationwide rollout of kidney offer filters. The initial offer will address mandatory kidney offer filters, and subsequently address all other organs based on sequencing.

The Mandatory Offer Filters Workgroup held their first meeting on Monday October 25, 2021 and was provided an introduction and overview of kidney offer filters, including current functionality, review of pilot data, and a demo of the offer filters explorer.

The Mandatory Offer Filters Workgroup will meet again in November to review the monitoring plan for kidney voluntary offer filters, and discuss maximizing the impact of offer filters with OPTN President Dr. Matt Cooper.

#### Summary of discussion:

The Committee had no questions or comments.

#### **Upcoming Meeting**

- December 15, 2021 – Teleconference

## Attendance

- **Committee Members**
  - Kurt Shutterly
  - PJ Geraghty
  - Bruce Nicely
  - Catherine Kling
  - Chad Ezzell
  - David Marshman
  - Debbie Cooper
  - Jeffrey Trageser
  - Jennifer Muriett
  - Jill Grandas
  - John Stallbaum
  - Kevin Koomalsingh
  - Larry Suplee
  - Malay Shah
  - Meg Rogers
  - Merry Smith
  - Samantha Endicott
  - Sue McClung
  - Valerie Chipman
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Vanessa Arriola
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Robert Hunter
  - Katrina Gauntt
  - Kayla Temple
  - Joann White
- **Other Attendees**
  - Charles Strom