OPTN Kidney Transplantation Committee
Meeting Summary
April 18, 2022
Conference Call

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

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 4/18/2022 to discuss the following agenda items:

1. Review Public Comment Feedback: Establish Minimum Kidney Donor Criteria to Require Biopsy
2. Review Public Comment Feedback: Standardize Kidney Biopsy Reporting and Data Collection
3. Review Public Comment Feedback: Establish OPTN Requirement for Race-Neutral Estimated Glomerular Filtration Rate Calculations

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

1. Review Public Comment Feedback: *Establish Minimum Kidney Donor Criteria to Require Biopsy*

The Committee received an overview of the *Establish Minimum Kidney Donor Criteria to Require Biopsy* proposal, reviewed submitted public comment feedback, and discussed several potential post-public comment changes.

Proposal Summary:

The *Establish Minimum Kidney Donor Criteria to Require Biopsy* proposal aims to standardize biopsy performance by requiring kidney procurement biopsy for donors who meet a set of proposed criteria. This proposal would not limit the OPO to only performing biopsies on those donors that meet the proposed criteria.

Proposed donor criteria to require biopsy, excluding pediatric donors:

- Anuria, as indicated by no urine output for at least 6 consecutive hours
- Renal replacement therapy received during current hospital admission or in the course of donor management
- History of diabetes, or Hemoglobin A1c of 6.5 or greater during donor evaluation or management
- KDPI greater than 85 percent at time of match run
- Donor age 60 or older
- Donor age 50 to 59 and at least two risk factors
    - Hypertension
    - Manner of death: cerebrovascular accident
    - Terminal creatinine ≥ 1.5

The Workgroup reviewed donor data from 2019 to evaluate this criteria. 28.44 percent of all deceased kidney donors in 2019 met the proposed criteria. The majority of those donors meeting this criteria

were already biopsied in 2019. This proposal is not expected to dramatically increase biopsy performance.

Public Comment Feedback Summary:

Overall feedback was supportive, with members expressing support for benefits to allocation efficiency as well as support for OPO flexibility in performing biopsy outside of these criteria. Several members and stakeholders also expressed concern, particularly among OPO members and stakeholder organizations. There were several themes in public comment, including biopsy practices, feedback on specific criteria, and concerns regarding broadness of criteria, transplant center acceptance practices, and utilization.

- Biopsy practices
    - Need for further standardization and quality control in biopsy sampling and practices
    - Pathologist experience and need to standardize access to renal pathologists
    - Support for centralized pathology readings, services, and biopsy slide imaging
    - Transplant program re-biopsy negatively and directly impacts utilization, and should be avoided
    - Biopsy results should be included in screening criteria
- Specific criteria
    - General support for the inclusion of acute kidney injury (AKI) indicators
    - Support and opposition for diabetes criterion
    - Recommendation to remove expanded criteria donor (ECD) definition as a criterion, as this is redundant with KDPI greater than 85 percent
    - Several recommendations to reduce stringency of the policy
        - Require biopsy only on request of the accepting transplant hospital
        - Waive the requirement if there is agreement the biopsy is not necessary
- Concerns
    - Criteria may be too broad, and potentially result in increased or unnecessary biopsies
    - Transplant programs give undue consideration to biopsy results in organ offer review
    - Concern for unintended impacts to utilization

Summary of discussion:

One member offered a scenario where a donor makes 3 milliliters of urine every hour for 6 hours, noting that biopsy would still be appropriate then, though the donor would not technically qualify as anuric. Staff noted that the Committee previously discussed this, and wanted to make sure the criteria were relatively tight, to represent a minimum of donors. Staff continued that the Committee reached consensus that no urine output for at least six hours was tight enough to capture very critical acute kidney injury (AKI) donors without being overly inclusive of potential AKI donors. The member asked if the OPO would still be permitted to perform a biopsy on a donor making only a few milliliters of urine an hour, if requested by an evaluating transplant center. Staff confirmed that transplant programs will still be able to request a biopsy. The member remarked that there is an associated cost with biopsy, and organ procurement costs are relatively fixed. The member noted that, as a result, OPOs may try to perform fewer biopsies, although it can hinder the efficient placement of organs.

The Vice Chair emphasized that this a minimum standard set of criteria, meant to represent a group of donors that more or less most people could agree should be biopsied, and that messaging is critical to this proposal. The Vice Chair noted that the fear this proposal will lead to increased biopsies is somewhat baseless, as the data shows that only a small percentage of donors meet the criteria, as opposed to more than 50 percent of donors who received a biopsy over all. The Vice Chair added that biopsies are already widely performed for various kinds of donors, with each OPO having their own

criteria for which donors they biopsy, more or less strict. This proposal means to standardize this practice for donors there is general consensus should be biopsied. The Vice Chair added that the decision to biopsy outside of this criteria very much falls to clinical decision making. One member agreed, noting that messaging is important in this proposal.

One member remarked that, from the public comment feedback, it seems that members are wondering how this proposal changes current practices. The member continued and asked if this criteria is largely captured already, is this trying to capture the few donors that meet the criteria that aren't biopsied and improve the allocation of these organs? The Vice Chair responded that the purpose of this proposal is to standardize. OPOs in one region may have strict biopsy criteria, while others may have looser criteria. The Vice Chair continued that, in broader sharing, it's important to standardize organ evaluation information. The member noted that there is significant heterogeneity in biopsy practice, but that 90 percent of donors of meeting this criteria are already being biopsied, potentially on center request. The member pointed out that there are those seeing this as negative, and their point of view should be considered in order to respond appropriately and assuage any concerns. The Chair commented that historically, each center had a relationship with the OPO responsible for their donor service area (DSA), with a set of expectations of what donors will be biopsied. In broader sharing, programs are interacting with more OPOs and confronting different criteria for biopsy. The Chair continued that the purpose of this proposal is to start homogenizing what donors there is consensus to biopsy and go from there. The Chair pointed out that not only might the 10 percent of donors meeting the criteria who were not biopsied be captured under this proposal, but biopsies may be decreased for some OPOs that potentially biopsy too many donors. The Chair added that this policy can be adjusted over time and with monitoring, and concluded that part of this is a downstream effect of the circles-based allocation policy. The member agreed that monitoring will be beneficial in determining changes in the number of biopsies performed. Staff added that one benefit of this proposal is streamlined communication between the transplant center and the OPO regarding biopsy for these particular donors.

A member pointed out that the ASTS supported this, but the AST and the NKF did not. The member asked what concerns these organizations had. Staff explained that the NKF and AST's comments relayed concern that the correlation between biopsies and outcomes wasn't well proved in the literature. Staff continued that the Biopsy Best Practices Workgroup discussed this literature and its limitations. Usually, donors being biopsied have a clinical indication for biopsy, and it can be difficult to break down whether programs decline the offer due to biopsy results, or the biopsy results provide the last piece of information they consider proving what they were already concerned about regarding that organ offer. Staff continued that the AST and NKF expressed concern that this proposal could lead to non-utilization and increased decline due to biopsy. Staff noted that these stakeholder organizations expressed that requiring biopsies did not make sense while the literature surrounding biopsy was limited. There were also concerns that the biopsy results themselves aren't reliable. Staff noted that these concerns are addressed in the *Standardize Kidney Biopsy Reporting and Data Collection* proposal. Staff concluded that the AST and the NKF's comments reflected opinion that biopsies should not be required while the biopsies themselves may not be reliable or accurate. Staff added that the Workgroup considered this literature and its strengths and limitations. The Workgroup also noted that biopsies are already performed, and that these biopsies should be standardized in some way. The Chair remarked that potentially biopsies are over-performed, but that standardization will help align these practices and could prove beneficial to the literature. The Chair continued that currently, the literature is limited to one or a few OPO and program's policies. The Chair added that over time, this could be foundational work that helps improve biopsy practices and general organ evaluation methods. The Vice Chair noted that biopsies are already performed, and the question is not whether or not a biopsy is helpful, but how

to standardize the criteria for biopsy so there is a baseline to go on. The Vice Chair agreed with the Chair, adding that there will be useable data with OPOs performing biopsy on a certain type of donor.

Post-Public Comment Changes for Consideration:

The Committee may choose to send the proposal to the Board of Directors in June as proposed, send the proposal with post-public comment changes, pull the proposal and continue working, or drop the proposal all together.

Options for Criteria Concerns:

- Establish a time frame for Anuria
- Remove criteria, such as ECD definition
- Keep as proposed

Options for Policy Requirement Concerns

- Include "reasonable effort" language
- Require documentation as exception if biopsy cannot be performed
- Waive the requirement if an accepting transplant program agrees not to biopsy
- Require biopsy only on surgeon request
- Keep as proposed

Summary of discussion:

Staff remarked that there was support for including a timeframe for the anuria criterion, to specify anuria during current hospital admission and in the course of donor management. The Committee supported the addition of this timeframe for the anuria criterion.

Staff explained that there was some suggestion in public comment to restrict the criteria to only KDPI greater than 85 percent. This change would reduce the number of deceased donors from 2019 that meet the criteria to about 15 percent. The Committee unanimously opposed restricting the criteria to only donors KDPI greater than 85 percent.

Staff added that there were also recommendations in public comment to remove the expanded criteria donor (ECD) definition from the proposed criteria, with the idea that KDPI greater than 85 percent is inclusive of the factors in this definition. This would reduce the number of deceased kidney donors in 2019 that meet the criteria to around 20 percent. About 7.9 percent of donors met the criteria only by meeting the ECD definition. The Vice Chair remarked that the ECD definition was included because not all high KDPI donors are expanded criteria donors, and vice versa. The Vice Chair explained that the Workgroup wanted to include clinical parameters, and that the ECD definition is more descriptive than KDPI greater than 85 percent. The Chair agreed that relying on KDPI alone will not capture all the kidneys needing a biopsy. The Committee unanimously opposed removing the ECD definition from the criteria.

The Committee supported the addition of the current hospital admission or during the course of donor management timeframe to the anuria criterion, and decided to leave the other proposed criteria as originally proposed.

Staff explained that the language "the OPO must make a reasonable effort to perform a biopsy" addresses concerns voiced in public comment that OPOs may not always be able to perform a biopsy for these donors, particularly at rural or community transplant hospitals where pathology services may not be available. Staff continued that public comment concerns noted that preparing and transporting the slides to be read by an external pathologist can delay allocation and negatively impact cold time.

“Reasonable effort” language gives the OPO some flexibility if a biopsy cannot be performed, and could prevent delays in allocation due to biopsy.

One member commented that there needs to be some sort of exception for OPOs working in rural hospitals, as otherwise equitable access may not be given to nearby rural programs most impacted by these delays.

The Chair noted that the “reasonable effort” language makes sense, but could potentially lessen the requirement to perform the biopsy. The Chair asked if some OPOs would utilize this language to avoid performing biopsy in instances where the means were available. A member agreed, adding that there would need to be some metric or definition for reasonable effort. The member continued that OPOs could potentially continuously avail themselves of the requirement. Another member agreed.

One member asked if this will be monitored for OPO adherence to the policy. Staff explained that the evaluation plan will not be updated, but that the OPTN can always request documentation. Staff noted that if an OPO can’t perform a biopsy, they would need to document why they could not follow policy. Another member pointed out that there is no penalty to the OPO, as long as they document why the biopsy could be performed. The member added that if, upon monitoring, certain OPOs perform well below the expected number of biopsies despite donors meeting this criteria, there may be an opportunity to work with the OPOs to improve biopsy practice via resources, technology, logistics, or other methods. The member agreed that the language should be left as is, and not provide a loop hole for qualifying biopsies to not be performed.

Staff explained that the “reasonable effort” language and the requirement to document reasoning if a biopsy is not performed are separate options, and the Committee may choose to update the policy with one, both, or neither. Staff noted that the “reasonable effort” language could help prevent significant delays to allocation. The Vice Chair remarked that the “reasonable effort” language makes sense, particularly with concerns voiced by OPOs in rural areas who may not be able to perform a biopsy and would face difficult logistical challenges obtaining one. The Vice Chair remarked that this change would weaken the requirement, and noted that there should be a strict definition of reasonable effort, inclusive of the resources these OPOs do have. Staff noted that “reasonable effort” is purposely vague, and the MPSC typically determines what a reasonable effort would look like in their holistic review.

One member expressed support for requiring documentation if an OPO cannot perform a biopsy, and asked if the documentation requirement would create additional burden for OPOs. Staff explained that this kind of documentation is generally kept with OPO case notes.

Staff noted that the documentation requirement language leads with “if the biopsy cannot be performed,” which could undercut the requirement that biopsies must be performed. Staff explained that the reasonable efforts language is used elsewhere in OPTN policy, and is purposely vague to allow the incorporation of things not currently thought of right now, but that may provide conditions that make sense and should be allowed for. Staff shared that ultimately, OPTN Policy supports OPOs who are unable to comply with this requirement but are able to document an acceptable reason. Staff continued that this language isn’t necessary to effectuate that, but it could help in communicating that it is an option.

One member agreed that the documentation requirement and “reasonable effort” language go together, but expressed concern with the terminology of reasonable effort. The member noted that regardless of the reasonable efforts language, the OPO will need to maintain documentation if they don’t perform the biopsy. The member supported the documentation clause, but not the reasonable effort language.

A member suggested utilizing "the biopsy *is* not performed" in the place of "the biopsy cannot be performed."

The Committee came to a consensus to require documentation if the biopsy is not performed. The Committee supported including language requiring OPOs to make a "reasonable effort" to perform a biopsy. The Vice Chair noted that the documentation and "reasonable effort" language will address concerns shared in public comment from OPOs and other stakeholders.

One member pointed out a potential issue with the option for OPOs to waive the requirement if an accepting transplant program agrees a biopsy is not necessary and the option to only require the biopsy on accepting program request. When a primary evaluating transplant program enters a provisional yes, there is still always a chance that program does not accept the kidney. If that is the case and the program has determined a biopsy is not necessary, then there are evaluating centers further down the list who want to review biopsy results for acceptance. The member added that this could lead to more discards. Staff shared that the Biopsy Best Practices Workgroup expressed similar concerns when discussing these options during project development. The Chair agreed.

The Committee opposed requiring biopsy only on surgeon request. The Committee also opposed allowing the biopsy requirement to be waived by the accepting transplant hospital.

2. Review Public Comment Feedback: *Standardize Kidney Biopsy Reporting and Data Collection*

The Committee received an overview of the *Standardize Kidney Biopsy Reporting and Data Collection* proposal, reviewed submitted public comment feedback, and discussed several potential post-public comment changes.

Proposal summary:

This proposal aims to standardize biopsy reporting by establishing a standard set of biopsy parameters to be reported when a procurement biopsy is performed. A data collection component is also included, with updates to the OPTN Donor Data and Matching system and the OPTN Data Collection system. This proposal aims to reduce inconsistencies in comprehensiveness and improve reliability.

Proposed standardized pathology report:

Data Element	Response Options				
Biopsy Type	Wedge			Core Needle	
Tissue Preparation Technique	Frozen			Formalin-Fixed Paraffin Embedded	
Number of Glomeruli	_____				
Number of Globally Sclerotic Glomeruli	_____				
Percent Globally Sclerotic Glomeruli	_____%				
Nodular Mesangial Glomerulosclerosis	Absent		Present		Unknown
Interstitial Fibrosis and Tubular Atrophy (IFTA)	<5%	5-10%	11-25%	26-50%	>50%
Vascular Disease (Percent Luminal Narrowing of the Most Severely Involved Vessel)	None: <10%	Mild: 10-25%	Moderate: 26-50%	Severe: >50%	
Cortical Necrosis	Absent		Present: _____%		
Fibrin Thrombi	Absent		Present:_____%		

Public comment feedback:

Overall feedback was supportive, particularly for benefits to allocation efficiency and more reliable reporting methods. Several members and stakeholders also expressed concern, particularly among OPO members and stakeholder organizations. There were several themes in public comment, including general concern for variation in biopsy practices, operationalization and challenges, and feedback on specific elements and response options.

- Concern for general reliability of the biopsy, particularly with external factors influencing the quality of the biopsy reading
    - Quality control of pre-transplant biopsies through standardized use of formalin-fixed, paraffin-embedded samples with adequate representativeness
    - There are variations in pathologist experience, with limited access to renal transplant pathology expertise
- Operationalization concerns and recommendations
    - Delays in biopsy results can impact allocation efficiency
    - Pathologist access can be limited, particularly in rural areas. Similarly, not all pathologists are comfortable with procurement kidney biopsies
    - Provision of a PDF sample can ease implementation
- Element specific feedback was provided, including support for the inclusion of nodular sclerosis and recommendations to include additional elements, such as:
    - Date and time the biopsy was performed
    - Indicator as to whether the donor was on dialysis
    - Diabetic changes
    - Number of arteries with elastic lamina
- Significant support for the inclusion of arteriolar hyalinosis
- There were several suggestions to update the response options, including:
    - The addition of a "not available" response option for IFTA, vascular disease, cortical necrosis, and fibrin thrombi
    - Recommendation to align the IFTA and vascular disease response options with the 2018 Banff Classification for Renal Allograft Pathology

Summary of discussion:

The Committee had no questions or comments.

Post-public comment changes for consideration:

The Committee may choose to send the proposal to the Board of Directors in June as proposed, send the proposal with post-public comment changes, pull the proposal and continue development, or drop the proposal all together. Post-public comment changes to consider include:

- Updating response options for the IFTA, vascular disease, cortical necrosis, and fibrin thrombi parameters to include a "Not Available" option, to improve reproducibility and data quality where general and non-renal pathologists may not be comfortable filling out the entirety of the report
- Update response options for IFTA to reduce granularity and improve reproducibility. This would combine the 5-10 percent and 11-25 percent response options to simply 6-25 percent.
- Include an "arteriolar hyalinosis" parameter, to capture chronic damage to arterioles, which is often due to diabetes and/or hypertension

Summary of discussion:

Staff asked the Committee how they felt about the inclusion of a "not available" response option for some elements. The Vice Chair noted that the "other comments" section at the bottom was meant to address areas of concern for inadequate biopsy or bad samples. The Chair expressed support for not including the "not available" response options.

Staff explained that under the current proposal, the OPO would need to input some data. If the pathologist did not provide an answer, the OPO would need to put some kind of standard indicator, which could be difficult and impact the data quality. For example, if Fibrin Thombi was marked present but estimated at 0 percent. Staff continued that the Committee could choose to make these elements not required, or else put in a "not available option" if they chose to address this issue. The Vice Chair noted that generally, these biopsy forms are filled out entirely, and that a requirement of some kind is needed so that these fields can't be left blank.

One member asked what kinds of scenarios would require the pathologist to describe something as not available. Staff explained that this could be a situation where the pathologist isn't comfortable identifying a parameter like vascular disease or the sample didn't include a vessel, and instead of saying absent or present, they could mark the field as "not available." The member noted that this is different from availability, and would be more along the lines of not interpretable – if the characteristic is present, the pathologist can't comment on it. Staff agreed, and added that it would be the data point itself that was unavailable. The Vice Chair pointed out that "not available" is not currently an option on many biopsy forms used by OPOs. Another member commented that some of these fields may not be present on forms used by some OPOs, and it is possible that a non-renal pathologist may not be comfortable identifying these fields. The member continued that, as a clinician who tries to make something of the biopsy results, they would rather the pathologist not be forced to make a reading on something they're not sure of. The member remarked that they would prefer the pathologist fill in what they know they are seeing than giving a false impression of the fibrin thrombi, and get a sense of where the pathologist reading the biopsy is confident making the call or not. A member agreed, and supported adding an "unknown" response option.

The Committee supported the addition of an "unknown" option for interstitial fibrosis and tubular atrophy, vascular disease, fibrin thrombi, and cortical necrosis.

The Committee supported reducing the granularity of the response options for interstitial fibrosis and tubular atrophy. The Chair noted that it could be difficult to differentiate at such a granular level, and the difference between 9 percent and 11 percent seems challenging to determine. Committee members agreed.

The Committee discussed the addition of an arteriolar hyalinosis element, which would allow specification of arteriolar damage, instead of general arteriolar and arterial damage indicated under the current vascular changes element. The Vice Chair explained that the vascular changes element grouped the arteriolar and arterial damage together to leave the parameter broad, in the case that some pathologists were not comfortable reading overly-specific elements. The Vice Chair noted that this was recommended by the renal pathology subject matter expert on the Biopsy Best Practices Workgroup. The Chair remarked that arteriolar hyalinosis is important information, noting that this is a more thought provoking finding when considering an organ offer. The Chair continued that the element should not be so overly-specific that non-renal pathologists are unable to comment on it, but expressed general support for the inclusion of an arteriolar hyalinosis element. Another member agreed.

The Committee supported the inclusion of a specific arteriolar hyalinosis element with a scoring scale aligned with the 2017 Banff Classification of Renal Allograft Pathology.[1] Members agreed that the alignment of the scoring scale and definition for the arteriolar hyalinosis parameter made the most sense, for data quality reasons.

3. Review Public Comment Feedback: *Establish OPTN Requirement for Race-Neutral eGFR Calculations*

The Committee received an overview of the *Establish OPTN Requirement for Race-Neutral eGFR Calculations* proposal, reviewed submitted public comment feedback, and voted to send the proposal to the Board of Directors.

Summary of proposal:

This proposal will prohibit the use of eGFR calculations that include a race-based variable in OPTN policy. This proposal is based on supportive community input from the *Reassess Inclusion of Race in eGFR Equation Request for Feedback*. This proposal defines GFR within OPTN Policy 1.2: *Definitions* so that any eGFR calculation that does not include a race-based variable may be used. This will increase equity in access to transplantation for Black kidney candidates by more accurately estimating their GFR values.

Sentiment in public comment was widely supportive across regions and member types. There were several themes revealed in public comment:

- Equity in access to transplant
- Unintended consequences, such as under estimation of GFR and a decreased number of qualified Black living donors
- Binary distinction of race in race-based GFR calculations perpetuates disparities, and leaving no distinction for mixed or multi-racial persons
- Education will be important and necessary for transplant programs, patients, and labs
- Waiting time modifications for those impacted by race-inclusive eGFR calculations
- Reconsider the use of race in other transplant tools, including KDPI

In previous discussions of the transition plan, the Committee did not identify any populations that may be treated less favorably than they would have been treated under the previous policies, because this policy change aims to correct an existing disadvantage to access for Black patients. Under this new policy, all transplant programs will be expected to transition to race-neutral eGFR calculations by September 1, 2022 to align with implementation. Programs may submit waiting time modifications through modified eGFR values for candidates who meet all of the following:

- Were first registered to the waiting list without a qualifying eGFR
- Qualified to accrue waiting time via eGFR value at a later date
- When recalculated with a race-neutral calculation, have an eGFR that is earlier than their previous eGFR date, but does not precede the listing date

In commenting on a transition plan, the AST noted that it is possible many patients are not referred based on a race-based eGFR calculation in the first place, and programs with long waiting lists may find it difficult to obtain an eGFR and convert it to a race-neutral estimate. The AST suggested implementing this policy prospectively. The OPTN Transplant Coordinators Committee recommended providing a method for candidates to gain back waiting time they should have received with a race-neutral eGFR.

[1] https://journals.lww.com/transplantjournal/Fulltext/2018/11000/A_2018_Reference_Guide_to_the_Banff_Classification.14.aspx

VOTE: The Committee unanimously approved sending the *Establish OPTN Requirement for Race-Neutral eGFR Calculations* proposal to the Board of Directors in June, 2022.

Upcoming Meetings

- April 26, 2022 – Teleconference
- May 23, 2022 – Teleconference

Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Asif Sharfuddin
  - Bea Concepcion
  - Deirdre Sawinski
  - Peter Kennealey
  - Kristen Adams
  - Marian Charlton
  - Marilee Clites
  - Peter Lalli
  - Erica Simonich
- **HRSA Representatives**
  - Marilyn Levi
  - Raelene Skerda
- **SRTR Staff**
  - Bryn Thompson
  - Grace Lyden
  - Jonathan Miller
- **UNOS Staff**
  - Lindsay Larkin
  - Ross Walton
  - Kayla Temple
  - Amanda Robinson
  - Ben Wolford
  - Chelsea Haynes
  - Darren Stewart
  - James Alcorn
  - Jannifer Musick
  - Joel Newman
  - Kaitlin Swanner
  - Kim Uccellini
  - Lauren Mauk
  - Lauren Motley
  - Melissa Lane
  - Rebecca Marino
  - Rebecca Murdock
  - Sara Moriarty
  - Tina Rhoades