

OPTN Organ Procurement Organization Committee

Meeting Summary

February 16, 2022

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 02/16/2022 to discuss the following agenda items:

1. DonorNet Clinical Data Collection Project Update
2. Standardize Kidney Biopsy Practices and Reporting Proposals

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

1. DonorNet Clinical Data Collection Project Update

The Committee received an update on the DonorNet Clinical Data Collection project in development by the Tech Tools Workgroup, and prioritized the recommended updates.

Presentation summary:

The purpose of this project is to update clinical data reported in DonorNet to better capture information used by transplant hospitals during donor and organ evaluation. Proposed changes include additional information on the following:

- Donation after circulatory death (DCD)
- Medications/fluids
- Infectious disease testing
- Echocardiograms

On their last call, the Tech Tools Workgroup prioritized the proposed categories based on Policy Oversight Committee (POC) discussions regarding programming resources and relative project benefit of the OPTN project portfolio. After this initial prioritization, programming estimates were updated for accuracy and alignment with the new proposed changes. The POC discussed this project and did not make a final decision, instead asking the OPO Committee to finalize prioritization of proposed changes in order to fit within the programming budget.

- DCD data collection: estimated at a very large programming effort (4,094 hours)
- Medications/fluids: estimated at a large programming effort (1,710 hours)
- Infectious disease testing: estimated at a small programming effort (432)
- Echo/other heart tests information: estimated at a large programming effort (1,710 hours)

There are a couple of options to prioritize the proposed changes within the programming budget, including re-evaluating the Echocardiogram data elements. Many of these data elements are collected in DonorNet in various places, and could be left unchanged. Instead, only the four data elements that are not currently collected could be added, and minor tweaks could be made to pre-existing data elements.

The OPTN Heart Committee Leadership provided some feedback on the proposed changes related to Echocardiograms and hemodynamics:

- Keep all hemodynamic drips together – many are both inotropes, vasodilators and/or vasopressors, and it will be easier for those entering and reviewing the data
- End systolic and end-diastolic dimensions – volumes are rarely looked at; most evaluating clinicians want to know the left ventricular end-diastolic diameter (LVEDD) size and qualitative function
- Echo data – blood pressure and heart rate are important for understanding right ventricular systolic pressure (RVSP) and magnitude of regurgitation
- Ejection fraction (EF) – need for serial echo elements and uploaded reports

Summary of discussion:

The Vice Chair recommended dropping changes to infectious disease testing, noting that the value of serial infectious disease data could be smaller than other proposed elements.

The Vice Chair commented that pulmonary artery catheters were rare in his experience, and that the information is captured in the Deceased Donor Registration form (DDR). Another member agreed pulmonary catheters are not routine, and added that if a catheter is placed, that pressure and related data is important to communicate to the evaluating programs. The member pointed out that the pulmonary pressure is only a single field and is not multi-instance, making it difficult to follow trends. Programs have to go to attachments and look at each individual echocardiogram to see what the ejection fraction (EF) has done over time, the measurements, etc. The member noted that DonorNet does not provide a good way to enter and share that data. The Vice Chair agreed that there is a need to collect echocardiogram data serially in order to truly capture the data appropriately.

One member asked if the OPTN Heart Committee leadership provided input on what information specifically should be in the data fields instead of attachments. Staff shared that the Heart Committee leadership did not provide much feedback about how difficult the information was to find. The Vice Chair commented that the benefit of creating data fields to provide the information, rather than in attachments, is that the data itself is easier to see, define, and evaluate trends. That data is also easier to pull for research purposes. The Chair offered that transplant programs likely review the attachments before the DonorNet documentation. Another member shared that there was mixed conversation in the Workgroup, with some transplant programs more focused on attachments, and others preferring to have data fields. The member continued that adding these data fields to DonorNet could improve research capabilities and improve efficiency downstream, with information cascading into the DDR. The Chair and Vice Chair agreed.

A member asked if the requested information was for data gathering post-recovery and placement or for offer evaluation. The member recommended, if the former was true, prioritizing those elements that will be most important to data mining post-case, instead of those things that can be found in attachments. Another member suggested prioritizing data elements that address potential patient safety issues, particularly donor medications. The member noted that updating the medications page will be hugely beneficial to patient safety. Another member agreed.

Staff clarified that the purpose of the project is to update clinical data collection in DonorNet to improve efficiency in the organ offer and evaluation process for both OPOs and transplant programs. Staff noted that prioritization will need to consider data most relevant and useful in organ offer evaluation.

One member remarked that prioritization will be important between data categories, in order to efficiently utilize programming resources. Breaking down each category into smaller parts, as opposed

to focusing on individual categories, could be detrimental to that efficiency. Staff noted that the Committee will need to make a recommendation for prioritization to help inform additional resource estimates.

One member pointed out that the infectious disease testing updates were really geared towards collecting serial infectious disease results, which occurs more infrequently. The member continued that the most important aspect of infectious disease reporting is reporting positive results. The member recommended holding off on making updates to infectious disease results in favor of prioritizing DCD, echocardiogram, and medications/fluids data updates. Staff clarified that the estimate for the infectious disease update is based on the addition of specimen date and time to existing infectious disease fields, and does not include serial data collection. Staff noted that this version is a downsize from the serial infectious disease data collection, which would have been a large effort when considering other related and downstream impacts on match screening, offer filters, and the DDR, for example.

A member remarked that all of these categories were important, but that a post-recovery reporting tool would be most helpful. The member continued that the DCD data collection could need more updates with increasing use of perfusion machines and normothermic regional perfusion (NRP). One member responded that this was considered in the Technology Tools Workgroup, but that NRP does not yet have clearly defined data fields that are generally agreed to be valuable. Instead, the Workgroup decided to include only a yes/no field for use of NRP. The member agreed that a post-recovery reporting tool would be helpful, but that the utility is not within the scope of the project.

The Chair asked the Committee what recommendation would make the most sense. The Vice Chair noted that there was little benefit to updating the infectious disease testing, particularly if changes will not include serial capture of infectious disease data. The Vice Chair recommended pulling infectious disease testing updates from the proposed list, and moving forward with DCD, echocardiogram, and medications/fluids data collection updates. The Chair agreed, pointing out that OPOs are required to test and report results for infectious diseases within a specific date and time window anyway. The Committee reached consensus to prioritize updates to DCD, echocardiogram, and medications/fluids data collection ahead of infectious disease data.

2. Standardize Kidney Biopsy Practices and Reporting Proposals

A Committee member and participant in the Biopsy Best Practices Workgroup presented the *Establish Minimum Kidney Donor Criteria to Require Biopsy* and *Standardize Kidney Biopsy Reporting and Data Collection* proposals, sponsored by the OPTN Kidney Committee.

Presentation summary:

In 2020, the Policy Oversight Committee determined that inconsistencies in biopsy practices and quality of analysis are a major hurdle to greater allocation efficiency, and identified two key areas for improvement. The Kidney Committee submits the following proposals to address these areas:

- Establish Minimum Kidney Donor Criteria to Require Biopsy
- Standardize Kidney Biopsy Reporting and Data Collection

The proposals were developed and are submitted under the principle that biopsy information should be part of a holistic review of donor organ information, and should be utilized to help determine whether a PTR will receive the most benefit.

Establish Minimum Kidney Donor Criteria to Require Biopsy

This proposal standardizes biopsy practices by establishing deceased donor criteria where an OPO must perform procurement kidney biopsy. Current policy does not prescribe when an OPO must perform

procurement kidney biopsy. This proposal establishes a minimum set of donor criteria where an OPO is required to perform a kidney biopsy, and will not limit OPOs from performing kidney biopsies on deceased donors that do not meet this criteria. This proposal will standardize biopsy practices and reduce variability among OPOs, streamline communication between transplant hospitals and OPOs, and potentially prevent unnecessary biopsies and analysis.

A recovering OPO must ensure a procurement kidney biopsy is performed for all donors meeting any of the following criteria, excluding donors less than 18 years old:

- Anuria, or a urine output of less than 100mL in 24 hours
- Donor has received renal replacement therapy
- History of diabetes, including HbA1c of 6.5 or greater during donor evaluation or management
- KDPI greater than 85 percent
- Donor age 60 years or older
- Donor age 50-59 and meets at least two of the following:
 - Hypertension
 - Manner of Death: Cerebrovascular accident (CVA)
 - Terminal creatinine greater than or equal to 1.5

Previous OPO Committee Feedback has included:

- Recommendation to include language allowing OPOs to provide documentation is a biopsy cannot be performed
- Provide a timeframe for the use of renal replacement therapy and anuria criteria
- Setting a minimum number of glomeruli visualized to qualify a biopsy as reliable, or a sample as sufficient for an accurate reading

Standardize Kidney Biopsy Reporting and Data Collection

This proposal aims to standardize biopsy reporting by establishing a standard set of information to be reported when procurement kidney biopsy is performed. This proposal will include modifications to DonorNet and Deceased Donor Registration (DDR) TIEDI data fields and related definitions. This proposal will standardize biopsy reporting and improve consistency in analysis between OPOs, streamline reporting of key donor information, and improve allocation efficiency. This proposal will also standardize biopsy data collection, align data collection within UNet, and improve donor information.

The Kidney Committee proposes the required reporting of the following elements:

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 <u>Glomerulosclerosis*</u>	_____ %				
<u>Nodular Mesangial Glomerulosclerosis</u>	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: 10-15%	Moderate: 26-50%	Severe: >50%	
Cortical Necrosis	Absent			Present: _____ %	
Fibrin Thrombi	Absent			Present: _____ %	
Other Comments:					

OPOs will need to coordinate with pathology services to ensure appropriate access, and that the necessary parameters are reported.

Summary of discussion:

One member asked why high creatinine wasn't included as a criterion. The presenting member shared that the Biopsy Workgroup decided not to establish a high creatinine criterion, as creatinine is less meaningful without other donor information and high creatinine is captured in both the KDPI and expanded criteria donor (ECD) definition. A member shared that transplant programs often look for cortical necrosis and other indicators of damage related to acute kidney injury in high creatinine donors.

A member commented that biopsies are over performed and over relied upon compared to other countries with higher transplant rates, and asked if the proposed policy would include language to limit the use of biopsies. The member also wondered how biopsy rates would change with implementation of the proposed policy. The presenting member shared that the Biopsy Workgroup retrospectively reviewed deceased donor biopsy data to see how many donors would have met the proposed criteria, related rates of biopsy, and the overall rate of biopsy. Less than 30 percent of all deceased donors recovered in 2019 would have met the proposed criteria, and of those donors, around 90 percent were biopsied in 2019. Generally speaking, more than 50 percent of deceased donor kidneys were biopsied in 2019. Staff added that this proposal is not expected to dramatically increase use of biopsy, and that the data shows these criteria capture a minimum standard of donors that are clinically indicated for biopsy. The member remarked that biopsy related policy should aim to decrease biopsy rates.

One member agreed that biopsy rates were currently too high, and expressed opposition to the proposal to establish minimum criteria to require biopsy. The member remarked that too many transplant centers accept kidneys, perform their own biopsies, and then decline those kidneys at high cold ischemic times due to those results. The Vice Chair shared that their OPO doesn't give biopsy waivers for kidneys that they believe shouldn't be biopsied. The Vice Chair continued that, if the program biopsies the kidney and declines to use it, the accepting program is still financially responsible for that kidney.

The member commented that the criteria should be more minimal, and encapsulate fewer characteristics. The member noted that the *Establish Minimum Criteria to Require Biopsy* proposal does not address issues related to wedge biopsies, pathologist experience and reproducibility, and reliability of biopsy in predicting graft function. The Vice Chair agreed that the criteria are somewhat loose, and commented that the proposal will not go a long way in reducing biopsies, although it will definitely help prevent unnecessary biopsy in some OPOs. The Vice Chair recommended requiring biopsy only if the accepting or primary program's surgeon requests it, noting that the kidneys described in this criteria will almost always be biopsied.

A member pointed out that, although the data shows a fewer percentage of donors met the criteria than were biopsied, there are 300 donors that were not biopsied in 2019 that would be considered required to biopsy under the proposed criteria. The presenting member remarked that the *Standardize Biopsy Reporting and Data Collection* proposal will improve consistency in the reporting aligned with some of the member's concerns. The presenting member continued that the proposed reporting requirements were developed with attention to reproducibility and consistency across different types of pathologists.

The member expressed concern that clinicians over-rely on biopsy in evaluating an organ, and often decline without holistically evaluating the donor and organ. The member suggested using biopsy results to recalculate the KDPI, such that a pre-recovery donor with a 70 percent KDPI and an unremarkable biopsy showing 3 percent global sclerosis could then have a lowered KDPI to encourage more faith in evaluating clinicians. The presenting member remarked that a flexible KDPI post-recovery is a great idea, but may not be feasible.

One member commented that requiring biopsy makes assumptions that biopsies are collected, prepared, read, and reported consistently and therefore all biopsies are reliable. The member pointed out that biopsies are inconsistently prepared, collected, and read, and often are given insufficient attention to quality or accuracy. The member expressed concern that decisions not to use kidneys within the proposed criteria will be based on questionable biopsy processes.

One member expressed support for standardization of reporting, noting that cortical necrosis and fibrin thrombi are critical to evaluating acute kidney injury kidneys to determine their potential function. The presenting member pointed out that the renal replacement therapy and anuria criteria are intended to capture and require biopsy for acute kidney injury donors. Another member noted that standardization of reporting would streamline offer evaluation.

A member suggested that the Committee discuss and recommend a simplified minimum criteria. The member noted that factors like hypertension, creatinine, and cerebrovascular accident are captured in the KDPI calculation. Another member agreed, noting that an acceptable KDPI threshold could be set to capture those factors, to create a decision tree process. Another member pointed out that most OPOs biopsy kidney donors with KDPI over 85 percent. The member commented that the minimum criteria should capture donors that should be biopsied outside of that criteria. Staff noted that the Biopsy Workgroup also discussed requiring biopsy only at surgeon request, and concluded that this could negatively impact allocation. A transplant program at the first sequence who decides not to request biopsy could turn the organ down post-recovery, creating a disconnect and lack of information for the transplant program at the second sequence who wants to evaluate biopsy results.

One member shared that the biggest challenge to biopsy reporting is trying to get rural hospitals to perform biopsy readings. The member recommended adding a brief page of education to the standardized report to encourage pathologists less accustomed to procurement biopsy.

A member asked if anuria and renal replacement therapy criteria specify terminal hospitalization, and the presenting member confirmed that the criteria do.

One member asked how delay in biopsy results should be dealt with, as delayed results can impact allocation and cold ischemic time. The presenting member agreed that it can take a while to receive biopsy results, and noted that the Biopsy Workgroup chose not to include a time frame, as some centers may want to accept the organ without it.

The Chair asked if the Association of Organ Procurement Organizations and American Society of Transplant Surgeons' recommendations for kidney biopsy were discussed by the Biopsy Workgroup. Staff shared that these recommendations may have been reviewed by some members of the Biopsy Workgroup, but were not pulled directly for literature reviews. Staff noted that a lot of this criteria was developed based on feedback from a kidney pathology subject matter expert, the literature, and clinical expertise of kidney physicians and surgeons.

A member recommended including language that prevents or strongly suggests that accepting programs not biopsy a kidney that the OPO hasn't biopsied. The member continued that such language could give OPOs leverage to bypass a transplant program who wants to perform their own biopsy, and instead allocate the kidney to a transplant program who won't perform their own biopsy. Staff shared that the Biopsy Workgroup didn't want to be overly directive of clinical care, and that could be considered patient care.

Upcoming Meeting

- March 15, 2022 – Chicago, IL
- March 28, 2022 – Teleconference

Attendance

- **Committee Members**
 - Kurt Shutterly
 - PJ Geraghty
 - Meg Rogers
 - Bruce Nicely
 - Chad Ezzell
 - Chad Trahan
 - David Marshman
 - Debra Cooper
 - Erin Halpin
 - Jeffrey Trageser
 - Jennifer Muriett
 - Jill Grandas
 - John Stallbaum
 - Kevin Koomalsingh
 - Larry Suplee
 - Malay Shah
 - Mary Zeker
 - Samantha Endicott
 - Sue McClung
 - Valerie Chipman
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
 - Vanessa Arriola
- **SRTR Staff**
 - Katie Audette
 - Nicholas Wood
- **UNOS Staff**
 - Robert Hunter
 - Kayla Temple
 - Katrina Gauntt
 - Courtney Jett
 - Leah Slife
 - Lloyd Board
 - Susan Tlusty