OPTN Operations and Safety Committee
Meeting Summary
November 30, 2023
Conference Call

Alden Doyle, MD, MPH, Chair
Kim Koontz, MPH, Vice Chair

Introduction

The OPTN Operations and Safety Committee (henceforth the Committee) met via Citrix GoTo teleconference on 11/30/2023 to discuss the following agenda items:

1. Housekeeping and Updates
2. Centralized Reporting of Extra Vessels
3. Task Force Update
4. Offer Filters Update

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

1. Housekeeping and Updates

Summary of Presentation:

The Committee was provided an update on the project idea referrals as follows:

- Centralized Reporting of Extra Vessels
  - Status: Further discussion by Committee needed to:
    - Sequence projects
    - Develop project outline
- Organ Labeling Clarification
  - Status: Gathering additional information to determine next steps (policy vs. label change)
    - If label change, will need to determine if impacted by OMB process
- Introduce Pre/Post Transfusion Field
  - Status: Identify active (data collection) project this effort could combine with

Summary of Discussion:

There were no questions or comments.

Next Steps:

The Committee will be provided with updates. The Committee will discuss the Centralized Reporting of Extra Vessels project further during their November call.

2. Centralized Reporting and Extra Vessels

The Committee discussed a plan for their new project, discussing and evaluating modifications to requirements and centralized reporting of extra vessels storage and use.

Summary of Presentation:

Purpose: OPTN Policy 16.6.B: *Extra Vessels Storage* includes a 14-day limitation on vessel storage. This leads to a lack of available deceased donor vessels for use in transplantation, and sharing with other transplant hospitals. No clear delineation of when the 14-day storage period for vessels begins. This effort aims to improve the safety, tracking, and storage of extra vessels and promote efficiencies in allocation and sharing of extra vessels.

Proposal: Revisions to Policy 16.6: *Extra Vessels Transplant and Storage* to define storage and include storage time period that is supported by clinical evidence, and develop a centralized system to track deceased donor vessel availability. The Committee recognized that the latter aspect of the proposal would require greater resources.

Previously, the Committee voiced support for this project. The Chair and Vice Chair reviewed active Operations and Safety projects, and recommended that the Committee begin work on the extra vessels project. The Committee expressed support for collaboration with the Organ Procurement Organization (OPO) Committee, the Transplant Administrators Committee (TAC), Liver and Intestine Transplantation Committee, and the Pancreas Transplantation Committees.

The first iteration of the project will be a concept paper, which will solicit feedback to help determine potential modifications to current OPTN policy and develop or update the standard definition of extra vessels storage time period. The concept paper would outline, provide recommendations, and solicit feedback/insight on the following topics:

- Defining extra vessel storage/recommendation on storage time period
- Hepatitis C and B requirements
- OPO practices and processes for extra vessels
- Living donors or re-transplant
- Packaging and labeling requirements
- Tracking and sharing of extra vessels

Timeline: The project outline will be presented to the Policy Oversight Committee (POC) for review, feedback, and approval at their December 14th meeting. Once approved, the Committee may begin work. In January 2024, the Committee will begin development of the concept paper, targeting the Summer 2024 Public Comment cycle. Re-prioritization may be required once directives from the Task Force are received.

Summary of Discussion:

One member asked if this would impact transplant program processes with extra vessels. Staff explained that much of current extra vessels policies address transplant program processes, but that this project could include changes to those policies. Staff added that previously, Committee discussions have centered around OPOs and what is permissible for OPOs in regards to storing and sharing vessels, which is not currently outlined in OPTN Policy. Staff noted that this concept paper would address transplant program requirements, which is also part of why the Committee is considering the Transplant Administrators Committee as a stakeholder committee.

The Vice Chair remarked that hopefully, releasing a concept paper first will ensure anything not currently considered by the Committee could be highlighted during public comment, particularly related to transplant center processes. Staff noted that this could be a feedback question for the community, and the Vice Chair expressed support.

The Chair asked if this concept paper would include topics related to storage and the role of the OPO in extra vessels storage. The Chair explained that, at the Committee's previous meeting, they discussed the

use of extra vessels for transplant recipients who received an organ from a different donor, particularly for Liver or Pancreas recipients. The Chair continued that, the same way organs are considered a national resource, extra vessels should also be considered the same way, particularly since they may also be lifesaving and carry similar infectious risks the same way an organ is. The Chair remarked that OPOs should have a more central role in storing and allocating extra vessels to other programs. Another member noted that tracking and sharing of extra vessels in a more centralized manner will be a much larger lift. The member shared that currently, extra vessels are shipped with the organ and that the recipient transplant hospital is responsible for the storage and disposal of the vessels. The member continued that the OPO and other centers are not aware of where the vessels are, their status, and whether they have been used. The member added that currently, if a program needs extra vessels, the program will need to call their OPO and wait for the OPO to find out if there are vessels available at programs they have recently allocated to, which is labor intensive and inefficient. The member concluded that centralized tracking allowing the OPTN and OPOs to know where the vessels are would be ideal, but that this could require significant resource allocation. The Chair agreed, noting that OPOs and programs could benefit from a tracking system. The Chair discussed a hypothetical system where OPOs collect unused vessels and act as a direct resource for extra vessels procured.

The member agreed, noting that most vessels used by their program are iliacs, which are typically sent with the liver and the pancreas. The member added that if there is a split liver, then the OPO may need to pull additional vessels from other areas. The member pointed out that most of the vessels will travel with the organs, unless it is a kidney or heart donor only, in which case one of the recovering surgeons will need to procure the vessels and send with the OPO. The member provided another alternative, where programs need to send unused vessels back to the OPO at least 48 hours after transplant. The member noted that this would be labor intensive as well. The Chair offered that this system may still be more ideal than the current system, where the extra vessels are have increased tracking, regulation, and care. The member agreed, noting that tracking ends as soon as vessels arrive in the hospital.

The Chair pointed out that vessels shared by one program with another program still carry disease transmission risk, and that currently, there is no way for the OPO to notify recipients of vessels of new donor-related infectious disease information because of lack of tracking. The Chair added that this is risky, and that it's important to mitigate such risks.

A member recommended vessel containers be barcoded, and that the container must be scanned every time it's opened in order to improve tracking. Another member pointed out that they are currently barcoded, but that there is no requirement for scanning or immediate reporting to the OPTN. The member added that this can be done with the tracking system available, but that this has not been implemented by most transplant hospitals. The member remarked that it's unclear how labor intensive it would be to establish such requirements. The Vice Chair noted that programs are not required to use TransNet, but that the system does incorporate these capabilities and that most OPOs use this system. The Chair remarked that TransNet is a good system, and that use of barcodes to allow improved tracking could be simple and effective. The Chair pointed out that the technology and system is built in TransNet, and recommended that this be established as a requirement for vessels. Another member agreed, adding that once there are requirements in place, it could be simple to build a registry from that information to help programs find and receive extra vessels when needed.

The Vice Chair recommended that the use of TransNet by transplant programs and OPOs should be incorporated into the concept paper. Staff shared that there are labelling and bar code requirements for OPOs, and that this could be considered a potential recommended requirement for transplant programs with respect to extra vessels.

One member shared that currently, programs are required to report the disposition of vessels back to the OPO, and that is how the OPO knows how to report infectious disease results to all recipients, including of extra vessels. The member continued that there could be challenges to returning unused extra vessels to the donor's OPO, particularly if the accepting program is not local to the donor's OPO. The member added that if the vessels are instead sent to the program's local OPO, it may be difficult for that local OPO to ensure authorization was obtained for those vessels. Another member asked if OPO notification about vessel disposition is in real time, or more of a monthly reporting process. The member responded that programs must report the disposition of vessels within 7 days of their use or discard. A member pointed out that it could be difficult to determine compliance, and the Chair remarked that it's hard to know. The Chair shared that, when tracking vessel reporting times, this was the main issue programs were flagged for. The Chair remarked that it is unlikely that the OPTN has the disposition of all extra vessels. A member remarked that this is another reason to support automating the process as much as possible.

Staff noted that it may be, in the first iteration of this effort, the focus may be on building effective, efficient requirements to establish processes, and that the creation of a system to support greater tracking may need to be part of a later iteration. Staff continued that there still may be certain aspects that could be identified as potential recommendations for later projects, particularly if adequate resources are not available.

A representative of the Health Resources and Services Administration (HRSA) recommended that the OPTN Disease Transmission Advisory Committee (DTAC) be included as a stakeholder in this work. Staff noted that DTAC has commented on hepatitis C and B requirements with regard to extra vessels, and noted that extra vessels will need to consider the US Public Health Service (PHS) infectious disease guidelines. Staff noted that DTAC can be included as a stakeholder committee with representation in the workgroup. The Chair added that DTAC noted issues with hepatitis C and B was a product of that time period, where hepatitis C and B positive organs were not transplanted as frequently. The Chair noted that much of that worry could also be due to limited tracking of such vessels, which impacts risk mitigation. The Chair added that if there was a reliable tracking system to mitigate risk of infection, that hepatitis C and B vessels could be considered safe to store and use. Staff noted that the US PHS Increased Risk Guidelines explicit state that hepatitis C and B positive vessels should not be stored or used, and that this would require a change to the PHS increased risk Guidelines.

Next steps:

Once the project is approved by the Policy Oversight Committee, the Committee will organize and sponsor a workgroup focused on developing the concept paper.

3. Task Force Update

The Committee received an update on the OPTN Expeditious Task Force on Efficiency.

Summary of Presentation:

Progress to date: The Task Force had their first meeting in October, in Chicago. Throughout November, the Task Force has held multiple Workgroup meetings to discuss and develop "Bold Aims," which will guide and provide scope for the Task Force. The Task Force will meet again in St. Louis in December, and provide a report to the Board on December 4th.

Summary of Discussion:

The Committee Chair, who is also a Co-Chair on the Task Force, shared that the Task Force's work is very different from the OPTN Committee work. The Chair shared that there will likely be a number of efforts

that are recommended to the OPTN Operations and Safety Committee to begin working on. The Committee Chair continued that the Task Force is currently investigating how to optimize and utilize a number of different methodologies, including running pilot projects and plan-do-study-act trials. The Chair shared that the Task Force is moving rapidly, and that a good portion of the Task Force's work will leverage trials to quickly understand what solutions may work best. Once these solutions have been tested, they can be recommended to the OPTN Committees to finalize changes. The Chair also noted that the Task Force is hoping to get commitments from members inside and outside of the OPTN.

There were no further questions or comments.

4. Offer Filters Update

The Committee received an update on the implementation of offer filters for non-renal organs and default kidney offer filters.

Presentation Summary:

Voluntary offer filters for lung will begin being rolled out in January 2024. An accompanying proposal will be out for Winter 2024 Public Comment that will provide an overview of lung offer filters to promote adoption and solicit feedback on potential lung-specific filters.

The OPTN Executive Committee will meet December 3rd and will review, discuss, and provide recommendations for timelines of the roll out of offer filters for other organs and the implementation of default kidney offer filters.

Summary of discussion:

The Chair shared that there is excitement about the recently approved *Optimizing Usage of Offer Filters* effort, but that other organ-specific communities are also dealing with high offer volumes and are requesting filtering tools. The Chair shared that because of this, the Executive Committee is going to discuss whether to sequence the roll out of offer filters for other organs prior to the implementation of *Optimizing Usage of Offer Filters*.

Staff shared that usage of offer filters for kidney programs will still continue to be monitored.

The Chair shared that there will also be ongoing efforts to reach out to programs who have not yet adopted kidney offer filters to encourage their adoption and effective use.

One member remarked that offer filters are critical to managing offer volume, and that programs cannot continue to address offer volume solely by hiring additional staff.

Upcoming Meetings

- January 25, 2023 (teleconference)

Attendance

- **Committee Members**
  - Alden Doyle
  - Kim Koontz
  - Andy Bonham
  - Anja DiCesaro
  - Anne Krueger
  - Annmarie Lucas
  - Julie Bergin
  - Kaitlyn Fitzgerald
  - Megan C Roberts
  - Sarah Koohmaraie
  - Shigemura Norihisa
  - Mony Fraer
- **HRSA Representatives**
  - Jim Bowman
  - Arjun Naik
- **SRTR Staff**
  - Avery Cook
- **UNOS Staff**
  - Joann White
  - Betsy Gans
  - Kaitlin Swanner
  - Kayla Temple
  - Kerrie Masten
  - Laura Schmitt
  - Susan Tlusty