

## **OPTN Organ Procurement Organization Committee**

### **Meeting Summary**

**December 15, 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 12/15/2021 to discuss the following agenda items:

1. UNet Multi-Factor Authentication
2. Endemic Disease Evaluation, Testing and Communication
3. Expedited Liver 6 Month Post-Implementation Monitoring Report

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

#### **1. UNet Multi-Factor Authentication**

IT staff presented an update on the Multi-Factor Authentication project, including the roll out plan and preparations UNet users can take

##### Data summary:

Multi-Factor Authentication will be rolled out in 2022. After implementation, members will be required to use a third party service when logging into UNet.

Users can download and set up an account now to ensure there will be no issues after implementation. For questions, visit <https://unos.org/technology/unet/mfa/> or contact the Multi-Factor Authentication support team.

##### Summary of discussion:

The Vice Chair asked how frequently the multi-factor authentication will be required, and staff clarified that users will be required to complete multi-factor authentication every time they log in to UNet. Staff added that the multi-factor authentication will be a push notification to reduce any potential impact to efficiency. For users outside of cellular communication, a six digit code will be provided that won't be affected by connectivity.

One member remarked that this could be inefficient for users that pre-screen or evaluate for multiple centers, who log in for offers through offer and program-specific email links to view the offers in DonorNet. The member continued that it is not uncommon to receive the same offer for multiple centers, meaning that those users must authenticate and log in for each individual program that received the offer. Staff shared that there are mobile and desktop applications for the authentication push notification and that the push notification itself appears quickly, both of which can reduce negative impact to efficiency. Staff also noted that users with UNet permissions for multiple programs can switch which program they are acting for within the DonorNet application.

## 2. Endemic Disease Evaluation, Testing, and Communication

The Chair of the Ad Hoc Disease Transmission Advisory Committee (DTAC) provided an overview of DTAC's current work regarding endemic disease evaluation, testing, and communication, and requested Committee feedback

### Data summary:

DTAC is focusing on the Tuberculosis (TB), Strongyloides, and Trypanosoma cruzi (Chagas) endemic disease, in particular the consistency of donor evaluation, testing, and communication to transplant programs. DTAC aims to better understand current screening and testing, and identify any potential gaps that may benefit from education, policy, or UNet data changes.

DTAC is concerned for several reasons:

- TB, Strongyloides, and Chagas all have high potential for complications and potential mortality if transmitted to recipients
- TB is the third most common donor-derived transmission investigated by the CDC, behind Hepatitis B (HBV) and Hepatitis C (HCV)
- Increase in travel for organ transplant needs to include increase in awareness of and communications for potential endemic diseases across regions

The primary risk factor for all three diseases is birth in, residence in, or travel to an endemic area:

- Tuberculosis
  - Central and Southeast Asia and Southern Africa have highest incidences
- Strongyloides
  - United States (US) Appalachian region has an endemic rate of 1-4 percent positivity
  - High rates of strongyloides have been identified in refugee groups in the past; up to 46 percent in Sudanese refugees
  - Rates in different countries vary, with Brazil around 13 percent and Nigeria around 48 percent
- Chagas
  - Primarily found in Mexico, Central America, and South America

Active tuberculosis is more easily identified by current required screening, such as chest x-rays. However, there is increased complexity in identifying latent TB, which has the potential to reactivate in the recipient. Strongyloides testing is widely available, and results are often received after procurement. Two Chagas assays have also been approved for donor screening.

Recipient prophylaxis and treatment varies:

- Tuberculosis – prophylaxis is available, and may differ in pulmonary versus extrapulmonary recipients and in donors with latent versus active TB
- Strongyloides – prophylaxis is widely available, and is effective even when administered post-transplant
- Chagas – prophylaxis is uncommon but available, and recipients typically receive post-transplant monitoring for disease occurrence

Communication through DonorNet:

- Donor birth, residence, and travel locations are currently not captured in discrete fields, but may be uploaded in attachments or entered in free text fields

- Testing – Strongyloides antibody testing has discrete fields, but there are no fields for TB or Chagas. Additional testing may be uploaded in attachments or entered in free text fields
- Donor history records TB history and Chagas history in discrete fields. Additional donor history may be uploaded in attachments or entered in free text fields.

Committee Feedback Request:

- Do you assess donors for risk factors for TB, Strongyloides, and Chagas?
- Do you test donors for these endemic disease?
- How do you communicate information on risk factors and testing?
- What do you think is the optimal way to educate OPOs and transplant hospitals on risk assessment and testing?
- What do you think is the optimal way to communicate specific donor information on endemic diseases between OPOs and transplant hospitals?

Summary of discussion:

One member shared their OPO's practices, commenting that the Donor Risk Assessment Interview (DRAI) used to compile donor medical and social history includes questions regarding history of TB. If there is any mention of TB, the medical director puts the case on hold and assesses the donor. Donors who have been in a Chagas or Strongyloides endemic environment for cumulative 30 days or greater are also assessed. The member noted that donors with granulomas are swabbed for culture and acid-fast bacillus (AFB) to ensure the granulomas are not TB-related. The DTAC Chair asked the member how they determine which donors to test. The member responded that the risk factors determine when a donor needs to be tested. The member also noted that the TB, Strongyloides, and Chagas test results are received and shared post-transplant.

A member shared that their OPO used to screen for TB, Chagas, and Strongyloides, and found the screening itself to be overly burdensome and potentially inaccurate. Their current practice is to test all donors routinely for TB and Chagas. The member continued that routine testing is not yet performed for Strongyloides, but may be added soon. The DTAC Chair asked what kinds of tests were being used, and the member responded that the trypanosoma cruzi test was used to detect Chagas, and the AFB test for TB. Previously, the member's OPO had used quantiferon gold to test for TB, but stopped due to low mitogen results for patients who received steroids.

The Vice Chair shared that their OPO screens every donor for Chagas, but rarely performs Strongyloides testing, and only on transplant center request. The Vice Chair continued that donors are screened TB risk factors, and those with potential risk are tested with a bronchoscopy, AFB, and other testing. The Vice Chair concluded that their OPO only screens for exposure to TB, not necessarily other factors such as where the donor has lived.

One member commented that their OPO screens for TB and Chagas with the standard TB and Chagas history on the DRAI, but does not screen for Strongyloides. The member noted that their OPO does additional testing for TB, but rarely if ever tests for Chagas or Strongyloides.

A member shared that their OPO tests post-recovery for Strongyloides if the donor has lived outside of the United States, Canada, Japan, and the European Union for more than a year. The member continued that since 2017, their OPO has screened 3000 donors and only had to test 270, of which 5 were positive for Strongyloides. The member added that Chagas testing is only done on request, and TB testing is only performed if there are risk factors or known exposures.

The DTAC Chair asked the Committee if and what barriers exist to assessing risk factors, testing, and communicating this infectious disease information. One member encouraged guidance on what factors to assess for and which donors to test, particularly with so much variation in practices. The member continued that routine testing on unlikely populations can lead to increased incidence of false positive, which in turn can result in non-utilization of organs. The member also noted that DonorNet is not currently sufficient to allow OPOs to share all of a donor's information, and having a specific and unique place within DonorNet to communicate this information would be valuable. Another member commented that there would be significant barriers if TB, Strongyloides, and Chagas results were required prior to donor recovery, including potential for false positives. The DTAC Chair remarked that the current literature doesn't support the need for pre-recovery test results for TB, Strongyloides, and Chagas. The Chair of the DTAC continued that utilization and safety should both be maximized, and positive results found post-transplant can be managed under a patient monitoring plan.

### **3. Expedited Liver 6-Month Post-Implementation Monitoring Report**

Staff presented the 6-month post-implementation monitoring report for the Expedited Liver Pathway policy update.

#### Data summary:

The Expedited Placement Pathway is an optional pathway for intraoperative turndowns. Candidates may opt-in to receiving expedited offers, and must opt in individually for expedited liver offers from donors after cardiac death (DCD) and donors after brain death (DBD). Transplant programs receiving expedited offers have a 30 minute response window.

The Expedited Placement policy was implemented on March 25, 2021. The pre-policy era is defined as September 21, 2020 through March 24, 2021 and the post-policy era is defined as March 25, 2021 through September 25, 2021. Most metrics evaluated are point forward, or in the post-policy era only. It is important to note that data surrounding in-recovery refusals are difficult to capture, and most of the late turndown data available and utilized in this report pertains only to events where the expedited pathway was utilized.

There were 251 match runs executed utilizing the expedited pathway, and 168 livers recovered for transplant. 67 of these livers were transplanted, resulting in a discard rate of 64.36 percent.

42.75 percent of transplant centers had no cases of in-recovery liver refusals that lead to an expedited match run. 18.84 percent of transplant centers had one case; 11.59 percent had 2 cases; 7.97 percent had 3 cases; 6.52 percent had 4 cases; and 12.32 percent had more than 5 cases of in-recovery refusals leading to an expedited match run. The most common reason for refusal that lead to an expedited match run was donor age or quality, by a large majority of cases. This reason was followed by donor size and weight, other specify, organ-specific donor issue, patient ill/unavailable/refused/temporarily unsuitable, organ preservation, organ anatomical damage or defect, patient transplanted/transplant in progress/other offer being considered, and COVID-19 candidate related reason.

34.39 percent of expedited pathway liver donors were between age 50 and 64, compared to 24.87 percent of standard pathway liver donors. 30.69 percent of the expedited pathway liver donors were between 35 and 49 years old, and 21.69 percent were between 18 and 34. Comparatively, 30.15 percent of standard pathway liver donors are between 35 and 49 years old, and 30.4 percent are between 18 and 34 years old

DCD cases were much more common in among expedited match runs, at 23.81 percent of donors recovered with an expedited match run, compared to 13.2 percent of donors recovered with a standard match run.

Regions 3, 4, and 10 had the highest percentage of candidates opted in to receive expedited liver offers from DCD and DBD donors. Regions 11, 6, and 7 had the highest percentage of candidates opting out of receiving expedited liver offers. Regions 1, 2, 7, 8, and 9 had the highest percentage of candidates with no response, opting in or out, for expedited liver offers.

Of the 251 expedited match runs initiated, 69 had a final acceptance, or 27.5 percent. Of those 69 acceptances, 67 results in a transplant, or 97.1 percent.

OPOs that choose not to utilize the expedited placement pathway still attempt to place late refusal livers utilizing the bypass code 863 – “potential recipient bypassed as a result of offers made during an expedited placement attempt. This includes offers of expanded donor organs, operating room time constraints, or family time constraints. (Requires written verification by OPO to Policy Compliance; this bypass and narrative justification will be shared with bypassed centers).” The use of this bypass code does not require the donor to be in organ recovery.

In the pre-policy era, 5.11 percent of liver donors had match runs utilizing the 863 bypass code to place “expedited” livers. In the post-policy era, 3.05 percent of liver donors had match runs utilizing the only Expedited Placement Pathway, and 4.78 percent of liver donors had match runs utilizing only the 863 bypass code. 0.35 percent of liver events utilized both the Expedited Placement Pathway and the 863 bypass code.

Pre-policy, the liver utilization rate was 65.11 percent; post-policy, the liver utilization rate was 62.72 percent. The liver discard rate in the pre-policy era was 9.07 percent and in the post policy era, 9.9 percent. Out of sequence liver placements increased slightly in the post-policy era, from 7.54 percent to 7.68 percent. The number of liver donors also increased in the post-policy era, from 4574 to 4742.

The pathway has been underutilized. The proportion of candidates opted-in to receiving offers varies by region. The proportion of matches with a final acceptance was low. Donor demographics of expedited donors was relatively similar to the demographics of non-expedited donors.

#### Summary of discussion:

The Chair remarked that their OPO has only transplanted 1 of the 24 livers utilizing the expedited placement process. The Chair noted the expedited list is typically followed after all other allocation options have been exhausted, which may not have been the original intent.

One member asked how many liver candidates were opted in, and Staff responded that 55 percent of liver candidates were opted in to receive expedited liver offers. The member commented that the 55 percent opt in shows why the expedited liver process is ineffective and underutilized. The member continued that it’s unlikely that 55 percent of candidates could and would truly accept an offer from the operating room.

A member shared that their OPO goes to organ recovery with local and aggressive program back up, and have found that to be the most successful way to allocate late-turn down livers. The member continued that placing a liver sequentially through a still large number of candidates is inefficient and unlikely to result in placement or transplant.

One member shared that their program opts their candidates in for everything, as their geographic location significantly limits the number of offers they typically receive. The member noted that their program was also used to livers with longer cold times. The member continued that their colleagues in the middle of the country are much more selective with the candidates that are opted in. The member concluded that the 55 percent of candidates opted in must also consider different geographic locations require different approaches.

A member commented that their OPO had little success utilizing the tool, noting that 75 percent of liver candidates in their region are opted in, despite multiple of those centers not being readily available to facilitate an expedited placement from the OR. The member continued that the single-recipient decline also slows down allocation. The member noted that contacting and offering a program that can manage and facilitate an expedited liver transplant, having the organ accepted, and getting a plane on the ground to ship it is much more efficient. The member added that this original practice was more effective in reducing potential impact to cold time, and so much likelier to result in organ utilization. Other members agreed.

One member noted that their OPO has been most successful placing livers turned down intraoperatively by securing parallel local back up pre-organ recovery. The member continued that they secure a primary and a secondary backup, and even those programs often back out prior to organ recovery. The member remarked that there needs to be more focus on the logistical complications arising from broader sharing.

A member remarked that geographic has significant impact on the efficacy of the tool. The member continued that their OPO has a single transplant program within their donor service area, and every other program is too far away. The tool isn't valuable in that kind of scenario, because the expedited match run is pulling from large distances. The member continued that their current practice is to back up the liver with the local center, and utilize the expedited match run to identify the program and patients who will actually be able to accept and transplant the organ.

One member shared that their OPO has had success in using the tool, particularly earlier on when the surgeons themselves fielded expedited offers directly. The member added that their OPO likely has a geographic advantage, with a high volume of transplant programs in a small radius. The member continued that the expedited placement has been relatively quick and advantageous, but that the bigger issue lies in finding and accessing transportation for the organ to the accepting center. The Chair agreed that the national shortage of transportation and planes has been impactful; OPOs often may not have access to appropriate transportation for an expedited liver. The Chair continued that securing local back up is often the most successful way to place a late-turndown liver, as the OPO can easily transport the organ within the necessary timeframe. The Chair added that while there should be support for continuous distribution and broader sharing of organs, efficiency needs to be emphasized to avoid non-utilization of organs.

Staff asked the Committee if they had any potential solutions to improve the policy, or if there was additional data that could provide insight to potential solutions.

One member recommended liberalizing when the tool can be utilized, so that an expedited liver placement process can be initiated before organ recovery. The member added that use of the tool pre-recovery can also reduce the logistical complications of expedited liver placement.

Staff asked if OPOs evaluate the original liver match run to identify which patients have opted in, in order to gain an understanding of where patients would land on an expedited pathway.

A member remarked that OPO staff can go in to organ recovery with a primary, back up, and secondary back up – if all three decline the liver, the situation becomes much more unique. If 27 of the next 28 patients from 5 centers are opted in, the expedited tool is not any faster or more efficient than manual offers, other than the 30 minute time frame. The member pointed out that offering to centers instead of recipients could improve efficiency significantly, as offering to single individual recipients can rapidly increase cold time. The member added that not every program is set up to facilitate an expedited liver transplant, despite opting in patients.

One member asked if the data can indicate the programs and types of programs that turn livers down with frequency. The member continued that it is also important to address the transplant program aspect of the issue, and added that the ability for programs to accept two livers inadvertently encourages late turndowns. Another member agreed, adding that the distances from donor hospital to expedited-accepting centers could provide valuable insight. The member remarked that getting to the root cause of the issue will be important to the development of an effective solution.

#### **Upcoming Meeting**

- January 19, 2022 – Teleconference
- February 16, 2022 – Teleconference

## Attendance

- **Committee Members**
  - Kurt Shutterly
  - PJ Geraghty
  - Bruce Nicely
  - Catherine Kling
  - Chad Ezzell
  - David Marshman
  - Erin Halpin
  - Jeffrey Trageser
  - Jennifer Muriett
  - Jill Grandas
  - John Stallbaum
  - Larry Suplee
  - Malay Shah
  - Mary Zeker
  - Meg Rogers
  - Merry Smith
  - Samantha Endicott
  - Sue McClung
- **HRSA Representatives**
  - Adriana Martinez
  - Jim Bowman
  - Marilyn Levi
  - Vanessa Arriola
- **SRTR Staff**
  - Katie Audette
  - Matthew Tabaka
- **UNOS Staff**
  - Robert Hunter
  - Katrina Gauntt
  - Kayla Temple
  - Kristine Althaus
  - Alan Nicholas
  - Cole Fox
  - Leah Slife
  - Lloyd Board
  - Matt Belton
  - Matt Prentice
  - Mike Ferguson
- **Other Attendees**
  - Ricardo La Hoz