

**OPTN Data Advisory Committee
Meeting Summary
April 13, 2020
Conference Call**

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Introduction

The Data Advisory Committee (DAC) met via Citrix GoToTraining teleconference on 04/13/2020 to discuss the following agenda items:

1. Modify Data Collection for Hepatitis C Virus (HCV) Donor+ to HCV Recipient- Transplants – Project Check-in
2. Updates on OPTN Emergency Actions
3. Wrap-up & Next Steps

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

1. Modify Data Collection for HCV Donor+ to HCV Recipient- Transplants – Project Check-in

A member of the Disease Transmission Advisory Committee (DTAC) presented the purpose of this project, which is to ensure safety and efficacy of HCV Donor+ to HCV Recipient- transplants through collecting critical data points. The intended new data elements would be collected through the Transplant Recipient Follow-up (TRF) Form and the Deceased Donor Registration (DDR) Form.

Data summary:

The proposed data elements to be collected in the TRF are:

- HCV transmission
- Lab monitoring for SVR
- Liver function tests
- Direct Acting Antiviral therapy
 - Adverse reactions
 - Timing of therapy and correlation to patient/graft outcomes
- Evaluate outcome data elements and current data collected on HCV testing

The proposed data elements to be collecting in the DDR are:

- HCV genotype

Summary of discussion:

A member inquired about whether Policy 15.3.c, which indicates the OPTN will evaluate post-transplant policies, procedures, and protocols related to these organs, has produced any data. The DTAC member explained that the data points of Policy 15.3.c are not as complete as DTAC would like and that this data is not being reported to DTAC because it's not an unexpected transmission.

DAC support staff inquired about why DTAC thought the viral load data element might not be helpful in this project. The DTAC member explained that, from what has been seen, it didn't matter whether the

donor had a high or low viral load because once the recipient was diagnosed with HCV they were receiving treatment. The DTAC member stated that it would be more impactful to look at the timing of the treatment because it allows the recipient to have shorter courses of these direct acting antivirals.

A member inquired whether this project aligned with the role of the OPTN. The DTAC member expressed concern that the Centers for Medicare and Medicaid Services (CMS) is not going to approve treatment for patients with HCV until there is unbiased data, which will create a population of patients that won't be afforded these transplants even if they really need them. Therefore, the DTAC member explained that the OPTN could provide this unbiased data, showing the safety of the HCV+ donor to HCV- recipient transplants.

A member expressed concern about the new HCV genotype data element on the DDR. The member explained that organ procurement organizations (OPO) don't currently do this testing, so adding this element would put more burden on OPOs. The DTAC member mentioned that the HCV genotype is currently being collected on the recipient side, so this would be a good topic for the workgroup to address.

A member inquired whether there's a way to look at the data captured by the kidney TRF, which collects post-transplant HCV serology levels and HCV Nucleic Acid Testing (NAT). The DTAC member stated that about 99% of recipients come back NAT+, but explained that the issue with the data is that it doesn't show what happens after these tests. The data doesn't show whether the recipient got treatment for HCV and whether they had good outcomes or adverse side effects.

The DTAC member also explained that the timing of receiving HCV treatments influences best practices – most centers have to wait for CMS approval, which can influence outcomes.

A member explained that from the OPO perspective, OPOs are blind to knowing the HCV status of candidates when they are allocating organs, so they don't know whether the organ is going to a candidate that has HCV or not.

83% of DAC members endorsed the DTAC Hepatitis C Virus Project and 17% did not endorse the project.

2. Updates on OPTN Emergency Actions

United Network for Organ Sharing (UNOS) staff gave the DAC on update on COVID-19 related Emergency Actions that the OPTN has implemented.

Summary of discussion:

A member inquired whether the UNOS data team has thought about making the run report more real time to allow OPOs to have a better understanding of who is actually transplanting at this time so they can accelerate some of the organ allocation efforts. UNOS staff stated that this question hasn't been brought up, but they would be happy to pass it along to the principal investigator in research and see what they can do.

A member inquired whether there are any specific laboratory tests required to be done at transplant centers, that might have already be done elsewhere, in order to list patients; and, if so, can they be examined to see if they can forego that in order to continue listing patients. Another mentioned that they weren't aware of anything that has to be done at the transplant center. A member mentioned that CMS does require a physical exam before listing patients and questioned whether transplant centers could sufficiently meet that requirement through telemedicine.

A member stated that transplant centers are falling behind in listing patients, so it would be helpful to remove some of these barriers due to COVID-19, such as physical exams, and re-evaluate the value that

they are providing the system. A member mentioned that listing patients will be part of the back log work being done by centers when this is over, so relaxing the barriers would alleviate some of the pressure on transplant centers. UNOS staff stated that this is great feedback and that the OPTN will continue to collect and document experiences of members and ideas from the community.

A member inquired whether anything new had come out regarding donor potential as far as imminent and eligible, since initially the language didn't include COVID-19+. The member emphasized that no one is going to accept a COVID-19+ organ and that their OPO is having a difficult time placing any kidney alone because they exhaust the waitlist almost every time. UNOS staff stated that they will circulate this to internal teams and other committees to better clarify this definition.

A member stated that, when clarifying the donor potential definition, it needs to be stressed that it's an active COVID-19 crisis and that there is no confusion between antibody and viral genome testing. The member emphasized the importance of flexibility in these definitions, so it doesn't cause more issues in future situations.

A member expressed concern about OPOs coming under scrutiny because they closed a transplant due to a donor testing active for a COVID-19 infection. UNOS staff emphasized that, after seeing how all of this plays out, they will be able to provide additional guidance and flexibility on all of these topics. UNOS staff assured members that there's a very long list that is still be worked on, even in absence of policy changes, and that Membership and Professional Standards Committee (MPSC) is going to be taking this era into account for future monitoring.

3. Wrap-up & Next Steps

The feedback given by the DAC will be used to make any necessary changes or revisions to the Modify Data Collection for HCV Donor+ to HCV Recipient- Transplants Project and OPTN Emergency Actions.

Upcoming Meetings

- May 11, 2020
- June 8, 2020