OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
October 21, 2019
Chicago, IL

Marian Michaels, MD, Chair
Ricardo LaHoz, MD, FACP, FAST Vice Chair

Introduction

The Ad Hoc Disease Transmission Committee met in-person in Chicago, IL on 10/21/2019 to discuss the following agenda items:

1. Policy Oversight Committee (POC) Alignment Update
2. Committee Vote: Renew HOPE Act
3. CDC Update: PHS Increased Risk Definition / HCV+HCV- Transplantation
4. Discussion: Committee Process Efficiencies
5. Manuscript, Abstract and Case Study Reviews
6. CLOSED SESSION: Case Review

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

1. Policy Oversight Committee (POC) Alignment Update

The Vice Chair provided an overview of the new strategic goals of the Policy Oversight Committee, followed by a request for new project ideas aligned to these goals:

- Continuous distribution
- Efficient donor/recipient matching
- Multi-organ allocation

Summary of discussion:

Several committee members reaffirmed commitment to the Committee's future project to adjust policy, and educate the transplant community on the changes to the guidelines surrounding "Increased Risk Organs," issued by the U.S. Public Health Service. This is aligned to the strategic goal: Efficient donor/recipient matching because it is intended to increase the number of organs matched to wait listed patients willing to accept organs with associated life giving organs that may have risk factors, but will allow for safe outcomes.

2. Committee Vote: Renew HOPE Act

Summary of discussion:

The HOPE ACT variance was set to expire January 1, 2020. The Committee voted unanimously (16-yes, 0-no, 0-abstain)to extend the HOPE Act, allowing approved hospitals to participate the variance to perform HIV+ organs to HIV+recipients to be extended until January 1, 2022.

The item will be sent to the OPTN Board of Directors on December 2, 2019 to vote on the extension.

3. CDC Update: PHS Increased Risk Definition / HCV+HCV- Transplantation

Dr. Srindhar V. Basavaraju (CDC) provided a presentation on the PHS guideline and revision update. The proposed revised guidelines were available for public comment on the federal register in September 2019. A request for the Committee to consider additional data to be collected relating to transplantation of organs from HCV infected donors into uninfected recipients was also presented.

PHS IRD Guideline updates:

The Committee helped OPTN Board develop a response to the August 27, 2019 Federal Register's proposed revisions to the PHS IRD Guidelines. with overall support to the Secretary in and several suggested changes and concerns pertaining to informed consent, repeat donor testing, and living donor testing. Dr Basavaraju gave a summary of all results of the federal public comment period:

- Strong support for elimination of specific terminology, shortening time frame for donor risk behaviors, elimination of some risk factors, donor testing, and recipient testing
- Concerns regarding proposed timing of donor testing
  - Proposed living donor testing (<7 days) may result in delays/cancelation of transplants
  - Second serum specimen (<24 hours prior to procurement) for deceased donor testing
    - Limited supporting evidence
    - Cost, logistical constraints, transplant delays
- Some concern for universal post-transplant recipient testing

HCV positive donors: Dr Basavaraju provided general background on the increased use of HCV positive donors for HCV negative recipients in the transplant community. He noted that moving forward it would be helpful to have DTAC assistance in determining additional data that should be collected to ensure patient safety.

Summary of discussion:

The Committee emphasized the need to ensure safety and also provide comprehensive education for the community. The Committee also discussed the advantages and disadvantages or universal testing. HRSA representatives mentioned it is important that centers are able to comply with the new guidelines and that new guidelines not be so restrictive as to cause unintended harm to transplant recipients and centers.

The OPO representative explained that timing of when samples are stored can vary, depending on timing of procurement and recovery team activity. Storage may be a challenge to those institutions that do no have the extra capacity. Retesting within 72 hours is also very challenging to manage. AOPO formally responded to the proposed guidelines, but it is uncertain what the specific nature of their opinion is on testing. DTAC Leadership decided to follow up on this.

The Committee members asked if any HCV+ to HCV- data is currently collected. Yes, this is collected for some privately funded research studies or clinical trials but only for those trials. Center for Medicaid Services (CMS) has indicated that for them to consider funding antiviral drugs for HCV mismatch transplants, they will likely want to see safety and outcomes data not funded by private companies. The OPTN can potentially collect additional data on these transplants. This would fit with efficient donor/recipient matching strategic goals.

The CDC requests that the DTAC form a workgroup to examine what data is currently collected and what should be collected going forward. Some stakeholder committees may include Kidney, Liver, or Thoracic.

The PHS Increased Risk project will also require data collection changes, so these two efforts should be aligned and parallel to prevent duplicative efforts.

Some private efforts are taking a retrospective (past transplant date) and prospective (current/future transplants) approach to understand full implications of HCV transplants. If other organizations are acquiring retrospective data, the OPTN may not need to collect this data.

4. Discussion: Committee Process Efficiencies

Patient Safety staff reviewed provided an overview of proposed changes to the way in which Committee members review and adjudicate each unexpected disease transmission reported to the OPTN. The intent of this is to create efficiencies in staff time and committee member time. It should allow the Committee to spend more time on policy work and non-consent cases.

The committee will receive case packets at a different time and will not see all data for "consent" cases.

All reported data and case information will continue to be recorded. Full follow up with centers and OPOS will continue.

Full case packets will not be created for consent cases.

Regular updates and reporting of cases not adjudicated by Committee members will be provided to the Committee.

This is a pilot process and can be changed or adjusted with time.

A change to the Committee charge was proposed, in order to allow for these changes.

Summary of discussion:

Committee members were generally supportive. They expressed concern about wanting to ensure timely reporting for potential HIV transmissions. Anything of concern, including HIV or other high profile reports, would be shared with the committee members.

The Committee agrees with regular reporting. This interval and format is not yet determined.

The CDC will still be notified of transmissions, as well, but this process and method is also not yet determined.

Staff will follow with implementing these changes and regularly reporting complied reports to the Committee. The Committee suggested quarterly reporting of all compiled cases, in addition to continue posting results and meeting information on SharePoint.

The Committee voted unanimously (15-yes, 0-no, 0-abstain) to charge the charge to allow for changes to the adjudication process.

5. Manuscript, Abstract and Case Study Reviews

The Chair provided an overview of recent abstracts and publications based on DTAC case review.

A committee member recently started to lead a review of all multi-drug resistant cases that have been adjudicated by Committee members. The group will work to make an abstract for the American Transplant Congress (ATC).

A renal cell carcinoma manuscript was published.

Several other accepted or published abstracts and manuscripts were highlighted during the meeting as well. An HBV manuscript is almost ready for HRSA review and approval from a 2018 ATC poster

Summary of discussion:

No discussion.

6. Closed Session: Case Review

Upcoming Meeting

- November 25, 2019, Conference Call