OPTN Transplant Administrators Committee
Meeting Summary
August 26, 2020
Conference Call

Nancy Metzler, Chair
Susan Zylicz, MHA, BSN, RN, CCTC, Vice Chair

Introduction

The OPTN Transplant Administrator Committee met via Citrix GoToMeeting teleconference on 08/26/2020 to discuss the following agenda items:

1. Align OPTN Policy with U.S. Public Health Service Guideline, 2020
2. Annual Call for Nominations
3. TAC Members on Work Groups and Sub Committees
4. Other Business

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

1. Align OPTN Policy with U.S. Public Health Service Guideline, 2020

Marian Michaels, ex officio member of the Ad Hoc Disease Transmission Advisory Committee (DTAC), provided an overview of the *Align OPTN Policy with U.S. Public Health Service Guideline, 2020* proposal currently in public comment.

Summary of discussion:

The U.S. Public Health Service (PHS) has provided guidance on the prevention of donor transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) infection for many years. This U.S. Public Health Service Guideline (Guideline) was previously updated in 2013 and put into OPTN policy in 2014. On June 26, 2020, PHS published an updated Guideline for assessing solid organ donors and monitoring transplant recipients for HIV, HBV and HCV infection in the Morbidity and Mortality Weekly Report. These updates followed a request from the transplant community and DTAC to revise the Guideline to more accurately reflect the current risk level of utilizing organs labeled "increased risk" based on availability of improved testing methods, such as Nucleic Acid Testing (NAT).

The Final Rule requires that OPTN policies are consistent with the Guideline. The intent of the proposal is to increase the use of organs with a low risk of unexpected disease transmission as well as allow for more contextualization when discussing the risks and benefits of accepting or declining organs from donors with specific risk factors. In addition, it provides a safety back up that promotes early identification of HIV, HBV, and HCV if transmission unexpectedly occurs by focusing on prompt implementation of therapy to minimize allograft damage and mortality.

The rates of donors recovered who were classified as an "increased risk donor" in a given year increased from a low of 7.5% in 2007 to over 27% by 2018 and 2019. Currently, accepting offers from these donors requires a separate informed consent from the potential recipient.

The proposal includes the following:

- Remove label "increased risk donor"

- Shorten timeframe for donor risk criteria assessment from 12 months to one month
- Remove hemodilution as infectious disease risk criteria in policy
- Require deceased donor testing specimens drawn within 96 hours of procurement
- Require living donor recovery hospitals to arrange storage of pre-transplant samples for 10 years
    - This matches current policy for deceased donor samples
- Remove requirement for a separate informed consent when donors meet risk criteria
- Require assessment of need for HBV vaccination during candidate medical evaluation and report vaccination status
- Add required testing:
    - Candidate pre-transplant for HIV, HBV, and HCV during transplant hospital admission but before transplant occurs
    - Universal NAT for HIV, HBV, HCV on all transplant recipients 4-8 weeks after transplant
    - Liver recipient testing between 11-13 months post-transplant for HBV NAT

From an Organ Procurement Organization (OPO) standpoint, the proposal will require the modification of the donor screening assessment for identifying donor risk criteria and repeat tests if procurement does not occur within 96 hours of when infectious disease samples are first drawn.

Transplant hospitals will be required to:

- Complete additional testing for living donors, candidates, and recipients
- Update candidate evaluations to include assessment for HBV vaccination need
- Report reasons HBV vaccination cannot be initiated or completed prior to transplant
- Arrange for living donor specimen storage

DTAC is seeking feedback during public comment from committees and regional meeting attendees.

The Chair asked what the current requirement is for living donor specimen storage. There is currently no requirement for storing samples but there is a one or two year requirement for storing deoxyribonucleic acid (DNA) for human leukocyte antigens (HLA) testing. Members raised concerns about the proposed length of ten years.

A member asked if increased risk organ utilization has increased. The DTAC representative commented there is a lot of variation in increased risk donor acceptance between hospitals. The member responded that some programs may pass on increased risk organs because they know that they will have other offers. They also commented that acceptance is dependent on how the risks are explained to the candidate.

A member asked what data is driving the requirement to perform HBV testing post-transplant as these numbers are low. The DTAC representative commented that this is to promote patient safety and noted that a former practice was to test all candidates.

A member commented that they understand the importance and support the intention of the proposal but noted that this will cause a significant financial burden for patients and programs. Presently, reimbursements are not allowed for post-transplant screening. They asked if this was considered when developing the proposal and if there are any efforts underway to address this issue.

The tests for HIV, HBV, HCV would be a one-time expense and are part of the public health structure. DTAC will review if these expenses would be covered by the patient's insurance. The member commented that polymerase chain reaction (PCR) and NAT testing is expensive, are not required

clinically, and there is no diagnoses for screening. The Guideline does not align with reimbursement if the patient is asymptomatic. DTAC will review the coding structure.

A member raised a concern around the cost of storing living donor samples for ten years as infrastructure will need to be developed to accommodate these samples. In addition, there are concerns about patient privacy and what the samples will be used for. The member noted that the ten year requirement is the same for deceased donors but living donors have more privacy protections. When PHS issued this Guideline, they were thinking more globally than just using the samples to test for HIV, HBC, and HCV and considering exposures such as tuberculosis or cryptococcosis which may present belatedly. The Final Rule requires alignment with PHS but does not need to be the exactly the same. From feedback received so far, this ten year requirement may decrease.

A member asked about the testing and storage process for living donors. The living donor sample would be taken the day of donation and held for potential testing. Privacy laws need to be established to ensure the samples are only used for donor-derived concerns.

The members raised questions about the sentiment voting process. UNOS staff shared that all comments and discussion from the Committee will be used to make a response to this proposal on behalf of the Committee. Individuals are encouraged to submit their feedback as well in the Public Comment section of the OPTN website.

The Chair asked the Committee for additional feedback on the proposal and summarized what was discussed so far. Members raised concerns around the data collection and reporting of HBV vaccination documentation. A member asked if this will be a regulatory requirement. UNOS staff commented that feedback received will help to determine how HBV data is collected and documented. Members commented that adding data collection increases staff time and thereby expenses to ensure that the data is being entered appropriately and compliance requirements relating to documentation are met.

A member commented that the Committee members want to deliver the highest quality of care and follow best practices but questioned how much work and burden it will be to operationalize the HBV vaccination documentation process. It was noted that patients without HBV immunities who are infected with HBV during transplant will incur the costs of HBV treatment and increase the risk of transmission to others.

A member commented that collecting vaccine source documentation for patients is challenging. The proposal, as written, is to test the patient's immune status. The member commented that it would be much easier to have the transplant program test for antibodies and use these results as the source document.

Next steps:

Committee members will email additional comments to UNOS staff to synthesize into a public comment response. This draft response will be reviewed by the Committee and submitted on behalf of the Committee.

2. Annual Call for Nominations

Anna Wall, the UNOS Talent Specialist in charge of recruitment and onboarding of UNOS volunteers, provided an overview of the annual call for nomination process and the current vacancies being recruited for.

Summary of discussion:

There are 72 vacancies for committee and board positions beginning in July 2021. Descriptions of these roles are posted on the OPTN website. The goal is to fill these vacancies with a volunteer workforce that represents the diversity of the transplant community in regard to relationship to transplant, ethnicity, gender, and expertise. It is important that many voices and perspectives are heard to promote equity when developing policy.

The Committee was asked to fill out their volunteer interest form if their term is ending and they would like to continue volunteering. They were encouraged to share the open positions with their networks to help in recruiting and consider applying for the open Board positions. Transplant administrators are being sought to fill some of these Board positions.

Interested individuals can apply for these positions on the OPTN website. The call for nominations closes on 9/30/2020.

3. TAC Members on Work Groups and Sub Committees

This agenda item was not discussed due to timing.

4. Other Business

The Committee members were asked if there were addition questions. No other comments were made.

Upcoming Meeting

- September 23, 2020

Attendance

- **Committee Members**
  - Andrea Tietjen
  - Brian Roe
  - Denise Neal
  - Deonna Moore
  - Erica Seasor
  - Gene Ridolfi
  - Jason E. Huff
  - Joshua Gossett
  - Kristina Wheeler
  - Melissa Porter
  - Michelle James
  - Nancy Metzler
  - Paul Myoung
  - Scott Wansley
  - Susan Zylicz
  - Valinda Jones
- **HRSA Representatives**
  - Raelene Skerda
  - Vanessa Arriola
- **UNOS Staff**
  - Angel Carroll
  - Anna Wall
  - Emily Ward
  - Peter Sokol
  - Sarah Konigsburg
  - Shannon Edwards
  - Susan Tlusty
  - Susie Sprinson
- **Other Attendees**
  - Marian Michaels