OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
December 1, 2020
Conference Call

Ricardo La Hoz, MD, FACP, FAST, FIDSA, Chair
Lara Danziger-Isakov, MD, MPH, Vice Chair

Introduction

The Ad Hoc Disease Transmission Advisory Committee met via Citrix GoToMeeting teleconference on 12/01/2020 to discuss the following agenda items:

1. Open Session: PHS proposal language changes
2. Open Session: Review data collection mock-ups
3. Closed Session: Confidential peer case review

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

1. Open Session: PHS proposal language changes

DTAC Past Chair and UNOS liaison presented on the proposed policy changes since the last DTAC committee vote on October 26, 2020.

Data summary:

The following changes were presented to the committee:

- The removal of "FDA-approved" from hemodilution assessment
- Clarification that Hepatitis B core antibody testing referred to the total result, not IgG or IgM
- Re-incorporation of the language that went out for public comment requiring reporting of Hepatitis B vaccination status to the OPTN
- Spelling out "Clinical Laboratory Improvement Amendments" where CLIA was used

Summary of discussion:

One member brought up that knowing transmission of HBV in regards to vaccination and immune response will be important.

HRSA representative asked if the HBV vaccination data collection would need to go back out for public comment.

One member asked at what point would the center be answering the question for HBV vaccination status, and wanted to make sure there would be sufficient time to check the medical record. UNOS staff proposed that this data collection occur on the Transplant Recipient Registration (TRR), which is submitted within 60 days of the recipient's transplant.

One member asked why "FDA-approved" was being removed from hemodilution calculation. The FDA representative explained that while the FDA does provide guidance on the calculation of hemodilution, it does not actually approve algorithms.

Vote: 15 yes, 0 no, 0 abstain.

Next steps:

The proposed language will be submitted to the OPTN Board of Directors for approval at their December meeting.

2. Open Session: Review data collection mock-ups

UNOS IT staff presented potential mock-ups for data reporting for HBV vaccination.

Data summary:

The proposed question was "Did the recipient receive a complete Hepatitis B vaccination series prior to transplant?", with the response options of yes, no, and unknown. The response options presented for when vaccines were unable to be given were based on current CMS and HL7 response options for the same question.

CMS responses:

- Time constraints (added by DTAC leadership)
- Medical reason: Allergic
- Medical reason: Adverse Reaction
- Medical reason: Other
- Personal reason: Cultural/religious
- Personal reason: Personal choice

Summary of discussion:

The committee discussed whether or not there was benefit in changing the question to "initiated or completed", with additional child questions for the "yes" response option in order to specify if the vaccine series was just initiated or had been able to be completed, or if there were multiple series given. One member discussed the balance between useful information vs. burden of data entry, and how the antibody result will be able to help distinguish if a recipient responded to the vaccination or not. Members were divided on the value of adding the question of if the vaccine was only initiated without completion. One member brought up that including if the vaccine was just initiated could help distinguish false positive surface antigen results if the recipient is transplanted within 30 days of vaccination/listing. Some members commented that keeping the question simple makes the most sense, especially with multiple types of vaccination available with different series and multiple potential providers administering. The proposed revised question was "Did the recipient receive Hepatitis B vaccination series prior to transplant?"

Members expressed concern that data entry coordinators might have trouble answering the question and the response options, since the reasons and number of vaccines within a series might not be clearly outlined within a patient's chart.

One member commented that it might be helpful to simplify the CMS response options to "medical reason, person reason, and time constraints".

Next steps:

UNOS IT staff will present a revised mock-up at a future meeting. UNOS staff will submit the parent question to OMB for approval.

3. Closed Session: Confidential peer case review

Summary of discussion:

The Committee had a closed session of confidential medical peer review of potential donor derived transmission events.

Upcoming Meetings

- December 21, 2020, Teleconference
- January 25, 2021, Teleconference
- February 22, 2021, Teleconference

Attendance (Open Session)

- **Committee Members**
  - Ann Woolley
  - Avinash Agarwal
  - Charles Marboe
  - Debbie Levine
  - Gary Marklin
  - Heather Stevenson-Lerner
  - Helen Te
  - Jason Goldman
  - Kelly Dunn
  - Marian Michaels
  - Meenakshi Rana
  - Raymund Razonable
  - Ricardo La Hoz
  - Saima Aslam
  - Stephanie Pouch
- **HRSA Representatives**
  - Chris McLaughlin
  - Jim Bowman
  - Marilyn Levi
- **CDC Staff**
  - Ian Kracalik
  - Jefferson Jones
  - Sridhar Basavaraju
- **FDA Staff**
  - Scott Brubaker
- **UNOS Staff**
  - Courtney Jett
  - Craig Connors
  - Darby Harris
  - Emily Ward
  - Kristine Althaus
  - Lara Danziger-Isakov
  - Laura Cartwright
  - Lauren Mauk
  - Leah Slide
  - Liz Robbins-Callahan
  - Nicole Benjamin
  - Sandy Bartal
  - Shannon Edwards
  - Susan Tlusty

Attendance (Closed Session)

- **Committee Members**
  - Ann Woolley
  - Debbie Levine

    - Gary Marklin
    - Helen Te
    - Jason Goldman
    - Kelly Dunn
    - Lara Danziger-Isakov
    - Marian Michaels
    - Meenakshi Rana
    - Ricardo La Hoz
    - Saima Aslam
    - Stephanie Pouch
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