OPTN Ad Hoc Disease Transmission Advisory Committee
HCV Workgroup Subcommittee
Meeting Summary
March 26, 2020
Conference Call

Marian Michaels, MD, MPH, Chair
Ricardo La Hoz, MD, FAST, FACP, Vice Chair

Introduction

The HCV Workgroup Subcommittee met via Citrix GoToMeeting teleconference on 03/26/2020 to discuss the following agenda items:

1. Introduction, Purpose, and Background
2. Problem Statement
3. Discussion of Data Collection
4. Next Steps and Future Meetings

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

1. Introduction, Purpose, and Background

DTAC Chair introduced the project and requested feedback on strategic plan alignment.

Data summary:

Slides attached.

Summary of discussion:

Committee discussed strategic plan alignment. The project best aligns with ensuring recipient safety, as these transplants require additional monitoring for safety and outcomes.

2. Problem Statement

DTAC Chair introduced the problem statement for discussion amongst committee members.

Data summary:

Slides attached.

Summary of discussion:

Committee is most concerned that not all transplants are occurring in IRB-approved clinical trials, as well as potential selection bias in clinical trials. More centers are starting to do transplants outside of trials, with no oversight or monitoring, and the committee is especially concerned about pediatric patients.

3. Discussion of Data Collection

DTAC Chair opened the floor to discussion for data collection on different patient types, different forms, and potential data elements to include.

Data summary:

Slides attached.

Summary of discussion:

The Committee was in agreement that the data collection should proceed with every deceased donor organ type and with pediatric recipients. They also were in agreement that this data collection will not need to occur on living donor organs, as living donors would be treated for HCV-viremia prior to transplant. The Committee discussed adding a new form to TIEDI vs. addition of all follow up data fields to current forms, but was unsure of feasibility in terms of IT implementation and OMB approval. Discussed if addition of data fields to existing forms, would likely develop all changes at once but stagger implementation for IT feasibility.

One Committee member brought up the current clinical trials for DAA-therapy occurring through HCV-Target and recommended looking at the data points they are collecting.

One Committee member brought up that some testing could occur on the donor instead of the recipient, such as HCV genotype, and if available a quantitative PCR.

Next steps:

IT will break down the level of effort required to add an additional form for these transplants vs. put the currently proposed data elements into all of the current TIEDI forms. Policy will meet with the Data Advisory Committee on the OMB process for addition of a form vs. addition of previously proposed data elements to existing forms. Liaison will provide a breakdown of data points being collected in current clinical trials to members prior to next Committee meeting.

4. Next Steps and Future Meetings

DTAC Chair presented on next steps of project.

Data summary:

Slides attached.

Next steps:

DTAC leadership to present project to DAC and POC for endorsement prior to next committee meeting.

Upcoming Meetings

- To be determined