Introduction

The Data Advisory Committee (DAC) met via Citrix GoToMeeting teleconference on 4/12/2021 to discuss the following agenda items:

1. HLA Equivalency Tables Update 2021 (Histocompatibility Committee)
2. Establish Membership Requirements for Genitourinary Organ Transplant Programs (VCA Transplantation Committee)
3. Develop Measures to Identify Primary Graft Dysfunction (Heart Transplantation Committee)

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

1. HLA Equivalency Tables Update 2021 (Histocompatibility Committee)

This project, sponsored by the Histocompatibility Committee, intends to add tables for DPA1 alleles and null alleles, as well as expand data collection to include more common alleles and epitopes in DonorNet.

Summary of discussion:

The Histocompatibility Vice Chair gave an overview of the Histocompatibility Committee’s proposal to update the human leukocyte antigen (HLA) equivalency tables to include a list of all common alleles that a donor or candidate may be typed for. This proposal seeks to add a field for HLA-DPA1 typing for candidates and donors, a field for HLA DPA1 unacceptable antigens for candidates, as well as additional selection options to other existing data fields for HLA typing and unacceptable antigens. This proposal also seeks to make the entry of unacceptable antigens consistent across all OPTN data collection instruments, specifically Waitlist, DonorNet, and TIEDI.

The DAC Chair asked who typically fills out these forms and how the data is entered. The Histocompatibility Vice Chair shared that the data is entered by making selections on a drop down list. This task is typically done by lab personnel and occasionally by transplant coordinators. Double entry is required in order to reduce errors and any discrepancy between the entries requires correction.

The DAC Chair commented that the proposal seems straightforward and asked if there is any increased burden for adding these fields. The Histocompatibility Vice Chair responded that because the DPA field already exists, this information should be easy to enter for donors who are typically performing this typing. He commented that on the recipient side, it is currently not a required element for candidate typing but will be available as an optional field.

The DAC Chair asked about considerations relating to optional data fields, incomplete values, missing data, and if this information is relevant to all donors. The Histocompatibility Vice Chair commented that
although not mandatory, entering the DPA information of the donor will allow further offer screening if unacceptable antigens are identified.

The DAC Vice Chair asked if there is any effort to automate this data entry. The Histocompatibility Vice Chair commented that there are API initiatives underway to accomplish this and noted that the API to enter unacceptable antigen into Waitlist is scheduled to go live this upcoming September.

The DAC Chair supported endorsing this proposal and asked the members if any opposed. No members opposed.

2. Establish Membership Requirements for Genitourinary Organ Transplant Programs (VCA Transplantation Committee)

This project, sponsored by the Vascularized Composite Allograft (VCA) Transplantation Committee, intends to establish membership requirements specific to genitourinary organ transplant programs in Appendix J of the OPTN Bylaws.

Summary of discussion:
A member of the VCA Transplantation Committee provided an overview of the changes in membership requirements being considered and described the potential related modifications to the OMB-approved membership application forms.

The DAC Chair asked about the numbers of current VCA programs and genitourinary programs that these changes would impact. The VCA member commented that all VCA programs recently submitted new applications as part of an ongoing implementation of updated VCA membership requirements. UNOS staff shared that there were approximately 65 VCA programs prior to the implementation, 10 of which offer genitourinary organ transplant services. This proposal is expected to primarily impact uterus transplant programs, and would require uterus transplant programs to re-apply to the OPTN to demonstrate compliance with the new requirements specific to uterus transplant programs.

The DAC Chair asked how often the programs will go through this application process. The VCA member commented that the program applies once and then provides updates if there are key personnel changes.

The DAC Chair asked about tracking and evaluating the data collected on the membership applications. The VCA member commented that the primary purpose of collecting the data is to ensure the program is qualified to perform VCA and genitourinary transplants.

The DAC supported the endorsement of this project.

3. Develop Measures to Identify Primary Graft Dysfunction (Heart Transplantation Committee)

This project, sponsored by the Heart Transplantation Committee, intends to add data elements to the Heart Transplant Recipient Registration Form (TRR) to identify primary graft dysfunction (PGD) in recently transplanted heart recipients.

Summary of discussion:
A member responded to the time points for data collection being considered by the proposal of 24 hours, 72 hours, and 7 days commenting that 7 days may be too far out from transplant. The Heart Transplantation Committee Chair commented that these time points are being considered but 24 and 72 hours received the most support in response to the request for feedback during public comment. The member agreed and commented that the International Society for Heart and Lung Transplantation (ISHLT) consensus statement requires the diagnosis of PGD to be made within 24 hours of transplant. The Heart Transplantation Committee Chair commented that this is why there is a need to collect the
data at 24 hours but noted that there is a challenge in identifying PGD at 24 hours due to device use and the variability of inotrope use in patient management post-transplant. The member agreed and commented that some patients come out relatively stable and then decline between 48 and 72 hours.

A member commented that the 7-day time point may be valuable in providing information on the resolution of the patient’s case. The member asked if there is a time limit for relisting a patient for a heart transplant due to PGD. The Heart Transplantation Committee Chair commented that there is no time limit.

A member asked what the data collected will be used for in the future, whether it be to assess therapies that worked or another reason. The Heart Transplantation Committee Chair commented that the data will assist in understanding the frequency of incident and support the identification of risk factors such as the use of DCD organs, procurement devices, or changes in the recovery team. She noted that the Heart Transplantation Committee members are evaluating the level of burden associated with additional data collection.

A member recommended focusing on identifying and defining the true incidents of PGD rather than risk factors. The Heart Transplantation Committee Chair commented that the Committee is also working to capture all the relevant variables prior to the development of a heart allocation score such as additional device data. The Heart Transplantation Committee Chair commented that the data elements being considered are the minimal data elements needed to identify PGD and most are readily available or easily obtainable. She commented that the Committee still needs feedback on the subjective yes or no questions and commented that the data element “left ventricular dysfunction: yes or no” could be removed and determined by evaluating the left ventricular ejection fraction values entered. However, there is no clear objective measure for right ventricular dysfunction. She commented that there was mixed support for including the “primary graft dysfunction: yes or no” data element during public comment.

The Heart Transplantation Committee Chair shared that the most challenging information to collect is data relating to inotropes due to the variability in dosing and how patients are managed. She commented that the Committee will continue to determine if ranges or unique values are most appropriate for the various data elements.

Next steps:
The Heart Transplantation Committee will continue to solicit feedback as the members prepare a data collection proposal for public comment this August.

Upcoming Meeting
- May 10, 2021
Attendance

- **Committee Members**
  - Anna Mello
  - Benjamin Schleich
  - Bilal Mahmood
  - Colleen O’Donnell Flores
  - Daniel Stanton
  - Farhan Zafar
  - Heather Hickland
  - Krishna Mahendraraj
  - Kristine Browning
  - Lauren Kehnars
  - Macey Levan
  - Melissa McQueen
  - Rachel Patzer
  - Sumit Mohan

- **HRSA Representatives**
  - Adriana Martinez

- **SRTR Staff**
  - Ajay Israni
  - Bertram Kasiske
  - Nick Salkowski
  - Maryam Valapour

- **UNOS Staff**
  - Adel Husayni
  - Brooke Chenault
  - Carly Engelberger
  - Courtney Jett
  - Eric Messick
  - Kaitlin Swanner
  - Kiana Stewart
  - Lauren Mauk
  - Leah Sliffe
  - Matt Prentice
  - Nicole Benjamin
  - Robert Hunter
  - Sally Aungier
  - Sarah Konigsburg
  - Sarah Taranto
  - Sharon Shepherd
  - Susan Tlusty

- **Other Attendees**
  - Jamie Bucio
  - John Lunz
  - Nicole Johnson
  - Shelley Hall