Introduction

The Fiscal Impact Advisory Workgroup met via Citrix GoToMeeting teleconference on 05/18/2021 to discuss the following agenda items:

1. Review Status Extension Requirements in Adult Heart Allocation Policy (Heart)
2. Develop Measures for Primary Graft Dysfunction in Hearts (Heart)
3. Establish Membership Requirements for Uterus Transplant Programs (Vascularized Composite Allograft)

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

1. Review Status Extension Requirements in Adult Heart Allocation Policy (Heart)

Summary of discussion:

While this project intends to require additional information for adult heart status extensions, these requirements will consist of clinical data that are already being collected. In addition, these data are already required for some status extensions and the proposed changes will promote consistency across all status extensions. The proposed changes will require modifications to heart status justification forms but the goal is for the IT implementation to be relatively seamless for transplant programs.

Members agreed that these modifications would require training for members, but there would be no significant changes in workflows or effects on transplant program volume. The Heart Committee Chair commented that the training would likely be straightforward since what would be requested is commonly accessed clinical data for heart candidates, only requiring about thirty minutes to train staff.

The members representing organ procurement organizations (OPO) and histocompatibility labs agreed that this proposal should not have any impact on those member types.

Next steps:

UNOS staff asked the members to follow up with any additional thoughts and comments via email or survey.

2. Develop Measures for Primary Graft Dysfunction in Hearts (Heart)

Summary of discussion:

Members asked if the data elements within the proposal are typically recorded within a patient’s chart. The Heart Committee Chair responded that they are common clinical data for heart candidates and recipients, and that the Heart Committee released a request for feedback from the community during the most recent public comment period to ensure the proposed data elements are easily discoverable within a patient’s chart. The proposal intends to keep data entry as simple as possible for the coordinators tasked with entering the proposed data elements. The Heart Committee is still considering
additional data collection related to organ procurement or the organ donor that are not as easy to obtain. If donor- or procurement-specific data elements are included in the proposal, there would be a small cost to OPOs to update donor records to add new data fields.

A member raised a concern about the potential for variation in burden between programs depending on the program’s electronic health record (EHR) system. The Chair of the Heart Committee commented that the burden should not be significantly different for programs, regardless of their EHR.

This proposal will require a slight workflow change and additional data entry for heart transplant programs. The proposed data elements will be added to the post-transplant section of the Transplant Recipient Registration (TRR) that is required to be submitted 60 days after transplant. The workgroup agreed this timeframe should be more than sufficient for entering the required data.

There is no anticipated fiscal impact to histocompatibility labs.

Next steps:
UNOS staff asked the members to follow up with any additional thoughts and comments via email or survey.

3. Establish Membership Requirements for Uterus Transplant Programs (Vascularized Composite Allograft)

Summary of discussion:
This proposal will require uterus transplant programs to re-apply for membership. Completing applications can be burdensome, but there would be the benefit of ensuring appropriate expertise at uterus transplant programs. A member raised a concern that the proposed requirements being considered do not limit access to membership for programs already established by being overly restrictive. UNOS staff explained that all three active uterus transplant programs in the country had representation on the workgroup that developed the proposal.

Members agreed that since hospitals with VCA transplantation programs must have a solid organ transplant program per OPTN Bylaws, the proposed changes should have a minimal financial impact as the hospitals have already established the necessary resources to meet membership requirements. In addition, the new membership application for uterus transplant programs would follow the same structure as the application that VCA transplant programs just completed, though the requirements that uterus transplant programs would have to meet are a bit broader than just changing the key personnel.

A member commented that completing membership applications are administratively burdensome for transplant programs. There may also be an additional cost for programs to hire an independent living donor advocate (ILDA) if they are establishing a living donor uterus transplant program, but programs are able to utilize a transplant coordinator in multiple roles. However, they may choose to hire an additional coordinator with experience in obstetrics and gynecology.

There is no anticipated impact on OPOs or histocompatibility labs.

Next steps:
UNOS staff asked the members to follow up with any additional thoughts and comments via email or survey.

Upcoming Meetings
- May 21, 2021
Attendance

- **Workgroup Members**
  - Andrea Tietjen
  - Debbi McRann
  - Gwen McNatt
  - Jerome Saltarrelli
  - Laura Stillion
  - Robert Howey
  - Ryan Haydu

- **HRSA Representatives**
  - Vanessa Arriola

- **UNOS Staff**
  - Courtney Jett
  - Kaitlin Swanner
  - Susan Tlusty

- **Other Attendees**
  - Nicole Johnson
  - Shelley Hall