OPTN Transplant Administrators Committee
Fiscal Impact Advisory Workgroup
Meeting Summary
May 28, 2020
Conference Call

Introduction

The Fiscal Impact Advisory Workgroup met via Citrix GoToMeeting teleconference on 05/28/2020 to discuss the following agenda items:

1. Membership Requirements Revisions
2. Programming VCA Allocation in UNet[sm]
3. Modify Data Collection on VCA Living Donation and Living Donor

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

1. Membership Requirements Revisions

A member gave an overview of the policy proposal and led discussion regarding the expected fiscal impact for transplant programs, organ procurement organizations (OPOs), and labs.

Summary of discussion:

A member read through the Membership Requirements Revisions policy proposal's project form included in the meeting materials. The proposal is sponsored by the Membership and Professional Standard Committee (MPSC) and seeks to review membership requirements in OPTN Bylaws Appendices A-D that support a process for periodic reassessment of membership status as required by the new OPTN contract.

The goal of the proposal is to improve the efficiency of members' application process by:

- Ensuring that requirements of members are consistent with current practice and qualifications;
- Eliminating discrepancies that complicate members' ability to comply but also MPSC's review of applications;
- Reducing the burden on members completing applications, the majority of which require resubmission currently.

This will be achieved by:

- Making appropriate revisions to the format for transplant program key personnel requirements
- Stratifying requirements based on the type of application

The member shared that these proposed bylaw revisions will have the following impact:

- OPOs will be required to submit additional information
- Labs reporting requirements will decrease

A member asked for more details about the frequency of reporting required. A member responded stating that the schedule is not yet determined. UNOS staff responded saying that the frequency of review would correspond with site surveys.

A member commented that a lot has been taken out of the bylaws regarding OPO requirements because the requirements are either not attended to under the OPTN or is already covered clearly by Centers for Medicare and Medicaid Services's (CMS) Conditions of Participation. The member commented that the burden on OPOs will be small and voiced support for the reviewing the requirements on a regular basis.

A member commented that from fiscal impact perspective, increasing efficiency of reporting and thereby decreasing need for resubmission would be beneficial to members as it will reduce time and resources needed.

Staff asked for input from a meeting attendee that represents labs. The member commented that the effect of the proposed policy will vary by the size of the lab and that they do not have any issues currently with maintaining the required reporting. The member noted that the complexity and documentation required may impact their ability to maintain requirements but any fiscal impact will not be a major barrier.

A member commented that they are excited that the application for transplant hospitals will be changing because it currently causes their team problems due to needing to submit and resubmit.

Staff asked for any other comments from the workgroup. There were no additional comments.

2. Programming Vascularized Composite Allograft (VCA) Allocation in UNet^{sm}

A member gave an overview of the proposed policy sharing that as VCA allocation continues to increase, the sponsoring committee is seeking integration of VCA allocation into UNet^{sm}, Waitlist, and DonorNet.

Summary of discussion:

A member shared that VCA allocation is currently managed outside of UNet^{sm} requiring OPO members to use a separate application. This inhibits data collection and integration with other organ types. As VCA volumes increase, particularly for uterus transplants, programming VCA allocation into UNet^{sm} will allow for greater access and efficiency for VCA programs to consider VCA offers and provides a platform that integrates with future or concurrent data collection projects. The proposal does not currently include data collection.

A member asked the committee about how this new process for VCA would differ from the current state in regard to time and effort beyond the need for staff training. A member commented they did not perceive additional effort required. UNOS staff invited the VCA representatives on the call to provide input. A VCA representative stated that they support creating consistency by including VCA into UNet^{sm}. Another member agreed, adding that their program's staff is already trained in UNet^{sm}.

A member asked about the implementation timeline. UNOS staff responded with, if approved by board in June, implementation is scheduled for December 2021.

Staff asked for input from OPOs and labs regarding if this change would require extra staff, training, or time. A member representing OPOs said they are excited for this change. A member representing labs also voiced support stating that the only impact would be staff training. A member said adding VCA allocation to UNet^{sm} will likely increase VCA transplants and the benefits will far exceed any resources expended which are expected to be minimal. A member agreed, commenting that the way VCA allocation is managed should be consistent with other allocation processes.

A member noted that VCA programs may receive a significant increase VCA offers and will need to be prepared if this occurs. Currently, most VCA programs perform less than ten transplants per year.

UNOS staff asked the workgroup if they had any comments. No additional comments were made.

3. Modify Data Collection on VCA Living Donation and Living Donor

A member summarized the Modify Data Collection of VCA Living Donation and Living Donor policy proposal and moderated discussion around its perceived fiscal impact to OPOs, transplant hospitals, and labs.

Summary of discussion

A member shared that currently, the OPTN does not require data collection specific to VCA uterus donors on the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms. All information specific to these donors is submitted voluntarily. This absence of data collection may provide a patient safety gap. Uterus transplants are increasing and more patients are being added to the waitlist.

A member shared that minimal fiscal impact to programs is anticipated. The member commented that transplant programs already have trained staff in place that could incorporate the proposed changes into similar processes already completed for other solid organ transplants.

The member asked the workgroup if the policy would increase wider adoption including payer support in addition to increasing patient safety. A member commented that these changes would be congruent with standard practices of evaluation and surveillance monitoring for other transplants.

A member asked the visiting VCA representatives for comments on if data modifications to the LDR and LDF would put them at a financial disadvantage. A member responded by sharing that uterine transplants are currently being coordinated by research trial teams and not the standard transplant clinical teams. These research teams are familiar with collecting a large amount of clinical data. The member's team is discussing OPTN regulations as uterus transplants will likely become commercially available in the near future.

Another member commented that it costs money anytime data is being collected and submitted via TIEDI forms. These expenses can be claimed on the Cost Report. The member asked for the number of data elements being collected and the time frame. Other members voiced that they also wanted this detail in order to assess the fiscal impact. The Workgroup reviewed draft data elements. Data elements are still being finalized by the VCA Committee.

A member commented that there may not be a lot of data being collected on living uterus donors currently but there is likely a lot of data about hysterectomies. A member agreed with these sentiments.

A member commented that teams would be willing to collect additional data but questioned the impact this will have as VCA transplants increase.

A member commented that transplant programs are financially responsible for labs at 6 months, 1 year, and 2 year follow ups. These labs are not charged to insurance so these expenses should be considered as part of this proposal.

A member commented that over time, data will need to be collected to better understand outcomes.

Another member raised a concern about the time periods required for follow-ups. A member responded that it will be the same time period as other living donor follow-ups and the only difference is adding data elements. A member noted that follow-ups for kidney occur at 6 months, 1 year, and 2 years whereas liver follow-ups occur at 6 months and 1 year.

Staff asked if the workload would be relational to the volume of transplants being performed. A member said the workload would be incremental depending on the number of data elements are required, how many follow-ups are required, and the volume of living donors.

A member shared that the time period has not yet been established and the number of data elements included in the proposal vary by type of VCA. Uterus LDR and LDFs will have more data elements added than non-uterine VCA LDR and LDFs.

A member asked the workgroup about risks associated with hospitals that may not collect data and if there was potential for this to cause commercial insurers to provide reimbursement to one center over another. A member responded that they anticipate uterus transplants only being paid for by private payers but this is uncertain.

Staff shared the data elements that the policy proposes to add to the LDR. The elements are similar to what is already collected for liver and kidney with additional data elements specific to uterus if applicable. The LDR is required to be submitted at donor discharge or within 6 weeks of donation if the donor remains hospitalized. UNOS staff also shared the data elements that the policy proposes to add to the LDF which will is required to be submitted at six months, one year, and two years.

A member noted that the VCA Committee based the proposal on existing protocols. The VCA Committee reviewed literature, research protocols, and assessed current practices to guide how the proposal is structured. A member of the VCA Committee mentioned that the VCA Committee strived to make the proposal as burden free as possible but acknowledged that there will be more staff resource and education needed. The existing team that enters TIEDI information will need to learn about uterus specific data elements. The member commented that the VCA Committee focused on only including essential data elements to keep the requirements as simple as possible.

Staff reminded the Workgroup that they have assessed that only transplant hospitals will be fiscally impacted by this proposal and invited OPOs and labs to make any additional comments if they believe otherwise. A member representing labs mentioned that they are prepared to add on to existing work to be consistent with other living donor processes.

Next steps:

UNOS staff will send project forms, slides, and survey to workgroup and requested feedback by Monday 6/1/20.

Upcoming Meetings

- N/A