OPTN Transplant Administrators Committee
Fiscal Impact Advisory Workgroup
Meeting Summary
October 22, 2020
Conference Call

Introduction

The Fiscal Impact Advisory Workgroup met via Citrix GoToMeeting teleconference on 10/22/2020 to discuss the following agenda items:

1. Clarify Multi-Organ Allocation Policy
2. Review Deceased Donor Registration Form
3. Required Reporting on HLA Typing Changes
4. Membership Requirements Revisions

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

1. Clarify Multi-Organ Allocation Policy

UNOS staff described the format of the meeting and posed questions for the Workgroup members to consider when assessing the fiscal impact of each proposal presented. A member provided a summary of the *Clarify Multi-Organ Allocation Policy* project and led the group's discussion on the anticipated fiscal impact.

Summary of discussion:

The member described that this policy proposal is seeking to address the lack of medical criteria and assessment of need in Policy 5.10.C, the unclear rules for multi-organ allocation beyond the local level, and the lack of specificity for allocation order when there are several eligible multi-organ candidates. Of multi-organ transplants in 2018, 82% of multi-organ transplants (MOT) were combinations addressed by current OPTN policy. A majority of these transplants were kidney-pancreas and liver-kidney. The combinations that are not addressed in current MOT policy are heart-kidney, liver-intestine-pancreas, liver-heart, and liver-lung which is why there is variability in how these combinations are allocated by organ procurement organizations (OPOs) and may not necessarily take medical urgency into account. The purpose of the proposal is to focus on thoracic organ combinations and prioritizing candidates with medical urgency.

UNOS staff asked the members to respond to the fiscal impact this proposal would have on OPOs. A member commented that this would not have a big impact on cost or workflow.

Another attendee agreed that this will not create additional burden on OPOs and that the language and specificity in the flow document will help address inconsistencies in multi-organ allocation.

A member asked if these changes would shorten allocation time. A member commented that it would likely shorten allocation time as it may help workflow. An attendee agreed that it would improve the efficiency of the workflow. A representative of the OPO committee commented that this policy proposal is expanding the current policy to 500 nautical miles and that there may be some delays with the allocation of liver as the primary organ but they are working to address any issues.

A member asked about the cost for programming. UNOS staff shared that this will be assessed when the final policy language is determined but it is not anticipated to be a large effort.

A member asked if the proposed policy includes specifics about how this will be reviewed during site surveys and what the expectations will be for determining whether a multi-organ or single organ allocation was appropriate. UNOS staff shared that the proposal includes a monitoring plan.

UNOS staff asked members if this proposal could produce any cost savings. An attendee commented that they do not anticipate any cost saving but do think it will improve efficiency and more clarity.

A member representing histocompatibility labs did not feel this proposal would impact labs in a major way.

2. Review Deceased Donor Registration Form

A member gave an overview of the proposed policy *Review Deceased Donor Registration (DDR) Form*.

Summary of discussion:

A member shared that the OPO Committee is reviewing the current DDR and reformatting to better align with data collection. A representative of the OPO Committee added that the project overall is to restructure the form to realign with headers, considered questions for elimination, and create more consistency of what is collected across organ types. UNOS staff commented that overall there may be 25-30 modifications including the deletion of some data elements such as "tattoos." No data elements are being added.

A member commented that completing the DDR takes a significant amount of time and the intent is that these modifications will decrease the amount of time needed. UNOS staff agreed that the time required may be lessened and that the help documentation is also being modified to improve its usefulness.

UNOS staff shared that this will be the only update to the DDR in the foreseeable future.

UNOS staff asked if there could be any potential issues with how the data will flow from the TransNet (UNOS) system to local hospital networks or software programs. Another UNOS staff responded that there will be continual discussion and improvements made in how OPO electronic medical records (EMRs) interact with DonorNet® and Transplant Information Electronic Data Interchange (TIEDI) forms.

UNOS staff asked members representing transplant programs and histocompatibility labs for comments. No comments were made.

3. Required Reporting on HLA Typing Changes

A member provided an overview of the *Required Reporting on HLA Typing Changes* project and requested input about the anticipated fiscal impact to histocompatibility labs.

Summary of discussion

This project furthers the work of an existing project sponsored by the Histocompatibility Committee to better correct human leukocyte antigen (HLA) typing errors. As background, in DonorNet®, dual entry of the same HLA data is required in an effort to reduce transcription errors. Due to the recentness of this new requirement, there is not enough data to prove this has been effective. Now with wider organ sharing, this proposal will address how to best document and share when HLA typing errors occur with OPOs and transplant programs that may have accepted or received these organs beyond their local OPO. This proposal requires more statistic sharing of these values that there were mistypes or changed in the HLA typing of a donor in UNet℠.

Under the proposal, critical discrepancies require notification. In these cases, a phone call from the histocompatibility lab or OPO would be most effective. This proposal is important in preventing patient safety issues associated with HLA mismatches.

The presenting member asked the Histocompatibility Committee Vice Chair at what point in the process, if this error occurs, should the match run be rerun. They also asked about an implementation timeline. The Histocompatibility Committee Vice Chair shared that the goal is to implement an automatic notification system. If a value is updated, an electronic notification would go out to any program accepting the organ so they can evaluate. There may be similar types of notifications being added for other projects by UNOS IT so this may be implemented alongside of these other initiatives. A hierarchy is being developed to determine what is considered a critical discrepancy. When critical discrepancies are identified, it will need to be assessed if any of the offers accepted are no longer compatible. Secondly, if will need to be assessed if the discrepancy requires the need to reestablish the match run to ensure appropriate candidates receive an offer and were not erroneously excluded based on the incorrect data.

The member commented that the impact to labs is minimal. In current practices, similar expenses would be incurred when there are errors.

UNOS staff commented that this project has been discussed with UNOS IT. There is already a notification system for discrepant typing and this would be fairly easy to automate within UNet^{SM}. There is a concern from the project's sponsoring workgroup that if there are instances in which many programs that have submitted a provisional yes, many phone calls may need to be made by the OPO. Automating the alerts is intended to alleviate this burden.

A member representing OPOs commented that programming notifications and list of critical discrepancies would be helpful operationally. Rerunning the match and contacting those with provisional yeses would increase workload. They asked who would be tasked with submitting a report that a discrepancy occurred. UNOS staff commented there is an automated report that track discrepant typings. A separate form is unlikely to be required.

A member questioned if those that denied the organ would be notified of the error. A member commented that it would depend on the where the organ was in the allocation process.

In 2019, there were 48 critical errors out of over 19,000 donor typing entries. 22 occurred pre-transplant. There is no current policy requirement to notify when HLA typing changes occur.

The Histocompatibility Committee Vice Chair commented that there are differences in whether the OPO or HLA lab is tasked with entering the data into DonorNet®. How errors are rectified should be considered when establishing an agreement between the OPO and lab.

A member commented that there would be a burden but the frequency is low and is likely to become lower due to the need for entering the data twice and therefore reducing errors.

The Histocompatibility Committee Vice Chair doesn't see this as a burden but as a necessity to ensure the donor HLA typing is correct. A member agreed.

UNOS staff commented that there could be cost savings since this will improve patient safety. The Histocompatibility Committee Vice Chair agreed and commented that the move to continuous distribution will further increase the importance in the accuracy of the data.

A member asked how the errors are being determined to be critical or not. The Histocompatibility Committee Vice Chair commented that the sponsoring Committee is still assessing this and are considering a tiered level of criticality.

UNOS staff asked the members to comment on the fiscal impact of this proposal. The members agreed that this would be consistent with existing practices and have a minimal impact to labs and OPOs. Although the occurrences are low, there is a chance that this policy change may increase staff time.

4. Membership Requirements Revisions

The members discussed the fiscal impact of the *Membership Requirements Revisions* proposal.

Summary of discussion

This proposal was evaluated by the members during the last public comment cycle. This proposal did not go out and changes were made requiring the need for more evaluation.

A member representing transplant hospitals commented that once the proposed policy changes are implemented, the ongoing costs and time required will be minimal. The cost will likely come from implementation and work involved in changing policies to make consistent with what is being proposed.

A member commented that they do not have enough information to comment on anticipated costs.

UNOS staff asked the OPTN Membership and Professional Standards Committee (MPSC) representatives to provide more detail about the proposal. The UNOS MPSC representative commented that this proposal should have the same fiscal impact assessment for OPO and labs as last cycle since these sections of the proposal have not undergone significant change.

UNOS staff commented that there are new revisions are to Appendix D which outlines the general requirements for transplant programs. These changes are intended to streamline and clarify the requirements for approving transplant programs. This appendix is organized into three sections: Final Rule requirements, OPTN requirements, and quality and performance requirements. There were numerous updates to provide more clarity and update to current practices. Language was removed that did not support contract tasks.

MPSC is recommending the removal of the requirement for a transplant program director. The bylaws place the responsibilities of leading a program on the primary surgeon or physician. Centers for Medicare & Medicaid Services (CMS) will still require a program director. There are more requirements around when programs would need to inactivate based on personnel. Other changes regarding key personnel requirements include requiring the names of the primary program administrator and primary program data coordinator and requiring a clinical transplant pharmacist position. This is intended to be consistent with current practices.

Routine membership requirement compliance review will occur on the same schedule as site surveys.

A member commented that they do not feel that they have enough information to comment on the fiscal impact on transplant centers.

A representative of the MPSC Committee commented that every change included in the proposal was made from the member point of view with the overarching goal to simplify the language and align requirements with practice.

Next steps:

UNOS staff will send an email with more detail about this proposal. The identified leads will be asked to complete the fiscal impact survey to in order to provide feedback.

Upcoming Meetings

- October 27, 2020

Attendance

- **Committee Members**
  - Andrea Tietjen
  - Carley Shaut
  - Debbi McRann
  - Gwen McNatt
  - Jerome Saltarrelli
  - Julie Bergin
  - Laura Stillion
  - Robert Goodman
- **HRSA Representatives**
  - Vanessa Arriola
- **UNOS Staff**
  - Courtney Jett
  - Emily Ward
  - Peter Sokol
  - Robert Hunter
  - Sarah Konigsburg
  - Sharon Shepherd
  - Susan Tlusty
- **Other Attendees**
  - Clifford Miles
  - Diane Brockmeier
  - John Lunz
  - Kurt Shutterly