

**OPTN/UNOS Data Advisory Committee
Meeting Minutes
February 25, 2019
Conference Call**

**Sandy Feng, MD, PhD, Chair
Rachel Patzer, MPH, PhD, Vice Chair**

Introduction

The Data Advisory Committee (DAC) met via Citrix GoTo teleconference on 02/25/2019 to discuss the following agenda items:

1. Modify Data Submission Policies

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

1. Modify Data Submission Policies

UNOS staff reviewed the actions discussed at the February 11, 2019 call and updated the Committee members about the OPTN Operations and Safety Committee's efforts to address the term "recovery date," and similar terminology. As part of a project involving labeling of extra vessels, the OPTN Operations and Safety Committee had become aware of the same inconsistent use of similar terminology throughout policy. The OPTN Operations and Safety Committee performed background research, contacted other committees, and determined that a more appropriate definition for "recovery date" would be the "cross-clamp date". In addition, the OPTN Operations and Safety Committee had begun discussing what would be equivalent terms for addressing living donors and Vascularized Composite Allograft (VCA) donors. However, before the OPTN Operations and Safety Committee could complete its work, the Committee was required to reprioritize its efforts on another project. As a result, the matter of addressing "recovery date" was transferred to the DAC. UNOS staff stated that that this issue would be brought back before the DAC at a later meeting.

UNOS staff also stated that they had met with policy analysts from the following committees: Organ Procurement Organization (OPO), Living Donor (LD), Histocompatibility (Histo), and VCA. The purpose of the meeting was to inform the other analysts about DAC's Data Submission project, and to get the analysts' feedback on potential equivalent terms for Recovery Date as it applies to living donors and VCA. UNOS staff discussed the possibility of providing status updates at the next in-person meetings:

- Histo (March 26th),
- Living Donor (April 1st), and
- OPO (April 16th).

Next, the Committee returned to two policy clarifications that had been brought before them previously. First, the Committee considered removing the term "recipient feedback" and replacing it with the term "waiting list removal for transplant." UNOS staff pointed to Policy 3.9: *Removing Candidates from the Waiting List* and Policy 3.5: *Patient Notification* as addressing the removal of candidates from the waiting list and the requirements around those actions. With such information, the Committee agreed that the requirement in Policy 18.1: *Data Submission Requirements* could be removed.

The second clarification the Committee considered involved clarifying that the Donor Histocompatibility (DHS) information is required for both deceased and living donors. The

Committee replied that the suggested revisions made the requirement clearer. However, they also wanted to discuss why the listed organs did not include VCA, and should VCA now be included? For example, what is the purpose of identifying all of the organs, when in fact they want the information for any donor? UNOS staff replied that it is likely that VCA has different requirements, but that would need to be researched more. The Chair suggested that there are two tiers of VCA-related questions:

1. Is there something about VCA that requires something different and special, and
2. Is there a need to be specifying each the organs?

The Committee indicated that as long as there is a consistent definition of “donor” in policy, then the language under “within” could state “any deceased or living donor.” The Committee members suggested that a solution might be to eliminate the language identifying the individual organs under “for” and replace it with “living and deceased donor” or “each donor (living and deceased).” The next step would be to find out from the VCA Committee what issues, if any, may be specific to VCA that would need to be included. The Chair stated that if the Committee can eliminate all the specificity, then the result will leave the policy language more flexible and durable.

Next, UNOS staff discussed the Data Submission Timeframes by displaying a graphic of the “Forms Submitted by Expected Date and Within 90 Days of Expected Date” for the second, third, and fourth quarters of 2018. The graphic shows the percentage of forms submitted by (a) the due date and (b) within 90 days of the due date.

The Committee discussed reasons why transplant programs and histocompatibility labs may not be meeting the initial deadlines. For example, this could be the result of members being confused about the primacy of the submission timeframes in Policy 18.: *Data Submission Requirements* versus those in Policy 18.4: *Data Submission Standard*. UNOS staff replied that there have been multiple occasions where staff have had to inform members that they must meet the reporting requirements in Policy 18: *Data Submission Requirements*.

In addition, there are some OPTN members who believe that the only requirements that need to be met are those outlined under Policy 18.4: *Data Submission Standard*. A Committee member stated that CMS’s data submission requirements dovetailed off of the data submission standard. UNOS staff added that the reason for the high percentage of submissions at 90 days following the deadline is because of the CMS requirement. A Committee member stated that they had never heard of a transplant program getting a condition level deficiency from CMS for data submission. The Committee member added that their belief is that the transplant programs work to the CMS requirement and then to the OPTN requirement. From this discussion, UNOS staff agreed to contact the Histo policy analyst to find out what, if any, regulatory requirements the labs must meet regarding data submission.

The DAC also discussed how best to keep the other OPTN Committees and members informed about the Data Submission project and the issues being discussed. For example, was it better to continue moving forward and providing status updates to the other committees following any decisions, or was it more appropriate to take the time to identify appropriate individuals from the other committees and ask them to participate in the Committee’s deliberations. The Committee Chair asked members to consider (1) how controversial and disruptive the changes are that the Committee is considering, and (2) whether there is someone already on the Committee who represents the interests of the other committees. If a change has the potential to be impactful, then the Committee should obtain input from the impacted parties earlier in the process. However, given the compressed timeframe of this project, the Committee can share minor

revisions afterwards with the impacted parties. Overall, the Committee members agreed with this approach.

Next, a Committee member stated that it appears the deletion of Policy 18.4: *Data Submission Standard* needs to be communicated to the public. As a result, there will need to be a great deal of education around that change, including the rationale detailing how the Committee came to that decision. A Committee member questioned whether the DAC's decisions are solely advisory or if another Committee would have to agree that to remove this policy. The Chair stated that the DAC does not have to present this as a final decision. Furthermore, any policy changes would have to go through public comment and approved by the OPTN Board before implementation. UNOS staff agreed to follow-up with other OPTN Committees' analysts to determine if this issue has ever come up before their committees.

The Committee members also had questions about some of the terminology used in Policy 18. For example, the Chair asked if the word "feedback" is necessary as it appears in Policy 18.1 regarding the Deceased Donor Registration form, "30 days after the organ disposition (*feedback*) form is submitted and disposition is reported for all organs." (Emphasis added.) At question is whether words like this are referring to actual things or just use words to describe things. A question for the Committee to consider is how closely does it want to tie policy to the labels in the electronic systems versus describing the information being requested? In the case of the Deceased Donor Form, a Committee member representing an OPO stated that when viewing the form it appears in the system as "Donor Organ Disposition (Feedback)."

Next Steps

UNOS staff agreed to contact the other committees' policy analysts and inform them of the potential the Committee may want to eliminate Policy 18.4. Furthermore, UNOS staff will contact the Histo policy analyst about what, if any, regulatory data submission requirements the labs have. Also, staff will contact the VCA policy analyst about why VCA is often listed separately in Policy 18. Lastly, staff will provide Committee members the policy definitions of deceased donor, and living donor.

Upcoming Meetings

- March 11, 2019
- April 11, 2019 (in-person meeting)