

**OPTN/UNOS Data Advisory Committee
Meeting Minutes
January 28, 2019
Conference Call**

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

Introduction

The Data Advisory Committee (DAC) met via Citrix GoTo on 01/28/2019 to discuss the following agenda items:

1. OPTN Policy 18: *Data Submission Requirements*
2. Discuss Potential Committee Meeting Dates

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

1. OPTN Policy 18: *Data Submission Requirements*

In early 2016, the OPTN and SRTR identified problems related to data submissions. From these problems, the Policy Oversight Committee (POC) approved moving forward in March 2016, but the Executive Committee (ExComm) decided to wait. In February 2018, the POC and ExComm both approved this project. Now, the Committee is focusing on modifying OPTN Policy 18: *Data Submission Requirements*, including policy verbiage, and timeliness of data submission.

Summary of discussion:

UNOS staff began discussion by outlining the three main problems that this project will address:

1. Inconsistent data submission timeliness may lead to confusion and suggested deadlines are unimportant
2. Vague data definitions and subjectivity of data values may impact data reliability
3. Lack of limits addressing when data values can be changed reduces data integrity

UNOS staff then outlined the proposed project timeline and next steps:

- January 2019: Timeliness and editorial revisions
- February 11 & February 25 2019: Data submission timeliness
- March 11 & March 25, 2019: Establishing criteria under which data changes may be made
- April 2019: In-person meeting and full committee vote on revised policy language
- July 2019: Submit to POC and ExComm
- August to October 2019: Public comment
- December 2019: Submit to Board of Directors

The Chair clarified that there were two main issues: the timeliness for data submission and data locking. However, due to time constraints, the Chair wanted to know whether both of these issues must be addressed prior to submission to the POC. UNOS staff clarified that the POC originally approved this project with both components involved; however, the Committee may possibly be able to scale back on one component if they need to. However, UNOS staff emphasized that these discussions surrounding a possible project "scale back" would be addressed in subsequent calls with Committee leadership.

UNOS staff then continued discussion by showing OPTN Policy 18.1: *Data Submission Requirements*, 18.2: *Timely Collection of Data*, and Policy 18.4: *Data Submission Standard*.

UNOS staff highlighted the inconsistencies in “time”, such as “within 30 days” and “60 days before”. Specifically, in Policy 18.4: *Data Submission Standard*, the Committee discussed whether to keep this table in OPTN policy, or to have it removed. UNOS staff clarified that submitting only 95% of data within the first three months conflicts with specific due dates in Policy 18.1: *Data Submission Requirements* (which require members to submit 100% of information by the mandated timeframes). Having these different requirements for data submission can lead to confusion and possibly unintended consequences.

One Committee member expressed doubt that Policy 18.1 expressly infers that 100% of forms must be submitted within the specified timeframes (e.g. 30 days after). However, the member also stated that the main problem with members only submitting 95% of their forms had to do specifically with the transplant recipient follow-up forms (TRFs). For example, only recently in TIEDI did it allow members to report a patient as “not seen” versus “lost to follow-up”. Therefore, this member opined that giving members more time to follow-up with patients would allow for more accuracy and reliability in the data. Furthermore, some members stated that it is already difficult for transplant centers to submit 95% of their forms within the timeframe specified. As such, most members might work towards meeting the requirements outlined in Policy 18.1 versus the timeframes listed under Policy 18.4. Other members agreed that there were no unintended consequences, except that transplant centers would have less time to submit 100% of their forms. Furthermore, many members agreed that having Policy 18.4. separate from Policy 18.1 and 18.2 was not logical. From a practical standpoint, other members questioned what actual difference there was between submitting 100% of forms versus submitting 95% of forms. In conclusion, the Committee members unanimously agreed to remove Policy 18.4: *Data Submission Standard* from OPTN policy.

One member asked what other deadlines there were in Policy 18. UNOS staff again showed Policy 18.2: *Timely Collection of Data*, and noted that there are deadlines that include “42 days” “60 days”, “1 year” and “2 year”. UNOS staff also clarified that the due dates or timeframes that appear in Policy 18.1 and Policy 18.2 are the TIEDI due dates. In effect, members are to submit the forms within TIEDI by the deadlines listed under these policies.

Other Committee members asked whether clarification language on the percent of forms to be submitted can be added to Policy 18.1 and/or whether the Committee could change any of the deadlines currently in this policy. Though the Committee can do this under this project, for the purposes of this Committee meeting, the Committee agreed to focus mainly on Policy 18.4 and other proposed changes. UNOS staff proposed that Policy 18.1 will be addressed in the next upcoming Committee meetings.

Another Committee member suggested that the Committee address each form in a chronological order. In doing this, it may help the Committee identify any important factors or potential impacts when changing policy. UNOS staff had originally anticipated going through Policy 18 from the beginning, but Committee members agreed that the project should focus on forms using a chronological format. Furthermore, Committee members agreed to reach out to other OPTN Committees (e.g. the Histocompatibility Committee) should they want to modify any relevant Committee-specific policies.

UNOS staff continued discussion by asking whether the Committee members wanted to do the following in Policy 18.1: *Data Submission Requirements*:

- Delete “all” following “OPOs” because of redundancy (Death notification records, and in Monthly Donation Data Report: Reported Deaths)?
- Replace “records” with “registration” for “Death notification records (DNR)”?

One member suggested that along with removing “all”, that the word “OPOs” be singularized to “OPO”. Other members agreed, because throughout Policy 18.1, OPO is used in its singular vernacular, and not pluralized. Furthermore, Committee members did not understand why the word “all” was included in the policy language.

Another issue the Committee focused on was the use of plurality or singularity throughout Policy 18.1. One member noted that the header states “the member” and not “the members”. Another point was that in the third column of Table 18-1: Data Submission Requirements, the noun is singular, and not plural. For example, the third column states “hospital”, not “hospitals”. Furthermore, by creating the language under Policy 18.1 singular would align with the language currently under 18.2, which is not pluralized. In conclusion, the Committee unanimously agreed to delete the word “all” following “OPO”, to replace “records” with “registration” for “Death notification records” and to singularize nouns under Policy 18.1.

UNOS staff ended discussion by highlighting the scope of the project, including addressing the “data lock” and “timeliness” of data submission. One member expressed concern that “timely data” and “submission data deadline” are different concepts. As such, both of these issues should be addressed prior to working on a potential data lock. Furthermore, a data lock might vary between the different forms, and may not be generalized for all forms. Other Committee members agreed with this sentiment, and asked that for discussion purposes the tables in 18.1 and 18.2 should be color coded. For example, a color coded visual may help the Committee see which areas of Policy 18 require data to be submitted by a certain timeframe (e.g. the color blue might highlight areas of policy requiring data submission within 30 days). In this way, the Committee might better see how each individual deadline fits into the “whole” policy. The Committee members were in general agreement that this color-coded visual will be helpful in analyzing the different data submission deadlines.

Next steps:

UNOS staff agreed to work on creating a visual highlighting the various deadlines and sharing it with the Committee members in the upcoming weeks. Furthermore, UNOS staff will distribute an updated project plan to the Committee so that members can anticipate what will be discussed for upcoming meetings.

2. Discuss Potential Committee Meeting Dates

Summary of discussion:

UNOS staff informed the Committee members that meetings will be held the 2nd and 4th Monday from 3-4pm. The Committee Chair acknowledged that while not all members would be able to make the calls, decisions can still be made by the members that are able to attend.

Furthermore, having multiple Committee calls a month will allow everyone who is able to make the calls to fully participate, and will increase both efficiency and timeliness of the project.

Furthermore, UNOS staff expressed that hopefully the DAC may only have one call a month later in the year, so long as sufficient progress on the project has been made. The Chair of the Committee agreed with this sentiment, adding that if the project is ahead of schedule, then the DAC may look at scaling back the number of Committee meetings that are held each month.

There were no arguments against having more frequent Committee meetings.

Upcoming Meeting

- February 11, 2019