OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Data Advisory Committee
Meeting Minutes
May 1, 2019
Richmond, Virginia

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Introduction

The DAC Committee met in Richmond, VA on 05/01/2019 to discuss the following agenda items:

1. The OPTN Data Advisory Committee under the new OPTN Contract
2. Overview of the Public Comment Process
3. Modify Data Submission Policy

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

1. The OPTN Data Advisory Committee under the new OPTN Contract

UNOS staff provided further detail on DAC's work under the new OPTN contract. Three examples illustrating the new tasks the DAC will be expected to undertake were outlined.

Summary of discussion:

UNOS staff clarified that the DAC can proceed under the new OPTN contract by providing recommendations to the Board of Directors (BOD), but that the DAC will need to determine how the BOD prioritizes proposed changes. UNOS staff went on to explain the new Office of Management and Budget (OMB) approval process.

A Committee member asked whether removing variables requires OMB approval under the new OPTN contract. HRSA staff replied that there is not a definitive answer to this, but that HRSA staff will look further into this. SRTR staff also stated that there may be some flexibility for changing the forms (e.g. smaller changes may not require OMB approval, such as clarifications). However, all participants agreed that a major concern in this process is about creating unnecessary data reporting burdens on the OPTN community.

One suggestion was to allow smaller changes be submitted in the form of "change memos" to the OMB. UNOS staff also clarified that they are currently working on a deliverable to determine the process for submitting changes to the OMB, including how to integrate these processes into the policy development process.

Next, UNOS staff presented examples of project-based and on-going work the DAC would be involved in. The first exemplified how DAC could collaborate with policy-making committees to review existing data elements. The OPTN Organ Procurement (OPO) Committee is working on a project entailing a comprehensive review of the information collected on the deceased donor registration (DDR) form. As part of this effort, the OPO Committee has requested input from the DAC. The DAC, with the OPO Committee, would utilize this opportunity to develop a standardized process and tools to review existing data elements.

UNOS staff presented another example of a project in which the DAC could engage with policy-making committees to recommend new data collection, another task they will be responsible for under the new contract. The OPTN Vascularized Composite Allograft (VCA) Committee seeks to modify existing VCA Transplant Recipient Registrations (TRR) and Transplant Recipient Follow-up (TRF) forms to capture additional transplant outcome data for abdominal wall, head

and neck, and upper limb transplant recipients. In addition, the project scope includes creating new TRR and TRF forms to capture transplant outcomes for uterus transplants, as well as a template for data collection for VCA types not captured in the above forms. The DAC could partner with the VCA Committee on this project, using the existing Data Collection Standard Checklist, and updating it as needed. For example, whether there anything missing or what could be enhanced via early partnership in the policy-development process.

Another Committee member questioned SRTR's level of involvement in DAC's new work under the new OPTN contract. For example, a member opined that SRTR may have insight on missing data elements and therefore should have a voice in this process. SRTR staff supported a collaborative approach, such as using monthly calls between them and UNOS staff to assess how data is collected and what data is relevant.

UNOS staff suggested having the Vice chair or Chair of other OPTN Committees participate during DAC meetings. From there, the Vice Chair or Chair can give an update on the DAC's work to their respective Committees. Another suggestion by DAC members was to formulate a communication plan to the other OPTN Committees. This communication plan may assist in bringing more awareness to the work the DAC is doing and the need to have other Committee input. In general, DAC members supported adopting a proactive approach to informing other OPTN Committees about the DAC's new work.

Another example of a project that would entail reviewing existing data collection is analyzing refusal codes. A few Committee members stated that the DAC will need to look at the donor, recipient and matching issues because there are inconsistencies with how data is viewed for each candidate. One Committee member suggested rephrasing the second refusal code on the list, because this code may be too broad and not specific enough for data analysis. UNOS staff agreed the DAC could assess the refusal codes listed in order to gain better specificity and reliability.

SRTR staff suggested that a focus group be formed in order to better assess the reasons why organs are turned down. Other DAC member supported this idea, citing differences in clinical behavior as a possible reasons why there are inconsistencies. For example, clinicians may subconsciously look to a candidate further down on the Waitlist if the organ being offered is not the best. Other Committee members agreed, and suggested that the DAC engages with other OPTN organ specific committees to think through these issues, and to collect feedback.

2. Overview of the Public Comment Process

UNOS staff reviewed the public comment process (from Policy Oversight Committee/ Executive Committee approval to Board Consideration) and outlined options to obtain further feedback during that timeframe.

Summary of discussion:

UNOS staff presented information regarding the public comment process. There were no questions or discussion from Committee members.

3. Modify Data Submission Policy

The Committee discussed and finalized the decisions surrounding data locking. Further presentations involved sharing and discussing draft policy language for OPTN Policies 18.1: *Data Submission Requirements* and Policy 18.4.: *Data Submission Standard*.

Summary of discussion:

To begin the discussion, Committee members voiced concern about the terminology being used in this project. For example, one Committee member expressed a need for OPTN policy to be

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clear that within 90 days means "expected date plus 90 days (add onto the initial date)". A suggestion was made to call any new dates as the "time after the event". Another suggestion was to consistently use the same naming conventions during conversations and discussion. For example, Committee members and UNOS staff should clearly say "locking of data". There was also strong opposition from Committee members when using the word "validation" because this terms assumes that OPTN members are looking at their data again. Committee members agreed to use the term "submission" because this word does not imply any assumptions and that "submission" equates to "locking". Furthermore, Committee members agreed that they did not want to use the word "enter" when describing data, because this could lead to more confusion.

Another aspect that Committee members agreed on was the need to provide early feedback to transplant hospitals. Currently, there are variances between how transplant hospitals validate their data, and the lack of information prior to validating the data. Due to these variances, the DAC needs to further clarify the timeframes for submitting and validating data.

SRTR staff clarified that from their perspective, the OPTN only needs one timeframe date. In this way, it is up to the transplant hospital to decide when to validate or submit their data by the stipulated timeframe. Furthermore, there are operational rules that allow the OPTN to hold all programs accountable for finalizing and submitting accurate data. UNOS staff expressed a need to align policy language with any programming changes in order to be consistent across multiple OPTN systems.

Process for Locking Data

Next, Committee members discussed how the OPTN should validate and lock data. One Committee member suggested setting up warning boxes prior to submission stating "once you submit this data, then it will be locked". However, other Committee members did not believe that submission naturally infers data locking. Committee members continued to discuss the safety checks performed prior to a member submitting data. UNOS staff clarified that the current system does check data values entered (e.g. maximum and minimum values), but that this is a form-by-form. Another operational check the OPTN performs is to alert members as to how many of their forms are due, and how many need to be completed. Furthermore, UNOS staff clarified that members have the ability to save forms without submitting them. Committee members agreed that to save data means to "check or validate" the data.

The majority of Committee members agreed that the OPTN must provide data quality checks for members. Their reasoning was that programs may be more receptive to the implementation of a data lock if they are provided the necessary tools and resources to meet the new deadlines. SRTR staff opined that though they supported having data quality checks, these checks should be provided post- data submission in order to allow more time for the OPTN to provided valuable feedback. Furthermore, members may have more time to make changes to the data post-submission. However, Committee members did not support this idea, because it may limit the time members are allowed to make changes, and because there are variances in the number of forms due on a particular day (e.g. five forms due one day, while ten forms due another day).

Another suggestion from a DAC member was to only allow changes to values found to be different by the OPTN. Some Committee members were against this idea, because there are too many values for the OPTN to evaluate on a singular basis. Other members supported providing feedback only on specific values per form, and providing performance feedback. This performance feedback might come in the form of data reports (e.g. 3 months, 6 months etc.) and might compare members against each other. UNOS staff clarified that they do provide data

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validation reports for all OPOs and transplant hospitals, but that the data reported is only for data fields marked "unknown", "not done" or "missing". DAC members suggested expanding on these data reports to also include real-time feedback, quality outcomes and monthly assessments.

Next, Committee members discussed the types of data tools or resources the OPTN could develop for members. Committee members agreed that this question should be asked during the public comment cycle for this proposal. The DAC members also agreed to ask for what reasons data may need to be changed post-submission during public comment. By asking these questions during public comment, the DAC hopes to communicate with small and medium sized programs earlier, in order to develop relevant and precise data tools.

During the discussion, Committee members debated a one-step versus two-step process for data submission and locking. UNOS staff stated that the purpose of the two-step process is to allow members to receive feedback from the OPTN. Though Committee members agreed that this should be done, they still strongly felt that data tools need to be available for member prior to data submission. These tools will allow the OPTN to gather the best quality data, whilst allowing members to improve their practices moving forward. UNOS staff suggested that the DAC create a list of robust data tools that may be helpful for members, such as a warning that alerts centers as to the amount of data missing on a form.

In conclusion, the Committee members agreed to the following:

1. There is one deadline for data submission whereby members will enter data, save/validate the data, perform quality checks on data, and then submit the data to the OPTN.
2. Submitting the data equates to locking the data.
3. The OPTN will provide tools to perform quality checks before submitting data (both prior to saving and when saving data)
4. A transition period will be developed for members implementing these new processes and using the data tools

Deceased Donor Registration (DDR)

Committee members began the discussion by looking at the data analysis done by UNOS staff regarding the timeliness and changing of data for the DDR. One DAC member stated that there is a decreasing amount of change as time increases. Furthermore, since lengthening the timeline to allow for data changes will not affect SRTR data integrity, many members supported setting a lock date that changes member's current behavior. As such, some Committee members agreed, and supported that the DAC place a threshold of either 60 days or 90 days per the data analysis. Furthermore, allowing members to have a monthly report will give them time to view and change any data prior to submission.

On the other hand, some Committee members argued that OPOs may need at least two weeks to process any new lab cultures (such as tuberculosis). These Committee members asked that members from the OPTN Disease Transmission Advisory Committee (DTAC) be asked on whether a 60 day time window is enough. During the meeting, one member reached out to a representative from DTAC, whom stated that in Switzerland, it may take up to 4-6 weeks for lab results. Therefore, the DAC decided that at least 60 days will be needed for this data submission.

Another Committee member questioned whether shortening the timeframe by 30 days is too restrictive and premature. Other Committee members voiced this concern as well, but also thought that the rate limiting data on the form should be the factor that determines the deadline.

Another topic of discussion was about the real time data collection by the OPTN. UNOS staff clarified for the Committee that all information posted on the OPTN site comes from multiple sources (TEIDI, Waitlist etc.) and is available prior to data being locked. Furthermore, because the information is subject to change, STAR files are provided to researchers with a 2 month lag. There was concern from one Committee member that extending the timeframe submission deadlines will have negative consequences for researchers, because the lag time for STAR files will increase. This could potentially be a barrier for researchers, and there may be push-back on these new timeframes during public comment. However, most of the Committee agreed that allowing members to make changes whenever they want decreases the reliability of the data and is not on par with the data locking that occurs in healthcare (such as ensuring the data is locked for clinical trials).

Next, UNOS staff clarified that the OPTN OPO Committee had been asked about the current deadlines in policy. The feedback generated from this discussion revolved around OPOs not having enough staff to perform quality checks within 30 days, and therefore having a high volume of data being submitted inaccurately. Due to this concern, Committee members agreed that no data lock should be set less than 30 days for OPOs.

In conclusion, the Committee agreed to the following:

1. In order to maintain consistency, there should only be one deadline to save, validate and submit the forms (e.g. 60 days, 90 days, etc.)
2. OPOs will have 60 days from the event to submit their forms
3. Histocompatibility labs will have 60 days from the event to submit their forms
4. Transplant centers will have 90 days from the event to submit their forms
5. During public comment, the DAC should ask the community whether they think the deadlines are wrong and why. Another question that should be asked is which data elements would not be possible for members to complete accurately by the deadline and why.

Donor Histocompatibility (DHS)

When analyzing the data, one Committee member opined that most of the data is available at the time of submission. Furthermore, there should not be much delay in submitting the data, because there is not a lot of information generated post-transplant. SRTR staff agreed with the Committee member, though also stated that a few Histocompatibility members voiced minor concerns. Due to these minor concerns, the DAC members agreed to ask histocompatibility labs whether the proposed deadline is unattainable and why during the next public comment cycle.

In conclusion, the Committee agreed to the following:

1. Histocompatibility labs will have 60 days from the event to submit the DHS form

Recipient Histocompatibility (RHS)

During the discussion, UNOS staff clarified that the RHS form is from the recipient HLA lab, not the OPO lab. Furthermore, the RHS form is supposed to be completed at the time of transplant. One concern brought up by a Committee member was how data may need to change post-submission. For example, there may be some HLA labs that recheck lab values. Despite this concern, in general Committee members agreed to the following:

1. Histocompatibility labs will have 60 days from the event to submit the RHS form

Living Donor Registration (LDR), Transplant Candidate Registration (TCR), and Transplant Recipient Registration (TRR)

When discussing the LDR, TCR and TRR forms, Committee members generally agreed that all three needed to be discussed together in order to maintain consistency. For the LDR, UNOS staff clarified that there is more data generated post-transplantation, and is why the original deadline was 60 days.

For the TCR, the data analysis presented showed many centers submitting data past 120 days after the event. UNOS staff stated that a reason this may be occurring is because some transplant centers think that they need to routinely update data for their candidate while on the Waitlist.

As for the TRR, UNOS staff stated that data submitted on this form can be modified for the PSRs. Most Committee members agreed that the OPTN needs to know the status of the candidate at the time of transplant. Furthermore, the data on the TRR can help a patient look at the chances of them having a transplant within a specific timeframe at a specific center. One Committee member was concerned that cognitive/neurological assessments may take weeks to perform and enter data on the TCR and TRR. Though this concern was relevant, the DAC agreed to tackle this issue at a future date while reviewing all OMB forms.

In terms of establishing a new timeline, some Committee members advocated for extending each deadline by 30 days. However, this would still result in inconstant deadlines between the three forms. Furthermore, the Committee members agreed to not change the date of event to date of discharge because candidates are discharged at different dates. Looking at the data analysis, one Committee member opined that there is little difference between the various bar chart colors displaying timeframes. Therefore, this Committee member supported setting 60 days as a standard timeframe for all these forms. Other Committee members supported 90 days as a standard timeframe because living donors may not have the necessary follow-up information within 60 days. Also, 90 days would provide consistency, extend the research lag by only 1 month, and would provide better data quality.

Therefore, the DAC agreed to the following:

1. The LDR, TRR and TCR forms will all be due within 90 days following the event

Transplant Recipient Follow-up (TRF) & Living Donor Follow-up (LDF)

UNOS staff began the discussion by explaining that the each form requires a transplant center to report 2 months of data on a 6 month form, and that this data needs to be information that you have at the time of submission. Many Committee members voiced concerns that data is being submitted outside of appropriate time intervals (e.g. data at 3 months is being submitted on a 6 month form). Therefore, Committee members agreed that there needs to be a tighter time interval on the 6 month form. A proposal was to have this interval be set at 5-9 months for the 6 month form (example: if a transplant occurred on January 1st, then data for the 6 month form could be allowed to be entered during the months of June through September). Furthermore, in order to distinguish between multiple data values, the DAC recommends that "most recent data value" be specified.

Another issue that the Committee was concerned about was the lack of reference to the TRF form in Policy 18.2, which may be a gap in OPTN policy. However, UNOS staff cautioned that addressing this issue may be out of scope for the current project, and that the DAC needs to address what has already been identified prior to pursuing other issues.

In the end, the Committee members agreed to the following:

1. Include time interval guidelines within the Help Documentation for the 6 month form
2. Do not change the 14 day reporting requirements for graft failure or death
3. Both the TRF and LDF should be submitted within 90 days from the event

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Reasons to Lock Date

To begin the discussion, Committee members asked whether programs should be required to have a sign-off occur from upper management at this institution in order to make any changes to the data. A few Committee members supported this idea because it placed the burden on the users entering data. However, some Committee members argued these changes should not merely be due to minor clerical issues, but rather systematic and significant problems (e.g. a poorly trained user who enters wrong data across multiple forms because they do not understand the difference between antibody versus antigen). Another suggestion was to have programs contact the OPTN contractor for approval prior to any data changes. UNOS staff agreed this could be done, but that it must be explicitly stated in OPTN policy.

This led to a discussion about who would the programs be contacting at UNOS for data changes. UNOS staff opined that they should not be the ones making these judgement calls, because this might inadvertently cause centers to claim UNOS staff as being "biased" in their decision-making. Furthermore, in order for programs to contact the OPTN for data changes, policy needs to define "systematic" and "significant". Committee members opined that in order to reduce any bias, the DAC should be the committee that approves any data changes, or exceptions to the data policy. This process for changing any data post-submission would need to be explicitly laid out in OPTN policy (similar to heart or lung exception policy language). DAC members agreed that this language needs to be incorporated, but that the process needs to appear burdensome or difficult for programs (such as adopting policy language along the lines of "extenuating circumstances").

Another suggestion was to have the DAC report members to the MPSC for excessive and recurrent data changes. UNOS staff clarified that the purpose of the MPSC is to help programs improve their practices, not merely being punitive. In this way, the MPSC can identify ways to help programs improve over the long term, such as paring poor performing centers with higher performing centers or developing incentives to encourage compliance.

In conclusion, the DAC members agreed to the following:

1. DAC will set up a review body or subcommittee tasked with reviewing any requests for post-data submission changes
2. If DAC identifies a trend for a program requesting data changes, then the DAC will report the program to the MPSC for further review
3. Policy language must create a burden for programs to request any data changes (adopting language such as "extenuating circumstances or systematic errors")
4. Define in OPTN policy any new data definitions

Upcoming Meeting

- May 20, 2019