OPTN/UNOS Data Advisory Committee
Meeting Minutes
March 11, 2019
Conference Call

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Introduction

The Data Advisory Committee (DAC) met via Citrix GoTo teleconference on 03/11/2019 to discuss the following agenda items:

1. Public Comment Proposal Review: Clarifications on Reporting Maintenance Dialysis proposal
2. New OPTN contract data requirements and the OPTN Data Advisory Committee
3. Data Submission Timelines

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

1. Overview of Clarifications on Reporting Maintenance Dialysis proposal

The Living Donor Committee (LDC) presented an overview of the Committee's current public comment proposal "*Clarifications on Reporting Maintenance Dialysis*". In general, the DAC was supportive of the policy proposal, however agreed that the proposed language changes may need to be revisited in the future post-implementation.

Summary of discussion:

The Living Donor Committee (LDC) presented an overview on the "*Clarifications on Reporting Maintenance Dialysis*" proposal released for spring 2019 public comment. The following is a summary of the proposed policy language changes:

Source	Current	Proposed
Policy 1.2: *Definitions:* Native Organ Failure	"For living kidney donors, native organ failure is defined as registering on the waiting list for a kidney, or requiring dialysis."	Strike because this phrase is no longer used in policy.
3.6.B.i *Non-function of a Transplanted Kidney*	Immediate and permanent non-function of a transplanted kidney is defined as either: … • Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis …	No change because this is a different standard.
8.4.A *Waiting Time for Candidates Registered at Age 18 Years or Older*	If a kidney candidate is 18 years or older on the date the candidate is registered for a kidney, then the candidate's waiting time is based on the earliest of the following: … The date that the candidate began regularly administered dialysis as an ESRD patient…	No change. Will update other sections to mimic this standard.
9.7.B *Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older*	"That the candidate has begun regularly administered dialysis as an ESRD patient" … "That the candidate has been on dialysis at least once every 7 days."	No change. Will update other sections to mimic this standard.
Policy 18.5.A: *Reporting Requirements after Living Kidney Donation* *LDF*	"6. Maintenance dialysis."	"Regularly administered dialysis as an ESRD patient"
Policy 18.5.A: *Reporting Requirements after Living Kidney Donation* *LDF*	"5. Kidney complications"	No change because this is a different standard.
Policy 18.6: *Reporting of Living Donor Events*, Table 18-4: *Living Donor Event Reporting*	"begins dialysis"	"begins regularly administered dialysis as an ESRD patient."

A DAC member questioned whether the LDC had any data on whether the term “maintenance dialysis” had been previously misinterpreted for living donors. The LDC speaker did not have any reason to believe previous analyses contained both chronic and acute dialysis data points.

Another DAC member asked whether the definition of dialysis for candidate registrations is mapped and consistent across the OPTN. The LDC speaker clarified that they chose this language to specifically maintain consistency with kidney policy language. For example, the LDC referenced current kidney allocation policy to ensure that terminology was consistent. Following on this, the DAC inquired whether the LDC evaluated the inclusion of glomerular filtration rate (GFR) lab values on the LDF. The speaker clarified that though the LDC had assessed the possibility of including GFR lab values, as well as adding other fields, the LDC did not feel these modifications so critical that it would be worth necessitating submitting additional data fields to the Office of Management and Budget (OMB). Furthermore, the LDC did not want to increase the data reporting burden on transplant centers at this time.

The LDC speaker elaborated that the LDC had developed a list of policy items they felt should have been done under their proposal. For example, in relation to kidney complications and the data entry labeled “Other-specified”, the LDC had received feedback from other OPTN Committees that having discrete options would be better for standardization and consistency. The LDC considered this feedback and determined four categories that kidney complications fell into. However, the LDC chose not to add these additional data points due to the OMB process at the time. In response, the DAC Chair suggested that both the DAC and other OPTN Committees maintain a list of data items that should be revisited (e.g. specific suggestions for improving data collection forms). The LDC speaker agreed to this suggestion, commenting also that it would help to maintain a record and documentation of these suggestions.

2. New OPTN contract data requirements and the OPTN Data Advisory Committee

UNOS staff presented an overview and summary of future DAC work streams and project next steps.

Summary of discussion:

The DAC will be expected to work in three domains as an operating committee under the new OPTN contract: project-based work, ongoing work, and improved data collection. Below is a high-level summary of the expectations and responsibilities for the DAC beginning in April 2019:

- Project-based work
    - Data policies: Policy 18 project
        - New data collection: working with sponsoring committees on new data collection, or acquisition of external data
    - Data standards: sponsor projects to align to industry vocabularies (e.g. ICD)
- Ongoing work
    - Data definitions: quarterly review of clarifications
    - Data element review: identify data elements to add or drop
    - Data quality review: identify recommendations to improve accuracy, completeness
- Improved data collection
    - Annual recommendations for: data elements to add or drop, and actions to improve quality

These processes will need to be determined by the end of this year, including whether to release certain definitions or data elements out for public comment.

UNOS staff continued discussion by presenting a series of projects and their current statuses and next steps.

- Project-based work
    - Underway: Policy 18 data submission project. *Target:* fall public comment.
    - Not started: Modify process for data collection proposals to achieve earlier engagement and structured review with DAC. *Plan:* staff develop process, DAC provides feedback. *Target:* 7/31/2019
- Ongoing-work
    - Underway: process for quarterly review of definitions. *Target:* 3/25 for next review.
    - Not started: systematic review of data collection elements to identify data elements to add or drop, and recommendations to improve quality. *Plan:* confer with DAC leadership to develop approach and targets.
- Improved data collection
    - Not started: recommendations for data elements to add or drop, and actions to improve quality. *Plan:* confer with DAC leadership and HRSA on approach. *Target:* due 9/29/2019

Overall, members were supportive of the new processes presented. One challenge mentioned would be incorporating these new processes into the DAC's current workflow. However members felt that once this occurs, maintaining the new processes will be easier. Furthermore, the DAC needs to address any initial barriers, such as how to engage other OPTN Committees for content expertise. For example, there are data elements that are cross-functional amongst many Committees, and there are data elements that are solely organ-specific. Members discussed having the organ-specific Committees provide feedback on which data fields need to be reviewed. One member suggested each DAC member be assigned to an organ-specific Committee and assisting in identifying data elements. The DAC requested that UNOS leadership provide them with more strategic guidance on how to proceed.

In the latter half of the discussion, HRSA stated that the DAC is allowed to create a "master list" of all OPTN data. This list may assist the DAC when analyzing multiple data variables across organs, thereby ensuring consistency.

3. Data Submission Timelines

UNOS staff presented an update on the Data Submission project, donor-related definitions in policy and compliance with data submission timeframes. Members discussed current project statuses, next steps and provided UNOS staff with appropriate feedback.

Summary of discussion:

UNOS staff reoriented Committee on the DAC actions to date (see below)

- Remove Policy 18.1: *Data Submission Requirements* requirement that transplant hospitals submit Recipient Feedback within one day of the transplant for solid organs
- Revise Policy 18.1*: Data Submission Requirements* language addressing Histo Labs reporting of Donor Histocompatibility (DHS) information to read Within "30 days after the DHS record has generated" and For "Each living and deceased donor"
- Requested that forms and/or data collection instruments be identified by their proper names

In terms of donor-related definitions in Policy 1*: Administrative Rule and Definitions*, there are two definitions:

- Deceased Donor: An individual from whom at least one organ is recovered for the purpose of transplantation after declaration of death
- Living Donor: A living individual from whom at least one organ is recovered for transplantation

In terms of compliance with data submission timeframes, compliance rates of transplant hospitals and histocompatibility labs were low at the initial deadline. Transplant centers' compliance with initial timeframes was between 64% – 85%, whilst the Histocompatibility labs' compliance with initial timeframe was between 68% – 83%. New data analyses are expected to be provided to the DAC Committee meeting on March 25, 2019. However, UNOS staff requested that Committee members provide them with any other questions (e.g. which pieces of information the DAC wants to know from the data).

At this point in the discussion, HRSA stated that they are working on improving the OMB approval process when making minor changes to an already existing registration form. Yet, HRSA clarified that a brand new form, or one needing approval, will have to be OMB approved. For example, data in the Patient Safety Portal is not currently a part of the approved OMB collection forms but they are required OPTN data collection. Under the new contract, all data will need to go through the OMB approval process and become designated as official OPTN data.

Next, UNOS staff discussed the potential member impact from eliminating Policy 18.4: *Data Submission Standards*. UNOS staff will perform outreach efforts on behalf of the DAC, and share the DAC is considering eliminating said policy. Although DAC is comfortable with the submission timeframes found in Policy 18.1:*Data Submission Requirements* and 18.2:*Timely Collection of Data,* UNOS staff will ask other OPTN committees whether they would also endorse not changing timeframes. UNOS staff will also elicit feedback from other OPTN Committees on the potential impact and challenges to eliminating Policy 18.4: *Data Submission Standards*.

Lastly, UNOS staff advised that the DAC consider Vascular Composite Allograft (VCA) references in Policy 18: *Data Submission* individually, along with the potential impact of the new VCA project: *Update to VCA Transplant Outcomes Data Collection.*

Next steps:

UNOS staff will reach out to other OPTN Committees for feedback on eliminating Policy 18.4: Data Submission Standards.

Upcoming Meeting

- March 25, 2019