

**OPTN Data Advisory Committee
Meeting Minutes
October 10, 2019
Chicago, IL**

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

Introduction

The OPTN Data Advisory Committee (DAC) met in Chicago, IL on 10/10/2019 to discuss the following agenda items:

1. DAC Charge Revision
2. Policy Oversight Committee (POC) Update
3. Modify Data Submission Policies
4. Data Advisory Committee and the OPTN's Journey to Improve Data Quality
5. Working Lunch: OPTN Data: the Past, Present, and Future
6. Minority Affairs Committee (MAC) – Proposal to Add New Data Collection to Capture Additional Dimensions of Socioeconomic Status
7. Vascularized Composite Allograft (VCA) Data Collection Proposal
8. Kidney Proposal Update

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

1. DAC Charge Revision

All OPTN Committees are being asked to review their current charges and update if necessary. The DAC reviewed an updated version of their charge that better reflects the role of the DAC under the new OPTN contract.

Summary of discussion:

The DAC reviewed the updated charge. They considered 2 additional suggestions that were submitted prior to the meeting. The two additional suggestions were to include language that would allow DAC to manage the OPTN Data Collection Principles and give the DAC purview over not just what data is collected but how data is collected.

The DAC agreed to include more specific language outlining that DAC is responsible for reviewing and sponsoring any updates to the OPTN Data Collection Principles. The DAC then agreed to include language describing DAC's role in advising how data is collected in the charge. This includes things such as seamless data exchange and APIs.

The DAC also discussed how the DAC collaborates with other OPTN Committees in their work and how that should be captured in the charge. The DAC agreed to incorporate language about collaborating with other OPTN Committees in those activities that require such collaboration. The DAC discussed including the performance standards listed for the DAC in the OPTN contract in the charge. The DAC agreed that the version of the charge included enough detail regarding the performance standards.

A formal vote was taken regarding: do you support sending the updated charge to the Board of Directors for approval?

Results were as follows: 13 (100%) Yes; 0 (0%) Abstain; 0 (0%) No

The DAC agreed to allow UNOS staff to make minor language or grammar modifications, with approval from DAC leadership, as necessary.

Next steps:

The charge will be sent to the Board for final approval during their December meeting.

2. Policy Oversight Committee (POC) Update

The DAC Vice Chair provided an update on the work of the POC to the DAC.

Summary of discussion:

The Vice Chair provided an overview on the strategic policy priorities that have been developed by the POC. A DAC member asked whether it was within DAC's purview to recommend data collection to align with these strategic priorities. The Chair stated the subject-matter committees would work on the projects to address the priorities and would include DAC in those efforts as appropriate.

The DAC discussed some projects that they could be work on that align with the priorities. One such project was updating the refusal codes, which could affect multiple priorities. A DAC member asked for more information on the priority to create more efficient donor/recipient matching to increase utilization. The Vice Chair noted that the POC subcommittees have not met yet.

Next steps:

The DAC will continue to figure out how it is going to interact with other OPTN Committees and work on prioritizing their work in the coming months. The DAC agreed to continue discussing how they could work towards the strategic priorities at an upcoming meeting.

3. Modify Data Submission Policies

The DAC discussed their public comment proposal titled, "Modify Data Submission Policies."

Summary of discussion:

The DAC received a presentation on the public comment feedback submitted on the proposal during the public comment period. The proposal was widely supported throughout public comment and across the regional meetings. The American Society of Transplant Surgeons did not support the proposal. All OPTN Committees that heard the proposal supported it. The DAC was presented information on the themes in public comment including that the proposal will increase existing data submission burden and the request for additional education and training addressing data requirements.

A DAC member asked if OPOs would be required to obtain and keep source documentation from the transplant hospital under the proposed policy. The DAC agreed this was not the intent of the proposal and the proposed language is not that specific. The DAC clarified that the intent of the language about maintaining documentation is to ensure that members are able to show that submitted data is accurate. This does not require obtaining and maintaining source documentation. The DAC agreed that there was not a need to change the policy language but they can provide education and clarification on this point throughout implementation of the proposal.

A DAC member asked if the extended deadline for the Transplant Recipient Registration (TRR) form would impact organ utilization reports. The DAC member noted that the information in the report is important because it allows members to identify trends and opportunities for improvement in real time. Organ offer data will not be affected by the extended timeline. The DAC noted that the extended timeline does not mean that members must wait for the deadline to submit data. The DAC agreed to

include this point in future education and provide specific outreach to the Transplant Coordinators Committee (TCC) and Transplant Administrator Committee (TAC). The DAC discussed the consequences of not submitting data in an appropriate manner. The DAC considered updating the monitoring plan but ultimately agreed that OPTN Policy and the Final Rule make it clear that data must be submitted.

A DAC member commented that the proposed policy may not be clear in stating that all forms are due by the proposed deadline. Under the previous policy, members only had to submit a certain amount of data and the proposed policy removes this requirement. The DAC discussed if the new policy meant that all data had to be submitted by the proposed deadlines. The DAC agreed that the proposed policy was sufficiently clear that all data would be required to be submitted by the proposed deadlines.

The DAC then discussed the proposed extension of data submission timelines. The DAC talked about the advantages and disadvantages of the proposed extensions.

A formal vote was taken regarding: do you approve clarifying and extending the data submission timelines as proposed in OPTN Policies 18.1.A and 18.1.B and by deleting OPTN Policy 18.4

Results were as follows: 13 (100%) Yes; 0 (0%) Abstain; 0 (0%) No

The DAC then discussed the proposed solution to implement a process for locking and unlocking data. A DAC member stated that it may be preferable for program leadership to get real-time notifications when forms are being unlocked instead of retrospective reports. The DAC discussed how frequently reports on data changes would be available and if they could be made “on-demand”. The DAC agreed that real-time notifications would not be preferred. The DAC also noted that the reports outlining the frequency and reasons for data changing will allow programs to make process changes to improve data submission. The DAC agreed that this should not be put into OPTN Policy and the programs should make their own process decisions. The Chair also noted that the DAC will need to discuss which drop-down options will populate the field for the reason why the data is being changed.

A DAC member noted that UNOS often reviews inconsistent data and reaches out to members to clarify the data. The DAC member asked how these sort of data changes will be handed with the data lock. The DAC Chair stated that this could be one of the explanations for why data was changing.

A formal vote was taken regarding: do you approve implementing a process for locking and unlocking data as proposed in OPTN Policy 18.1.C?

Results were as follows: 13 (100%) Yes; 0 (0%) Abstain; 0 (0%) No

The DAC then discussed establishing an annual reporting requirement to the OPTN Board of Directors.

A formal vote was taken regarding: do you approve establishing an annual reporting requirement to the OPTN Board of Directors as proposed in OPTN Policy 18.1.D?

Results were as follows: 13 (100%) Yes; 0 (0%) Abstain; 0 (0%) No

The DAC then discussed the timeline for implementation of educational resources and other data quality tools. The DAC supported having the education and tools available prior to the implementation of the proposal.

A formal vote was taken regarding: do you approve sending the proposal to the OPTN Board of Directors for consideration at their December 2019 meeting?

Results were as follows: 13 (100%) Yes; 0 (0%) Abstain; 0 (0%) No

Next steps:

The proposal will go before the OPTN Board of Directors for consideration during their next meeting.

4. Data Advisory Committee and the OPTN's Journey to Improve Data Quality

The role of the DAC is expanding under the new OPTN contract. UNOS staff presented information on the expanded role of the DAC.

Summary of discussion:

The Data Governance Program Manager provided information on the role and responsibilities of the DAC within the OPTN. The DAC is responsible for reviewing all data collection proposals and ensuring that the proposals are in alignment with the OPTN Data collection Principles, that the proposed data collection has been evaluated against the Data Element Standards of Review, and providing recommendations on improving completeness, accuracy, and timeliness of data collected. The DAC is tasked with combining project-based work and ongoing operational work to improve data collection. The DAC is working towards taking a more proactive approach in the development of proposals that involve new data collection by being involved earlier in the policy development process and creating more frequent touchpoints between DAC and the sponsoring Committee. UNOS staff presented proposed processes to incorporate those touchpoints. The DAC is also responsible for clarifying data definitions. UNOS staff presented the process for clarifying data definitions. The DAC is tasked with helping to complete a holistic, systematic assessment of OPTN data collection.

Next steps:

UNOS staff will continue to develop processes to organize the DAC's work.

5. Working Lunch: OPTN Data: the Past, Present, and Future

Representatives from the Scientific Registry of Transplant Recipients (SRTR) presented information on OPTN data and ways it can be enhanced through improved data collection.

Summary of discussion:

The SRTR representative gave a presentation on OPTN data collection and principles that could be used to improve OPTN data. The SRTR representative provided information on the history of OPTN data collection. The SRTR then presented information on current challenges and opportunities for OPTN data collection. The SRTR noted that current challenges include continually changing data, subjective data, and data accuracy. The SRTR representative provided possible solutions for these challenges. The SRTR representative provided potential guidelines for OPTN data collection.

A DAC member asked if the SRTR and the OPTN could help create a parking lot of problematic data elements that DAC can keep top of mind when going through the systematic review of existing data elements. A DAC member also noted that data entry can vary between clinical and non-clinical personnel. Non-clinical data entry personnel may not have a good understanding of the purpose of some data elements. A DAC member commented that the OPTN could consider collecting data not just to assess risk but to also understand transplant access, disparities, and other things associated with outcomes. A DAC member suggested including the cost/burden of collecting the data in the guidelines. Another DAC member raised the concern that some data is collected at listing or a single point in time and the designated point in time might not be the best time to collect the data point. The DAC chair suggested that the SRTR support DAC in their efforts to prioritize their future work.

Next steps:

The DAC and SRTR will continue to collaborate in improving OPTN data collection.

6. Minority Affairs Committee (MAC) – Proposal to Add New Data Collection to Capture Additional Dimensions of Socioeconomic Status

The MAC is working on a data collection proposal to better capture socioeconomic status (SES). They are proposing adding the collection of household size and income to the Transplant Candidate Registration (TCR) form.

Summary of discussion:

The DAC heard a presentation on the MAC proposal to collect additional SES data. The MAC previously submitted a data request that showed that disparities do exist in outcomes by SES status of zip code but knowing these disparities also exist at a patient level would be preferable. Therefore, the MAC is proposing adding household size and income to the TCR. This would provide additional data that would help provide better insight for future policy decisions and enhance and inform discussion of transplant equity. There are established methods for collecting both data elements and neither have to be incredibly accurate to be informative. The MAC expects that social workers at transplant centers are already collecting this information at many programs. The MAC explained how the data collection aligns with the OPTN Data Collection principles.

A DAC member asked if the MAC had discussed how the data would be collected for candidates who are on the waitlist for a long period of time. The data could change over the course of their listing. The MAC agreed that this would need to be accounted for but that some data collection is better than none. A DAC member commented that it is important to collect these data because they are associated with healthcare outcomes and it will provide the opportunity to describe disparities for vulnerable populations. Additionally, the proposed data could dispel conscious or subconscious bias in treating these patients by better adjusting risk models.

A DAC member stated that not all social workers at transplant programs collect this data. The DAC member also stated that patients may be reluctant to provide this data. Patients are already concerned about ability to pay for care and this could cause them to be reluctant to provide the data. The DAC member was also concerned with the accuracy of self-reported data.

The SRTR representative commented that they tried to collect this data from living donors as part of a pilot project and it was ultimately unsuccessful because many living donors did not provide the information. The DAC Chair suggested using patient address as an alternative to zip code, given the concerns about collecting this information.

A DAC member asked how the income data would be collected (exact number as opposed to a range). The MAC stated that they were planning on collecting a number, not a range, so that poverty status can be calculated. A DAC member noted that poverty status is not the only outcome that should be calculated. A DAC member commented that if this data is collected by financial counselors or social workers it already exists so it may be possible to link to them in a form. The DAC discussed the utility of address data and how it could be more informative than other SES data. However, there are challenges associated with collecting and validating the data. A DAC member commented that address data can be useful if the form is designed correctly. The DAC noted that the data collection effort would actually be easier for small programs with fewer patients.

The DAC agreed that the MAC should present the proposal to the TAC and TCC. The DAC also agreed that the data was important to collect but that the MAC still had some questions to answer. A DAC member was concerned that the proposed data collection would be too subjective and would not be able to be verified. Another DAC member commented that the proposed data collection would not be subjective but the problem is that it is self-reported.

HRSA noted that the data would be used to assess how the transplant system is inequitable for certain groups.

The DAC unanimously agreed that the MAC project is moving in the right path but requested that the MAC report back to the DAC addressing the concerns discussed above. The DAC also suggested adding a DAC member to the MAC project workgroup. The DAC also suggested following up with the SRTR to discuss the living donor pilot that did not work.

Next steps:

The MAC will follow-up with the DAC to provide a more detailed proposed solution at a future meeting.

7. Vascularized Composite Allograft (VCA) Data Collection Proposal

The VCA Committee previously presented a project to update the TRR and the TRF for VCA candidates. They have since decided to pursue a project to collect data on babies born to uterine transplant recipients. The VCA Committee provided an update on the project to collect data on babies born to uterine transplant recipients.

Summary of discussion:

The current data submission for these babies is voluntary and insufficient to assess the safety of uterine transplant recipients. A DAC member suggested that the VCA Committee reach out to the Transplant Registry International, who may collect data on this population. The DAC agreed that data should be collected on this population but the transplant center may not be the best organization to collect the data. The VCA Committee felt that the data would be able to be collected at birth by the transplant program.

Next steps:

The VCA Committee will follow-up with the DAC to provide more detail on this piece of the data collection proposal and ensure that they follow the appropriate processes.

8. Kidney Proposal Update

The Kidney Committee is sponsoring a proposal to remove the use of DSA and Region from kidney allocation.

Summary of discussion:

UNOS staff informed the DAC that the Kidney Committee is still discussing the medical urgency solution as it did not get much feedback during public comment. This part of the proposal would likely entail additional data collection. The Kidney Committee is deciding whether to proceed with sending the medical urgency solution to the Board in December or sending the additional data collection piece back out for public comment. A DAC member noted that each DSA already has a policy for this and suggested that the Kidney Committee reach out to the community to get this information.

Next steps:

The Kidney Committee will follow-up with the DAC on their plan for medical urgency.

Upcoming Meetings

- November 18, 2019
- December 10, 2019