# OPTN Organ Procurement Organization (OPO) Committee
# In-Person Meeting Minutes
# April 16, 2019
# Chicago, IL

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**Diane Brockmeier, RN, BSN, MHA, Vice Chair**

## Introduction

The Organ Procurement Organization (OPO) Committee met in Chicago, IL on April 16, 2019 to discuss the following agenda items:

1. Expedited Placement of Livers
2. Imminent and Eligible Death Data Reporting Analysis
3. Association of Organ Procurement Organizations (AOPO) Late Turndown Study
4. Improving the Efficiency of Organ Placement Analysis
5. Ad Hoc Systems Performance Committee Update
6. Informed Clustering of Donor Service Areas for Better Benchmarking
7. Donation After Circulatory Death (DCD) Policy Review Project
8. Deceased Donor Registration (DDR) Review Project
9. Data Advisory Committee – Modify Data Submission Policies

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

## 1. Expedited Placement of Livers

The Committee reviewed and discussed the public comment responses of the Committee's Expedited Placement of Livers proposal.

Summary of discussion:

The Committee Chair provided members with an overview of the public comment responses on this proposal.

UNOS staff reviewed the regional meeting responses and votes. The proposal received overall support among nine of the eleven regions. Some of the common themes from public comment include the following:

- Concern of proposed 20 minute time limit
- Expedited placement should start several hours before scheduled OR time
- Concern every center will opt in
- Improve DonorNet® functionalities

Committee leadership presented the proposal to the following committees:

- Operations and Safety Committee
- Membership and Professional Standards Committee (MPSC)
- Liver and Intestinal Organ Transplantation Committee
- Transplant Coordinators Committee (TCC)
- Transplant Administrators Committee (TAC)

The Committees were generally in support of the efforts and intent of the proposal. There were some concerns about delaying cross clamp. This topic was discussed by the OPO Committee's expedited placement work group during the development of the proposal and it was decided

that this should not be mandated in policy. There were a lot of comments concerning how this proposal would affect current backup processes. It was clarified that the proposal would not affect the backup processes that are already in place.

The Committee Chair stated that the comments about the efficiencies of DonorNet is beyond the purview of this policy proposal. There were two areas from the public comment responses that Committee Leadership wanted to discuss further with the Committee and felt would be reasonable to incorporate in the policy proposal:

- Increasing the time limit from 20 minutes to 30 minutes: The origin of the 20 minutes was when the process was proposed to be all from the OR. In moving this process prior to the OR, 30 minutes would be a reasonable time frame.

- Initiating the expedited placement process two hours prior to the OR: The Association of Organ Procurement Organizations (AOPO) suggested that the expedited process begin three hours prior. Committee Leadership felt that this would be too early to initiate the process and agreed to propose two hours prior to the OR.

A member asked if a program had local back up already for liver, but expedited placement was initiated, can the program use their back up or is this choice lost since the expedited placement filter was initiated? The Committee Chair stated that the intent of this proposal was to make it permissible for the OPO to go to the expedited placement list, but not require it. It was clarified that this process would all be within the same list with filters for the expedited placement list.

Another member stated that the work group initially discussed having the expedited placement process initiated prior to the OR but ultimately decided to start with expedited placement for late turndowns in the OR. One Committee member asked how the process would change if the Committee modified policy language to allow expedited placement to be initiated prior to the OR. The Committee Chair clarified that the work group faced a challenge in determining what donor characteristics would trigger the expedited placement list. The current proposal is based on the organ being placed and then turned down in the OR. In relation to next steps for the revised proposal, the themes were clear from the feedback provided, which has allowed the Committee to revise the policy language based on these suggestions for Board consideration.

The member continued by asking what OPOs would have to do to help UNOS monitor the OR times. From an OPO standpoint, the OR time is recorded in their notes. The Committee Chair stated that the policy language voted on by the Committee would be submitted to the Board and then the logistics of the implementation would continue to be worked on. The vision is that there would be a filter button that would be activated based on the OR time entered in by the OPO, which could be monitored through a Member Quality review.

A member asked that if expedited placement was initiated prior to placement, would this be considered a backup offer to transplant programs? Once the expedited placement filter is applied, how would rankings be distinguished? The Committee Chair stated that this would be up to the transplant program on how they treat the offers. The transplant programs will still have 30 minutes to review and respond to the offer. In terms of the ranking, the candidates who were not on the expedited list would be grayed out once the expedited placement filter is applied. The candidate with the highest priority would get the offer.

The member continued by asking if this process would work for Donation after Cardiac Death (DCD) cases. The Committee Chair stated that this particular scenario is not addressed in the proposed policy as the workgroup did not have consensus on the various situations that could occur and what donor characteristics would trigger the expedited placement list prior to the OR.

Another member asked what the difference was between the two hours or three hours prior to the OR to initiate expedited placement. The Committee Chair stated that it raised the question of if this option would have OPOs access the expedited placement list too soon. With too much time prior to the OR, an OPO may not go down the list and use the backups as they should. The Committee leadership discussed the pre-OR timeframe with many members in the community who had the consensus that two hours would be appropriate.

A member stated that the way the proposal is now written, if a team turns down an organ offer that is in the OR, they should not be required to stay and procure the organ for another center. The Committee Chair clarified that in order to place the liver for final placement from the expedited process, the liver would have been turned down in the OR. The policy is just allowing for the match run and conversations to begin prior to going to the OR.

A member asked for clarification on if the OPOs still have the ability to determine how many backups they can go to before initiating the expedited placement filter. The Committee Chair again clarified that the expedited process does not interfere with backup processes.

A member asked for clarification on if the provisional yes responses can still be contacted. The Committee Chair stated that this was correct. The member continued by asking how confident is the Committee in assuming that programs will hold themselves accountable in really looking at the list and identifying their true intentions. There is a concern that programs will opt into expedited placement and that there will be an issue of going down a list trying to get an offer accepted. The Committee Chair stated that the workgroup discussed waitlist management and transplant program behavior. There is the expectation that transplant programs will initially have more patients listed on the expedited list than they intend to accept but hopefully that behavior will change due to the number of offers they will receive.

Another member asked if there would be penalties if the expedited placement list was bypassed. The Committee Chair stated that it is assumed that it would be a policy violation if the expedited placement list is used without following the expedited placement policy.

A member stated that with the allocation changes that are expected in the future, this process is a good policy to have in place. As a community, there is currently no policy which leads to variation and complications. This policy proposal is a way of demonstrating that there is an attempt to standardize practices in anticipation of future allocation changes. The Committee Chair stated that if there is a policy, it is the expectation that policy is followed.

Another member stated that they received feedback that the interaction with MPSC will be different. There is concern that there will be an increase in organ discard due to the fear of having to report to the MPSC if the expedited placement list is bypassed. The Committee Chair stated that there has been some changes within the MPSC on the processes for reporting.

A member asked if there would be a limit on how many programs are sent offers from the expedited placement list. The Committee Chair clarified that when using the expedited placement process, the OPOs will have the ability to send as many offers as necessary and will be up to individual OPO discretion. Another member stated that the requirement to physically enter each candidate's information into the expedited placement list will prove to be a lot of work on the transplant program side. The member continued by commenting that in finding a regional program, the internal process would be to have a backup offer in place regionally, which is developed outside of the proposed policy.

UNOS staff asked for clarification on when the actual offers for expedited placement would be sent out. The Committee Chair stated that the expedited filter can be initiated two hours prior to the OR. Communications and offers can be made with the programs knowing that this would be

for expedited placement. The organ cannot be allocated through expedited placement until there is a turndown in the OR.

A member voiced concern that transplant programs will not take this process seriously. Another member stated that this would not change the process from what is being done now.

The Committee Chair asked members how they thought this process should be operationalized. A member stated that the time limit should not change from 20 minutes to 30 minutes. Another member stated that if the accepting center is inclined to say no, it would be hard to make an offer two hours prior. They could say no once the allocation is initiated in the OR. The member continued that it was the thought that the expedited placement allocation would happen two hours prior to the OR. The Committee Chair clarified that this was not what was being proposed and was not discussed during the work group as there was no consensus around how to develop a policy around expedited allocation prior to the OR.

Another member asked if the expedited filter will be based on the criteria that was initially proposed. If the filter is being used two hours prior to the OR, the biopsy results would not be available at that time. The Committee Chair stated that the characteristics that are available would be entered into the system. Since the biopsy results would not be available prior to the OR, this information would be omitted. The member continued by commenting that if the biopsy results were entered in the OR, there could potentially be more candidates added on the expedited list once this information is entered. The Committee Chair agreed and stated that there has not been a discussion regarding the operational aspect of the list and would be an implementation question around how this information would get updated

The Committee Chair proposed that as there was uncertainty around revised policy proposal, the additional feedback received should be taken back to the work group to revise the policy language and discuss the evaluation and implementation plan of the expedited placement process. The revised proposal would be submitted for public comment during the fall cycle.

A member asked for clarification as to when the fall public comment period begins. UNOS staff clarified that the fall public comment cycle will be from August 2, 2019 – October 2, 2019. The Committee Chair stated that the work group would need to meet every two weeks to discuss the policy language and process in preparation for fall public cycle.

The Committee Chair asked members who would be in favor of using the existing match run or a new list. The Committee unanimously agreed to work within the existing match run and filter the same list with the expedited placement filter.

The Committee unanimously agreed to take the proposal back to the work group and submit a revised proposal during the fall public comment cycle.

Next Steps:

- Revised policy language will be presented to the work group for further discussion and development of an implementation and evaluation plan.

**2. AOPO Late Turndown Study**

Summary of discussion:

The Committee was provided with an overview of a late liver turndown study to committee. The study cohort was from late 2016 to late 2018 that required OPOs. The goal of the study was to answer the following questions:

- How prevalent is the problem?
- What is the fate of livers declined in the OR?

- When and why are they declined?
- What are the donor/OPO/transplant programs risk factors for decline?
- What can we do to maximize utilization?

Among the 58 OPOs, 38 submitted data as part of the study. Some OPOs were more consistent than others in submitting data to the study. The data obtained underrepresents the problem as there is some bias in terms of volume of donors within each OPO.

The data collected within the two years of the study showed 880 total declines in the OR. Among the 880 total declines, 243 cases were not recovered. There were 619 (70%) cases that were recovered with the intent to transplant, but there were only 323 (52%) which were actually transplanted. Among those organs that were transplanted, 165 (51%) of the cases were back up placements and 137 (42%) cases were expedited placements.

The Committee was provided with data on outcomes by region. Region 4 stood out as a region that was doing well at reallocating and transplanting livers. There was some discussion within the AOPO and regional meetings that this result could be due to Region 4 having a robust local recovery network.

In estimating the prevalence of the problem, OPOs who consistently submitted data during 2017 were observed. The data was extrapolated to the nation. The presenter reiterated that this data was a dramatic underestimation. At least 14% of all the livers that are allocated with the intent to transplant are turned down in the OR. Based on conversations with OPOs, the percentage is closer to 25-30%. UNOS staff asked if the denominator included declines that were subsequently transplanted. The presenter clarified that this information was included in the denominator.

The Committee was provided with data on when the livers were declined. The livers that ultimately were used were five minutes before cross clamp. The livers that were not used were 23 minutes after cross clamp. The later the livers were declined, the less likely the organs were to be transplanted.

The Committee was provided with the reallocation time once the livers were declined. It took 17 minutes on average to reallocate the organ through back up even when the back up program had been identified before entering the OR. The median time to get a liver placed through expedited placement took 70 minutes to reallocate. This data suggests that it takes longer to reallocate livers through expedited offers than anticipated.

The presenter noted that the presence or absence of a biopsy did not impact the utilization of an organ. Just over half of the livers in the study were biopsied. Neither the fact that the organ was biopsied nor the type of biopsy performed impacted the utilization of the organ.

The presenter summarized that OPOs should anticipate late declines. About half of the livers that are declined in the OR are utilized.

The Committee Chair asked if there were a few fields that would be helpful to collect this data in UNet$^{sm}$ in a more efficient fashion. The presenter noted that it is not believed that the specific information collected for this study could be captured from UNet$^{sm}$. The form that was used for this study was able to record the allocation efforts in real time and the amount of time it took, which would be hard to capture in UNet$^{sm}$.

The Vice Chair asked if the data would be specific of the declines for each center. The presenter stated that any OPO that had a decline would show up in the data. Often, there were multiple OPOs. The Vice Chair commented that it would be interesting to see where the variability is especially as broader distribution moves forward.

A member asked how many livers were transplanted in the country during the same timeframe the study was facilitated. UNOS staff noted that the number of deceased donor liver transplants in 2017 was 7715 and in 2018 was 7849.

There were no further questions or comments.

### 3. Imminent and Eligible Death Data Reporting Analysis

UNOS Research staff provided members with an update on Imminent and Eligible Death Data Reporting.

Summary of discussion:

UNOS staff began the discussion by providing background for members. Previously, some changes were implemented in the definitions of eligible and imminent neurological death. Language around organ failure was replaced with organ specific criteria. The intent of these changes were to help correctly classify deaths resulting in donation and clarifying criteria for more consistent reporting across OPOs.

UNOS staff noted that the analysis was done from the two year period before and after the definitions were changed to observe the policy impact. The analysis included the percentage of eligible deaths resulting in donation, national, regional and Donation Service Area (DSA) variation, and variation by patient demographics.

UNOS staff reviewed the national trends that were observed. Eligible and imminent deaths were increasing before the definitions changed. The eligible deaths showed a continuous increase that was present before the definition changes and then plateaued in 2018. All of these metrics varied by DSA.

UNOS staff summarized that the data showed:

- Increase in eligible deaths
- Stable percentage of eligible deaths becoming donors
- Decrease in imminent neurological deaths
- Continued increase in deaths from anoxia
- Geographic variation in reporting deaths over age 70

A member stated that the variation shown may be due to the amount of sedation or mild hypothermia. There are various interpretations of these definitions of sedation and hypothermia that can differ with each OPO.

The Committee Chair clarified that there were eleven OPOs that did not have any eligible deaths over 70 years of age in the two year period post-policy but an increase has been observed after that time frame. The Committee Chair stated that it appeared to be a change in practice.

A member asked for clarification of the stable percentage of the data. UNOS staff clarified that there was about 70 donors per 100 eligible deaths that stayed the same during the time frame observed.

A member inquired about the definition of intraoperative biopsy and if this ruled the organ out to count them as eligible or ineligible. As more bedside biopsies are being done, is there any consideration in including this into the definition? The Committee Chair stated that this would be a good question to ask and should discuss further on how this information could be applied.

Another member asked what the analysis was for how many eligible organs that were not transplanted. The Committee Chair clarified that the requested information by the Committee

would be: By organ type, how many would fall into a classification of eligible but not transplanted? The next question would be why. Members agreed with this request.

The Committee Chair suggested that once more information is obtained, UNOS research staff can present this information to the Committee during a future Committee meeting. UNOS staff agreed with this.

Next Steps:

- UNOS staff will look further into the Committee's request and will provide more information during a future Committee meeting.

**4. Improving the Efficiency of Organ Placement**

UNOS Research staff provided members with the results of an analysis of the impact of the implementation of this proposal.

Summary of discussion:

UNOS research staff provided background information on this request which was to evaluate the impact of a policy changes made in the summer of 2018 to improve the efficiency of organ placement. This proposal included the following changes:

- Reduced time limits for responding to organ offers
- Introduced new time limit for primary offers to enter final decision
- Limited the number of organs accepted at one time
- Required OPOs to manage organ acceptances in real time

UNOS staff clarified that there were some limitations to what could be analyzed for this specific policy change. UNOS research staff were able to analyze the change in distribution of times from notifications to first response. Since OPOs were not managing acceptances in real time prior to the changes, the data collected for this was only post-policy changes.

UNOS staff continued by explaining that the data observed was roughly six months pre- and post- policy implementation. The time limits were changed in May 2018 and the number of concurrent acceptances was implemented in June 2018. The analysis of the study that were shared with the Committee were:

- Time from notification to first response for electronic offers
- Offers bypassed due to exceeding time limit
- Registrations ever accepting two organs concurrently

Time from notification to first response

For pre-policy, over 90% of offers across organ groups were responding within 60 minutes of notification. With the policy implementation, explicitly calling out that a response was needed within 60 minutes of notification, the responses increased to over 95%.

Offers bypassed due to exceeding time limit

There was a change observed at the offer level, specifically for the number of kidney and liver offers that were bypassed. At the match level, where there was at least one offer bypassed, the same trend was seen where there was an increase in the use of the bypass codes for the kidney and liver offers.

The Committee Chair asked if there was a percentage that could help in informing members. UNOS staff clarified that it was a small percentage – less than 1%. The Committee Chair stated

that it would be good to understand this as a committee to better respond. It was suggested to present the data with a percentage rather than the raw numbers. Members agreed with this.

Concurrent Final Acceptances

The percentage recovered with at least one registration on the match run with a concurrent acceptance was analyzed. Heart, kidney and kidney-pancreas donors are infrequently affected. There was an impact among 9% of all liver donors that were recovered during the six month period and 4% of lung donors.

The Committee Chair asked for clarification on whether the heart allocation change would be captured within this period or the data being reviewed. UNOS staff confirmed that the heart allocation changes were captured in this data and clarified that the six month time frame observed was from June 2018 – December 2018.

A member asked if this information would be shared to the Liver Committee. UNOS staff clarified that this information would be shared with the Liver Committee. The Committee Chair also asked if this would be valuable information to share at the upcoming AOPO meeting to show the success and challenges with this implementation. Members agreed with this.

UNOS staff continued with a review of lung registrations with concurrent final acceptances among regions. It has been happening prominently in Region 11 but does not happen as often in Regions 6, 7, 8, or 9. The Committee Chair clarified that this data was based on the center. UNOS staff stated that this was correct.

There is further analysis anticipated for this study. In the original data request, there was a question looking at the registrations that had two final acceptances at the same time whether they had a provisional yes.

There were no further comments or questions.

**5. Ad Hoc Systems Performance Committee (SPC) Update**

The Vice Chair provided members with a summary of the work of the Ad Hoc Systems Performance Committee (SPC).

Summary of discussion:

There are three work groups made up of representatives from OPOs, transplant hospitals, patient and donor affairs, Health Resources and Services Administration (HRSA) and the Scientific Registry of Transplant Recipients (SRTR). Each group was led by a transplant hospital and OPO representative. The SPC's charge was to engage in a strategic, community-driven, interdisciplinary conversation.

The Vice Chair summarized the workgroup's recommendations of the following themes:

- New tools and technologies
- Performance monitoring enhancements
- Broader horizons: Beyond the OPTN
- Collaborative improvement and Relationship Management

Research Tools

There was a lot of discussion around what types of self-monitoring metrics should be looked at collectively. Could this be benchmarked against each other to improve performance and is it transferrable? There was also discussion about enhanced research and IT tools and whether predictive analytics should be used. What would those opportunities look like for OPOs? For

example, when looking at organ recovery and transport, how can these processes be more transparent and create efficiencies within the system.

Collaborative Improvement and Relationship Management

There was also some discussion about how to put in place more Collaborative Innovation and Improvement Network (COIIN) projects. It was noted that collaborations have helped to enhance relationships, especially during regional meetings. In looking at how to manage these relationships, should regional meetings be redefined?

MPSC Monitoring/Measurement Enhancements

There were a lot of discussion around looking into composite metrics. A lower mark on the metric could identify pre-MPSC intervention to make improvements. There would need to be determination on who the intended audience would be, which metrics would matter, and why they would matter.

Beyond the OPTN

There was a lot of conversation around the possibility of having a coordinated, national transportation system. Could opportunities be present around risk adjustment reimbursement for transplant centers and OPOs? It was recognized that there are several formal partnerships that could be identified with an opportunity to collaborate with these partners and drive common advocacy platforms. What sort of recommendations could be presented to external stakeholders?

The Vice Chair summarized that SCP leadership will deliver a report to the OPTN Board of Directors in June with the key themes and takeaways that were identified during the work group discussions. There will be specific recommendations for projects or strategic action that will be proposed to the OPTN Board of Directors.

The SPC will also have the opportunity to share this conversation within the community and possibly publish a manuscript that summarizes this work.

There were no additional comments or questions.

**6. Data Request (DCD Downtime)**

SRTR staff provided an overview of DCD downtime data.

Summary of discussion:

During the previous in-person committee meeting, there was a request by a committee member to go through the changes to the OPO yield models. The main concern was that there was an over-calculation of donor yield and how this affected the yields of other OPOs.

SRTR staff reviewed data for downtime and expected yield and highlighted brain dead donors having substantially more yield than DCD donors. Among DCD donors, the expected liver yield goes down as the downtime increases. Liver yield is highest among DCD donors when the downtime is less than 20 minutes or between 20 and 30 minutes. The liver yield goes notably down when the downtime is between 30 and 40 minutes or greater than 40 minutes. There is a dramatic drop in the expected liver yield for these types of donors. Donors with downtime over 40 minutes have a significantly less yield than other types of DCD donors.

A member asked if there was any discussion about including liver biopsy results. SRTR staff stated that this was being discussed, but there will not be any changes until later in 2019 or possibly the following cycle. There were no additional comments or questions.

## 7. Informed Clustering of Donor Service Areas for Better Benchmarking

UNOS staff provided members with an overview of a project observing informed clustering of Donor Service Areas (DSAs) for better benchmarking.

Summary of discussion:

The goal of the project was to have a more holistic approach in benchmarking comparison groups that could be refined over time.

UNOS staff explained how the groups were developed. There was a clustering algorithm that was used called partitioning around medoids (PAM). This partitioning technique was used to cluster the 58 DSAs. Throughout all of the iterations of this analysis, all 58 OPOs were observed. For the purpose of including additional information through the clustering algorithm, Puerto Rico was not included.

UNOS staff continued by discussing the information included in the study. Data was used from both OPTN databases and external data sources. It was important to include characteristics of the living populations served by each OPO as well as the deceased population. Using SRTR data, aggressive and conservative transplant programs were observed. Organ specific aggressive transplant programs were characterized as having an overall acceptance rate significantly greater than one and had more than the median number of acceptances.

Conversely, conservative transplant programs for an organ specific program were characterized as having an overall acceptance rate significantly less than one and the program was over the median number of acceptances. In order to summarize the 68 identified characteristics, a principal components analysis (PCA) was used. The goal of the PCA was to explain the highest percentage of variation while minimizing any loss of information.

UNOS staff reviewed the principal component themes which included the following:

- Supply and demand – number of the population, organ specific programs and registrations, and number of deaths
- Ethnicity and social features – social association rates, non-proficient English speaking percentages, and rural populations
- Socioeconomic features

UNOS staff continued by discussing the clusters on principal components. Once the new variables were identified, the clustering algorithm was run and key statistical measures were used to determine how many clusters were most appropriate for the data. The analysis resulted in the identification of seven clusters of the 58 DSAs.

UNOS staff provided members with a summary of the seven clusters that were identified. There were five OPOs that seemed to potentially fit into other groups more appropriately than the first clustering they were put into. There are a wide variety of OPO performances within each cluster. This information provides a solid framework and foundation for OPOs within each group to consider working with OPOs to consider best practices going forward.

The Committee Chair asked for further clarification on the clusters goodness-of-fit and the variation on whether they fell above or below the red line. UNOS staff clarified that within the clustering, this was called the average silhouette width. There may be other measures that weren't considered that may help with placing OPOs better in the next iteration. There were no additional comments or questions.

**8. Donation after Circulatory Death (DCD) Policy Review Project**

UNOS staff provided members with an update of the Committee's pending Donation after Cardiac Death (DCD) policy review project. The Committee discussed the next steps for the project.

Summary of discussion:

UNOS staff began by providing members with background information on the DCD project. Committee leadership received an e-mail from a member expressing concerns about the DCD policy and the timing of when OPOs can initiate organ donation discussion. There was a request for the OPO Committee to review the policy language. A small work group was formed where an initial conference call was held in January 2018. There was a project form developed and the work group reviewed the policy in March 2018. There were a number of priorities that put the project on hold. UNOS staff asked the Committee if this project was considered a high priority to reconvene.

The Committee Chair asked for clarification that the DCD project would be something the Committee might consider keeping on hold until the expedited placement proposal gets revised in time for the fall 2019 public comment cycle.

A member stated that this is a tool that could help OPOs perform better. Another member added that involving palliative care would offer the opportunity for families to help make that decision and honor the wishes of their loved ones.

The Committee Chair asked for clarification that in moving forward with this project, the next step would be to submit the project form for review and approval to the Public Oversight Committee (POC). UNOS staff confirmed that this was correct and that it would require a review of the project form to determine if there was additional information that should be included. Additionally, the project form will need to be updated with a revised timeline.

UNOS staff asked members if it would be reasonable for the Committee to finish the expedited placement proposal and then reconvene with the DCD project at the end of the summer.

The Committee agreed to move forward with the DCD project. The Committee would first focus on the revisions of the expedited placement proposal then submit the project form for the DCD policy review project for POC approval. The DCD project would still be worked on within the work group during this time.

**9. Deceased Donor Registration (DDR) Review Project**

UNOS staff provided an overview of the Committee's Deceased Donor Registration (DDR) review project and discussed next steps of the project with members.

Summary of discussion:

During the fall 2018 meeting, the Committee reviewed a list of member questions about the data elements and help documentation in the DDR.

UNOS staff proposed that this project would consist of reviewing and revising the DDR. Members noted that the information entered on the DDR is important for data analysis by both the SRTR and OPTN. The members agreed that this is a project the Committee would like to move forward with.

UNOS staff stated that in addition to the organ specific committees, the Committee would also collaborate with the Data Advisory Committee (DAC) and the UNOS Data Governance department. UNOS Data Governance is charged with setting and supporting data policies and standards, assessing and improving data quality, and standardizing data asset documentation.

UNOS staff stated that for next steps, there would need to be a small group of volunteers to help develop the project plan. UNOS staff outlined the information that would need to be included in the project form.

Next Steps:

- UNOS staff will send out an e-mail to the Committee for volunteers to help with the development of the project.

**10. Data Advisory Committee (DAC) – Modify Data Submission Policies**

UNOS staff provided an overview of the Data Advisory Committee's (DAC) proposed project to modify data submission policies.

Summary of discussion:

Currently, the DAC is in the process of revising sections of *OPTN Policy 18: Data Submission Requirements* with the plan to submit a public comment proposal in time for the fall 2019 public comment cycle.

UNOS staff noted that there are conflicting policies that have led to confusion about the primary timeframe that data needs to be submitted. This project is focused on the forms that are in the Transplant Information Electronic Data Interchange (TIEDI). Per *OPTN Policy 18.1: Data Submission Requirements for OPOs and Deceased Donor Registration Form*, OPOs are required to submit the DDR within 30 days after completing the donor organ disposition. Under *OPTN Policy 18.4: Data Submission Standards*, the policy language indicates that only 95% of the required forms are required to be submitted.

The DAC is asking the OPO Committee for feedback on the plan to eliminate OPTN Policy 18.4 and to get the information submitted in a more efficient manner. This proposed change would not require OPOs to submit any additional data. The DAC also proposes the implementation of a "data lock" to ensure data integrity. This could take the form of policy language, IT programming, or a combination of both.

A member asked if there was an audit log done to see how often changes were made. UNOS staff confirmed that there is an audit log. Research has looked at what those differences are and it differs on the form type. The member continued that they would need to ask their staff about the timeframes and having data to review would be helpful in determining this.

Another member stated that many OPOs have quality departments that enter the information. Since these staff are not clinical, there could be considerable changes that need to be made, but a lot of times these cannot be completed within the 30 days. The member noted that there are issues with the DDR and there continues to be errors with data entry within these forms. The member noted that it highlights the importance of developing a DDR review project.

The Committee Chair stated that the data would provide and help guide the conversation. In concept, locking the information would make sense as it is currently done in practice within OPO's electronic medical record (EMR) systems. The data would need to show what timeframe makes sense. UNOS staff clarified that the committee is conceptually in agreement with a data lock but would like to find out how frequently OPOs are currently making changes and the timeframes they are made. Members agreed with this.

UNOS staff asked what current challenges OPOs are facing. A member stated that the redundancy is a challenge because ultimately, the information has to be re-entered. Another member added that the questions in general are not helpful or relevant for any research study.

UNOS staff asked members if they were in favor of the DAC's proposal of eliminating OPTN Policy 18.4. A member stated that it would be difficult to go back to Policy 18.1 without some variation of Policy 18.4 because 30 days in unrealistic to be able to internally audit what has been entered. Another member stated that the data could be entered within 30 days, but it is not guaranteed that this information would be accurate. There may need to be some revisions of the data after the 30 day timeframe.

The Committee Chair stated at this time, it is uncertain to determine the elimination of OPTN Policy 18.4. The data would show a lot more information, such as how often OPOs are going back into the DDR, what time intervals, and which data are continuously being revised.

HRSA staff stated that the data process is clearly addressed in the new OPTN contract. It is understood that the data goes into the system and that the data needs to be available to the community. The OPTN cannot function without the data and these discussions will be ongoing. UNOS staff noted that the DAC will be interacting with every committee to gain their feedback.

A member asked if there is broad representation on the DAC. UNOS staff clarified that there currently is not representation from the histocompatibility community but there have been discussions increase the representation.

There were no additional comments or questions. The meeting was adjourned.

**Upcoming Meeting**

- TBD