

**OPTN Board of Directors
Meeting Summary
June 29, 2020
Conference Call**

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Introduction

The Board of Directors met via teleconference on June 29, 2020 to discuss the following agenda items:

1. Finance Committee Report
2. 2021-2024 Strategic Planning Work Group Report-Outs & Discussion
3. Adjourn

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

1. Finance Committee Report

The UNOS Director of Finance and the BOD Treasurer presented the FY 2020 finance overview, including the FY2021 proposed OPTN budget and FY2019 audit, which were discussed with the OPTN Finance Committee on June 8, 2020.

Data summary:

An FY2019 single audit occurred since the last Board meeting to ensure UNOS has met all compliance requirements in material aspects with federal appropriations from HHS and HRSA. The audit was clean with no adjustments needed. The philosophy for the investment portfolios is active management, meaning the investment advisor maintains allocations so the assets are liquid. As of May 2020, the investments are performing slightly below certain agreed-upon benchmarks, but nothing alarming due to the volatility in the market currently.

The budget and fee proposed for FY2020 were discussed at the 6/8/2020 meeting. The Finance Committee therefore recommended the budget and fee for approval, but recommended that the OPTN fee remain consistent at \$748, thereby negating the need for the Board to vote on the fee, but the Board will still vote on the budget and audit.

Due to COVID-19, registration funding has been below expectation. Budgets will very likely be evaluated again after the summer, when curves return to more normal levels. Back in 2016, 2017 and 2018 when registrations were going to record levels, UNOS had more cash and set a level that reserve operating cash would have to exceed at least 2 months of operating expenses, roughly \$10 million. At the end of June, there will be about \$22 million in the cash accounts, down from \$27 million from 9/30/2019. Cash reserves are beginning to be used, as designed, and will likely come back down to the minimum levels of reserve. There has been a lot of volatility in investments, so there was reallocation was done in March and April, but the portfolio remains conservative.

The budget fell short of \$748 for every registration lost. April and May fell short of the budget by \$3,840. As of June 2020, the registrations are short 3,751, equaling about \$1.1 million that would have come into UNOS to be spent at a later time on services. The 3,500 June 2020 registrations look better than what the new forecast predicted, but still far off from last year's prediction.

As of May 2020, revenue equals expenses. When people go on the registration list, they are sent a bill, pay UNOS, and \$748 of the \$926 fee goes into the cash account. All expenses have to be calculated and a monthly voucher is submitted to HRSA. HRSA then reimburses expenses that meet guidelines and compliance factors. Therefore, for example, the money collected in May might not be used towards expenses until July. A million dollars more has gone into OPTN costs than what was budgeted for. Resources are still being used on OPTN-approved tasks. Dollar amounts and operating accounts are coming down because not as much money is going into them because of the decrease in registrations. The organization is actually exceeding requirements and delivery of tasks, while cash and investments are actively managed.

The OPTN balance sheet as of May 2020 was presented, showing the cash position is strong. As the money comes in, services must be performed before the money may be kept.

The Board will vote today on the 2021 budget, and the budget overview is presented. It estimates 62,500 registrations for FY2021, \$748 for each registration. Of the operating cash previously collected, \$5.6 million will be put into OPTN expenses in FY2021. The contract calls for \$6 million of federal appropriation for FY2021. There is negotiation currently around contract modification for \$617,000, which will likely happen, but if not, expenses would remain at \$58,967,000 and withdrawal from operating account would increase the \$5.6 million by 617,000.

Expenses were also reviewed. Salaries and benefits increased by 5% or 6%. In December/January, due to amount of requests from committees and members, as well as record registrations and the good economy at the time, IT staff, member quality, and research employees were added. However, a pause has been put additional staff that have not been hired yet, accounting for about a million dollars of the \$2.5 million variance. Additionally, a 1.5% merit increase is being budgeted for staff, which has historically been 3.25%, accounting for about \$600,000 of the variance. Indirect costs for FY2021 will be about 14.58% versus 12.5% in FY2020.

The OPTN fee calculation is broken down to \$46.75 million registrations to meet the OPTN expense goal. Again, there is no fee change proposed for FY2021.

Summary of discussion:

One Committee member asked why UNOS takes an active management strategy, which to his understanding tends to be associated with higher fees without any improved performance. It was clarified that there are two different philosophies. With SunTrust, the fees are generally higher than a passive industry, which makes sense for benchmarks and index funds for the casual investor. The investment portfolio could potentially be split to be half active and half passive.

Another Committee member stated the Secretary needs to approve the fee, so the OPTN will need to send a notification to HRSA of the fee, even though it will remain unchanged. This will be done by 7/1/2020. The fee is not in a resolution because it is in the policy.

Regarding changes due to COVID-19, no new significant cost or loss is expected due to COVID. There has been a level of downturn in cash position due to COVID. Covering more of the OPTN cost with previously-collected dollars will be proposed.

One question was regarding how the rebalancing of the portfolio was done. During the course of the period when things were falling, the portfolio went from allocation of 65% in equities to perhaps 58% of equities, leaving half a million to a million dollars of market value off the table. The current position may not give the best upside, but protects from a large downside.

One concern brought up was that in the past it seemed UNOS spent lobbying money to prevent other entities from competing for OPTN contracts. If that is true, how is that financed? UNOS staff clarified that there is no OPTN money being spent on government relations at all.

Following the presentation and discussion, a motion was made and seconded for the Board of Directors to approve Resolution 1 to accept the 2019 audit report. A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

A motion was made and seconded for the Board of Directors to approve Resolution 2 to approve the OPTN 2020-2021 operating budget as highlighted today and as in the provided materials. A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

Next steps:

The Chair thanked the Finance Committee for their hard work and stated that although the BOD voted today to approve the budget as proposed, it may need to be reevaluated on a more frequent basis than in the past.

2. 2021-2024 Strategic Planning Work Group Report-Outs & Discussion

The Board President introduced the next speakers. As announced at the previous Board meeting, the 2021-2024 strategic planning process was kicked off virtually in June. All current and incoming Board members and Committee Chairs were divided into six groups of about 15 people each and invited to weigh in via collaboration sites on the initiatives on the current plan: whether an initiative should be kept, amended, or removed, and whether new initiatives should be added to the next plan. Then, each group met by phone to identify the high strategic priority items for future focus.

The work group leaders individually presented high-level report-outs of their discussions.

a) Group 4

One charge for the work groups was to look at the many initiatives. The work group did not want to lose the focus and the ability to recognize or continue to do better by eliminating any of the initiatives. The number one goal should always be increase in number of transplants, and all other goals need to continue to support this. The success of processes of OPOs and transplant programs needs to continue to be communicated. It is not feasible to have similar expectations for different processes of 58 different OPOs, if there is a better way within policy to standardize more of that. The work group believes there are too many impediments for the sharing of organs. Success has been made on groups like MPSC to focus on collaborative improvements, rather than disciplinary action, as well as encouraging members to avoid making the same mistakes in self-reporting. Vulnerable populations need to continue to be identified, as this is a great opportunity for distribution. For example, are kidney transplant alone patients being disadvantaged and not receiving the same opportunity as multiorgan candidates? The work group discussed at length the longevity of transplants, as well as organ wastage and looking closely at matching donors and recipients.

UNet should continue to be modernized and upgraded with real-time communication availability. There was trouble around refusal codes and whether the focus should be more on why organs are not being accepted. Unless there is a concomitant change in how organs are allocated, the survival benefit falls flat if the organ cannot get to the right patient who will have the greatest survival with that particular organ. Efficacy of policy and implementation process was challenging, as some members felt the process takes too long to be able to pivot when there is a need for a change.

The equity benchmark for each organ is unclear at this time and is being worked on. Safety for living donation was discussed looking more long-term towards donors and more need to focus on the logistics in transplant transportation and tracking. There was less concern around safety incidence regarding organ transplant.

There was little discussion around improving waitlist living donor and transplant recipient outcomes, but the focus was more on waitlist goals and outcomes as a surrogate for attention to vulnerable populations and improved efficiency in organ allocation, as well as creating a dashboard to see how the system as a whole is functioning to take responsibility on metrics that need to be improved upon. There was also discussion about success of the COIIN process around DCD donation and utilization.

The overall discussion of Work Group 4 was a good start in trying to move the plan forward.

b) Group 1

Everyone generally agreed with all of the goals and that those are the goals, although there was some discussion about goal #5 perhaps being a little redundant with goal #1. Goal #5 should not be abandoned, but perhaps looked at differently.

Most of the conversation centered around the need to beef up refusal codes, how they need to be more consistently applied, as well as the idea of promoting DCD donors, and utilization of perfusion machines and their overall importance. There were many comments regarding the initiatives in providing equity in access to transplant, as well as the notion of evaluating diversity.

Goal #3 regarding improving the waitlist got as many as five likes, later getting as many as seven likes. They believe the enhancement of the transplant program tools in education and selection and follow-up of living donors is a good idea.

One group member suggested that based on the public comment submitted by the OPTN supporting decreasing disincentives to living donation, Goal #1, promote, educate, and increase living organ donation, should be considered, as well as transparency about risks and benefits, and increasing support for organ donors. Another group member made a suggestion around getting the right kidney to the patient in the right amount of time, and that the allocation system needs to be refined to get less-than-ideal kidneys to aggressive kidney transplant centers with limited cold ischemic time. Another suggestion was to create a national system of shared scanned kidney biopsies, including pictures, to increase transplant centers' abilities to access biopsies and have all the kidneys read by experienced transplant pathologists.

Regarding Goal #1, one member felt there should be a focus on pediatric waitlist outcomes, with the intent to focus on OPTN Pediatric Committee as presented through a poster at the recent ATC meeting, and to identify specific age and status determinants that impact mortality for each of the organs specific to children.

For Goal #5, one member suggested continuing more projects like the Kidney Allocation Project with the intent to allow members to see what is actually accepted for utilization to more efficiency offer kidneys to others.

One last suggestion was that idea of people becoming organs should be promoted more. Currently, ambassadors and OPOs promote this, but there may be some lobbying efforts in Washington that could be fostered. Transplant programs should be educating recipients about

donor registries. Their relatives and friends should be encouraged to become donors as part of the education provided to potential transplant recipients.

There were no suggestions to remove any initiatives, but there was also little discussion around some of the initiatives.

c) Group 2

Group 2 had a variety of different perspectives. In the beginning, some of the initiatives seemed vague, and so they had to get some clarification and have discussions about that. Initiatives that garnered the most discussion were around the diversity of the board and collecting data of vulnerable populations, as well as doing a better job of serving all patients in all communities and making sure all voices are heard. Specifically, they discussed what the vulnerable populations are. They need to be granular and thoughtful about collecting data on all populations, not just vulnerable populations, for the sake of comparison.

The refusal codes could be made as a drop-down menu, so that it will be easier to get data from them. This work group was led by a donor family member and so discussion was around how increasing the amount of better matches in a shorter amount of time is important from the donor family perspective. Sometimes getting hung up on trying to do the right matches increases time, so using technology previously brought up, such as to share biopsy information, would be helpful.

The group felt most of the initiatives were good, though some overlapped a little. Specifically, in Goal #4, initiative 3, would really mark on that and initiatives 4 and 5 overlapped. Therefore, there may be ways to combine some of the initiatives, as some work has already been done on some of them. They felt a better job could be done with living kidney donors. There are many different kidney paired exchange programs across the country and perhaps one better system for paired kidney paired exchange could be created.

d) Group 5

As the work group met, it was clear that a lot of work had already been done on many of the initiatives, but there is still work to be done.

Goal 1, initiative 4 to continue to define and refine OPO transplant performance metrics was at the top of the work group's list of work that needed to be done. They also want to continue to evaluate reducing geographic disparity and access to transplant, especially in vulnerable populations, and evaluate effective messages for assessing living donor outcomes.

For Goal 3, they wanted to focus more on increasing living donation. There was much discussion on an effective message for assessing living donation. They also felt improvement was needed for Goal 5, initiative 3, improving efficiency and policy management, as well as increasing seamless data exchange between members in UNet.

Regarding Goal 2, initiative 3, increased racial ethnic and professional diversity on the Board, the group would like to refine and expand the list of diversity targets beyond racial, ethnic, and professional to consider gender, age, and things like transplant considerations.

The group struck many initiatives that they felt had already been addressed, were strong enough to live on their own, and could be replaced by other initiatives. These include improving the ability to perform analysis or refusal reasons and expanding the use of collaborative improvement methodologies.

They also wanted to make new initiatives. The first is to improve DCD donation rates, which is a wide and varied process across the country. It needs to improve in both organ donation and transplant acceptance rates. They also want to make a new initiative of supporting machine perfusion.

e) Group 3

The work group found it difficult to cover 36 initiatives in an hour, so tried to simplify things. They felt there are many things already in place regarding kidney paired exchanges, but to keep it as a strategic goal. One issue brought up was trying to make sure that as transplants are increased, there are no disparities such as the wealthy getting more and the poor getting worse. They liked Goal 2, equity and access to transplants, but felt equity needs to be more clearly defined so that when strategic goals are sent to the committees, they can follow along those lines. They also agreed that they need to look at vulnerable populations more closely. Patients who are on the waitlist are taken care of during the transplant and post-transplant, but there is the issue of evaluating between having end-stage organ disease to the point of being evaluated for the waitlist. The end-stage renal disease group works on that, but there is no opportunity for other ones, which may give a better idea about equity to access. Places like South Dakota, Idaho and Wyoming do not have access to a liver transplant center for hundreds of miles, thereby creating an access issue.

For Goal 3, one issue that came up in conversation is trying to find out what's more important, longevity or the sickest transplant candidates. They felt the transplanting the sickest people first should be the general rule of thumb, but this does not necessarily mean longer organ life. In addition, they felt there is a lot of redundancy between Goals 4 and 5.

The work group agreed with increasing efficiency of organ allocation and efficiency of clamp time to placement time, but feel that the OPO Committee should develop their own strategic goal, rather than the Board deciding what each initiative is for each committee. They feel the Board should just give general strategic goals and make the committees and the membership work on the rest.

f) Group 6

The work group went through the initiatives one by one and their consensus was that the overall goal is to increase transplants, but they also wanted to concentrate on the initiatives that do not have any collaborations or projects going on at the moment. They also felt that many initiatives were redundant and could be combined with other goals or initiatives.

They agreed Goal 1 was important, but wanted to change the focus of initiative 4 to unifying the metrics to increase transplants, not so much as punitive measures. They felt initiative 3 was too broad, but wanted more collaboration with the community on that.

They decided to remove almost all of the initiatives in Goal 2, as they have already been addressed at length.

The group added an initiative to Goal 3. They felt that one thing not mentioned was adding an initiative to change the practice and programs, which can be very difficult to do. Change of practice to utilize organs that transplant centers are offered should be worked on. Initiative 4 and 5 are redundant and could be combined.

For Goal 4, they felt resources should be allocated to improving accuracy in HLA reporting. They were unsure whether initiative 2, decreasing the number of safety incidents, was a big issue and removed it to concentrate on bigger issues.

After brief review of Goal 5, they felt initiative 2 was appropriate, as it is unrealistic to not ever have any down time in UNet.

Summary of discussion:

The Board President stated that the challenge will be to try to define the bigger buckets. There were some themes that came through during work group report-outs. This will be the start of the process, to continue through eventual ratification at the June 2021 Board meeting.

A Board member expressed that when thinking of strategic goals, they think strategically and not tactically, but many of the initiatives were very tactical. He inquired as to whether this is how it has been done in the past. UNOS staff clarified that with the number of Board of Directors' members and the range of things that they cover, they ended up with a hybrid strategic plan. If they had the broad goals of increasing transplants and creating more equity, it would not provide a great deal of direction to the committees or the staff as to what the Board wanted them to focus on in order to reach those goals. Therefore, they would not want to predetermine the exact calculation of a new metric in the strategic plan yet. For example, if they wanted to create equity, but focus on a particular area that is inequitable, calling out that area would give the committees and the staff some to direction as to what the project is. Doing this allows room for the committees to create and innovate in pursuing those directions from the Board. Overall, all groups touched on the fact that there were too many initiatives, and expressed a desire to focus strategic efforts over the next several years on a few key areas. This does not mean stopping work on other important areas.

Another work group member agreed that there are areas of policy development that are directed by the Board to support the specific strategic goals. Then the committees would do the work of developing the specific projects themselves that will support the initiatives and goals. She did feel that some of the initiatives seem too specific, but still wants to keep some initiatives to so a committee such as the Policy Oversight Committee can take that direction and coordinate the work across the committees effectively.

One Board member felt this is generally a complicated process and felt the overriding issue and the defining issue for the OPTN is to look at OPO performance. This has not been done in a meaningful way as far as he understands. He stated that the potential pool of donors is three times what it actually is and there are OPOs right next to each other that have dramatically different donation rates. He also felt there is an opportunity to end the deaths on the waiting list for lung, liver, and heart recipients within the next few years, but there has not been a lot of work around it and no one has been held responsible for the performance of the OPOs.

Another Board member stated his work group agreed that OPO performance is an issue, particularly the variability of OPOs, but does not want to give the impression that changing OPO metrics will eliminate the transplant waiting list. Further, the data cited by their colleague is not supported by evidence. Focusing on one thing is not a healthy strategic planning process. OPO performance is indeed critical, but he disagrees that it is the one issue that needs to be focused on.

After public comment, it will go back through the Executive Committee, back through the Board, and finalized in June of 2021. That will then be the plan to guide the next 3 years.

Next steps:

Things that are within the scope of OPTN will be addressed as the actual plan is being developed. UNOS staff clarified that it is still early in the process. If it were not for COVID, the discussions would have taken place on the same day at an in-person Board meeting. Board members, incoming Board members, Committee Chairs, and incoming Committee Chairs can continue to submit comments. They will then take all that information and shape it into a draft based on the where the priorities of the Board are. They will engage the committees by reviewing a draft by going through the POC and the Executive Committee will edit and finalize the draft. Then a draft report will be brought before the Board at the December meeting for the Board to review, edit, and approve to go out to public comment in January 2021.

3. Adjourn

All upcoming fall regional meetings are scheduled and will be held virtually, with details forthcoming.