

**OPTN Living Donor Committee
Meeting Minutes
April 1, 2019
Chicago, IL**

**Randy Schaffer III, MD, Chair
Heather Hunt, JD, Vice Chair**

Introduction

The Living Donor Committee met in Chicago, IL on 4/1/2019 to discuss the following agenda items:

1. Living Donor Data Request
2. Maintenance Dialysis Proposal Update
3. Scientific Registry of Transplant Recipients (SRTR) Living Donor Collective Update
4. Vascularized Composite Allograft Transplantation (VCA) Committee Presentation
5. Open Discussion
6. Committee Service Recognition and Incoming Roster
7. Data Advisory Committee (DAC) Presentation
8. Stakeholder Committee Engagement and Updates from Other Committees
9. Social Media Guidance Document Planning

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

1. Living Donor Data Request

United Network for Organ Sharing (UNOS) staff presented a data report based on a request from the Committee to analyze living donor short-term outcomes. The Committee specifically requested an analyses of short-term outcomes for living donors as reported to the Organ Procurement and Transplantation Network (OPTN) via living donor registrations and the Living Donor Follow-up (LDF) form.

UNOS staff reviewed the current, available data for the Committee, which then discussed the relevant findings and potential pathways for dissemination of this data to the transplant community / general public as well as future data collection goals. The Committee had several clarifying questions regarding available Kidney Paired Donation (KPD) follow-up information and how to better collect this data. The Chair suggested the Committee compile a list of questions to forward to the KPD Workgroup and Data Advisory Committee (DAC) to consider for further data collection in the future. The Committee discussed that future work will involve evaluating and developing policy surrounding living Vascularized Composite Allograft (VCA) donation follow up.

2. Maintenance Dialysis Proposal Update

UNOS staff gave the Committee an update on the recently closed public comment period and analysis of feedback on the *Clarifications on Reporting Maintenance Dialysis* proposal. Regional and public comment feedback were very positive with majority of sentiment supporting the proposal.

There were no questions from the Committee.

Next Steps

UNOS staff will be writing the post-public comment briefing paper to go to the Board of Directors in June. Committee leadership will also be involved in drafting the briefing paper. Once written, it will go back to the Policy Oversight Committee (POC) and a Board Policy group and then the

Executive Committee where they will decide whether the proposal will go on the consent agenda or regular agenda.

3. Scientific Registry of Transplant Recipients (SRTR) Living Donor Collective Update

SRTR staff presented an update on the Living Donor Collective pilot. The pilot is a living donor registry to study long-term outcomes of living donation to include health outcomes, psychosocial implications, and economic burden.

SRTR has identified ten kidney programs and six liver programs to serve as pilot sites for the project. A Living Donor Advisory Committee has also been established. The Advisory Committee collaborated to develop data collection forms which were approved by the OMB in January of 2018. A public website with information about the project has been published and is geared toward patients for education about the project. The web-based data portal has been developed and started collecting data in May of 2018.

Summary of discussion:

The Committee asked what percent of total donors at these centers are data being collected for. SRTR staff answered the programs participating in the pilot are recording 100% of their living donors.

One Committee member asked what the purpose of collecting household income level data is considering some patients are uncomfortable disclosing this data. SRTR staff said it is a question that has been challenging and will need to be revisited.

One Committee member suggested as a long-term goal to develop a way to remind patients of the importance of follow up care.

Next steps:

SRTR will conduct calls with pilot sites to discuss challenges, successful processes, data issues, etc. There will be an in-person meeting in July 2019. SRTR will also review the data elements that have been challenging to collect and assess time and effort for programs to identify best practices going forward.

SRTR will also conduct follow up with candidates in April 2019 starting with an automatic email outreach campaign with a link to a survey, followed up by phone calls or other communication methods.

4. Vascularized Composite Allograft Transplantation (VCA) Committee Presentation

The Chair of the VCA Committee gave an update on the current state of living donor elements of VCA transplantation and potential collaboration between the VCA and Living Donor Committees. The current data collected for VCA living donors are limited and are collected for two years post-transplant.

One of the VCA Committee projects is to modify the data being collected on VCA transplants. They've formed subcommittees to work on specific data collection and could work collaboratively with Living Donor Committee members.

Summary of discussion:

A Committee member asked what the mechanism is for VCA living donor follow-up reporting. UNOS staff answered for VCA recipients and candidates, fillable PDFs are sent by secure email. For VCA living donors, UNOS does not currently have forms and instead uses voluntary data submission. A spreadsheet is sent to them by secure email and it's sent back by secure email.

Another Committee member asked within the VCA community, if there is a common approach to the evaluation of VCA living donors. The VCA Chair answered every transplant hospital has their own guidelines.

The Committee discussed the ethical implications of living VCA donation. The VCA Chair stated that is a concern of the VCA community as well. In addition, the psychosocial component of living VCA donation is very important to the subcommittee and they will be looking at ways to collect this data.

A Committee member asked what the acceptable cold ischemic time (CIT) is for a deceased donor uterus. The VCA Chair answered there is not enough data to determine the CIT.

Next steps:

The VCA Committee is sending their *Eliminate the use of Regions in VCA Distribution* proposal to the OPTN Board of Directors in June with a proposed circle size of 500 NM.

5. Open Discussion

The Chair opened the floor for Committee discussion.

Summary of discussion:

A Committee member suggested taking a deeper look at the data included in the UNOS data report presented earlier in the day. For example, the Committee would like to use the data to determine the risk of end-stage renal disease (ESRD) for prior living kidney donors. The Committee has heard feedback from the transplant community on the challenge of living donor follow-up and the need to make the forms more relevant and efficient. UNOS staff will create a new committee project form for optimizing living donor follow-up data.

A Committee member referenced the ethnic disparity in living donation shown in the UNOS data presentation and questioned whether some transplant hospitals are more reluctant to use donors from certain populations due to genetic medical factors and potential outcomes. Other Committee members expressed seeing similar disparities at their respective transplant hospitals. The Committee member suggested the Committee develop some guidelines for transplant hospitals regarding this issue.

6. Committee Service Recognition and Incoming Roster

UNOS staff gave an overview of the committee roster changes effective July 1, 2019. The Chair recognized the service of outgoing committee members and welcomed incoming committee members.

There were no comments from the Committee.

7. Data Advisory Committee (DAC) Presentation

UNOS staff presented an update on a project the Data Advisory Committee (DAC) is working on. The Committee is proposing changes to *OPTN Policy 18: Data Submission Requirements* to go out for public comment in the fall of 2019. Members expressed confusion between the language in *Policy 18.1: Data Submission Requirements for Recovery Hospitals and Pertaining to Living Donors* and *Policy 18.4: Data Submission Standards*. The DAC is considering eliminating *Policy 18.4* to relieve this confusion. The DAC is also considering ways to ensure data integrity and possibly implementing a “data lock” date when changes would no longer be possible after a certain time period. The DAC is reaching out to stakeholder committees impacted by the requirements in *Policy 18* to get a sense of challenges the members may have in terms of submitting their data timely and accurately and how these potential changes could impact them.

Summary of discussion:

A Committee member asked how this change would impact the pre-validation process for use in SRTR reports. UNOS staff answered the goal is to make the initial submission as accurately as possible so there isn't a need to go back and change information.

The Committee asked what the average reason is for changes to data entry. UNOS staff answered some values that had been entered were being changed as opposed to values that were missing being filled in. The goal is to have the initial submission be the accurate submission which is why DAC is reaching out to stakeholder committees to see what barriers prevent that from happening.

The Committee expressed concern over the limitations of a specific time frame to enter data without being able to go back and edit the data for accuracy. The Chair clarified in the living donor community, a transplant hospital may acquire the appropriate data on a later date and want to go back and update the record. One Committee member suggested creating a data lock more in sync with CMS timelines.

In summary, the Committee suggests:

- Keeping current deadlines according to *OPTN Policy 18.1*
- Extending the data lock period past 60 days, possibly 90 days
- If after the data lock period a member must update the form for accuracy, there should be a process to identify why the member needs to make the changes and what changes are made

Additionally, the Committee requested clarification on what specific forms are included in *OPTN Policy 18.1*.

8. Stakeholder Committee Engagement and Updates from other Committees

The Chair asked Committee members for updates on other committees they serve on.

Summary of discussion:

The Patient Affairs Committee has been reviewing public comment proposals. They recently held their in-person meeting and kicked off some subgroups, one of which is focused on patient engagement. Also in response to patient feedback, UNOS policy staff is working on creating more digestible language for upcoming proposals and briefing papers.

The Policy Oversight Committee (POC) did not have a fall in-person meeting but will have one in May 2019. The POC is currently overseeing all of the geography projects.

The Chair presented the Committee with the newly developed cross-committee collaboration dashboard which details which committees are collaborating together for specific proposals.

9. Social Media Guidance Document Planning

The Vice Chair gave the Committee an update on the project. The project form was reviewed by the Policy Oversight Committee (POC) last week and was approved. It will now move to the Executive Committee on April 12.

Summary of discussion:

The Vice Chair asked for the Committee's feedback on what is drafted so far.

The Committee members made the following suggestions for consideration:

- Create a survey for transplant hospitals to query their best practices
- Consider the patient or patient family perspective

- Include guide on proper terminology for potential donors
- Develop guidelines on how transplant hospitals can process a large volume of calls
- Use community listservs to solicit feedback
- Create a project timeline to help limit scope of project

UNOS staff and the Chair reminded the Committee to consider this guidance document as an education piece for best practices for transplant hospitals, not a patient resource.

Next Steps

The Vice Chair asked the Committee members to think about these suggestions and collect their thoughts to be discussed at the next committee meeting. Committee members were also encouraged to think of potential obstacles and how to overcome them as the project moves ahead. Committee members will also consider which project elements and focus areas interest them individually going forward.

UNOS staff will also work to assemble a presentation on the development of the past Collaborative Innovation and Improvement Network (COIIN) project and identified successes and challenges throughout that project.

Upcoming Meeting

- May 8, 2019 – Teleconference
- June 12, 2019 - Teleconference