**OPTN/UNOS Living Donor Committee**
**Meeting Minutes**
**March 27, 2017**
**Chicago, IL**

**Krista Lentine, MD, PhD, Chair**
**Randolph Schaffer, MD, Vice Chair**

## Introduction

The Living Donor Committee met in Chicago on 03/27/2017 to discuss the following agenda items:

1. Opening Remarks
2. Status of Recent Projects
3. Current Projects
4. Living Donation and Transplantation
5. Living Donor Collective
6. Improving Living Donor Follow-up
7. Drug Overdose Deaths in Organ Donation
8. Tribute to Members Ending their Term on the Committee
9. UNOS Kidney Learning Center
10. Informational Items
11. Potential New Projects

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

## 1. Opening Remarks

Summary of Discussion

The Committee Chair opened the meeting and welcomed the HRSA representative and UNOS' Director of Policy. All members were encouraged to participate in the meeting to help insure all perspectives are heard. She announced that a current and former member of the Committee have been elected to serve on the OPTN/UNOS Board beginning in July 2017. The Chair led a review of the Committee charge:

> The Living Donor Committee develops policy and guidance related to the donation and transplantation of organs from living donors to recipients. The goal of the Committee's work is to continue to improve the informed choice of prospective living donors, and the safety, protection and follow-up of all living donors.

The vice Chair provided a Policy Oversight Committee (POC) update. He explained why the POC reviews projects which included to:

- Assign the project to the correct primary strategic goal (1-5)
- Continue to work towards alignment of the project portfolio with the OPTN Strategic Plan
- Prioritize resources
- Ensure collaboration with key stakeholders and provide feedback to sponsoring committees
- Make a recommendation to the Executive Committee

The vice Chair reviewed the strategic plan and provided an update on the current strategic alignment. He reviewed a list of recent projects approved by the POC and provided information on how the POC reviews and scores proposed projects.

The Committee vice Chair led an ice breaker activity. In preparation for this meeting, all members were asked to propose a potential new project and to complete a new project worksheet for their project. Committee members were randomly split into three groups and instructed to discuss their project within their group. After 30 minutes the meeting resumed and members were asked to briefly introduce themselves and to give a one minute synopsis of their project. Members were asked to listen to the presentations and to consider which proposed projects they would support as future work for the Committee.

**2. Status of Recent Projects**

Summary of Discussion

The Chair discussed the status of a recent project entitled Modifications to Informed Consent Requirements for Potential Living Donors that was approved by the OPTN/UNOS Board in December 2016. Based on feedback from members of the Transplant Coordinators and Transplant Administrators Committee, the implementation date for these new or modified informed consent requirements will be delayed until June 1, 2017. The delayed implementation will allow more time for living donor recovery hospitals to update their informed consent forms and processes.

**3. Current Projects**

Summary of Discussion

*Removing Disincentives for Candidates to Consider Living Donation*

The Chair explained that this project has involved the development of a new brochure to educate transplant candidates about strategies for identifying a potential living donor. As an education resource, the brochure will not require public comment. The project includes an Evidence Supplement as a resource for transplant professionals describing the evidence that has been published to support the strategies identified in the candidate brochure. The brochure was developed by a work group of committee members and then sent for extensive review by subject matter experts, a Health Literacy organization, and six UNOS Committees (Patient Affair, Minority Affairs, Pediatric, Transplant Coordinators, Transplant Administrators and the Organ Procurement Organization Committees). Final editing on the resource is nearly complete. Next steps will include formatting and branding by UNOS Communications and to identify potential corporate funding to produce hard copies of the brochure.

Next steps:

Current dissemination plans include promotion of the new resource by UNOS Communications or Instructional Innovations. The Committee will plan to provide an update at regional meetings during the next public comment cycle to promote this new resource.

*Template for Informed Consent Requirements*

The Committee received requests for an informed consent policy checklist during public comment for recent changes to informed consent policy. A checklist had been provided when the informed consent policies were first implemented (February 2013) but were later discontinued by UNOS Department of Evaluation and Quality (now Member Quality). The checklist has been completed and UNOS Member Quality and Legal have approved a disclaimer for the resource which reads

*This checklist contains elements typically reviewed as part of OPTN routine survey activities of living donor recovery hospitals. Use of this checklist is not an OPTN obligation and does not guarantee an assessment of compliance with OPTN obligations upon a site survey. This checklist is intended to guide the development of center-specific processes and tools.*

Next steps:

The dissemination plan is to promote this new resources over the next few months and to make the resource available through the OPTN web site when the updates to current living donor informed consent requirements take effect on June 1, 2017. The checklist is based on living donor informed consent policy effective June 1, 2017. Members could choose to use this resource on a voluntary basis. The Living Donor Committee will be responsible for updating the checklist to reflect any future changes to living donor informed consent policies.

*Lay Person Version of Informed Consent Requirements*

The Committee received comments about the complexity of the current living donor informed consent requirements during the fall 2016 public comment cycle. The Committee determined that current informed consent policies are written for transplant professional at a college reading level and may be difficult to understand by potential living donors. In response, the Committee is developing a lay language version of the informed consent policies. UNOS Communications is assisting with this project and provided an update on progress to date during the Committee's March 8th web conference. The current draft, provided in the meeting materials, is now at 10th grade reading level.

Next steps:

The goal is to continue to lower the reading level and to have this resource available on the OPTN web site when the updates to informed consent policies take effect on June 1, 2017. Members could choose to use this resource on a voluntary basis.

Members discussed and supported developing a lay language version of the living donor psychosocial and medical evaluation requirements as a future project.

*Revise Living Donation, Information you need to know*

The Chair explained that this is resource is available through the OPTN website as a print on demand resource and it is also a resource that UNOS sends to members of the general public who contact UNOS with questions about living donation.

The current stock of this brochure will be depleted soon and the Committee liaison was asked to review the resource for any necessary updates before reprinting. Committee members who reviewed the resource concluded that the resource was out of date and needed substantive revisions.

A member questioned if this resource could be made available in languages other than English and Spanish.

Next steps:

The Committee agreed to form a workgroup to begin meeting by web conference on the fourth Wednesday of each month at noon ET to continue work on this resource.

**4. Living Donation and Transplantation**

UNOS Research staff provided an overview of data that had been presented during recent regional meetings. The presentation had been updated to report national data rather than regional data.

Data summary:

For 2015-2016, deceased donors recovered increased by 9.8%, and deceased donor organs transplanted increased by 10.7%

Donation after Cardiac Death (DCD) donors now comprise 17% of deceased donors overall (with ranges from 10%-25% by region)

For 2015-2016 there was a 0.4% decrease in living donation.

Summary of discussion:

A member questioned why live donation to pediatric patients had declined. A member responded that parents of pediatric candidates may be waiting to donate should their child need a second transplant (as an adult) when they will not have prioritization.

**5. Living Donor Collective**

Staff from the Scientific Registry of Transplant Recipients (SRTR) provided an update on the Living Donor Collective.

Summary of discussion:

They explained that this project would seek to register all potential donor candidates evaluated at transplant programs including those that become donors, are suitable but do not ultimately donate or are found not to be suitable to donate. An immediate issue is determining how to define a candidate. The current definition for a candidate is someone who reports to a transplant hospital to be interviewed and to have a history and physical. The project would record reasons for not donating from a list of potential reasons for not donating developed with the assistance of hospitals in the pilot. The SRTR will obtain the follow-up information, report to transplant programs and report result to the general public. SRTR will collect donor follow-up data through surveys and data linkages.

As proposed, the study should allow analysis of the reason why someone chooses not to donate with what actually happens in the future. Similarly, someone approved as a living donor who ultimately does not donate due to a problem with the intended recipient could be compared with living donors in the future.

A Living Donor Collective web site is in development and could include life time risk prediction of end stage renal disease and other resources such as a link to the living donor assistance program.

The pilot program was approved in September 2016 and includes ten sites. Since this is a federally funded pilot it was planned to be announced in the Federal Register in January 2017, with subsequent review and approval by the Office of Management and Budget (OMB). The new administration put a hold on new announcements for the Federal Register, so future steps in the pilot are currently on hold.

A Committee member questioned if potential living donors will have the ability to discontinue the evaluation process without disclosing a specific reason why they want to stop the evaluation process. Another commented that a potential donor might want to stop the evaluation process for multiple reasons rather than one specific reason and asked if pilot centers will be able to report multiple reasons why the potential donor did not proceed to donation.

The pilot will be informed by a ten member Living Donor Advisory Subcommittee that includes eight past or current members of the Living Donor Committee.

## 6. Improving Living Donor Follow-up

Summary of discussion:

*New Tools to Assist with Living Donor Follow-up*

UNOS Research staff reported the Committee first began reviewing living donor follow-up rates in 2007. In 2007, the donor follow-up rate was 26.5% nationally. For the first half or 2016, living donor follow-up rates increased to 86% nationally.

UNOS Research staff reported that the Research department is developing new tools to assist hospitals with living donor follow-up. As currently envisioned, the new tools would be similar in look and function to the waitlist management tool in UNet$^{sm}$. These future tools should notify hospitals when donors will soon need follow-up, the window when the follow-up should occur and when the follow-up form must be submitted to the OPTN.

Several members asked if living donor information could be added to the Benchmark Report currently provided to members by UNOS.

*MPSC Update*

The Chair of the Membership and Professional Services Committee (MPSC) joined the meeting via web conference to provide a presentation entitled: MPSC Review of Living Donor Follow-up Form Data Collection and Submission.

Summary of discussion:

The Committee Chair introduced the Chair and vice Chair of the MPSC and shared that these members of the MPSC had attended the previous Living Donor Committee meeting to discuss the status of living donor follow-up with regards to policy compliance.

The MPSC Chair reported that national follow-up rates have improved and many centers meet the minimum thresholds required in OPTN/UNOS policy. However, more than half of all living donor programs have missed at least one of the required follow-up thresholds at 6, 12 or 24 months. He reported the MPSC does not have the capacity to review all programs that are out of compliance and that the problem should be addressed by considering different levels of compliance. The Committee previously supported the MPSC's use of a tiered response to focus its review on hospitals with the worst performance.

At its recent meeting, the MPSC did not support reviewing a percentage or set number of programs because some programs would always be reviewed because it seemed punitive rather than focusing on improved member compliance. The MPSC supported including a routine review of all program's follow-up rates during the site survey process. Additionally, the MPSC supported setting lower thresholds to trigger more immediate and in-depth review for the most noncompliant programs.

The MPSC Chair provided an overview of the operational rule the MPSC will use to address hospitals not achieving the minimum required thresholds for living donor follow-up as follows:

- The MPSC will review all programs whose follow-up rates are at least 50 percent below the policy threshold.
    - Will request a Corrective Action Plan (CAP) and require evidence of improvement
    - Will continue until the MPSC determines the program has made satisfactory progress

- All other programs will have their follow-up rates reviewed as a part of their next site survey.
    - If the program's rates are below the established threshold, they will be asked to provide a CAP with their survey response.
- The MPSC will evaluate the effectiveness of the operational rule each year and may change the process as needed.
- The MPSC Chair explained that the MPSC had identified potential pros and cons with the operational rule as follows:
- Pros:
    - Anticipate this will reduce potential reviews.
    - Should identify members that are truly not trying or making no improvement.
    - Allows MPSC to focus on the programs that are having the most difficulty.
    - All programs still monitored through site survey process.
    - Surveyors are already reviewing data accuracy on follow up forms.
- Cons:
    - Trigger is still based on percentage of total donors and may identify small volume programs more than large volume programs.

A Committee member questioned how the MPSC determined it should address hospitals not achieving at least 50% of the threshold required under policy. The MPSC Chair comment that the MPSC members opined that not achieving at least 50% of the required threshold indicates a hospital is grossly out of compliance.

A Committee member questioned if the operational rule could be modified if necessary. The MPSC Chair responded that the operational rule will be reviewed frequently and could be changed if needed.

A member commented that enforcing this operational rule should send a message that hospitals need to improve their follow-up to improve patient safety.

A member questioned if a hospital missed the required follow-up threshold at 6 months and was reviewed by the MPSC would they get "a pass" at 12 and 24 months? The MPSC Chair responded that the hospital would get "a pass" during subsequent cycles if the hospital is showing progress and improving donor follow-up.

Next steps:

MPSC will review the next available cohort of living donor follow-up forms in May 2017. In June 2017, the MPSC will apply the new operational rule to the follow-up forms using it to assess its effectiveness.

**7. Drug Overdose Deaths in Organ Donation**

Summary of discussion:

A member of the UNOS Research department joined the meeting via web conference to lead a presentation entitled Drug Overdose Deaths in Organ Donation.

She reported recent data revealing that 129 people per day are dying from opioid abuse or overdoses. These deaths have contributed to an increase in organ donors (12.6%) whose

deaths are related to drug abuse. Regions 1, 2, 9 and 10 had the highest percentage of donor deaths related to drug abuse.

These deaths tend to involve younger potential organ donors with few comorbidities but typically are considered higher risk donors. Organs from these donors, and especially kidneys, are underutilized and may be discarded due to concerns with potential disease transmission. The risk of dying while a candidate is on the waitlist is much higher than the risk of disease transmission from a higher risk donor.

OPTN collects data on drug related deaths through the Deceased Donor Registration (DDR) form but it does not capture details on the type or dosage of the drug.

DonorNet® captures some information but it does not collect the details on the type or dosage of the drug, the history or duration of drug use, and it does not collect how recently the history of drug use occurred.

**8. Tribute to Members Ending Term on the Committee**

After lunch, the Committee Chair thanked and acknowledged the past contributions of nine members who will end their service on the Committee on June 30, 2017. These members received a service certificate and a gift.

**9. UNOS Kidney Learning Center**

Summary of discussion:

UNOS' Director of Communications joined the meeting via web conference to provide an update on the UNOS Kidney Learning Center.

He explained that the Obama administration held a recent summit on transplantation to challenge the transplant community to increase the number of transplants. One of the ideals that came out of the summit was to provide a central repository for transplant related educational materials and that those materials will soon be available through the UNOS Transplant Living web site.

Hospitals that submitted materials include Beth Israel, Duke, Emory, John Hopkins, UCLA, Northwestern and Temple University. Their materials were review by Health Literacy Matters so all the educational material will have a similar style and voice. The web site changes necessary for the UNOS Kidney Learning Center are in progress.

**10. Informational Items**

Summary of discussion:

The Committee Chair led a presentation entitled New KDIGO Guidelines for the Evaluation and Care of Living Kidney Donors. These guidelines should be released in summer 2017. The purpose of the guidelines is to evaluate the state of evidence regarding the risks and benefits of living kidney donation. Scope of the guidelines include goals of evaluation and a framework for decision making, informed consent, psychosocial and medical evaluation and acceptance criteria, and post donation follow-up.

Goals include defining a threshold of lifetime risk of end stage renal disease (ESRD) for donor exclusion, quantify donor candidate's expected lifetime ESRD risk compared to the threshold to help guide decision-making (consistent, transparent and evidence based while honoring ethical principles).

Next full Committee meeting is scheduled for October 23, 2017 in Chicago.

The Committee will meet at UNOS headquarters in Richmond, Virginia in Spring 2018.

## 11. Potential New Projects

Summary of discussion:

The Committee Chair led a discussion of potential new projects for the Committee.

The Chair suggested that the Committee should develop an educational resource(s) for the ESRD Risk Tool for Kidney Donor Candidates. A member recommended the development of a plain language resource that explained the risk calculator. A member suggested the plain language resource could explain what potential donors could do to lower their risk (e.g. life style modifications). Several members commented that they are using the risk calculator in their practice. A member questioned if the risk calculator should be included in the list of calculators on the OPTN web site.

The Committee supported the development of lay person language versions of current psychosocial and medical evaluation policy requirements. These would be new resources that hospitals could voluntarily choose to provide to potential donors.

Interest in a project to address the use of social media in living donation continues. As envisioned the projects could provide guidance for both transplant candidates and transplant hospitals. The use of social media creates disparities in the transplant system. Some waitlist candidates have the ability or resources to mount social media campaigns to find a potential donor, while other waitlist candidate may not have the ability or necessary resources needed for a social media campaign. The project could address potential pitfalls and suggest safeguards for using social media.

At this time, some transplant hospitals are using social media to encourage donation which creates inequity if a waitlist candidate is listed with a transplant hospital that does not use social media. The project could address how transplant hospitals should respond to social media campaigns that results in hundreds of people wanting to be evaluated as potential donors.

A member suggested that the Committee should propose a project concerning priority for prior living donors for all types of organ transplants. The Chair explained that the Committee had considered this issue previously and deferred work on a project to provide priority to living liver donors after consultation with the Liver Committee. Prior living liver donors could get priority through regional or a national review board, but there is no guarantee that a prior living liver donor would be considered by a review board. A member suggested that a prior living donor who needs a liver transplant could be bumped to the top of the MELD category. A member commented that some transplant hospitals will recover an organ from a donor who does not have medical insurance, and if that donor does not have insurance and later needs a transplant they likely could not get on a transplant list.

The meeting was adjourned.

### Upcoming Meeting

- May 10, 2017