OPTN/UNOS Living Donor Committee
Meeting Minutes
May 10, 2017
Conference Call

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Introduction

The Living Donor Committee met via Citrix GoToTraining teleconference on 05/10/2017 to discuss the following agenda items:

1. Removing Disincentives for Candidates to Consider Living Donation
2. Current Projects
3. Potential New Projects

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

1. Removing Disincentives for Candidates to Consider Living Donation

A workgroup has finished content for a new transplant candidate brochure to help transplant candidates identify a potential living donor. The brochure is entitled Living Donor Transplantation may be the Best Treatment Option for You.

Summary of discussion:

The project includes three components, the new brochure, an evidence report, and a file with feedback from reviewers and the response from the workgroup. The reviewers included health literacy experts and the resource is written at an eighth grade reading level.

The brochure is now with UNOS Communications for formatting and branding. UNOS Communications has promised a mockup of the resource within the next week. A mockup should be available by the time the Policy Oversight Committee meets here at UNOS headquarters on Monday, May 15, 2017.

Next steps:

The Committee liaison will be meeting with UNOS Communications to discuss options for printing the brochure.

The current plan is to provide copies of the new resource at the upcoming Board meeting in June and to promote the new resource at Regional Meetings starting in July.

Future steps include a Spanish version of the resource.

2. Current Projects

Lay person language version of informed consent policies

During a previous meeting, Committee members discussed the complexity of the current informed consent policy requirements, and commented that many in the general public would not be able to comprehend the policy requirements. In response, Committee members supported the development of a lay person language version of the informed consent policy requirements.

Summary of discussion:

This new resource will align with the new and revised living donor informed consent requirements set to take effect on June 1, 2017. This new resource is intended for potential living organ donors and would explain the informed consent requirements from the perspective of a potential living organ donor. The workgroup has found it challenging to develop a resource in plain language. For example, the term transplant recipient is problematic because "recipient" is a four syllable word. The current working draft of the resource is at an eighth grade reading level.

Next steps:

A final version will be provided to Committee members in the next week.

The resource will be sent to Health Resources and Services Administration (HRSA) for review and if approved it will be posted on the OPTN website on June 1, 2017. A Spanish version of the resource will be developed.

The Committee will plan to promote this new resource at the upcoming Regional Meetings.

Template for Informed Consent Policy

During recent public comment on proposed modifications to living donor informed consent requirements, the Committee received requests to develop and provide an informed consent policy template to assist members with policy compliance.

UNOS staff has completed a draft informed consent policy template that has been approved by UNOS' Member Quality and Legal Departments.

Next steps:

A final version will be provided to Committee members in the next week.

The resource will be sent to HRSA for review and if approved it will be posted on the OPTN website on June 1, 2017.

The Committee will plan to promote this new resource at the upcoming Regional Meetings.

Revise the Brochure entitled *Living Donation, Information you need to know*

UNOS Communications will soon need to reprint the current living donor brochure because stock will be depleted. The current supply will be depleted in three months. The Committee liaison was asked to review this brochure and to recommend possible changes before reprinting. Some Committee members reviewed the brochure and recommended substantive revisions. A project form to address this work was completed, the project does not require Policy Oversight Committee approval because this is an education resource.

Summary of Discussion

The Committee Chair provided an update on the status of updates to this brochure. She explained that a workgroup updating the brochure had met on the previous day and had a productive meeting. She shared that it may be helpful to have a health literacy group review the brochure.

Next steps:

The workgroup revising this brochure is scheduled to meet again on May 24th.

3. Potential New Projects

Improve Categorization of Living Donor Adverse Events

The Committee Chair explained that she had proposed this project several years back based on an experience at her hospital. Current policy requires reporting some events that would be better categorized as "unanticipated" rather than "adverse" events. For example, a living donor organ may be recovered but found to have a cancer that had not been detected during the donor evaluation process and the organ cannot be transplanted because the potential recipient had not consented to receive a higher risk organ. Also, a living donor organ may be recovered but may not be transplanted due to a transportation failure. Living donor deaths may occur within two years of donation due to unrelated medical problems or trauma. These types of events should be reported to the Improving Patient Safety Portal but should not be categorized as "adverse" events.

Summary of discussion:

The Committee supported resuming work on this project during it March 27th meeting. The Committee reviewed Policy 18.6.A (Reporting of Living donor Adverse Events through the Improving Patient Safety Portal). The policy includes six reportable events and some of the events would be better categorized as unanticipated events rather than adverse events.

A member questioned if events reported to the Improving Patient Safety Portal are publicized? At this time adverse events are not included in living donor hospital Program Specific Reports, but it was noted that adverse events could be added to the report in the future. A member asked how frequently events are reported under Policy 18.6.A. UNOS Research staff reported what had been reported in the past seven years (7 deaths.19 aborted procedures, 1 redirection and 4 categorized as other). A member questioned if these events may be under reported? UNOS staff does check prior living donors against the Social Security Death Master File to determine if living donor deaths may be under reported.

A participant suggested that it would be difficult to know what define and determine what should be categorized as an adverse event versus an unanticipated event.

A participant reported that the Centers for Medicare and Medicaid Services (CMS) Conditions of Participation defines an adverse event as follows:

> Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended beneficiaries; and unintended transmission of infectious disease to a recipient.

The HRSA representative commented that if possible OPTN/UNOS and CMS requirement should align.

The Committee discussed splitting Table 18-4 (Living Donor Adverse Event Reporting) into two separate tables. One table would include adverse events to be reported and the second table would include unanticipated events that would need to be reported via the Improving Patient Safety Portal.

A member later suggested removing the word "adverse" from Policy 18. As proposed Policy 18.6 could be changed as follows:

18.6 Reporting of Living Donor ~~Adverse~~ Events

18.6.A Reporting of Living Donor ~~Adverse~~ Events through the Improving Patient Safety Portal

Recovery hospitals must report these living donor ~~adverse or unanticipated~~ events through the Improving Patient Safety Portal or the OPTN Contractor according to *Table 18-4* below.

Table 18-4: Living Donor ~~Adverse~~ Event Reporting

Recovery hospitals must report:	To the:	Within 72 hours after:
A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.	Improving Patient Safety Portal and the OPTN Contractor	The aborted organ recovery procedure
A living donor dies within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living liver donor is listed on the liver wait list within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living kidney donor is listed on the kidney wait list or begins dialysis within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living donor organ is recovered but not transplanted into any recipient	Improving Patient Safety Portal and the OPTN Contractor	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Improving Patient Safety Portal	Organ recovery

The Membership and Professional Standards Committee will review all cases reported according to *Table 18-4* above and report to the OPTN Board of Directors. The Committee supported this option.

Next steps:

The Committee liaison will prepare a briefing paper on this proposed policy change for consideration by the Executive Committee of the Board of Directors.

4. Consider Previous Projects Currently on Hold

The Committee discussed and supported developing patient versions of the current living donor psychosocial and medical evaluation policies as a next project.

The Committee discussed and supported developing educational resources regarding end-stage renal disease (ESRD) Risk Tools and Calculators.

The Committee discussed and supported developing guidance on the use of social media by transplant candidates, potential donors and transplant hospitals. A member shared that the use of social media was a hot topic at the recent American Transplant Congress.

The meeting was adjourned.

Upcoming Meeting

- June, 2017