

**OPTN/UNOS Living Donor Committee  
Meeting Minutes  
November 14, 2018  
Conference Call**

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

**Introduction**

The Living Donor Committee met via Citrix GoTo teleconference on 11/14/2018 to discuss the following agenda items:

1. Clarifications on Reporting Maintenance Dialysis
2. Living Donor Committee (LDC) Project Check-in and Next Steps
3. Kidney-Pancreas (KP) Workgroup Update and Kidney-Pancreas Donor (KPD) Questions

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

**1. Clarifications on Reporting Maintenance Dialysis**

The Policy Oversight Committee (POC) approved this project in August 2018 and the Executive Committee (ExCom) approved it in October 2018. The Committee reviewed mock-ups developed by UNOS IT, including changes that may require Office of Management and Budget (OMB) approval and those that may not require OMB approval.

Summary of discussion:

UNOS staff began by reorienting the Committee to the project timeline and context for changing the policy language. Specifically, this project should make reporting living donor events considerably clearer for transplant hospital staff by bringing consistency to terminology used in policies and in UNOS IT proprietary systems. Altogether, this project focused on increasing clarity and will not increase nor alter reporting requirements.

UNOS staff reviewed the revised policy language. The review included showing Committee members the potential changes in the OPTN policy document. A summary of the policy changes are shown below:

1. Policy 1.2: strike definition of "native organ failure"
2. Policy 18.5.A: replacing "maintenance dialysis" with "regularly administered dialysis as an ESRD patient"
3. Policy 18.6: Table 18-4 to include "regularly administered dialysis as an ESRD patient within 2 years after"

UNOS staff presented a mock-up of the Patient Safety Portal form and highlighted the policy language that would be stricken. UNOS staff explained that by addressing these inconsistencies in policy language, policy should become clearer. At this time, UNOS IT and UNOS Member Quality expressed a desire to include a link to OPTN policy on the Patient Safety Portal, that way people who have questions can use the link and find relevant policy answers.

UNOS staff also presented mock-ups of the Living Donor Follow-up form and cited examples of changes that might require OMB approval, and examples that may not require OMB approval. The Committee discussed the pros and cons of making changes that would require OMB approval. The advantages of adding more discrete fields to the "kidney complications – other" field include potentially collecting better data by prescribing or limiting the options Transplant coordinators can input. The disadvantage to modifying this field more substantially is that OMB

review and approval would greatly extend implementation. The disadvantages to leaving this field as an open text box, regardless of the Help documentation or labels tailored to help users, is that the data reported may still be widely diverse or potentially inappropriate. However, by not changing the question to require programs to submit additional, specific data avoids OMB review and approval, thus implementation for this project should follow the normal schedule outlined by UNOS IT.

UNOS staff shared potential options to provide more context and instruction on the form itself. After hearing these, there was a general desire to attempt to avoid extending the implementation process by making substantive changes that would require OMB approval. However, the Committee also agreed that they wanted to review the modified mock-ups more in depth prior to mid-December in order to give thorough consideration to both options.

In the following discussion, one Committee member asked for clarification on the non-OMB route for the Patient Safety Portal. This Committee member suggested that a parenthesis with examples (e.g. AKI requiring dialysis, CKD I-IV) be placed after the text box stating "Other, specify" on the non-OMB mockup. Though UNOS staff explained that IT created a text box with grayed out examples below where people could type in their responses, the Committee member stressed that these examples need to be made clearer. UNOS staff informed the Committee that they had presented the mockups to the IT user experience team and whom agreed it was a better route to put examples in the textbox. From their perspective, the IT user experience team was concerned about an overburden of text on the form. However, UNOS staff informed the Committee that they could still include a parenthesis with examples if they decided this is clearer. As such, the Committee agreed to review the mock-ups further and decide whether or not a parenthesis with examples should be included on the form for clarity.

Another Committee member mentioned that previously, they had decided to take the middle portion of the follow-up form (e.g. "Regularly administered dialysis as an ESRD patient") and move that in conjunction with the section reporting "Kidney Complications". In this way, both text boxes would be adjacent to one another, and not have the section "Diabetes" between the two of them. The Committee opined that since both sections deal specifically with "the kidney", then it would be logical to have these two sections nearer to one another. Furthermore, the Committee reasoned that having both text boxes close to each other will increase continuity and clarity for people entering data. UNOS staff informed the Committee that they did consult UNOS IT, and that this should not be an issue since it will not require OMB approval (e.g. "moving data" not "adding data").

UNOS staff informed the Committee that they met with both UNOS IT and Member Quality, and that from this meeting, there will be future updated mockups for the Committee to see prior to December. UNOS staff reiterated the importance of getting feedback from Member Quality, which the Committee agreed with. The Committee also supported sharing the mock-ups with other UNOS staff or Committee members in order to receive feedback prior to December. UNOS staff reiterated that the Committee has time to change the formatting of the IT mock-ups until mid- December 2018, with non-substantive changes occurring after spring 2019 public comment.

The Committee members had no further questions or comments prior to voting on the policy language.

The Committee unanimously agreed to approve the changes to the OPTN policy and then to subsequently send out for public comment in spring 2019.

### Next steps:

The Committee agreed to review current mockups in order to deliver timely feedback to UNOS staff, particularly changes that would require OMB approval. The Committee agreed to review future mockups and give final feedback by the first or second week of December. UNOS staff suggested that the Committee provide this feedback via Basecamp, because it will be easier to track and discuss. LDC leadership agreed to discuss the use of Basecamp further with UNOS staff.

## **2. Living Donor Committee (LDC) Project Check-in and Next Steps**

UNOS staff summarized their current understanding for two potential OPTN/UNOS Committee projects: the Social Media Guidance and the Living Donor Assessment Tool. The discussion revolved around determining the next steps for each of the two projects.

### Summary of discussion:

UNOS staff updated the Committee on two potential Committee projects: the Living Donor Social Media Guidance and the Living Donor Assessment Tool. UNOS staff had reviewed Committee meeting minutes from the previous year in order to acquire the most updated information. UNOS staff acknowledged the Committee's frustration stemming from a perceived lack of progress on both projects. Also, UNOS staff noted that there may have been various obstacles impeding progress on either project.

UNOS staff summarized their findings derived from previous meeting minutes and conversations. UNOS staff also informed the Committee that they have placed all project information into the UNOS project management system. This centralized location will allow OPTN/ UNOS to accurately track any conversations and discussions surrounding both projects. A status update for the Living Donor Self-Assessment Tool was summarized for the Committee:

- Idea conceived early 2018
- Idea tabled due to higher organizational priorities; resurrected in spring
- Progress made "off-line"
- Some OPTN/UNOS organizational interest a few months ago, unclear whether that is still the case
- UNOS Professional Education, Communications & Policy deferred
- UNOS IT to speak with UNOS leadership about whether to proceed and whether they are the appropriate department to lead
- Confirmed not an OPTN project by UNOS Policy Director, no POC or Executive Committee (ExCom) approval, not for public comment
- Requires securing private funding if pursued
- UNOS IT/UNOS leadership to advise how to proceed; UNOS Philanthropy to secure funding if approved

In the discussion that followed, one member asked when UNOS created a policy mandating the private funding of patient education projects. As such, this is a drawback committees should consider when determining whether to pursue a patient-education initiative.

In the discussion that followed, a few Committee members expressed frustration that the focus of UNOS is elsewhere at the moment. As such, Committee members felt that they needed to decide how much volunteerism they would want to commit trying to develop something that may or may not be considered an add on to the part of the organization.

Another member was unclear as to why the Committee had previously been allowed to pursue projects focused on patient education. UNOS staff stated that there may have been a recent

change to have patient education materials be privately funded. However, the Committee member also opined that as long as UNOS IT can program this project for implementation, the Committee should be able to combine their clinical and donor knowledge in pursuing this project. UNOS staff clarified that that they were not saying the Committee cannot contribute to the project. Instead, in order for UNOS IT to work on the project, there would need to be adequate funding for the implementation process. For example, there has to be enough funding to support the resources (e.g. staff hours) needed for UNOS to implement a Committee project.

Committee members suggested that it would be helpful for UNOS to provide a one or two page summary of current UNOS policy, any OPTN/UNOS changes that have occurred (e.g. OPTN/UNOS contract changes) and the process for acquiring philanthropic funding (e.g. How long is the process? Who is in charge of the process?). In this way, the Committee members reasoned that such information will be useful in determining whether it is logical to put Committee resources towards this project. Another Committee member requested that staff provide the Committee with a “decision tree” or “organizational structure” of UNOS. This information will inform the Committee of the internal processes by which OPTN/UNOS Committee projects are approved. Furthermore, this information could help the Committee make future decisions as to which projects they want to pursue. UNOS staff agreed to reach out to UNOS Communications, UNOS Philanthropy and UNOS Leadership to provide the Committee with this information.

There was also general consensus amongst Committee members to make sure UNOS is committed before dedicating Committee time and resources to this project. The concern from many Committee members is that this project might languish without committed resources.

The next project the Committee discussed was the Living Donor Social Media Guidance. The Committee was provided with a status update:

- Idea conceived in 2016
- Original iteration was patient-focused, UNOS leadership (and perhaps HRSA) advised against proceeding due to concerns, such as the OPTN making recommendations to patients, or social media campaigns.
- In spring 2017, refocused to be directed towards professional, with possible accompanying patient resource; problem statement refined
- Summer/ Fall 2018: Interest and intent to move forward with this project
- For professional guidance, must be approved by the POC and ExCom, go out for public comment, be approved by BOD

In the discussion that followed, one Committee member corrected the information above for the project had initially focused on a dual track: one patient resource and then one professional resource. Later on, the Committee redirected this project to solely focus on transplant professionals. Another Committee member asked for clarification between the term “guidance document” and “best practices”. UNOS staff replied that “white papers” are similar to “guidance documents” in the process by which UNOS approves them for public release.

UNOS staff outlined the next steps the project might follow. If the Committee decides to pursue the project, then the Committee would need to update the project form for POC consideration in either January or early February. UNOS staff assured the Committee that they would work with them to go through the project form prior to submission to the POC. UNOS staff would develop a project plan or timeline (such as the date for possible ExCom approval). Once ExCom approves this project, the Committee can create a Subcommittee or workgroup in order to develop the project for release in fall 2019 public comment.

Another Committee member opined that once they start the project, it would be valuable to receive feedback from other OPTN/UNOS Committees, especially the Ethics Committee and the Transplant Coordinators Committee. In particular, the Committee agreed that they desire early feedback and involvement from other OPTN/UNOS Committees so that the project does not require huge modifications in the future. Furthermore, the Committee agreed that engaging other OPTN/UNOS Committees in project discussions would be considerate.

Another Committee member suggested that as they update the project form, the Committee should circulate more information about the project so that new members can be adequately informed. UNOS staff agreed with the Committee, however also asked that members forward any relevant project information to the UNOS liaison. There were a few Committee members who stated they had relevant project information and would make sure to share this information with UNOS staff.

Next steps:

UNOS staff will reach out to other UNOS internal teams (Communications, Philanthropy and Leadership) to provide the Committee with UNOS organizational information and on the processes for acquiring philanthropic funding.

Furthermore, UNOS staff will work with the Committee to begin populating the “Living Donor Social Media Guidance” project document for future POC approval.

**3. Kidney-Pancreas (KP) Workgroup Update and Kidney-Pancreas Donor (KPD) Questions**

The Committee was unable to get to this agenda item and agreed to table this discussion to the next Committee meeting in December 2018.

**Upcoming Meeting**

- December 12, 2018