

**OPTN/UNOS Living Donor Committee
Meeting Minutes
October 15, 2018
Chicago, IL**

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Introduction

The Living Donor Committee met in Chicago, Illinois on 10/15/2018 to discuss the following agenda items:

1. Constituent Council Update
2. Policy Oversight Committee (POC) Update
3. Clarifications on Reporting Maintenance Dialysis
4. Update on Liver and Intestinal Organ Transplantation Committee (LIOTC) - Special Public Comment
5. Kidney Paired Donation (KPD) Work Group Update
6. VCA Living Donation Discussion
7. VCA Living Donation Project Idea Discussion
8. Social Media Project Idea Discussion
9. Donor Self-Assessment Subcommittee (DSAS)

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

1. Constituent Council Update

The Patient Affairs Committee is piloting a constituent council model for committees. A concept paper on improving OPTN/UNOS committee structure was distributed in this past spring, originally proposing bylaw changes to remove the prescription of specific committees and describe broadly that OPTN would have a volunteer work force structure. The committees would be divided into two groups, subject-matter committees such as organ-specific or broad policy, and expert councils with a perspective that has needed three or more subject committees.

There was a lot of public comment with overall support for the concept because the overall goal was to have broader constituency support. There was agreement that the overall project concept may increase broader participation. Concerns were over perceived loss of the constituency voice in the policy development process with the committees splitting into two groups.

The Executive Committee (EC) approved to test the concept, which will be piloted with the Transplant Coordinators Committee (TCC) and the Patient Affairs Committee, which is now called the Patient Affairs Constituency Council (PACC). The proof of concept started in July and will go through the end of the year. Then they will provide feedback to the EC, basically focusing on insufficient diversity and perspectives and insufficient connections between the Board and Committees.

The goal of the proof of concept is to look for ways to facilitate real-time communication and collaboration between the Committees and the Board. It is really an attempt to amplify constituent voices and give opportunity for people to be heard. The proof of concept is not intended to change bylaws, change PACC's or TCC's ability to propose or sponsor projects, or interfere with existing committee work.

There was a meeting in August to kick it off, starting with 17 members on the Patient Affairs Committee leading to 50 members in PACC. The official coordinator representatives on other committees or Board of Directors will merge. Those added to PACC will attend both their monthly calls and in-person meetings through December. Patient or donor family reps from all the different committees sort of merge with the core roster of PACC.

Overall, the feedback is that the proof of concept has increased communication and collaboration, as well as that rules need to be clarified. Unintended consequences and things to think about include that when people volunteered, found that the assignment to be a considerable time commitment to be on two committees.

In addition, not all members always have a lot to say. Only 10% of the group of 50 actually posted, but that does not mean that a majority are not logging in and following conversations, so they need to measure their own level of engagement. It is more meaningful for them to add something of value, rather than to check off a box that says they commented.

From the in-person meeting, the feedback was that this is an opportunity to engage larger groups of patients in the policy-making process, but there is the need to understand how that works and what is needed in terms of education. The overarching goal is to engage with patients and living donor families. This Committee can help UNOS understand the best way to do that. With the proof of concept there is also the opportunity with the Committees for increased receptivity and acceptability of the constituent voice by bringing groups together.

Summary of discussion:

One question was regarding Basecamp and what exactly it is being used for. The goal for Basecamp is to encourage dialogue between the meetings, such as subgroup work can be posted for feedback from the larger group. It allows both leadership and staff to post agendas, policies, assignments for policy review, such as items that were put on SharePoint (which was put on hold during the Basecamp testing). It is organized well and allows them to find tools and resources on their specific pages. It also acts like social media where one member could propose a topic for other members to respond to. The public forum was also used for sharing feedback during public comment periods. Members did share things like news items or topics of side discussions at in-person meetings, ideas.

Another question was how the communication between committees is supposed to play out. It is supposed to be more of a two-way conversation. It just happens that all of the organ-specific committees are working on the same type of project in the same timeframe. Half of the committees are policy-developing committees and then half of those are turning out complex policy projects. The reporting structure is the liaison and the patient reps will fill out a form with high-level information about whatever project and activities their committees are working on. Then it is shared on Basecamp and if leadership will decide if it should be discussed on a call. Right now only LDC and Minority Affairs have projects relative to PACC, so because of time constraints, those will be posted to Basecamp, but not presented. There were no responses on Basecamp indicating any work by a committee that may be of interest to PACC or TCC, but this process could be improved.

One Committee member commented that she does not have time to read what seems to consistently be the same posts from the same posters on Basecamp. She does not always comment unless it is something that she feels will bring value to UNOS. Her hope is that Basecamp might be the place to get more people involved like a Facegroup group, rather than giving everybody on the board another microphone to post another comment. Another member agreed that she wants to be engaged, but just does not have to the time to keep up on all the

notifications and constantly post. Also, some are not social media savvy and find it hard to engage in that way.

One comment is that the posts on Basecamp do seem to reveal a large knowledge gap. For example, an average patient would not know what an OPO is, and if they do, they still do not know about all the steps to transplantation. Another member felt she does not feel comfortable giving input unless she is truly educated. More education is needed besides monthly phone calls.

The important thing to figure out is the objective for Basecamp. How is the sharing of information between Committees going to happen so patients and donor families feel empowered and they know what's going on? How might you feel more engaged? What can we do to make sure your voice is getting heard? The lead-up time to get this going was too short.

One member who was part of TCC and PACC felt most of her comments on Basecamp were to clarify questions from patients about the business side of transplant and not from the living donor.

The proof of concept will likely be extended another 6 months to a year, as the structure is now patient members adding on to the core PACC, rather than having additional patients on every committee, which is a different structure option. Another structure idea is that the general public, lay people, patients not participating in the policy development process should be brought to UNOS' attention. There are lots of opportunities for patients to tell their stories if that's what they want to do. This particular volunteer opportunity within an OPTN Committee is the policy development process as it applies to membership policies. Perhaps one solution is not changing the committee system, but the type of person recruited to be on a committee.

Unlike PACC, the TCC only gained 7 new members as part of the proof of concept. Part of this is due to the fact that not every OPTN Committee has a transplant coordinator despite the bylaw requirements.

The EC/BOD will decide the next steps, which might include another iteration of the pilot and then public comment if the bylaws change based on the pilot.

Summary of discussion:

One question was regarding level of engagement because one feedback comment was that it was intimidating. Perhaps with 50 people being on PACC calls, it becomes discouraging for patients and he wanted to know if anyone noticed that being the case. With fewer members on the TCC, what is a good number of members? The TCC members went out of their way to talk to the constituent council and they took ideas presented by the constituent council members as equal to their own opinions. With 50 members on a call, after content is presented on a 1-hour call there is only 1 second of time per person. Therefore, size is impactful on engagement during calls. Level of engagement is more of an issue on conference calls, rather than in person, as the vast majority of people spoke at the in-person meeting, with participation being about equal between core members and constituent council members.

Another question was whether the Board identified the metrics by which success was measured. There are metrics that were not set by the Board, but agreed upon by PACC and TCC leadership. As the proof of concept expands, it may include additional Committees, or they may decide on a different structure or different constituency.

One observation was that if someone asks a question on Basecamp and it's not answered, they could feel like no one really cares about the question. It will take a full-time staff member similar to some of the Facebook/social media groups to manage it and keep it factual. The concern is

that someone needs to take ownership of responding and monitoring. This is one metric that will be included for staffing for the future.

2. Policy Oversight Committee (POC) Update

Data summary:

POC has had few meetings this year. In July they reviewed the six proposals that have already gone out for comment. LDC provided comments in two areas, HLA typing and geography. The geography issue did not affect why former living donors get priority on the kidney waitlist and does not affect living donor expectations for priority status. At the August meeting the maintenance dialysis proposal was presented, which went through unanimously.

UNOS resources have been focused on all the Committee geography projects mandated by HHS. Extra staff hours have gone into research, policy work and IT programming hours involved with the allocation policy changes. Therefore, the other projects have become lesser priorities and have been slowed in the meantime.

Summary of discussion:

One Committee member asked about the OPTN strategic plan and how promoting efficiency is different from increasing transplants, providing equity, and improving outcomes. Oftentimes a project will impact more than one goal, but POC selects the primary reason for the proposal. The average total percent of staff hours going to efficiency projects has been about 5%. It has mainly been things like clarifications of language in policy.

3. Clarifications on Reporting Maintenance Dialysis

The LDC discussed their active project, "Clarifications on Reporting Maintenance Dialysis."

There were questions raised about the meaning of the phrase "begins dialysis," which was in policy 18.6, the UNOS policy for reporting of living donor events. It wasn't clear whether the phrase "begins dialysis," means chronic dialysis or one or two treatments for acute dialysis. There are several other areas within the policy language like the Transplant Information Electronic Data Interchange (TIEDI) and the Patient Safety Portal, which referred to areas of decrease or loss of renal function in the living donor and/or dialysis is brought up. There is a checkbox in the Patient Safety Portal on loss of native organ function.

The policy states a living kidney donor is listed on the kidney waitlist or begins dialysis within 2 years after organ donation. Then it says the date the candidate began regularly-administered dialysis as an end-stage renal disease ESRD patient in a hospital-based, independent non-hospital-based, or home setting. The idea is to try to use the same terminology in beginning regularly-scheduled dialysis. "Begins dialysis" is where this all came up. Somebody had acute renal failure 2 weeks after donation from a septic even, got dialyzed twice, and then got better. The question was whether or not that would be a reportable event. "Begins dialysis" was probably not intended for this type of situation. Therefore, the language that was done correctly under the wait time should be used in this policy.

In policy 18.5.A, the term "maintenance dialysis" comes up again. This time it means the same thing as regularly-scheduled dialysis as an end-stage renal disease patient. This is clear language. There is a checkbox in TIEDI for maintenance dialysis that just needs language clarification. There is a checkbox in the Patient Safety Portal for loss of native organ function under a living donor event. This goes back to policy 1.2 that lists the definition of native organ failure for kidney living donors as registering on the waiting list for kidney or requiring dialysis. The goal here is to drop the "native organ function" term from the kidney standpoint and substitute it with "regularly scheduled dialysis and/or signing on to the waitlist."

Possible solutions to clarifications on reporting maintenance are:

- Policy 18.6: "Dialysis" can be clarified by adding "regularly administered dialysis as an end-stage renal disease patient."
- Policy 18.5.A: "Maintenance dialysis" changed to "regularly-administered dialysis."
- Policy 1.2: "Native organ failure" can be removed.
- Policy 18.5.A: "Kidney complications" will have additional terms added to the label (not additional data collection fields).

IT solutions could help with clarification and simplification in TIEDI.

The maintenance dialysis reporting was presented to the Kidney Committee to get their feedback on "regularly administered dialysis patients in an ESRD patient," as extracted from the current kidney policy. Their feedback was to state, "According to CMS guidelines...", which could be done, but then the language would also need to be clarified in kidney policy language to keep the language the same throughout.

There is a discrepancy between items on Patient Safety Portal and of the policy reporting requirement, so this is an opportunity to make that language more consistent as well. It is important to remember that labels of an item that exists on any forms within UNOS under government regulation can be changed. However, adding or modifying the forms in any other way such as adding additional click buttons needs to go through the OMB for approval and might result in time delays.

For clarification, OMB approval is only needed should there be substantive changes to the follow-up form.

Summary of discussion:

One comment was whether the Patient Safety Portal form also applied to a living liver donor and not just kidney in the case that a living liver donor that is doing extremely poor would need to be reported. Liver failure is listed under liver-specific complications. Indeed, the portal needs an upgrade to better align with policy language for reportable events. If that route is chosen, listings can be broken apart from need for dialysis in a kidney patient. The listing would then include whether it is a liver or kidney patient. There may be other ways to better align that form with the policy requirements.

One question was whether there was the assumption that every living donor who has end-stage renal disease will go on the waiting list. There will be an attempt to capture that group because most people go on the waitlist after their kidney function drops below 20. That needs to be put under "other" to be captured. Requesting notification when everyone drops below 20 will create additional work for the coordinators.

Another question was whether the Patient Safety Portal "loss of organ function" that was supposed to capture 18.6 was a drop down. The portal is actually built off of table 18-4 under Policy 18.6. The issue is when looking at policy language in 18-4 and comparing it to the Patient Safety Portal, it hardly matches. The goal is to superimpose the far left column of the table onto the current structure of the Patient Safety Portal. The table might also be consolidated when clarifying the language. For example, "loss of native organ function" is seen on the Patient Safety Portal under living donor event and then the only other reference to that phrase is in the Policy 1 definitions library and is not anywhere else in policy.

One comment was that many people who are doing the maintenance dialysis reports are lay staff who are trying to go through the medical record, and do not understand language

commonly used by nurses or physicians. In addition, most centers do not have the ability to program their electronic data warehouses to input these data. That person might interpret a person who has had multiple dialysis sessions as regular dialysis, rather than actually an acute kidney injury that recovers. It will be challenging to make sure it is accurate. This does not occur so much in the hospital setting as it does in the outpatient setting or home setting. It would be clearer to those lay staff if the language were as simple as "not in a hospital setting." That is why policy "regularly administered dialysis" needs to be clarified as an end-stage renal disease patient. That is the existing language in the kidney policy for what justifies listing and wait time accrual for a patient on the kidney list.

Another way to capture this is to see if they filled out the CMS 2728 form that says they have started regularly-scheduled dialysis as an end-stage renal disease patient. The idea was to streamline and make policy language clean and consistent across all different UNOS policies. Rewriting something completely different runs the risk of it being interpreted differently than another area of policy. The Committee can discuss this further at this meeting if they feel there are other options. It is possible that after the language is changed, the Policy 1 definition library can be changed so that "regularly administered dialysis" is defined as filling out a CMS 2728 form, etc. It is unknown how the policy language was first chosen and by whom. One comment was to put a direct link from the form to the policy language document, and that will make it easier to find.

Another possibility is bringing in the UNOS professional education department if new modules need to be developed that specifically target the individuals who are inputting the maintenance dialysis data so. Resources would be available on UNOS Connect.

When events like acute kidney injury that require dialysis have been reported, they have been in a free text using inconsistent language. It would be difficult to extract this information from a data analysis perspective. Feedback received from the TCC and the Kidney Committee on the area of acute kidney injury indicated they would like a more granular way of reporting the data and one that is clearly defined ideally in just click button format. One could click a button that applies to a particular patient and then not have to fill in the free-text box, which is currently in place. The Kidney Committee requested that the click buttons be very medical terminology, namely "AKI per KDIGO guidelines stage 2 or stage 3, AKI requiring at least one episode of hemodialysis or CRRT," which per the discussion so far may not be very user friendly.

Therefore, the options for understandable and granular but extractable data include building click buttons with the expanded TIEDI form (requiring OMB approval and may be viewed by the community as an additional layer of work). Another option would be to take the phrases and spell them out within the "other, specify," with a list of things such as "acute kidney injury requiring at least one episode of dialysis" or bullet points downward (again requiring OMB and risk of it being interpreted as more work).

One comment was that the RIFLE, AKIN and KDIGO guidelines are very similar, but have very defined definitions for acute kidney injury. Leaving the terminology loosely as acute kidney injury requiring an episode of dialysis or requiring renal replacement therapy, dialysis can be CRT or regular dialysis, and that would be an encompassing form. There was a big effort a while ago to rewrite policy into a much more lay language, interpretable version, but it is reasonable to keep some medical terminology to a certain degree.

Regarding complications, if it is a liver donor, the liver complications are listed as hernia, liver failure, etc. Details are included in the Committee members' meeting handouts. This will be verified because if not, then there will be an opportunity to make that part of the follow-up equally as robust. Then something similar could be done for kidney complications to be consistent.

One question was regarding a person who goes to Canada ends up on the waiting list. UNOS staff were unsure as how to track that. There are some transplant centers that list donors and don't know that they can get donor priority. Another commented that UNOS should know every person that is on a waiting list regardless of whether or not the center has put it in as full priority. UNOS staff did confirm that if a living donor develops ESRD later and is put on the waiting list, once a week linkage is run to try to find donors who are on the waiting list, but this can only be done for donors after 1987. If a donor is located who is not getting priority points, the center must look into it and fill out the paperwork, but there is not a direct correlation between TIEDI and that waitlist record to get that person priority.

Policy states that the transplant center that listed the living donor on that waiting list has to request the priority. UNOS does not re-contact the donating center and they are not involved in it at all. One comment was that the donating center should be reached back to by UNOS, but that is a legal matter because the fact that the center has had someone as a patient in the past does not give them the right to see their records in the UNOS system from another center.

Another question was whether the kidney complications question on the TEIDI follow-up form was there to double check to ensure priority. UNOS staff stated it probably predates the priority points and is just looking at donor safety.

One Committee member asked whether the events are reportable by the donor center just within the first 2 years or if at any time they learn of these issues happening. The living donor form is filled out at 6 months, 1 year, and 2 years only. The policy in the patient reporting system, the patient event system, says only within 2 years of donation. They are not obligated to report an event that happens more than 2 years after donation, but they can voluntarily report events beyond that window. The Kidney Committee is pushing for reporting past just the 2 years.

One comment was that donors do not want to see nephrologists years after donation. They are seeing their general practitioners, who don't know much about all these things. The Committee might want to work on helping general practitioners know how to follow kidney donors.

In the living donor follow-up form, many of the fields have yes, no, or unknown choices and questions must be answered or it will not let someone to complete the form. Selecting "unknown" will allow for form completion, but it will not count as a completed form to UNOS. The IT department came up with options for this, including better reporting back to centers of their incomplete forms. UNOS runs a quarterly report to see if anyone has recorded an event within 2 years but not reported it on LDF or vice versa. If so, they call the center and ask them to fix that. No one is perfectly happy with the forms, so the LDC will likely have to address these forms sooner rather than later them to make sure the data most useful to the community is being collected. This is a project that could be done with the Data Advisory Committee. The timeline when to address the forms would be up to the LDC.

One question was regarding the forms are being filled out on an ad hoc basis and whether there was any operability with one of the EMR systems or some sort of EMR interface transplant database, rather than this having to be done manually. For over 10 years there have been ways to batch up through third party software form data into the OPTN database. In addition, the IT department has been working on APIs that can grab the data. It is unknown if that effort includes working with the transplant centers on the living donor forms.

One question posed to the Committee was regarding what works best for transplant coordinators, whether it be checkboxes or "other, specify" (example). One coordinator felt it best to the specific examples listed on the form, especially for running queries. Another agreed that click buttons would be the easiest.

What things should be collected in the "other, specify" answer? Is there a degree of persistent chronic kidney disease that might be captured in the donor population that does not quite meet being listed or starting dialysis but still is relevant? There will be a lot of variability in based on nephrologists. There is one small group that might not be captured in the less than 20m clearance who are not on the waitlist and are on more palliative care or are older and then there are those who go on to dialysis. One above 20, it gets into too much work.

The conversations with the Kidney Committee revealed that stage 3 CKD may be more relevant because that is the level at which some of the peripheral complications are seen. People are actually doing their creatinine reporting and then EGFR is automatically computed and people could be staged. Another nephrologist stated that the formulas are designed to estimate EGFR in patients with chronic disease, so it may not apply to living donors.

Another Committee member asked if the lab values that are required to be reported at 6 months, 1 year, and 2 years could be used to calculate whatever formula will be used. Then if the patient reaches a level, an event form is automatically triggered. It would be difficult for IT to put that all together. It is also important to remember the follow-up form is the population-level information, but the adverse event forms lead to reports that may require immediate attention and review.

Based upon Kidney Committee feedback and conversations at this meeting, it may be of interest to try to find some area of persistent renal dysfunction that would be of value to begin to chart. The question asked of the LDC was whether they have seen any other issues that they would like UNOS to target as a data collection point.

Three kidney complications mentioned were acute kidney injury requiring at least one episode of dialysis, kidney stones, and then a generic other. The hope is to eventually do follow-up of donors and maintain contact. CKD 3 is important, but would be difficult to capture and it would require more work.

One point of concern was that AKI is only being mentioned in conjunction with dialysis. This correlates with the conversation about CKD, in that there are many different criteria for AKI and they may not all apply to a living donor. As mentioned, it might be difficult for a center to extrapolate that data and report it.

One committee member was concerned that a lot of the complications she sees in her center are not being captured, such as bowel blockages, depression, and nerve damage. It was her understanding that this data was being collected so that living donors in the future would know what to expect. The current reporting requirements are loss of medical insurance (health or life), readmission, kidney complications, maintenance dialysis, hypertension requiring medication, diabetes, and death.

One Committee member asked if UNOS has ever looked at the mental health aspect. Technically there is supposed to be a component of that. This could be addressed at the time the Committee starts to look at updating the forms. One comment was that with the project of updating the forms, the professional organizations such ASTS and AST should be involved from the very beginning.

There was agreement for the Committee to start looking at what the data is starting to show.

For new members, a brief update was given on the Collective Project. The SRTR has a pilot out with a few living donor programs around the country. Registration data is being collected on living donors and donor candidates that are evaluated in clinics but don't end up donating. The donors will self-report their follow-up and the hope is that the follow-up on those people will be for a long time in the future; however, right now it is in the pilot stage.

One Committee member was hesitant to suggest going through an OMB process of changing the follow-up forms while the Living Donor Collective project is going on. The data collection has been approved by OMB through HRSA to do this and includes a lot of the measures that the Committee might be looking for. Duplicating efforts would be burdensome because it would be the same people working on the same problems. Through the work of the Collective pilot, new data points to add might be identified. Also, the infrastructure is being set up to make this more a national project and not just with 10 pilot centers. The suggestion was that the LDC could support asking UNOS to work on the living donor follow-up form API, which would allow data to be transferred between different platforms.

Next steps:

UNOS staff will draft language for the LDC to review and vote on during their next meeting.

4. Update on Liver and Intestinal Organ Transplantation Committee (LIOTC) - Special Public Comment

The Liver Committee currently has a proposal out for public comment that eliminates DSA and region from allocation in response direction from HRSA and the Board, as DSA and region are not aligned with the Final Rule. Two approaches were modeled: broader two circles (B2B) and acuity circles. Both models are based on the concept of a fixed distance from a donor hospital and use distances of 150, 250 and 500 nm.

Summary of discussion:

The Chair pointed out that in the supporting evidence was not included the modeling for B2C with MELD 29, if that's a model that might be considered. Modeling for MELD 35 and 32 were requested and after the results were received, the Liver Committee came up with the idea of bringing it down to 29. There was not enough time to do an additional model with 29. However, modeling results are not exact, so conclusions can be drawn in a general sense about which direction things will move with MELD 29.

The Chair also pointed out that the largest acuity circle provides the least MELD variation at allocation, trivial difference in transport time, and distance and lowest waitlist mortality, but that was not favored as the primary model for consideration. Choosing a model was a balancing act with amount that would be flown and whether that could reach the point where it becomes prohibitive with availability of flights, potential to increase discards. LSAM modeling is not good at predicting discards, so there was concern if they went too far too quickly, it might increase number of discards. The Chair commented that there are some regions that currently share with greater distances so historical data for discards could have been looked at.

Comments that were just put in on the kidney side talked about the importance of geography not interrupting kidney living donors getting priority status if they needed an organ. In liver there is no priority status. Would it be appropriate to have the same sorts of rules for liver versus kidney? It was thought that liver donors with liver failure would get in line.

The Chair felt this might be an opportunity to have the NLRB develop a consensus position on the appropriate MELD exception score that might be given to a former living donor with more quality of life issues than failing liver/high MELD score issues. This is something that might be added on after Board consideration in December or might be added into the proposal.

At the moment there are no criteria for specificity. If living donor had to be listed for liver transplant, if their MELD score was not reflective of their need for transplant, they might be presented to their regional review board for a regionally-approved MELD exception score, so that would vary region to region. Moving to a national board would standardize the approach

across the nation and make clear that petitioning for a MELD exception is an option for former living donors.

5. Kidney Paired Donation (KPD) Work Group Update

The KPD update will be deferred to the next meeting call in November, as the Committee's liaison to the KPD Work Group is unavailable at this time.

6. VCA Living Donation Discussion

A brief background of VCA was presented. All-encompassing VCAs were included in July 2014 as "a covered human organ" in the OPTN Final Rule. In June 2015, a guidance document on VCA was created by a joint project by Living Donor, Ethics and VCA Committees. For clarification, guidance documents are not policies that must be followed, but instead are best practices documents. VCA was not included in policies at that time to make the included organs very specific and then to partner with the VCA Committee to develop guidance with the intent being policy development would follow. In August 2016 was the first living VCA donor in Dallas, Texas. Since 2016, it has picked up with 8 uterus living donors.

More recent developments include in September 2018 release of a guidance document on deceased and living donation from the American Society of Reproductive Medicine on uterus transplantation. Then in October 2018, the VCA Committee began discussion on whether guidance was enough or whether VCA needs to be added into policy language.

7. VCA Living Donation Project Idea Discussion

Summary of discussion:

The Living Donor Committee needs to identify whether VCA living donor policy is needed and to what extent. In addition to living donation Policy 14, Policy 18 also does not state anything about VCA living donor data collection.

The Chair commented that since August there have been maybe 10 living uterine donation transplants in the U.S., 9 at Baylor in Dallas and 1 at the Cleveland Clinic. Baylor does have the financial go-ahead to do 10 more uterine transplants are covering this as a research project under IRB protocol, following the guidelines of liver and kidney. The individual at Baylor who helped to start their program previously served on the Living Donor Committee, the Ethics Committee and has started living liver donor programs, but for other institutions, they may not have the knowledge base or experience to build a strong VCA program. This is one reason for moving forward with VCA policy.

One struggle when developing VCA guidance was deciding what would be appropriate with uterine versus other types of VCA. VCA spans a wide spectrum of tissue transplants, including face, extremities, composite soft tissue structures like skin, muscle and fascia, or uterine. It would be difficult to pull it all together because while uterine might be comparable to other solid organ donations, that may not be applicable to someone. For example, in the past when this topic first came up one of the Committee members shared that they had plastic surgeons that were recovering abdominal wall VCA grafts--skin, fascia, muscle--to reconstruct another woman's breast after mastectomy.

Suggested in the guidance is follow-up and reporting back, but there are no forms for that. Right now OPTN policy does not require any follow-up for living VCA donors. It is specifically excluded. But UNOS has been in touch with the programs and has sent them a spreadsheet that lists most of the basic questions such as complications and surgical safety. The programs were happy to submit that voluntarily, but they are under no obligation to do so. Thus far, data has been received once, but not yet 6-month, 1-year, or 2-year. An LDF has not yet been created for VCA. The form could include specific quality of life issues, psychosocial issues, etc.

As a reminder, current Policy 14 has a basic template for evaluation requirement of living donors of all types, but there is a subset of additional requirements for kidney and liver donors. That same model could be taken with VCA to develop a unique set of evaluation requirements for uterine donors or broader VCA population. It could be specified that living donor VCA programs be under IRB protocol.

Johns Hopkins is currently starting a VCA program. There was debate on deceased versus living and they decided on doing living and living related. These are experimental procedures being paid for by the hospitals. One suggestion was that before thinking about what is necessary for the follow-up, the Committee should start at the beginning and discuss how to help independent living donor advocates, as they have no experience working with VCA. In addition, hesitancy was expressed over making policy about VCA experimental procedures that may not even be a viable avenue for patients. One comment was that in theory, living donor pancreas transplantation is covered, but has not been done in several years and may no longer be clinically relevant. That does not mean it should be removed from policy.

Currently there is no cost structure such as Medicare or other conventional payors to support living donor VCA. Hospitals are paying internally or with funding for the sake of pushing the field forward. Therefore, there needs to be some discussion of debt.

One point raised was concern in the past over potentials for living donor limb transplantation by religious groups. In the past there were conversations with the Ethics Committee regarding arguments over if someone was willing and able that they should not be denied their decision of doing that. It would be important to have the Ethics Committee involved in any policy creation.

Baylor may have published an article on their approach to evaluation of a living uterine donor written in conjunction with some of the uterine transplant programs in Sweden. Their experience will be helpful down the line.

Next steps:

The VCA guidance document will be distributed to Committee members to study in more detail and to think about where they want to head with this in the spring.

8. Social Media Project Idea Discussion

A project that has been discussed for some years is with social media. Discussions about a social media project focused on creating a tool or resource for transplant hospitals, as opposed to patients directly. The primary interest was in collecting from current transplant centers that are active in social media with their patients and sharing that information with others to help reduce disparity across living donor transplantation across populations. This has been ongoing for some years due to controversy about the Living Donor Committee taking on projects intended to promote living donation.

The social media project will be:

- To develop best practices associated with transplant hospitals on how people are approaching giving advice to patients about how to use social media safely and ethically to reduce disparities across populations
- To collect best practices associated with how centers react in the most efficient way to "successful" social media campaigns.

Currently the project is in the pipeline for spring 2019. In the meantime, the Committee should pay attention and keep a log of programs that might have some best practices.

Summary of discussion:

One Committee member mentioned her center does get hit with social media. The problem is that with media campaigns and having 100 people interested coming at once, it is difficult to screen them, but important not to ignore them. Another problem is those interested often incompletely fill out the forms without disclosing all information that only comes to light when they come in for screening, so the process has to restart with choosing another potential candidate to come in. There are many components that need to be shared for programs to learn from one another.

Social media is part of a longstanding line of campaigns. In the past people have put up billboards, gone on television, put up newspaper ads, etc. The focus is how to prepare for the resulting rush of work in screening hundreds or thousands at a time. Social media blasts actually slow down the process. One Committee member indicated the first thing her center does is get consents and medical records so they can first go through it and weed people out. Another member indicated other steps that can be done before bringing people in to reduce staff workload, such as education and having their ABO drawn.

It is important not to turn people away too quickly and to remember that with all the people coming in, there is the potential, if they are willing, to match them with another recipient than the one they came in for.

There was agreement that the social media project needs to move forward sooner rather than later because patients are currently using social media without oversight or best practices guidance and will continue to do so. The Committee does need to be very clear with problem statements. It needs to be directed to the transplant centers, as well as the patients. They have always been careful about promoting a project that falls under increasing the number of transplants because it has not always been welcomed from leadership.

In the past, the how to find a living donor brochure project that was done touched on issues with race and socioeconomic disparities, and taking some of the best practices of centers that deal with challenging populations and how they positively promote this concept. This will hopefully be an endpoint to the social media project. When thinking about disparities, one thing discussed last year how social media will not be the answer for every part of the country. For example, there are counties in Alabama without Smartphones or broadband internet and poverty levels on par with third world countries, so their only access to social media is at the center.

Also in moving forward it will be important to talk with other Committees and get HRSA's perspective.

9. Donor Self-Assessment Subcommittee (DSAS)

This is a project for the Committee to start thinking about now. Unlike some of the other things talked about today, this is really patient-centric. Centers on a day-to-day basis are always explaining the process to potential donors and how risk factors factor in. The idea is to have transplant centers and the UNOS website to be a patient resource for appropriate information about the living donor transplant process. There are other resources out there and those will be looked at to see how this might differ, but this would be something housed on the Transplant Living website which was recently revamped with patient educational resources. This will go one step further and help potential donors understand what it means before they present themselves to a transplant hospital. It will be an educational tool, not a preselection/prescreening tool.

Many centers have BMI selection criteria, but this varies from center to center. BREEZE is an online tool that can be constructed to meet a transplant center's specific criteria and preselect donors. If a donor enters information that does not meet the basic introductory selection criteria of the center, they receive a message informing them of that. This will rather than being used as a tool that would exclude donors, would take the BMI information, present it back to the person

and inform them of what it is, what it means, and why it's used, as well as that the criteria varies from center to center. This introduces the concept to people that they can go somewhere else to be reevaluated.

This will also avoid one center having different criteria than another that might preselect someone. At the same time, pre-exposing donors to this information might result in potential donors withholding that information when presenting to a center. For example, they had a kidney stone 20 years ago or take a certain blood pressure medication and those might be exclusion criteria. They could be notified up front that before presenting to a center, their chances of being approved may be influenced by the risk factors. It is not necessarily turning them down, but giving them more of a realistic expectation.

BREEZE has prescreening elements and the opportunity to fill out an extensive medical, personal, and family history. BREEZE is set up center-specific and is not used by all centers, but the tools can be looked at to take some of the format used that the Committee could consider to applying to the self-assessment tool.

Several years ago a law was passed in California in partnership with Steve Jobs to develop a living donor registry within the State of California. This was developed with educational resources and an eligibility screening survey for non-directed donors. This will be made available for Committee members to look through. Centers were allowed to submit their individual donor criteria. Then the donor would go through the screening questions and be given a list of centers that might be willing to evaluate them. The center would also be emailed that a potential donor has reached out through the registry with their contact information. However, there was rigid prescreening element of that where the questions were not structured well and caused people to be turned away with no explanation. There are lessons to be learned from these experiences.

There is interest from UNOS leadership to develop a self-assessment tool. The PACC and TCC would also be involved. Patient education projects do not require POC approval, but this project might require POC approval due to the necessary IT programming.

Summary of discussion:

The Committee will need to look at possible elements that someone might answer in which they should be excluded. For example, there is a living donor exclusion criteria table in Policy 14. If someone answered with one of those exclusions, a pop-up could say that based upon UNOS policy, transplant centers are not allowed to accept them as a kidney donor due to the exclusion. One comment was that this could also include generic education as to why they cannot move forward and that they could talk to their transplant center about this to better understand how it may impact on their risk. This doesn't push them away or convince them that they need to hide information, as well as it does not pigeonhole one center.

One comment was that the National Kidney Registry (NKR) created their own version of BREEZE that is maybe called DASH that seems better than BREEZE and could be looked at by the Committee as well. NKR does well with making changes quickly to accommodate customers or when there is a problem, they fix it right away.

One question was whether there is any precedent in UNOS partnering with another organization that has an established registry such as NKR. The Chair indicated the Committee should be careful about not promoting any particular organization by referring patients to that resource because UNOS wants to be a go-to resource for patients.

The next level element of the project might be helping potential donors understand why the whole workup process varies from center to center and one may take longer than another to do

screening. One comment was that a patient advocate has started an online petition directed to the UNOS Living Donor Committee asking that they mandate all transplant centers complete all living donor evaluations in a timely and uniformed fashion because it is not fair that some transplant centers only do intake by phone a couple of hours a week versus centers that do it immediately online and get positive results.

One concern was that the tool would be very different for different centers and then will be very different for patients. Making it work for everybody might be challenging. There is agreement that an educational component would be valuable.

In the past there was a reluctance to make the patient educational resources surrounding the psychosocial evaluation too granular because people would script their responses. This could be a pitfall of the tool as well. It will be important not to move into the medical/physical/psychosocial prescreening.

There are different ways to approach the tool. For instance, as the donor goes through it, in order to move on they would have to click an "I understand" button. Maybe at the end they get something they could take to their center showing they have done their homework beforehand. Also, the information could be presented in a way that would capture the layperson's attention because they get so much information to read already, they start to lose interest. Because it is an online tool, graphics or other visually stimulating, engaging aspects can be added.

In addition, for people building a social media campaign, they could direct people to this tool as a starting point.

A subcommittee will be formed to get the work going or work groups can be set up to address different components of it. These will be open to anyone in the Committee who wishes to volunteer.

Next steps:

Committee members are encouraged to share any other tools or resources that they know of, as well as think about key points of information (for donors, things they wish they would have known) to include in the educational piece.

Upcoming Meetings

- November