

OPTN Living Donor Committee

Meeting Summary

September 13, 2021

Conference Call

Heather Hunt, JD, Chair

Introduction

The Living Donor Committee (the Committee) met via Citrix GoTo Meeting teleconference on 09/13/2021 to discuss the following agenda items:

1. Opening Remarks and Round-Table Introductions
2. Exclusion Criteria Project Working Session
3. Establish Membership Requirement for Uterus Transplant Programs
4. Overview of Other Public Comment Items
5. Exclusion Criteria Project Working Session Continued
6. Open Forums

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

1. Opening Remarks and Round-Table Introductions

There were no comments or questions.

2. Exclusion Criteria Project Working Session

The Committee discussed their project regarding living donor exclusion criteria.

Data summary:

Living donors by age:

- 76 living donors under the age of 18, since 1988
- 12 living donors under the age of 18, since 2012 (when exclusion criteria was implemented in policy)
 - 1 living donor between 6-10 years of age
 - 11 living donors between 11-17 years of age
- 2 living donors under the age of 1 both occurred in 2006

Total living donors less than 18 years old by relationship to recipient:

- 26 biological, blood related full sibling
- 24 non-biological, unrelated domino
- 11 biological, blood related child
- 7 biological, blood related identical twin
- 6 biological, blood related parent
- 1 biological, blood related half sibling
- 1 not reported

Living donors by age and relationship to recipient

- Of the 2 total living donors less than 1 year old, 1 was to a blood related identical twin, the other was a non-biological, unrelated domino donor
- The 2 total living donors between 1-5 years old were both non-biological, unrelated domino donors
- Of the 6 total living donors between 6-10 years old, 4 were non-biological unrelated domino donors, 1 donated to a blood related identical twin, and 1 donated to a blood related full sibling
- Of the 66 total living donors between 11-17 years old, the majority (25) donated to blood related full sibling, followed by non-biological unrelated domino donors (17), and blood related child donations (11)

Summary of discussion:

The Committee evaluated and discussed the exclusion criteria for living donors, per *OPTN Policy 14.4.E: Living Donor Exclusion Criteria*.

Exclusion criterion: Is both less than 18 years old and mentally incapable of making an informed decision

The Committee reviewed additional data regarding living donors less than 18 years of age and relationship to recipient. Additionally, the Committee acknowledged that per *OPTN Policy 14.9.B: Psychosocial and Medical Evaluation Requirements for Domino and Non-Domino Therapeutic Donors*, it is the transplant program's discretion to incorporate living donor exclusion criteria.

A member stated that the Committee will need to have just cause to modify this exclusion criterion, as a precedent has already been set. The member stated support for how the exclusion criterion is currently written. The member explained that the intent of the exclusion criterion is that if you are under 18 years of age, then you have to have the mental capacity to make an informed decision.

Another member expressed concern that separating this exclusion criterion might exclude a handful of candidates from becoming living donors. The member expressed hesitancy in imposing stricter exclusion criteria for these types of situations. The member stated that if medical professionals deem a candidate less than 18 years old appropriate to be a living donor, they would not want to have exclusion criteria exclude those rare instances.

The Committee discussed whether the term "mentally incapable" was too subjective for policy language, but ultimately decided that determining mental capability for informed consent is part of the evaluation process. Therefore, the term "mentally incapable" is acceptable language to include in policy.

A member asked whether transplant programs should determine whether someone less than 18 years old is capable of making an informed decision or whether to add more specifics. Another member responded that transplant programs have internal protocols for evaluating living donors, and that adding specifics into policy would be unnecessary.

A member acknowledged that the brain is not fully developed until the age of 25. The member suggested modifying the exclusion criterion to exclude any donor under the age of 18, and if there was a circumstance in which an individual under the age of 18 wanted to donate, the transplant program would apply for an exception. Another member responded that the Committee should balance between protecting living donors but not implementing barriers to living donation. The member stated that due to the small number of living donors less than 18 years old and transplant programs determination of informed consent, there does not seem to be just cause to modify this exclusion criterion. A member agreed.

A member asked whether age should be included in policy due to the Committee's conversations focused around ability to provide informed consent. Another member responded that, in general, there

are legal age limits to consent because there is the assumption that age connects with the ability to understand, internalize, and repeat back information. The member acknowledged that the American Pediatric Association has previously outlined extenuating medical circumstances in which individuals under the age of 18 may be living donors. The member explained that the combination of extenuating medical circumstances and the ability to make an informed decision leads them to support keeping the exclusion criterion as is rather than modifying it to be a strict age limit exclusion.

The Chair supported the exclusion criterion remaining as is in policy, given that there is not a problem that needs to be solved. Another member agreed and expressed concern regarding changing the exclusion criterion and possible consequences that may result. Other members agreed. The Chair stated that the Committee can review living donor data by age, and specifically domino donor data, in the future to reevaluate their decision.

The Committee agreed to leave the exclusion criterion *is both less than 18 years old and mentally incapable of making an informed decision* as is in policy.

Exclusion criterion: High suspicion of donor coercion

The Committee reviewed their proposal to modify this exclusion criterion with the intent to align language with other OPTN policy references to donor coercion for consistency. The Committee supported the following language modification: *High suspicion of donor inducement, coercion, and/or other undue pressure.*

Exclusion criterion: High suspicion of illegal financial exchange between donor and recipient

The Committee reviewed their proposal to modify this exclusion criterion with the intent to be more clear and align language with informed consent and NOTA. The Committee supported the following language modification: *High suspicion of knowingly acquiring, receiving, or otherwise transferring anything of value in exchange for any human organ.*

Proposed exclusion criterion: Active Incarceration of the living donor

Feedback compiled from Committee members prior to this meeting included a proposed suggestion for the Committee to discuss potentially adding an exclusion criterion related to actively incarcerated living donors.

A member stated support for adding this exclusion criterion into policy due to the cost of evaluating an incarcerated living donor, the increased risk of transmission of diseases, and logistics of follow up after a transplant while still incarcerated. Another member stated that their transplant program has internal policies for excluding actively incarcerated individuals from living donors due to the aforementioned reasons.

The Chair posed the scenario of a parent who is incarcerated due to a drunk driving situation, and while serving their sentence they have a very sick child who needs an organ transplant. The Chair stated that adding this exclusion criterion would not allow for a parent in the described situation to become a living donor for their child. The Committee acknowledged that adding this proposed exclusion criterion would require all transplant programs to have an absolute contraindication for actively incarcerated individuals, which would remove transplant program autonomy and discretion for these potential living donor candidates.

A member stated that their program is currently evaluating a potential living donor who is on trial. The member explained that if the candidate passes the psychological and psychosocial evaluations, the case would go to the hospital's Ethics Committee before continuation of the evaluation in order to have a separate body, outside of the transplant team, provide input on the ethical issues. The member

supported not including this as an exclusion criterion in policy and allow transplant programs to have discretion in evaluation decisions.

Another member stated that one reason actively incarcerated individuals are turned down is because they are thought to be too vulnerable to coercion, and there might be a possibility they are getting an exchange of valuable consideration. The member added that actively incarcerated individuals are stripped of their rights, including the right to choose their own destiny, and due to this, actively incarcerated individuals may not be able to give free and informed consent. The member agreed that singular cases can make great impact, and supported not adding this exclusion criterion in order for transplant programs to be able to give due consideration to every donor, regardless of their circumstance. Other members agreed to not add this exclusion criterion and allow individual transplant programs make their own decisions.

A member stated that there are parallels between the conversations regarding actively incarcerated individuals and those under the age of 18 because they are both vulnerable populations. The member added that for both of these populations, the ability to make an informed decision and provide informed consent is a concern. The member asked if there could be language to the policy regarding coercion which adds an example of populations who are vulnerable to coercion such as incarcerated persons. The member agreed this should not be added as an exclusion criterion, but suggested the Committee should revisit this as a potential project idea.

The Committee agreed to not propose to add *active incarceration of the living donor* as an exclusion criterion in OPTN policy.

3. Establish Membership Requirements for Uterus Transplant Programs

The Committee received a presentation on the OPTN Vascularized Composite Allograft (VCA) Committee's proposal, *Establish Membership Requirements for Uterus Transplant Programs*.

Summary of discussion:

A member asked if the VCA Committee foresees having to add additional requirements in the future as the field develops. The VCA Committee Vice Chair agreed that the field is evolving and added that procedures are very limited and low in volume as of now, but acknowledged that the requirement may change over time dependent on expertise needed and type of transplant.

Another member stated that radical hysterectomies and living donor uterus recoveries are different procedures and asked if two living donor uterus recoveries is enough for living donor uterus surgeon requirements. The VCA Committee Vice Chair responded that the VCA Committee is requesting feedback on whether two living donor uterus recovery surgeries are enough. The VCA Committee Vice Chair explained that the procedures are rare, but they do not want to prohibit programs from advancing while also ensuring patient safety. A member suggested that those involved in living donor uterus transplant should be the ones to make these decisions.

The Chair stated, that from a living donor perspective, they would want it to be disclosed that the surgeon had performed only two living donor surgeries and have the ability to consent to that.

A member asked how requirements for living donor uterus surgery compare to that of living donor kidney or living donor liver surgeries. A member stated that there is a timeline for these requirements to be performed, which is an important element. The VCA Committee Vice Chair stated that it is hard to compare due to the high volume of living donor kidney transplants performed and low volume of living donor uterus transplant performed. The VCA Committee Vice Chair added that there have only been about 32 uterus transplant performed in the United States by different surgeons.

Another member stated that, from a liver perspective, it is very useful experience to perform liver resections that are not living donation. This lead the member to understand the usefulness of radical hysterectomies as experience for living uterus donation surgery.

A member stated that in addition to the decided upon number of living donor uterus surgeries performed as a requirement, there should be a measure of competence included. The member suggested that a measure of competence be certified by another primary surgeon or their co-surgeon before independently performing a uterus transplant.

4. Overview of Other Public Comment Items

The Committee reviewed a summary of other Summer 2021 Public Comment items. The Chair encouraged the members of the Committee to review these items, as well as leave a personal comment on the Lung Transplantation Committee's *Establish Continuous Distribution of Lungs* proposal regarding prior living donor priority. There were no comments or questions.

5. Exclusion Criteria Project Working Session Continued

The Committee continued discussions on living donor exclusion criteria.

Summary of discussion:

Exclusion criterion: Active malignancy, or incompletely treated malignancy

Feedback compiled from Committee members prior to this meeting included:

- No consensus
- Rationale for keeping exclusion criterion as is:
 - Disruption or delay of cancer treatment in the living donor can increase the risk of recurrence or incompletely treated cancer
 - Risk of transmission of cancer to the recipient can affect outcome of transplant and recipient survival which negates the benefits of organ donation for the donor
 - Risk of decompensation due to stress caused from liver resection/major operation
 - Active cancer patients have increased risk of thrombotic and hemorrhagic dysfunction (0.6-7.8 percent incidence of venous thromboembolism (VTE) and 10 percent hemorrhagic conditions, most commonly disseminated intravascular coagulation (DIC))
- Rationale for modifying exclusion criterion:
 - Most benefit for older patients/spousal donation/older caregivers
 - Expand the pool of donors
 - Prostate cancer is a highly heterogeneous disease, ranging from remarkably slow progression or inertia to highly aggressive and fatal disease. Therapeutic decision-making and outcome highly depend on the appropriate stratification of patients to risk groups which help differentiate between benign versus more aggressive states and remarkable progress has been made in this area
 - It is possible that donor centers may not be able to completely exclude active malignancy despite adequate workup, suggest modification to add "known" to this criterion
- Several suggested modifications were proposed:
 - Modify to provide for the possibility of donors who may not have a known malignancy
 - Modify to base exclusion on type of malignancy
 - Modify to limit allowable donation to those with minimal/low risk malignancies

- Modify to allow donation for those with localized squamous cell carcinoma and basal cell carcinoma (no melanoma)
- Modify to allow donation for those with low grade prostate cancer

A member stated that there is a broad spectrum of malignancies and an individual with a low risk malignancy may be acceptable as a living donor. The member added that it will be difficult to define “low risk” in policy language for it to be clear for transplant programs.

Another member stated that the U.S. Preventative Services Taskforce, as well as other organizations, have found that observation of low grade prostate cancer to be an acceptable treatment. The member stated that low grade prostate cancer could be thought of more as a medical condition than a cancer, and asked whether suitable living donor candidates with low grade prostate cancers should be excluded based on one broad exclusion criterion. The member suggested the exclusion criterion could be modified to specify certain malignancies which would be allowable in living donation, or modify the exclusion criterion to say “low grade, non-progressive, non-symptomatic, and decision made in conjunction with local oncology team”.

SRTR staff asked for clarification if renal cell carcinoma is considered a therapeutic donation. Staff informed members that renal cell carcinoma was previously identified by the Committee as a possible condition of potential therapeutic donors as part of a 2015 proposal to establish requirements for therapeutic organ donation.¹

A member asked if there is data which shows that low grade prostate cancer cannot be transmitted via organ transplantation. The Committee reviewed Table 2: Suggested risk categorization for specific tumor types in the article *Donor-transmitted malignancies in organ transplantation assessment of clinical risk*. The Committee acknowledged the categorizations are based on the risk to the recipient, and there needs to be a focus on the risk to the living donor.

Another member stated that the patient 10-year survival for an individual who has low risk prostate cancer is 99 percent without any therapy.

A member posed the scenario where an individual is a living kidney donor, and two years later has a recurrence of cancer and has to undergo a form of chemotherapy that can have nephrotoxicity. The member stated in this scenario the individual is at risk of future consequences due to the decision to donate. Another member responded that it could be argued that any donor has risk of future consequences related to chemotherapy because there is always the potential they will develop a malignancy in the future. Another member responded that the scenario is different due to the fact the transplant team is aware of the malignancy pre-donation.

Another member asked if there are other malignancies that would be allowable besides low grade prostate cancer and non-melanoma superficial skin cancers. A member responded and referenced the table in the *Donor-transmitted malignancies in organ transplant assessment of clinical risk* article. The member responded that minimal risk malignancies outlined in that table pose very little risk to the donor, even if there is recurrence, and most will be treated with local treatment. The member responded that there are more recent articles that might provide further insight.

The Chair stated that in a scenario of being a living donor candidate with prostate cancer, which had 0.1 percent risk of transmission to their sibling receiving the organ, and they were told by multiple medical

¹ *Proposal to Establish and Clarify Policy Requirements for Therapeutic Organ Donation*, OPTN Living Donor Committee, 2015.

professionals that the best course of action is observation, they would be very frustrated they were unable to donate.

Another member stated that it is important for donors to be a part of the decision making, and perhaps the Committee should discuss whether there are certain types of malignancies and thresholds of risk in which it is appropriate for the individual to make their own decision to be a living donor.

A member asked whether there is a way for transplant programs to request exceptions for living donor exclusion criteria. Staff responded there is currently no pathway, and such a process would need to be built into policy.

Another member suggested modifying the exclusion criterion to state “active malignancy, or incompletely treated malignancy that does not require current or future treatment (other than active surveillance) and considered as minimal risk of transmission”. The member explained this language modification avoids creating a list of acceptable malignancies and allows programs to make their own determination. The member asked whether “minimal risk” should be defined further by stating an acceptable threshold for risk of transmission. The Committee agreed to not define a percentage of minimal risk that is allowable. Another member agreed that it is important for policy to allow transplant programs to make their own decisions. Additionally, members agreed that the exclusion criterion should specify “known” active malignancies.

The Chair asked if “current and future treatment” would allow for minor skin cancer patients to be acceptable living donors. A member responded that if an individual had basal cell carcinoma which needed to be removed that would fall under the “current treatment” language. Another member stated that an individual who has basal cell carcinoma should have it resected before undergoing living donation surgery. The member explained that basal cell carcinoma can be treated in a short time frame, so it is not necessary to account for this malignancy when discussing potential language modifications. Another member posed the scenario of a kidney paired donation pair in which the donor has an active basal cell carcinoma malignancy. The member stated that often times kidney paired donation surgery dates are out of transplant programs’ control, therefore scheduling a resection of the basal cell carcinoma on the living donor prior to transplantation would be difficult and may result in inactivating the pair. A member stated that in the best interest of the donor, the skin cancer should be treated before donating an organ. Another member agreed that if they were aware their patient had an active case of basal or squamous cell carcinoma, they would want the patient to be treated first in the interest of their own health. Another member stated that it is difficult to definitively determine whether a patient will need future treatment or not, especially in cases of low grade prostate cancer.

The Committee agreed to propose modifications for this exclusion criteria with the intent to allow transplant programs more autonomy in deciding which living donor candidates they would except. The proposed language modification is as follows: *Known active malignancy, or incompletely treated malignancy that does not require current or future treatment (other than active surveillance) and considered as minimal risk of transmission.* The Committee will continue to discuss the proposed modifications for this exclusion criterion, specifically how “minimal risk” would be monitored and evaluated for compliance purposes.

Exclusion criterion: HIV, unless the requirements for a variance are met, according to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

Feedback compiled from Committee members prior to this meeting included:

- Overall consensus to keep

- Some exceptions to this exclusion criterion were if donation was to an HIV positive recipient. Additionally, it was noted there may be exceptions if there was reassuring intermediate term data – at least 10 years of longitudinal follow up comparing HIV positive living donors to non-HIV living donors.
- Rationale for keeping exclusion criterion as is:
 - Long term outcomes of HIV viral load suppression in donors with single kidneys and post nephrectomy glomerular filtration rates (GFRs) will lead to variability in dosing parameters and risk of break through infections
 - HIV positive organs transplanted in HIV negative recipients would be transmission of an incurable disease
 - Unclear of future risks if the patient develops a breakthrough infection in the future
 - Should the donor be on a nephrotoxic highly active antiretroviral therapy (HAART) agent with good HIV control leaving them with a singular kidney with ongoing exposure to nephrotoxins may result in progressive chronic kidney disease (CKD) and/or additional toxicity from medications

The Committee agreed to keep *HIV, unless the requirements for a variance are met, according to Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* exclusion criterion as is in policy.

Exclusion criterion: Evidence of acute symptomatic infection (until resolved)

- Overall consensus to keep
- No exceptions where a living donor candidate with evidence of acute symptomatic infection would be allowed to be a living donor
- Rationale for keeping exclusion criterion as is:
 - Most infections are treatable, usually with short term antibiotics and donor candidacy can be re-visited after resolution
 - Timing of an elective surgery, with no direct physical benefit can wait until infection is resolved
 - Taking patients to the operating room for an elective surgery while infected can increase the risk of complications or transmit disease to the recipient who will be immunosuppressed, which could lead to graft loss or death

The Committee agreed to keep *evidence of acute symptomatic infection (until resolved)* as is in policy.

Next steps:

The Committee will receive their data request presentation and continue discussion on living donor exclusion criteria during their September 29, 2021 meeting.

6. Open Forum

A member expressed interest in further discussing and reviewing informed consent to ensure the living donor is knowledgeable and protected. A member responded that in their center, if the expected post-transplant survival outcome is low, they receive permission from the recipient to give the donor details regarding medical information and reasons for the low expected outcome. The member added that then the donor would need to decide whether or not to proceed with the donation. A member asked if there is policy surrounding a process such as that or if it is up to individual transplant programs to address each circumstance.

The Committee briefly reviewed *OPTN Policy 14.3: Informed Consent*. The Chair asked whether the language “The recovery hospital can disclose to the living donor...” should be changed to “must

disclose”. A member responded that the Committee could discuss whether transplant hospitals must disclose this information or if they should disclose in certain circumstances.

The Chair agreed the Committee should further discuss informed consent. The Chair expressed interest in specifically discussing the need for living donors to give informed consent, however there is no long term data collection to inform medium and long term outcomes for living organ donors.

Another member suggested the Committee should work with the Minority Affairs Committee regarding living donation disparities. The member explained that data shows great variation in the ethnicity of recipients and the ethnicity of living donors. The member suggested the Committee could review policy to ensure that there is nothing that helps create this disparity. Another member agreed and added that their health center serves mostly Pacific Islander populations but this population is the least likely to donate or receive transplants. The member suggested the Committee discuss if there is a pathway in policy to educate communities and provide more access to transplantation.

There were other no comments or question. The meeting was adjourned.

Upcoming Meetings

- September 29, 2021 (teleconference)
- October 13, 2021 (teleconference)

Attendance

- **(Sub)Committee Members**
 - First Name Last Name
 - First Name Last Name
- **HRSA Representatives**
 - First Name Last Name
- **SRTR Staff**
 - First Name Last Name
- **UNOS Staff**
 - First Name Last Name
- **Other Attendees**
 - First Name Last Name