Introduction

The Living Donor Committee (the Committee) met via Citrix GoTo Meeting teleconference on 09/08/2021 to discuss the following agenda items:

1. Welcome & Announcements
2. Exclusion Criteria Project Work
3. Virtual “In-Person” Meeting Preview

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

1. Welcome & Announcements

The Committee was informed that the Committee’s Modify Living Donation Policy to Include Living Vascularized Composite Allograft (VCA) Donors proposal was implemented into OPTN policy and became effective on September 1, 2021.

The Committee was informed that their discussions regarding prior living donor priority will be presented to the organ-specific committees as they develop their continuous distribution proposals. Currently the Lung Transplantation Committee’s continuous distribution proposal includes prior living donor priority for all living donors. This proposal is currently out for Summer 2021 Public Comment period. The Chair encouraged the Committee to leave individual comments for the Lung Transplantation Committee’s Establish Continuous Distribution of Lungs proposal regarding the inclusion of prior living donor priority. Additionally, the Chair will present the Committee’s prior living donor priority recommendations to the Kidney-Pancreas Continuous Distribution Workgroup this month.

There were no comments or questions.

2. Exclusion Criteria Project Work

The Committee discussed their project regarding living donor exclusion criteria.

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

Feedback compiled from Committee members prior to this meeting included:

- Overall consensus to split criterion into two separate exclusion criteria
  - Proposed modification to split age and mental capacity into two separate criteria
  - Proposed modification to clarify which minor donors would be acceptable
  - Proposed modification to provide more clarity on the exclusion criterion
- Some exceptions to this criterion were noted:
A child, aged 16 or 17, whose parent needed an organ and the child was the parent’s only option

O An emancipated minor

O Court order

O Possible “domino donor”

- While there is a majority stance on excluding minors from becoming living donors, there is no consensus – should policy exclude if the research has no basis to do so?

- Rationale for keeping an exclusion criterion related to age and mental capacity in policy:
  - Removal would be detrimental to short and long term impacts to the living donor
  - Living donation as an elective surgery that carries meaningful risk without any medical benefit has a high threshold for informed consent. The bare minimum requirements of informed consent are that the potential donor is of legal consenting age (18 and older) and is competent to make medical decisions for themselves.

The Committee requested additional information regarding data on living donors under the age of 18. The Committee agreed it is important to distinguish living donors under the age 18 who were domino donors and those who were not.

Members suggested changing “and” to “or” within the exclusion criterion because mentally capacity is a concern regardless of age.

A member discussed the concept of a “mature minor” and whether policy should exclude those under 18 years of age unless they were proven to be a mature minor.

Another member reminded the Committee that the language used within policy needs to be as objective as possible. The member explained that it would be difficult to determine “superior capacity”, if language such as that was used in proposed modifications. Another member agreed this verbiage should be avoided due to its subjective nature.

A member commented that, while they understand the need for a hard cut off for objectivity, 18 years of age can be arbitrary. Another member suggested that a modification to this exclusion criterion could be to change the language to say “legal age” since States have various legal ages (e.g. Alabama’s age of maturity is 19 years old). A member responded that for policy which affects the whole country, it is reasonable to have 18 years of age as a cut off in order to stay objective. The member added that if other OPTN policy uses 18 years of age as a cut off, it is also reasonable to maintain it as a cut off in this exclusion criterion for consistency.

A member asked for examples, outside of the field of transplantation, in which court systems have determined whether a minor is capable of making adult decisions. Another member asked for more information regarding emancipated minors. Staff will follow up with more information next meeting.

The Committee was informed of language in NOTA which states the OPTN shall “recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children” and the “term ‘children’ refers to individuals who are under the age of 18”.

The Committee was informed that part of the original rationale for this exclusion criterion was to allow parents, less than 18 years of age, to donate to their child in need. The Committee was further informed that the intent of this exclusion criterion was to express the idea that, in general, living donors should be adults but to allow for special circumstances.

The Committee will continue to discuss is less than 18 years old and mentally incapable to make an informed decision during their next meeting.
Exclusion criterion: High suspicion of donor coercion

Feedback compiled from Committee members prior to this meeting included:

- Overall consensus to keep, with one proposed modification for clarity
  - Proposed modification to align exclusion criterion language with other OPTN policy references to donor coercion, as this is what social workers and independent living donor advocates are asked to evaluate
- No exception in which an individual where there is a high suspicion of donor coercion would be accepted as a living donor
- Rationale for keeping an exclusion criterion related to donor coercion in policy:
  - Potential living donors who are being influenced by coercive factors are unable to make autonomous and informed choices to donate
  - Removal would introduce the possibility for increased number of donations where coercion occurs
  - As stewards of the potential donor’s well-being and safety, especially in the context of a surgery with no medical benefit, the transplant team must regard coercive factors as contraindications to living donation
  - Removal would be damaging to the ethical basis of living organ donation

The Committee agreed that modifying this criterion to align with other OPTN policy language is important for consistency. The Committee reviewed language in OPTN Policy 14.1.A Living Donor Psychosocial Evaluation Requirements and OPTN Policy 14.3: Informed Consent. The Committee agreed to propose the following exclusion criterion: High suspicion of donor inducement, coercion, and/or other undue pressure.

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

Feedback compiled from Committee members prior to this meeting included:

- Overall consensus to keep, with one proposed modification for clarity
  - Proposed modification to align exclusion criterion language with NOTA/OPTN policy references to illegal financial exchange to provide a wider scope/breadth
- No exception in which an individual where there is a high suspicion of illegal financial exchange would be accepted as a living donor
- Rationale for keeping an exclusion criterion related to illegal financial exchange in policy:
  - Financial compensation for an organ is prohibited by law
  - A factor such as compensation interferes directly and substantially with donor autonomy and decision making
  - Removal would introduce the possibility for increased number of donations where illegal financial exchange occurs
  - Removal would be damaging to the ethical basis of living organ donation

The Committee agreed that modifying this criterion to align with other OPTN policy language is important for consistency as well as a broader scope. The Committee reviewed language in NOTA Sec. 274e. Prohibition of organ purchases and OPTN Policy 14.3: Informed Consent.

Members agreed that the phrase “valuable consideration” may be difficult for donor and donor families to understand. A member suggested that if the term “valuable consideration” is used, it may be beneficial to include examples (e.g. property, vacation, cash).
A member asked if legal financial exchanges are acceptable since the exclusion criterion specifies illegal financial exchange. Another member responded that recipients are allowed to reimburse donors for certain expenses but the reimbursement has to be an exact amount.

The Committee agreed to modify this exclusion criterion with the intent to align language with OPTN Policy 14.3: Informed Consent. The Committee agreed to use language to specify that the exclusion is based on illegal exchanges of anything of value, not solely illegal financial exchanges. The Committee will review proposed modifications to the language of this exclusion criterion at the next meeting.

**Exclusion criterion: Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality**

Feedback compiled from Committee members prior to this meeting included:

- Overall consensus to keep, with two proposed modification
  - Proposed modification to include substance abuse, as research on donor psychiatric conditions often distinguishes substance abuse separately
  - Proposed modification to specify “chronic” or “active” psychiatric conditions
- Two exceptions to this criterion that were noted:
  - If donating would sustain the life of someone the living donor relies on for support/their own mental health, denying the donation could be contrary to the potential living donor’s mental health interests
  - If determination was made with biased conditions, such as discrimination due to racial bias
- Rationale for keeping an exclusion criterion related to uncontrolled diagnosable psychiatric conditions in policy:
  - For individuals with a known history of certain types of mental health concerns, undergoing surgery and the additional relational and emotional complexities of the living donation situation can trigger psychiatric decompensation and symptomology
  - Removal would be detrimental to short and long term impacts to the living donor

The member who suggested modifying this exclusion criterion to include substance abuse, stated that upon further thought recognized that substance abuse is in the Diagnostic and Statistical Manual of Mental Disorders (DSM) as a psychiatric diagnosis. The member explained that due to this, it would be unnecessary to include substance abuse into this exclusion criterion.

The Committee discussed adding “chronic” or “active” to this exclusion criterion, but ultimately agreed that the exclusion criterion, as written currently, captures the intent.

The Committee agreed to keep uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality as is in policy.

**Next steps:**
The Committee will continue discussions during their September 13, 2021 meeting.

**3. Virtual “In-Person” Meeting Preview**

During the Committee’s virtual “in-person” meeting, they will have round-table introductions, continue working on the exclusion criteria project, have a presentation from the Vascularized Composite Allograft Committee on their proposal, Membership Requirements for Genitourinary Programs, and review other items out for Summer 2021 Public Comment.

There were no comments or question. The meeting was adjourned.
Upcoming Meetings

- September 13, 2021 (virtual “in-person”)
- September 29, 2021 (teleconference)
- October 13, 2021 (teleconference)
Attendance

- **Committee Members**
  - Aneesha Shetty
  - Angie Nishio Lucar
  - Camille Rockett
  - Carol Hay
  - Katey Hellickson
  - Heather Hunt
  - Mary Beth Stephens
  - Omar Garriott
  - Stevan Gonzalez
  - Tyler Baldes
  - Vineeta Kumar

- **HRSA Representatives**
  - Adriana Martinez
  - Jim Bowman
  - Raelene Skerda

- **SRTR Staff**
  - Christian Folken
  - Krista Lentine

- **UNOS Staff**
  - Anne McPherson
  - Lauren Motley
  - Leah Slife
  - Lindsay Larkin
  - Meghan McDermott
  - Rebecca Goff

- **Visiting Board Member**
  - Brad Kornfeld