Introduction

The Living Donor Committee (the Committee) met via Citrix GoToMeeting teleconference on 10/21/2020 to discuss the following agenda items:

1. Review of Post-Public Comment Changes
2. Update on COVID-19 Emergency Policy Data

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

1. Review of Post-Public Comment Changes

The Committee continued discussion of public comment feedback on the *Modify Living Donor Policy to Include Living VCA Donors* proposal.

Summary of Discussion

*Ethics of VCA in Informed Consent*

Based on additional feedback from the VCA Committee, the Committee revisited the discussion on whether the Informed Consent table should be expanded to cover all genitourinary or be restricted to uterus only. Some VCA Committee members expressed concerns for:

- Uniformity in the approach to policy language between Living Donor and VCA policies
- Public perception of policy inclusion of genitourinary
- Timing of policy inclusion as outcomes for other types of genitourinary transplant are not yet known

The Chair reminded the Committee there was some opposition during Public Comment from the general public. However this opposition was offered without explanation or comment. Additionally the Patient Affairs Committee spent considerable time reviewing the language and supported the proposal.

A member commented the project originally begun out of mutual concern from both the Living Donor and VCA Committees for transplants that could be occurring without policy structure. The member further commented the policy as proposed provides a minimal level of oversight for living VCA donors by requiring the specified informed consent conversations. Another member commented they prefer to keep the proposed table as drafted, with the goal of refining the requirements further in the future as the field of VCA develops.

A member commented the table as proposed was a result of robust discussion and was drafted with the goal of providing language broad enough to encompass where the VCA field may evolve and ensures there is not a policy gap should other VCA transplant types emerge. Another member further commented the proposal establishes requirements for both categories that are enforceable and measurable.
The Committee decided to keep Informed Consent table as proposed and emphasized establishing such policies is not meant to incent or deter specific types of living VCA transplantation. The Committee also recognized the need to revisit the VCA policy on a periodic basis as the field evolves and as the VCA Committee further refines VCA policy.

Changes to the Informed Consent Table

The Committee revisited the post-public comment change to remove gender-specific language from potential surgical risks. The Committee recognized some of the surgical risks would not be broadly applicable. Therefore, the Committee agreed to amend language to remove “decrease of fertility”, “inability to bear children”, and “loss of function” to be replaced with “partial or complete loss of organ-specific function including reproductive function”.

Next Steps

The Committee will discuss the post-public comment changes and considerations with the VCA Committee during a joint session on October 26. The Committee will also vote on the final policy language to go to the Board.

2. Update on COVID-19 Emergency Policy Data

The Committee reviewed form submission data following the implementation of the COVID-19 Emergency policy.

Summary of Data

A member of the Research staff presented an update to the Committee on living donor follow-up forms (LDF) forms in amnesty status. In April, the OPTN Executive Committee approved several emergency policies in response to the COVID-19 crisis, including a policy to relax requirements for the LDF forms. Suspension of these requirements is backdated to March 13, 2020 and will expire on December 31, 2020 if the Executive Committee or Board of Directors has not acted before that date.

The Committee reviewed the following data points specific to living donation:

- Status of forms as of September 7, 2020 by the week they were expected/due
- Percent in amnesty status as of September 7, 2020 by the week they were expected/due, organ, and region

The data showed the proportion of forms with expected dates that move into amnesty status initially increased after policy implementation, while the proportion has been fairly stable over recent weeks. The proportion of forms in amnesty status increased through the spring and early summer, and has been stable over the past several weeks at around 33 percent. The percentage in amnesty status has been more variable for liver than for kidney. There is variation by region as well.

The Chair asked the presenter why amnesty was given for follow-up phone calls. The presenter responded the rationale was partly to keep patients from having to go into transplant hospitals for follow-up but also to alleviate the data burden for programs during the COVID-19 pandemic. The presenter did note that the data shows approximately two-thirds of programs are still submitting the LDF forms.

The Chair also asked the presenter why the liver numbers are more variable. The presenter responded that is most likely due to the smaller number of liver donors relative to kidney.

Summary of Discussion
A member recommended the Executive Committee and Board of Directors should keep observing trends as they are changing rapidly. A member asked if programs would be required to retrospectively provide the LDF data. The Committee was informed the Executive Committee has been having discussions on ways to encourage programs to submit the back data but have not approved a requirement as of yet.

A member commented the amnesty period will continue to impact the program compliance data for at least two years after the amnesty period is over.

The Committee requested more information on the geographic distribution of amnesty status relative to the prevalence of COVID-19 outbreaks to review on a future call.

Upcoming Meetings

- October 26, 2020 (teleconference, formerly in-person meeting)
Attendance

- **Committee Members**
  - Aneesha Shetty
  - Angie Nishio Lucar
  - Carol Hay
  - Carolyn Light
  - Heather Hunt
  - Katey Hellickson
  - Mary Beth Stephens
  - Nahel Elias
  - Omar Garriott
  - Stevan Gonzalez
  - Vineeta Kumar
  - Randy Schaffer
  - Jessica Spiers
  - Titte Srinivas

- **HRSA Representatives**
  - Vanessa Arriola
  - Arjun Naik
  - Raelene Skerda

- **SRTR Staff**
  - Bertram Kasiske
  - Michael Conboy

- **UNOS Staff**
  - Kristine Althaus
  - Leah Slife
  - Lindsay Larkin
  - Kerrie Masten
  - Sarah Booker
  - Susan Tlusty
  - Tina Rhoades