OPTN/UNOS Minority Affairs Committee
Meeting Minutes
September 18, 2017
Chicago, Illinois

Sylvia Rosas, MSCE, Chair
Irene Kim, MD, Vice Chair

Introduction

The Minority Affairs Committee met in Chicago, Illinois on 9/18/2017 to discuss the following agenda items:

1. Welcome
2. Policy Oversight Committee Update
3. Fall Public Comment Proposal Update: Guidance for Non-A1 (A2/A2B to B) Kidneys
4. Minority Affairs Active Projects Update
5. Fall Public Comment Presentations (other Committees):
    a. Improving Allocation of Dual Kidneys (Kidney)
    b. Concept Paper: Allowing Deceased Donor-Initiated Kidney Paired Donation (KPD) Chains (Kidney)
    c. Enhancing Liver Distribution (Liver and Intestinal)
    d. Broadening Allocation of Pancreas Transplants Across Compatible ABO Blood Types (Pancreas)
6. Overview: Vascularized Composite Allograft (VCA) Transplantation – Data Report and Donor/Candidate Matching
7. Update: APOL1 Study – Long Term Kidney Transplantation Outcomes

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

1. Welcome

Summary:

The Committee Chair welcomed attendees and members and began the meeting. The Chair shared details about the upcoming Second Annual Texas Medical Center Hispanic Transplant Symposium, September 26, Houston, TX. The Chair will be a featured speaker and the Minority Affairs Region 4 representative will attend.

The Chair conducted an icebreaker in which members introduced themselves and offered one unique activity recommendation in his or her current city.

2. Policy Oversight Committee Update

Summary:

The Vice Chair provided an update of the Policy Oversight Committee activities. Approved ongoing projects among all committees total 23 and 3 new projects were reviewed and approved in July. The new projects will proceed to the Executive Committee for approval.

The Committee reviewed the 13 public comment proposals currently out for public comment.

Staff also added that the project dashboard can be viewed at any time on the Tableau link on the Board and Committees websites.

Summary of Discussion:

No questions.

3. Fall Public Comment Proposal Update: Non-A1 (A2/A2B to B) Guidance

Summary:

The workgroup lead provided a brief overview of the proposal currently out for Public Comment, which can be found here.

Formal presentations were given to the following committees: Histocompatibility, Patient Affairs, Kidney. All three committees express support and added public comments. It is on the nondiscussion (consent) agenda at all regional meetings.

All regional meetings through 9/18 have unanimously approved the guidance.

Suggestions from presentations include:

- Add suggestions/sections for post-transplant follow up
- Frustration with need (policy requirement) for informed consent
- Separate effort detail: currently waitlisted candidates vs. new waitlisted candidates
- Educate about what can go wrong and how to manage that as those aspects promote patient safety and patient education

Staff explained that the Committee will vote to send it to the Board with any changes after Public Comment closes. The Committee should discuss any changes requested now.

Summary of Discussion:

The Histocompatibility Committee would like to remove informed Consent completely, but this will have to be a policy change. A note can be added to indicate that informed consent is currently required policy. If the Kidney and Histocompatibility Committees would like to begin a project to change the informed consent requirement, the Minority Affairs Committee can collaborate on this.

The Kidney Committee requested additional information be added for outside labs performing titer testing. Enhancing guidance on monitoring antibodies post-transplant was suggested.

The Minority Affairs Committee (MAC) is not required to change anything based on feedback. Anything that is already policy cannot be changed.

The goal of the document is to encourage programs to implement this provision locally. It is not intended to enforce titer thresholds.

It is important to listen to the Patient Affairs Committee and possibly present data to them that shows the safety in implementing the provisions. Adding sentences to the Guidance to prove or ensure safety is also an option.

If Guidance for post-transplant is added, the Histocompatibility Committee should be consulted.

A member asked if additional informed consent, after general informed consent, is needed to accept this match. It is similar to providing informed consent to accept a high KDPI kidney. These kidneys fall outside of “standard criteria kidneys.” There is no evidence that there is increased risk to receive these kidneys.

There is overwhelming support for the Guidance to move forward.

Are centers required to check the titers every 90 days? They only need to update the titers every 90 days, but not necessarily retest. The transplant center sets the titer thresholds to be eligible.

This Guidance is to encourage centers to set standards, not to specify standards. Centers are more advanced and equipped than the OPTN/UNOS.

This Committee does not "need to reinvent the wheel" since there is such broad support for the proposal. It would be important to educated patients on what could go wrong. Do not be overly prescriptive.

Individual programs can decide how risk adverse they would like to be when determining titers.

Next Steps:

Changes and feedback will be considered by Leadership and added to Guidance before the full Committee vote.

A meeting for the committee to vote to send the Guidance to the Board in December will be scheduled for October.

4. Minority Affairs Active Projects Update

a) OPTN Project Checklist –

The workgroup lead provided an overview of the project. The group met once. It is often late in committee project work when impact to minority and vulnerable populations is examined. The MAC would like to ensure that impact on these populations is assessed consistently and early in project work.

A draft is being developed by the workgroup and it will be shared with the other committees when is it ready. The primary goal of the project will be equity in access to transplant. The committee agrees with this. It is not required to be sent to the Policy Oversight Committee for approval. The workgroup will meet monthly.

The Committee suggested including insurance status, zip code (if possible), continuous or non continuous state, rural or urban, census tract data, level of education. Data can be converted from outside sources. Sometimes data is challenging to work with if data set is too large. Census tract level data cannot be correlated on every level.

Does immigration status get tracked on candidate? Yes.

How much does the OPTN data link to external sources? CMS data can be used for kidneys, but not available for all organs. One example is veterans. There is no data captured on this, but it is important that the committees go through the mental exercise of considering this group's access to transplant.

Census tract data is not designed for healthcare, but some other data sets developed from that have been created. There is often a fee for this.

UNOS/OPTN has full access to USRD 27 28 form.

Veterans Affairs medical center much capture transplant data. If veterans are transplanted outside of VA centers, this is data is not captured.

Please send any literature or examples to staff to share with workgroup.

HRSA, Division of Transplantation, is supportive of the project. It appreciates the Committee creating this proactive step to consider disparity.

b) Other Projects

The Geographic Disparity project idea must be further developed. The workgroup lead explained her center has a fund to help people get access to transplant.

How can access resources be shared with centers nationwide?

How is geographic disparity defined? Miles or time? Flying and distance can be an impediment. This can be combined with income, insurance status, or crossing state lines.

Crossing DSAs can be included. Insurance is limiting and often determines where patients can be listed.

Liver and geographic disparity has been researched. If any allocation changes are considered, it would need to initiate by the organ committees.

A MAC workgroup could recognize that there is widespread and unique disparity in regions and compile some best practices to mitigate the disparity. How do centers provide care to those that cannot access it? This information can be distributed to provide assistance. A survey could be conducted. Centers or OPOs can be contacted.

This can turn into a concept paper or best practices brochure.

A member suggested that definition of geographic disparity be divided into contiguous and noncontiguous U.S.

Telemedicine has helped to mitigate disparity, since doctors can often now see and review patients remotely. It is important to define how centers can use telemedicine for pre and post-transplant care.

This project is more of an access project, not geographic disparity.

Another good project idea is to help get people waitlisted. Average time to get waitlists should be reviewed. Can centers getting patients waitlisted be rewarded? The OPTN does not gather data on how quickly patients get waitlisted, but CMS does collect this. Are centers with high minority populations taking longer? Maybe a map can be created to see how quickly patients around the country get waitlisted. A data requested would need to be submitted on behalf of the committee.

The HRSA representative explained the recently introduced five tier system was developed by the SRTR and was not supported by the transplant community. Programs do not like to be openly compared. This is currently not active. Please think carefully about this project idea. The intention was for patients to have a better understanding of programs. SRTR is revising this and working on additional measures.

Many patients on dialysis are not referred for transplant. If this is a project idea, a problem and solution must be developed. Medicare billing data would need to be examined. How can referrals be improved?

Not all programs want to grow. Is the goal for every single patient to be evaluated for transplant? Physicians have autonomy to talk about transplant with patients. Patients should be empowered and educated enough to discuss transplant with nephrologists.

The OPTN does not regulate dialysis.

Next Steps:

- Work will continue on the checklist project
- A workgroup member will further develop the idea to increase referrals from dialysis units.

- The chair will review the beta five tier system and consider any future MAC project ideas based on this.
- The chair will consider writing an editorial on APOL1.

5. Public Comment Presentation: Improving Allocation of Dual Kidneys (Kidney)

Summary of Discussion:

There were no questions. The MAC voted to support the proposal: 12 yes, 2 abstain (stepped out of room).

6. Public Comment Presentation: Concept Paper - Allowing Deceased Donor-Initiated Kidney Paired Donation (KPD) Chains (Kidney)

Summary of Discussion:

Staff requested the Committee recommend preferred concept, of the three presented. Detailed modeling of impacted populations will be performed after a preferred concept is chosen.

One member thinks that securing a living donor and then not transplanting the recipient would be unacceptable. Candidates for this must be considered carefully. Time, age, and sensitivity limits should be considered. This may be applied to generally healthy candidates.

What is someone receives priority and then the living donor does not donate? Candidates receive priority if living donors donate first (list exchange model) or after (candidate driven).

Everyone will back out if the living donor does not donate first.

Another committee member does not think living donors back out. If it happens, it is a change of situation (health or job are two examples). The Donor-Driven model is preferred by this member.

Another member does not like the Donor-Driven Model because this method may shift organs to higher volume KPD centers.

There are fewer Living Donors among minority populations, so they rely on the deceased donors. This may hurt minority access because it may boost non minorities on the waitlist. It is important to see models of how these options may impact minority candidates. Minority candidates may be disenfranchised. The member prefers the List-Exchange option.

If all KPD programs are not included, this may further create disparity. If candidates cannot use a local OPO or have fewer choices, this may limit all patients.

Cartoons more clearly explaining each option were shown.

The right time to do this is difficult to determine. It is important that coercion is not a factor. This is why the transplant center teams must work closely with each peer.

How many KPD programs exist? There are many (160 signed up) and some programs are national, while others are internal. Active programs include 70. There are about 200 pairs in every match run. A survey or project to examine KPD programs has been discussed. Current minority participation is not current. There are 45 KPD transplants per year.

There was a MAC presentation KPD pilot update from the March 2017 MAC meeting. This presentation and discussion can be found in the March 2017 meeting folder and in the meeting minutes.

There is not a strong opinion on one option over another.

Can the final step in this chain prioritize minority recipients? It is possible.

The committee can vote and recommend an amendment.

Base recommendations on science.

The Committee would like to see which option affects minorities the least.

All of the options will not be modeled, but the Kidney Committee would like to know which option should be modeled. This will not be the first time that MAC will see this proposal.

The Committee is concerned about the effects of running both the UNOS program and outside programs.

Minorities may participate in the program as living donors, but the same number may not benefit. More donations go from Caucasians to minorities because there are more Caucasians.

The Committee will comment and not vote.

7. Public Comment Presentation: Enhancing Liver Distribution

Summary of Discussion:

Hawaii and Puerto Rico is not shown on the map. Many more livers are flown out of Puerto Rico then flown in. There is not insurance in Puerto Rico that covers patients while waiting for transplant. The death rate of those waiting is much higher. It is very expensive to import livers.

What Hawaii and Puerto Rico included in the modeling? Yes, it was, but just not included in this map. The data will be sent to committee for review. Non continuous versus mainland impact has not been considered, however.

The MELD score at which candidates are transplanted in different regions in strikingly different. There is a difference in depth of donations around the country and a difference in demand/need for donation. There are multiple variables affecting supply and demand.

White spaces on the map indicate no liver program.

Can you tell more about impact on race? The SRTR conducted analysis on current system compared to the future proposed system for impact on African American, Hispanic, and Asian candidates by DSA. Disparity improves for every group except Asian.

Is racial analysis available by region? If that was done, it may result in a problem with sample size (too small). SRTR will be asked about this shortly.

Will there be a change to minority waitlist mortality? Yes, this was shown on slides. It is favorable for all candidates.

Much of Hawaii identifies as Asian, so there is concern about impact on this.

What are major insurance types? It is usually different from kidney, and more of a mix of public and private. It also differs across the country. Data is available from SRTR, but not yet released. It is a mix of public and private. The Medicaid subgroup is important when considering geographic disparity. Some patients may be limited by choice, depending on state. Living somewhere does not assume a transplant was received there.

Does this proposal affect simultaneous liver kidney transplants? It candidates are eligible for SLK, this may allow them to access a broader area.

The chair attempted to hold a vote, but the committee requested to wait for additional data on Hawaii and Puerto Rico. The committee cannot vote via email.

Staff shared the Hawaii and Puerto Richmond raw data by email. It is not clear if regional data can be acquired by the SRTR.

It is challenging to build relationships with OPOs outside of one's own region, as well.

Hawaii and Puerto Rico data was sent to Committee members via email immediately following presentation.

Comments will be recorded, but no Committee vote was taken on the Liver proposal.

Next Steps:

Liver Committee to ask SRTR to provide impact analysis by region.

8. **Public Comment Presentation:** Broadening Allocation of Pancreas Transplants across Compatible ABO Blood Types (Pancreas)

Summary of Discussion:

Will Blood type B candidates be at a disadvantage since some of the A and nonA1 kidneys would go to KP patients? This puts all kidney candidates at a slight disadvantage. There is an overall decline in pancreas transplants, so this may help mitigate that. The data used for projections is a bit old, so the impact on type B candidates may be less.

Vote: 10 yes, 2 no, 1 abstention

9. **Overview:** Vascularized Composite Allograft (VCA) Transplantation – Data Report and Donor/Candidate Matching

Summary of Overview:

The VCA Chair provided an overview of VCA transplants for pediatrics, considered a vulnerable population. The Chair summarized the statistics of VCA discussed how the field is evolving. Neck and upper limb make up the majority of VCAs. It has been done domestically And internationally. Only five centers in the United States are clinically active sites for VCA. The obstacle is expanding is fiscal, rather than willingness to perform surgeries. A uterine transplant was recently performed. There are very few Latin American patients and only one African-American patient. The waitlist list includes an equal distribution of male and female and is predominately Caucasian. As the field expands, it will likely become more racial diverse. The barriers to access is predominantly financial. The number of transplants over the last three year totals 25.

Summary of Discussion:

The first pediatric candidate was an ideal selection. The candidate is doing well.

10. Presentation: APOL1 Study – Long Term Kidney Transplantation Outcomes

Summary:

UNOS staff provided an update on this study, currently being conducted. The study establishes a multi-center, multi-disciplinary study group to be known as the APOL1 Long-term Kidney Transplantation Outcomes (APOLLO) Research Network. The APOLLO Network Consortium will consist of 13 Clinical Centers (CC) and one Scientific Data Research Center (SDRC).

Screening for APOL1 susceptibility variants in kidney donors prior to surgery may have an important impact on outcomes for kidney transplant recipients. African- Americans commonly have this genotype and can be considered high-risk.

The group will be primarily responsible for insuring the scientific integrity, comprehensiveness and robustness of the research design, biostatistics, data quality, implementation, and data analysis of all study protocols. The APOLLO SDRC investigators, including biostatisticians, will work with the Clinical Center investigators to develop the scientific design of the study

It is envisioned that the Clinical Centers of the Network will obtain clinical and genetic information from every one of the African-American kidney donors in the US, and from the patients who receive these kidneys.

Clinical centers and the SDRC will establish cooperative relationships with UNOS and OPOs.

Summary of Discussion:

If information is obtained from African-American donors, must it be shared with family members? This is not yet determined. UNOS currently does not collect this information.

Does this apply to living donor and deceased donors? Yes. The goal of the study is to genotype both.

What about other groups that are mixed with African-American, such as Afro-Cuban? This data might not be available since the data is self-identified.

There may be premature disclosure of findings. Existing treatments may work better to prevent poor outcomes. OPTN Committees, such as Ethics, Kidney, Living Donor, and Minority Affairs are good sources of comments. Continue to update committees on this study.

What is the timeline for the study? It is a five year funded consortium. Data collective may start next spring. Follow up remains to be determined. Data would be separate from OPTN collected data. Individuals can apply to use the data.

There were thirteen recruitment sites funded but the goal is to try to enroll all African American donors in the U.S. African Americans and non-African American donors will be genotyped. This will occur for a year. It will include prospective and not retrospective donors.

Next steps:

Please provide regular study updates to this Committee.

Upcoming Meeting(s)

- November 20, 2017, 1pm-3pm EST, Teleconference
- January 22, 2017, 1pm-3pm EST, Teleconference

Attendance

- **Committee Members**
  - Timothy Mose
  - Antonio de Vera
  - Sylvia Rosas
  - Irene Kim
  - Felicia Wells-Williams
  - Amishi Desai
  - Vonzie Barnett
  - Alejandro Diez
  - Amit Mathur
  - Scott Wansley
  - Jerry McCauley
  - Ignatius Tang
  - Reynold Lopez-Soler
  - Richard Ruiz
  - William Freeman (Visiting Board Member)
- **HRSA Representatives**
  - Mary Ganikos
  - Joyce Hager
- **SRTR Staff**
  - Katie Audette
- **OPTN/UNOS Staff**
  - James Alcorn
  - Amanda Robinson
  - Emily Ward
  - Chelsea Haynes
  - Darren DiBattista
  - Abigail Fox
  - Chad Southward
  - Chris Wholley
  - Matt Prentice
  - David Klassen
  - Ruthanne Leishman
- **Other Attendees**
  - Nicole Turgeon
  - Julie Heimbach
  - Scott Levin
  - Silke Niederhaus