Introduction

The Patient Affairs Committee (Committee) met via Citrix GoToMeeting teleconference on 11/16/2021 to discuss the following agenda items:

1. Cross Committee Workgroup Updates
2. Public Comment Preview

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

1. Cross Committee Workgroup Updates

The Committee received updates from members on a variety of workgroups and committees, including the Kidney Paired Donation Workgroup, Match Run Rules Workgroup, Technology Tools Workgroup, Policy Oversight Committee, Kidney Committee, and Minority Affairs Committee. A summary of their reports is included below.

Overview:

Match Run Rules Workgroup

- The Match Run Rules Workgroup grew out of a group considering the problem of late turndowns in organ allocation
  - Two key problems:
    - Overuse of Provisional Yes in the match
    - Too many offers being sent out
  - Both of these factors contribute to significant information clog, potentially slowing down allocation
- The solution is to institute a set of parameters that will filter out programs that have never transplanted an organ of similar quality level
  - Additionally time limits will also be set

Kidney Paired Donation Workgroup

- The Kidney Paired Donation (KPD) Workgroup is working to align KPD policies with current kidney allocation policies
  - They noted that donor computed tomography (CT) scans were difficult to upload in KPD in comparison to DonorNet

Kidney Committee and Minority Affairs Committee eGFR Update

- At present, there are two formulas to calculate estimated glomerular filtration rate (eGFR), one that uses an ethnicity variable, and a second that does not
The formula that uses ethnicity disadvantages black candidates by inaccurately conveying their level of illness

There is no guidance at present as to which formula to use, which the project will address

Summary of discussion:

Match Run Rules Workgroup

The presenter noted that they were slightly concerned by early analysis of the parameters which did not show a significant impact on allocation. They commented that it was unusual to do that large a statistical analysis and find out the allocation process was being performed as efficiently before the use of the tool as after. Additionally, following a question on it, they confirmed part of the problem was willingness to wait until the last minute to refuse an offer. They elaborated that this can actually occur in two positions: first, when they are in the primary position and refuse the organ, and second, when they receive the primary offer ex vivo with an old provisional yes in the system. A member also contributed that they felt Organ Procurement Organizations (OPOs) could be more transparent with what information will be available about the kidney post cross-clamp. They specifically noted it is sometimes unclear whether a kidney will be biopsied or pumped. Furthermore, they added that a possible consideration for the Match Run Rules Workgroup could be for provisionally accepting programs to add their acceptance criteria to the match.

The Chair asked for clarification on how the presenter felt that the preliminary results were not indicative of significant change to allocation. The presenter commented that they felt the filters that were applied were too broad, and were not removing enough programs from the match, which in turn resulted in match runs that were very similar to the current ones.

The presenter also said that there would be some flexibility to the filters, in order to account for programs that want to be more open with their acceptance criteria. So, while some of the process will be automated, the program will be able to control for different surgeons’ acceptance criteria. However, they did add that programs would likely have to set their acceptance criteria to the most aggressive surgeon’s preferences. They summarized that the key goal of the project was to remove “noise” from the system.

A member also asked whether there had been any thought given to periodically allowing programs to view the kidneys that they were screened off for after the offer in order to potentially recalibrate their screening criteria. The presenter indicated that that was not currently being considered, but they’d request feedback from the workgroup on it.

Kidney Paired Donation Workgroup

The presenter noted that they were considering breaking into smaller groups to consider a number of different aspects of KPD policy, rather than tackling one issue at a time.

Kidney Committee eGFR Update

The presenter explained that there is no guidance surrounding which eGFR formula should be used, but when they approached their nephrologist about it, they learned that the American Society of Nephrology had met and decided to try to phase out the race-inclusive eGFR formula. By using ethnicity as a variable in the calculation, black candidates’ level of sickness was not accurately determined.

Next steps:
The members of the workgroups will provide the feedback of the Committee to their respective workgroups.

2. Public Comment Preview

The Committee was briefed on the proposals being submitted for public comment for the January 2022 public comment cycle.

Data Summary:

Proposal: Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Transplantation

This proposal will create medical eligibility criteria for when kidneys should be allocated with a heart or lung and create ‘safety net’ criteria for heart and lung similar to those established for liver.

Proposal: Minimum Set of Donor Kidney Criteria (Biopsy Workgroup)

The proposal will establish a minimum set of criteria that determine when a kidney should be biopsied on recovery. This does not limit when biopsies can be performed and only will impact procurement biopsies.

Proposal: Standardized Format for Pathology Report (Biopsy Workgroup)

This proposal will, in conjunction with the previous proposal, establish a standardized set of information that can be gathered on procurement biopsies and create a standardized reporting form for this information. This will provide information at all levels to help inform programs evaluating offers.

Proposal: Improving the MELD Calculation and Reducing Pediatric Liver Waiting List Mortality

This proposal has two primary goals: include a sex variable that would grant points to candidates listed as women, to counteract women’s model for end-stage liver disease (MELD) scores being historically low, and update the pediatric model for end-stage liver disease (PELD) score calculator.

Proposal: Ongoing Review of the National Liver Review Board (NLRB) Policy and Guidance

The Liver Committee will provide updates to the guidance documents which are used to provide exceptions for MELD scores. These are considered when a program believes a candidates MELD or PELD score does not accurately convey their medical urgency for transplant.

Proposal: Reassessing the Inclusion of Race in eGFR Equation Proposal

This proposal will require programs to use an equation for eGFR that does not include a race-based variable for candidates. This proposal will not identify a specific formula for programs to use, only specifying that the equation cannot use a race-based variable.

Proposal: Continuous Distribution of Kidneys and Pancreata Concept Paper

This concept paper will propose ideas for how the continuous distribution formula should be applied within kidney and pancreas allocation. There is a request for information surrounding which variables should be considered when building a composite allocation score for kidney and pancreas candidates.

Proposal: Modify Policy Language on Contraindications to Living Donation

This proposal will examine contraindications to living donation and review the continued relevancy of each one. This will ensure that there is increased opportunity for living donation, while not compromising the safety of living donors.

Proposal: Change CPRA Calculation
This proposal will update the calculated percentage of reactive antibodies (CPRA) to better reflect candidate sensitization, with the most impact to African American candidates and women.

**Proposal: Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing**

This proposal adjusts when pre-transplant infectious disease testing must be done. At present, current disease testing timeframes can overdraw blood from smaller candidates in comparison to larger candidates. This is especially impactful in pediatric candidates. The proposal will extend the window in which this testing can be done to ensure blood is not overdrawn.

**Proposal: VCA Graft Failure Definition**

This proposal will update the definition of graft failure to more accurately align with the constraints and functions of vascularized composite allografts (VCAs).

**Proposal: Redefining Provisional Yes**

This request for feedback is to redefine how provisional yes is considered. While not presently a proposal, based off of community feedback on how allocation can be improved, a proposal will be generated.

**Summary of discussion:**

The Chair inquired whether any of the committees submitting proposal had specifically requested the Committee provide feedback. It was noted that it is still early, but at present none have requested feedback from the Committee. UNOS Staff also noted that it is likely the proposal to reassess the inclusion of race in eGFR will likely request feedback from the Committee. A member also postulated that, from a similar perspective, the Liver Committee’s proposal to reevaluate MELD scores would also request feedback from the Committee. Another member also requested that the safety net eligibility criteria proposal be considered.

**Next steps:**

UNOS Staff will distribute the meeting slides for the Committee to review in more depth and consider which proposals they would like to provide feedback on.

**Upcoming Meetings**

- December 21, 2021
- January 18, 2021
- February 15, 2021
Attendance

- **Committee Members**
  - Garett Erdle
  - Diego Acero
  - Julie Ice
  - Sarah Koohmaraie
  - Earl Lovell
  - Anita Patel
  - Kristen Ramsay
  - James Sharrock
  - Julie Spear
  - Eric Tanis
  - Justine van der Pool
  - Darnell Waun
  - Justin Wilkerson
  - Christopher Woody
  - Chris Yanakos

- **HRSA Representatives**
  - Arjun Naik
  - Jim Bowman
  - Raelene Skerda

- **SRTR Staff**
  - Katie Audette

- **UNOS Staff**
  - Isaac Hager
  - Eric Messick
  - Susan Tlusty
  - Sara Rose Wells