Introduction

The Living Donor Committee met via teleconference on 09/12/2018 to discuss the following agenda items:

1. Public Comment: Addressing HLA Typing Errors
2. Public Comment: Frameworks for Geographic Distribution
3. Final Questions/Comments

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

1. Public Comment: Addressing HLA Typing Errors

Data summary:

The first proposal discussed for public comment is HLA typing errors from the Histocompatibility Committee. It is a setup within UNet where the HLA data entered manually into UNet must be entered twice. Whoever is entering the data takes raw data, enters it into UNet and saves the data, at which point it wipes the data clear and it has to be entered in a second time. Software then compares the two typings to make sure the information was entered the same twice. If not, it alerts that the entries were not a match and prompts the user to review the data and ensure that the numbers are entered correctly both times. Anywhere that HLA typing is entered into UNet will require this double entry. Any donors that are entered into the UNOS KPD, this requirement will also be in a case.

Second is some wording in the bylaws state that members (laboratories and OPO) must have a process for verifying the data that is uploaded into UNet. Instead of manually entering data, the software can upload the donor typing directly into UNet. There needs to be a process to verify the data was entered correctly. This is more for software that will be available in the future.

Third is to require laboratories and OPOs to include the raw data from typing assays and attach that into the donor record so anyone else looking at the donor and potential recipients can look at the raw data. That would be the lone error-free source of truth with correct typing on it.

In order to implement this proposal, all the members will need to understand that the information as above will have to be entered in twice. There will be verification from the labs, which will need to work with their OPOs and transplant hospitals to work on whether or not any of their written agreements need to be modified. Finally, for deceased donors, the OPOs will have a process for submitting source documentation with the raw HLA typing data in it.

IT staff at UNOS have put up a few early drafts that seem to be working well. There are several fields within either the donor record or match run where the HLA typing data are presented to the user that has the data on their screen. Currently anyone can edit the data, which might be done accidentally, so currently a change is being made so once the HLA typing is entered, it is locked and cannot be edited. If there is a situation where it needs to be changed, there will be a procedure for that which is being worked on.

Summary of discussion:
For living donors specifically, one Committee member asked what form that goes in and why it is limited to KPD and not all living donors. It was unknown all the places where HLA typing is included, but any entry involving HLA type in entire UNOS system will be a part of this double-entry process, not just KPD.

One question was how the three-pronged approach in implementing the process translates to living donors. The three-pronged approach will not apply to living donors. The impetus for the project was the rapid allocation of deceased donor organs requires immediate typing. In some cases, patients go to transplant without having final cross-matches done so they're relying solely on typing information entered. In living donation, there is more than plenty of time to run multiple tests within the lab, cross-matches, or antibody screens, so the entries do not hold the same kind of weight that it does for the deceased donors.

Any place the data are entered will need to be entered twice, but source documentation and related material are relevant to the deceased donor situation, and HLA typing of recipients will also have to be entered twice from scratch.

The double-entry process is based on the likelihood of error in the same situation twice in a row would be minimal. After initial entry into UNet and first save, the screen immediately pops up again and will be entered again by the same person, so the extra time spent would only be about a minute. Many labs have a similar system to safeguard against errors.

Currently there is not a way to have the information uploaded into UNet automatically because laboratory and UNet software for match runs in allocating organs are not compatible. The raw data upload from instrumentation will be an attachment from the donor record as a PDF. Eventually software will be created to automatically upload data from the laboratory resulting software into UNET automatically, but that programming is not available yet.

2. Public Comment: Frameworks for Geographic Distribution

The Board of Directors approved 5 Principles of Geographic Distribution at the June 2018 meeting. Each of the 5 principles align with components of the Final Rule. Three distribution frameworks that align with the principles were also approved to go out for public comment, which is going on now.

The three frameworks are:

- Fixed distance from donor hospital. This is basically concentric circles based on distance between donor hospital and transplant candidate hospital. There would be a smaller and a larger circle. Advantages are the community is familiar with this model, so it is easy to explain, and it allows for wider distribution or other characteristics such as medical urgency. Disadvantages are it relies on fixed boundaries and differences in population density may affect patients with similar matching characteristics, particularly in more rural areas and in non-contiguous states.

- Mathematically optimized boundaries. This is based on a statistical formula designed to achieve the best result for one or more specific goals, such as a consistent ratio of donors to recipients within each distribution area. The areas could range from large districts to a large number of smaller localized neighborhoods, and can overlap. Advantages are that it provides consistent results and can be monitored and scaled accordingly. Disadvantages are that it once again relies on fixed boundaries, which may be complex and certainly not uniform.

- Continuous distribution. This uses a statistical formula that combines with important clinical factors such as medical urgency, likelihood of graft survival, or proximity to donor location. All candidates would receive a relative distribution score and there would be no
geographic boundaries. Candidates who best meet the combination of factors receive the highest priority. Advantages is that two patients with similar suitability would be treated the same and priority would consider specific clinical characteristics, and more likely organ offers would be matched efficiently with candidates with highest medical need. Disadvantages are that it's more difficult to understand or explain because there would be no boundaries.

More detailed explanations of the frameworks with narration and animation are available on transplantpro.org under the policy page for Committee members to further review.

Currently the three frameworks are out for public comment now and will be considered by the Board at their December 2018 meeting. Liver Committee will have its own special comment period for the liver distribution model, most likely using the fixed distance concentric circles. The other organ-specific committees will start on removing DSA from policy as a means of distribution, with public comment in 2019 and Board consideration at 2019 Board meeting.

The Geography Committee will oversee the different allocation committees and provide feedback as needed.

**Summary of discussion:**

One question was whether there are any preliminary results from the change to lung allocation policy. Specific questions or just a general overview can be provided to the Living Donor Committee.

There was a lawsuit challenging liver allocation policy's sole reliance on DSA and region in distribution. OPTN was not able to defend DSA region as compliant with the Final Rule. Therefore, the plan was to remove DSA and region from organ allocation. DSAs will continue to exist for administrative purposes, but will not be used in organ distribution.

Regarding each of the organ-specific committees coming up with their own models, it was asked whether the committees were allowed to choose any of the three geographic frameworks or not. Indeed, they could each see which framework works best for their own allocation system. The fixed distance/concentric circles would require the least IT adjustment and seems to be the easiest model to transition to. There was some enthusiasm for the continuous distribution, but moving to that model would be difficult to be finalized within the expedited timeline. The thought is to start with concentric circles and eventually move to continuous distribution. Sizes of circles and other details are still being discussed within the committees.

Five members of the Board of Directors opposed the 5 Principles of Geographic Distribution, but the reasons behind the objections are unknown.

One of the potential impacts of geography on living donor is that in the kidney allocation policy, former living donors waitlisted for a kidney transplant receive priority for organs based upon organ availability within the local DSA. Therefore, Living Donor Committee will monitor how any modifications to kidney allocation might impact on the accessibility to organ transplant for a former living donor.

One thing with the Living Donor Committee, it can't be established that the living donor is more or less sick than someone else and waiting time is primarily being used, which would automatically take a lot of the kidneys out to the coasts. Current models used to establish sickness as a cause of poor transplant and need for a kidney do not have good predictability. Caution needs to be taken to ensure the living donor community is not disenfranchised further as to access to transplant kidney if needed, which has happened with the new kidney allocation system (KAS).

**Next steps:**
Committee members are encouraged to visit the public comment site and leave a comment on any of the three frameworks they prefer.

3. Final Questions/Comments

Summary of discussion:

Committee members should review the Donor Self-Assessment Subcommittee and let leadership know if they are interested in joining. Travel arrangements should be made for upcoming in-person meeting. All members will receive an individualized link to provide individual responses (which will be posted to the OPTN website anonymously) on the two proposals for public comment presented today, so that a formal response from the Committee can be formulated.

Upcoming Meetings

- October 15, 2018, in-person in Chicago, 8 am - 3 pm CST