OPTN Operations and Safety Committee
Meeting Summary
February 7, 2024
In Person Meeting

Alden Doyle, MD, MPH, Chair
Kim Koontz, MPH, Vice Chair

Introduction

The OPTN Operations and Safety Committee (henceforth the Committee) met via Citrix GoTo teleconference on 2/7/2024 to discuss the following agenda items:

1. Update: Offer Filters
2. Public Comment Presentation: Promote Efficiency of Lung Allocation
3. Public Comment Presentation: Concepts for Modifying Multi-Organ Policies Request for Feedback
4. Public Comment Presentation: 2024 – 2027 Strategic Plan
5. Update: OPTN Expeditious Task Force
6. Review and Discussion: Living Donor Packaging by Transplant Hospitals
7. Discussion/Report Outs: New Project Ideas
8. Discussion: ABO Genotyping

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

1. Update: Offer Filters

The Committee received an update on the work being done on offer filters.

Summary of discussion:

The Committee will continue to receive updates and provide feedback when applicable.

The Committee Chair asked if it was possible to tell what filters a program is using or which filters in effect are being changed. Staff responded that this has not been monitored as much. It can be seen which recommended filters a program has turned on and candidate exclusions that have been added. It has been observed that programs are modifying recommended filters; it has not been monitored specifically if programs are turning the filters on or off or if they remain consistent.

The Committee Chair stated that when the Committee previously looked at data, the programs that were not adopting the offer filters tool were examined and prompted outreach. A member asked if the assumption programs did not use offer filters was due to the feeling of missing out on offers. The Committee Chair responded that this was one of the reasons some programs did not want to use the offer filter tool and inquired if there should be evaluation of any characteristics that could provide insight to a program not adopting offer filters. Staff responded that there are not a set of characteristics for programs that use or do not use offer filters. There has been an increase in offer filter adoption through previous efforts of outreach. The Offer Acceptance Collaborative, which kicked off last year, was not kidney specific, but attendees from kidney programs were able to get training for offer filters.

Among the 49 programs who participated in the collaborative, roughly half were using offer filters. After the collaborative, adoption of offer filters increased to almost 95% among those programs who participated in the collaborative. It was observed that the counseling sessions helped – the programs that enabled filters kept them enabled. The feeling of missing out takes some assurance to address. The Committee Chair added that there should be an effort to reach out to remaining programs. The more programs adopt the offer filters tool, the better the effect will be when the opt out model is rolled out.

A member asked if there was data showing the numbers on non-use or efficiency of placement. Staff stated that an increase in non-use was still observed with increase offer filter use. There is a multifactorial analysis being done to tease out the specific effect of offer filters. Additionally, there is work being done to look at how the filtered offers are affecting the match results. There is still an increase in cold ischemic time (CIT) at transplant being observed, however, a decrease in CIT at acceptance is being observed; these organs are arriving further down the list (and being accepted) at a lower CIT and allocation is being done faster.

A member asked if there were less expedited placements. Staff stated that this was still increasing over time. The information is still being monitored to evaluate if there are more offers filtered and whether there is less allocation out of sequence (AOOS).

The Committee Chair stated that there should be consideration whether it is a kidney filter and whether the Committee should also be involved with the next iterations for offer filters for other organs. Staff stated that the phased approach for offer filters work will allow the organ specific Committees to be involved in filters while also collaborating with the Committee to be an overall guiding Committee for filters.

A member asked if more information could be added for the filters. The member continued by asking if offer filters take into account changing donor information. Staff clarified that offer filters would be applied every time a new batch of notifications are sent out. It is applied to any offer that does not have a response and would not override a provisional yes. The Committee Chair confirmed that it is a bypass code, but it has a great impact on programs being measured by pre-transplant metrics. There are less calls and less cost (if programs are using a service to take offers) by not receiving offers a program would not normally take. Staff stated that when offer acceptance rates are calculated, bypassed offers are excluded.

A member added that this improves a program's acceptance rate, therefore it is a positive impact. This alone should be a big motivator. The Committee Chair agreed with this but stated that this is not the understanding yet of the benefits of the offer filters tool.

Another member asked when the default kidney offer filter would be implemented. Staff stated that the implementation for the default model has not yet started, but it is intended to start after work on offer filters for heart and liver and intestines are completed in May 2024. The targeted implementation date for the kidney default filter model is October or November 2024. The Committee Chair added that the OPTN Executive Committee supported the expansion of offer filters for other organs first because it should be accessible for other organs as well.

The Committee Vice Chair added that there was previous discussion about enabling filters for pancreas as they were not seen on the timeline. It was noted that pancreas programs are most likely similar and

near to kidney programs. Staff replied that this was discussed, and it was determined that there are similarities with kidney-pancreas (KP) and kidneys; a model is being run to determine if the model identifies whether the kidney filters apply to KP. In a similar manner, a subset of kidney criteria was used to build the heart and lung offer filters.

The Committee Chair stated that pancreas alone is a small population, however there are a lot of offers that are received; KP offers can lean into the kidney filters, but there needs to be consideration to the pancreas alone offers as well. Staff stated that the data and model would inform which characteristics or filters would be useful for other organs. Staff added that additional discussion will be held with the Pancreas Committee on offer filters during their in-person meeting in March.

A member stated that programs used to be able to set how far they wanted offers from distance wise and asked if this has now gone away or is being added back on. Staff asked for clarification if this was in reference to wait list acceptance criteria and responded that this doesn't replace that, but it does allow for distance filtering specifically to certain donor characteristics as well. This can be set at a program level for all offers or for other factors. The Committee Chair asked if exceptions could be set. Staff responded that exceptions could be set at the candidate level for waitlist criteria.

Another member stated that programs need to understand this before they turn their offer filters on. A program may need to adjust something at the candidate level once certain offer filters are turned on. The member stressed the importance of education.

Staff asked for lung, heart, or liver, why weren't donor location and donor risk factor for blood-borne disease transmission not included as potential filters. The presenter clarified that donor location referred to donation service areas (DSAs)/region/national, which was deprecated in favor of distance. The data showed that any kind of region or DSA filters went way down, but distance filters went way up. Distance is more useful; therefore the other filters are being removed. For risk factors, there was not much data that came out of this but can be revisited. The presenter continued that some of these factors may be more relevant as other factors are added on as well and might need to be in combination with certain lab values.

The Committee Chair asked that if it was not more complicated, why not give the programs more detailed, granular tools? Staff replied that this was kept as a small set to keep it simple across programs. If it is observed that programs want these more granular options, this could be considered for phase two of this project.

A member asked if kidney-pancreas (KP) affected kidney listing. Staff clarified that the offer filters would only apply on the kidney alone match run. There would be a different conversation about offer filters for KP and pancreas. Staff continued by explaining that offer filters can be turned on and off and it will immediately take effect. Similarly, default filters would operate in the same manner – the offer filters would be applied by default and transplant programs would be able to go in and change the filters however they want to. Programs will still have flexibility as they do now with the offer filters tool, but with the default filter model, they will have to engage with the tool.

A member stated that their OPO is doing normothermic regional perfusion (NRP) devices and observing programs that are screening off due to their use of NRP on older donation after cardiac death (DCD) donors. Because these programs are using filters, they are being screened off from these types of offers.

The member continued by stating that their OPO is educating the transplant programs with NRP and asked as OPOs perform various types of recoveries, is there a plan to add NRP as a data point to the OPTN Donor Data and Matching System. The presenter stated that this is not included in the current models and that additional discussion would be needed to include data for this. Staff clarified that there is a data field for NRP that will be added to the OPTN Donor Data and Matching System, which was recently implemented from a proposal by the OPTN OPO Committee. The addition if this data field is still going through the Office of Management and Budget (OMB) process.

The member responded that it changes because a donor after cardiac death (DCD) with NRP is different. The Committee Vice Chair added that this impacts kidneys, intestines, and other organs. The ability in the offer filter to exclude NRP from those exclusions would make sense. The Committee Chair stated that there were all kinds of donor support that are relevant in understanding the donor and the organ quality. There may need to be consideration in filtering on this. Staff responded that there has been feedback about donor dialysis use and that affecting creatinine. It was clarified that NRP could be incorporated in the filters. There may need to be discussion about old filters before new data fields are added; it was suggested that the Committee could discuss this further.

The Committee Chair stated that even just a yes/no response is helpful; this could be nuanced later. Staff stated that it could be a filter if not NRP, and then leave criteria or leave it out so that it applies to both. There could be a donor flag that could enable a type of functionality. The Committee Chair voiced this being a potential project for the Committee to consider.

The Committee Chair added that there is a skew where programs that have adopted early are probably more engaged in the process.

Next steps:

The Committee will continue to receive updates and provide feedback when applicable.

2. Public Comment Presentation: Promote Efficiency of Lung Allocation

The Committee received a presentation on the OPTN Lung Transplantation Committee's *Promote Efficiency of Lung Allocation* proposal.

Summary of discussion:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

The Committee Chair commented that based on experience with kidney offer filters, there are early, middle, and late adopters to the tool. It is important to figure out how to reach out to the middle and late adopters and their fear of missing out on offers; it was suggested that educational efforts would be beneficial.

Another member stated that their program has not used the offer filters tool yet as they have not noticed any changes on the match runs. For now, it seems as though it is just about education and the notices that are sent out and it is unknown to them how many people sign up for them at the transplant program level. Their program tries to have communication with their transplant programs when these notices come out.

The presenter stated that besides notices going out to members, there will be a webinar in a few weeks to familiarize members on offer filters. In addition to the webinar, there is also outreach being done directly to answer questions and get those programs on board to adopting the offer filters tool. With 72 active programs, some are small, with the majority being medium in size, and a few at the other end of the spectrum that will not adopt because they are large and can afford to fly across the country. There are programs that will not use the filters, but the small and medium programs will need to be educated to show the benefits of the usage of offer filters.

The Vice Chair inquired about the proposed member action for OPOs to report additional data on donors regarding anaphylaxis to peanut and/or tree nut. A member stated that this is not a question that is asked by OPOs or in the DRAI. The presenter stated that the Lung Committee worked with the OPTN OPO Committee to narrow down these data points. The history of anaphylaxis was included because it was determined to being a true passable issue, whereas allergy could include a lot of variation and misinterpretations. The presenter added that sternotomies is not in the DRAI and that the feedback from OPOs is that they would note on the X-ray of the donor if there had been a previous surgical incision that would initiate further inquiry on what that previous sternotomy was for and/or if there was a previous sternotomy.

A member asked if there was consideration in taking the history of anaphylaxis through the standardized DRAI approval process. The member continued by explaining that this is an addendum that would need to be added in their medical records to be able to collect on a standard basis. If it were added to the DRAI, it would be more consistent standard reporting for OPOs.

The Vice Chair stated that there is a question about previous surgeries and inquired if it is possible to merge this field into OPTN Donor Data and Matching System to reduce the burden of asking an additional question. A member commented that there is a surgical question in the DRAI, but it would be helpful if this was a part of the Mini-Medical/Social. The member added that on the UDRAI, there is only a question about allergies, and it is not specific. Another member noted that the anaphylaxis would be missed.

A member stated that adding to the addendum is not ideal and challenging. The Committee Chair agreed with this and commented that it is easier to track data if there is a discrete data field.

Another member stated that it appears to be that the DRAI is the same across programs and that if there were a way to connect it into the system, that would be helpful. The member continued by voicing agreement that the bypass button is a good idea and that it is useful rather than sending offers that would require a response when it is clear it would not meet a program's needs. The Vice Chair agreed with this. The presenter replied that the offer filters tool is not yet mature, but it is a place to start. As more members begin using the offer filters tool, it would provide for the opportunity to build upon this to make it more complex and allow for easier efficiency in going through the match run.

Staff commented that from the prior presentation on offer filters, it has been observed that progress is being made on the use of the lung offer filters already. The presenter commented that this was encouraging and noted that staff had been responsive to a few glitches users came across and addressed them right away; other programs provided similar feedback and noted appreciation and the ease of knowing what to do moving forward in using the offer filters tool.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

3. Public Comment Presentation: Concepts for Modifying Multi-Organ Policies Request for Feedback

The Committee received a presentation on the OPTN Ad Hoc Multi-Organ Transplantation (MOT) Committee's *Concepts for Modifying Multi-Organ Policies* request for feedback.

Summary of discussion:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

A member commented on the complexity of this topic. With the challenges OPOs have with multi-organ transplantation (MOT) currently, there is hesitation in making any changes. The member asked if the OPO would need to hold off on other organs making primary offers. If the offers are exhausted on the heart, lung, and liver list, but the OPO is waiting on the kidney list, there is hesitation on waiting for the kidney match to make primary heart, lung, or liver offers if those recipients need multi-organ. The struggle for OPOs is having time constraints and needing to get through the heart-liver or lung-liver before the liver can be primary. The challenge is that policy requires the MOT offers be made before the single organ offers; the time constraints related to this make this process complicated and challenging and result in non-use of organs.

The Committee Chair commented that this point has been brought up and that if machine perfusion is added, that presents another challenge. The Committee was asked their thoughts in offering one kidney to the kidney list and the other kidney as an MOT offer.

A member provided a scenario that included a status 1a liver recipient. If you have a heart-kidney, and the OPO is supposed to give out a kidney offer, but there is a status 1A liver that also needs a kidney, there needs to be some clinical urgency for the thoracic and liver organs. There would be a fear in this scenario in offering a kidney alone. The member suggested that maybe in cases like these, status 1A recipients should receive prioritization.

The Committee Chair followed up with a question on if there was a 100% CPRA and a patient has been waiting for 8 years, and then there is a heart-kidney with a GFR of 20 who could have a safety net and stay on dialysis. There may be some argument from the heart community that based on current data, their mortality is higher, but it could be countered that this is based on older data and before safety net.

A member asked if there was data showing one year survival for the simultaneous liver-kidney (SLK) versus safety net. The Committee Chair stated that the one-year survival for SLK is a bit better. The nuance for liver vs. thoracic is that kidneys do not work because they are still on ECMO for a period of time. You would not get the benefit of the early kidney function vs when the patient is healthier and never on ECMO, they are getting the benefit of the early kidney function. There are transplant programs that are not in agreement with OPOs making different decisions about how they sequence multi-organ and want allocation to be more based on policy than clinician decision. On the other hand, the OPOs is risk of non-use/utilization of organs.

A member commented that the thought needs to be on the donor hospital both rural and urban programs. The testing that is available during a particular time of day can vary. If there is an allocation issues that needs a certain test result that may not be available for 12 hours, there is a potential for non-use of an organ. If organ allocation has not been done and going to the OR, there will be an increase in non-use of an organ than if allocation was just done based on the results available at the time.

Another member stated that one kidney for MOT and one for single kidney would need to have a policy in place that would prioritize which MOT gets that specific kidney designated for the MOT. The decision making would be back on the OPO. A member agreed with his and noted that this would be between heart and lung as well as pediatric and kidney-pancreas (KP) patients as well.

Another member stated that KP and MOT is probably mostly pediatric patients with the full abdominal. The Committee Chair commented that there is no obvious path forward. A member commented that anything that would complicate or prolong allocation is scary. For lung-liver right now, livers are backed up until sequence 200 on the lung list. The OPO is unable to allocate the liver until the lung is accepted, which can add 12 hours. To add another organ can complicate things further.

The Committee Chair asked if there was differentiation among kidneys. The data reviewed shows that KPs and pediatrics are directly negatively impacted. A member responded by stating that from a policy perspective, all of the MOT data lives with recipient candidates and not the donor itself. There are no data points from a donor perspective that would exclude that donor from the MOT like age criteria.

The Committee Chair stated that there are program level screening and filters. It is known from data that pancreas (for example) – there is an effort to grow pancreas transplant and known complexities with donor surgeries. It almost always comes from sequence A and B donors. The organs that are used come from the same donors, though it is unusually from the DCD donors. Most thoracic are from non-DCD. There are OPOs working on more DCD and NRP may change this.

A member commented that direction is needed to save the OPOs time from arguing with the transplant programs. The Committee Chair stated that it may not be that one organ is prioritized and that there may be statuses within that organ that have to be considered.

Another member stated that the only thing that should be stressed moving forward is if there are firm time constraints and set OR times, then OPOs need to bypass the policy and offer to the programs. The member provided an example: this may be complex such as if there is a heart-kidney at sequence 2 and lung-kidney at sequence 4 and a liver-kidney at sequence 10. If an OPO thinks there is a heart-kidney at sequence 2 and it is then declined, the reallocation efforts this may initiate could add the complexity from an OPO perspective. It could be difficult to manage if there is only one kidney available for the multi-organ. The member asked if the high CPRA kidney needs a physical crossmatch and they need blood, which typically they do, is the OPO waiting for that to come back to release the other kidney?

The Committee Chair stated that a possible solution is that as a community, virtual crossmatch should be the standard. The Committee Chair reminded the Committee that this was a concept paper and not a proposal. The concepts presented are not specific policies because it is unknown what the right answer is yet.

A member voiced agreement that right now the allocation system is confusing and complicated and with last minute declines and reallocation, the process needs to be made easier. There needs to be a solution that could help streamline rather than add more steps to the process.

Staff commented that the MOT Committee also has a proposal out for public comment that addresses modifications to the policy effect of acceptance, which (proposed language) states that if an organ has been accepted by a transplant program, that organ is no longer available for subsequent offers, including those according to *Policy 5.10: Allocation of Multi-Organ Combinations*.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

4. Public Comment Presentation: 2024 – 2027 Strategic Plan

The Committee received a presentation on the OPTN Executive Committee's *2024 – 2027 Strategic Plan* proposal.

Summary of discussion:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

A member commented that it is confusing when optimizing use of organs is discussed and then in the definition it is maximizing the use of organs for transplantation. The use of the terms "optimizing" and "maximizing" can be confusing to what is really meant. The member suggested education for the public around offer acceptance rate.

The presenter clarified that the education part of the strategic plan would be in relation to the patients being waitlisted. The member stated that similar to the Committee's previous discussion on offer filters, it would be important to educate everyone about what this proposal means as far as how filters play into this and how they are reducing offers. It feels counterintuitive in some respects. It is important for this proposal to be clear in what is being addressed. The presenter replied that there is new language that is becoming important – what is an offer and what is an acceptance. The goal is to see offers go down and acceptances go up, which is an important distinction to make. The presenter agreed with the maximize vs. optimize comment and stated that the strategic plan doesn't use any of these words and instead outlines the goals to "honor the gift of life to the fullest". The presenter welcomed other suggestions.

A member stated that from a transplant program perspective, there is nowhere in the plan that discusses cost and benefit. Transplant programs are disproportionately experiencing the cost side of the equation and seeing words like "maximize" results in a negative reaction from their perspective. The member voiced favor in the term "optimize".

Another member commented that it becomes unclear when discussing kidney non-use rate of 28%; though not wanting to see this rate go up, there is a reason for it. There are older donors being pursued, and more DCDs. A lot of non-utilization happens in the operating room (OR), which ultimately ends in non-use based on reasons that are unknown. We would need to collect data up to that point that the organ is recovered. The member asked how there can be a balance – the risk of non-use of a

transplantable organ. Is the focus on decreasing non-use or increasing utilization and recovery? It seems counterintuitive.

The presenter summarized the member's comment to an understanding that there is a greater interest in understanding the circumstances surrounding organ non-use and non-utilization and a general recognition that current data is insufficient to illuminate what is happening. There will be more to come on how this is measured, how it is understood, and how to balance these various components. The presenter added that this is on most people's minds and that this feedback was important.

The Committee Chair added that the way this is being thought through in the OPTN Expeditious Task Force is putting the growth at the top. The Task Force wants to grow successful transplants, counter measures to ensure equity, increase efficiency, etc. The desire is to maximize the donor organs available. It has been shown that the top 20% of programs that have shown successful growth have been found to be due to current technology – organ preservation, surgical techniques, etc. Additionally, there are transplant programs that use a wide variety of medically complex donors. This presents an opportunity for best practices to be shared. A member agreed with this.

The presenter also agreed with this and stated that the discussion was favorable in the direction of being able to put these variables on the table and figure out the best approaches to address them simultaneously. The Committee Chair added that that a turn of phrasing is important – rather than saying more transplants, there should be consideration in rephrasing this to say more successful transplants.

A member voiced agreement in the inclusion of the equity piece. The allocation out of sequence has increased, but it is behavioral. The member stated that their program is pursuing more donors and allocating more aggressively for these cases. The data shows that this is being done in order to optimize, but what is missing is if the policies are based on equity, this may not be maintained. It is a balancing act.

The presenter stated that the feeling is that equity has veered away from utility and there is a need to bring these components back together. The member replied that this is challenging to figure out. The Committee Chair stated that there is agreement that there needs to be data, agreement with stakeholders, and transparency with the committee, and that the goal should be to be better.

A member asked if there were any conversations related to offer filters. The delay OPOs see from getting things into the OPTN Donor Data and Matching System for data fields is significant. With programs using NRP and a data field in September, there is a year where programs are filtering off by accident, which is significant. This data is important. It seems like there is quite a delay for a simple data field and it should not be this way; data should be added to the OPTN Donor Data and Matching System sooner.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

5. Update: OPTN Expeditious Task Force

The Committee received an update on the OPTN Expeditious Task Force.

The Task Force's work is focused on four Expeditious Pillars: growth, efficiency, and use/utilization. Additionally, there is a focus on a patient-centered approach to improve the patient experience. The goal is to streamline processes to reduce donor case times, meaning fewer late declines, and drive more reliable transplant outcomes for patients. Thus, creating an optimization in the framework for allocating hard-to place organs, lower non-use rates, and increase the number of transplants.

Summary of discussion:

The Committee will continue to receive updates and provide feedback when applicable.

A member asked what percentage of transplant programs or OPOs are using preservation pumps for heart/lung/liver. The Committee Chair advised that there are efforts being made to address data related to this topic. The member continued by asking if there was discussion about hubs for preservation machines and if this was a role that the OPOs took on. The Chair stated that there have been discussions related to this; the Committee Chair reminded members of the National Academies of Sciences, Engineering, and Medicine (NASEM) report highlighting donor centers and having those distributed. There is continued discussions on whether it should be run through the OPO, transplant hospital, or some combo, which raises the concern for pay. A member advised that pay is handled differently across organizations, all of which are costly. This raises the question of whether the transplant programs would want the responsibility to be of the OPO, and if so, there would need to be trust that forms between the two entities.

The Chair stated that this needs to be examined further to determine how this can be scaled at a national level. Once programs are educated on the technology and processes, it should then be determined how it can be trialed with OPOs that aren't using the technology. Current donors could have a huge growth in successful transplants by simply capturing better use of DCD. There are many examples with this which include AOOS and virtual crossmatch.

A member asked if there was a desire to increase the number of patients at the regional meetings. The Committee Chair confirmed that the intent of the meetings and discussions was to include the patient perspective. At meetings, the assigned seating arrangements allow for a mixture of individuals and intentional representation of patients and donor families in each of the groups. There is continuous learning through feedback received on how to best incorporate everyone's voices (especially patients). The Committee Chair added that there are continued efforts in thinking of ways to get patients on board, look at outcomes, and look at the growth factors of topics being discussed. It is the hope to share the research with the patients to better understand their experiences. A member asked how this process works with a large group such as this Task Force. The Committee Chair responded that there is work being done with Accenture, who have expertise in facilitating meetings and projects of this magnitude.

A member advised that outreach at a C-suite level is critical and added that there are challenges with resources, especially for transplant centers. The Committee Chair stated there is an opportunity for better transparency, providing better data, and ensuring that everyone has access to these innovations.

Next steps:

The Committee will continue to receive updates and provide feedback when applicable.

6. Review and Discussion: Living Donor Packaging by Transplant Hospitals

The Committee reviewed and discussed a potential project regarding living donor packaging.

Summary of discussion:

The Committee will continue to discuss this potential project and determine next steps.

A member stated that this is a relevant topic, especially for paired exchanges. The Committee Chair agreed with this and noted that this is not an issue when the living donor organ being transplanted at the same program.

The Committee Chair asked if there have been any sentinel safety events related to packaging and if there was any additional information as to why the OPOs decided to stop offering their packaging services. Staff replied that the reasoning was unknown as to why the OPOs stopped their packaging services to the transplant programs.

The Committee chair suggested a solution in getting all the OPOs on board to provide these services and remove the barriers. A member cautioned on the burden this could present. The member continued by stating that at their OPO, the focus is on their core work. There is staff that help out their transplant programs, but they are moving away from this to focus their resources on volume and donors.

Another member agreed with this and stated that some of this is because of the metrics outlined by the Centers for Medicare and Medicaid Services (CMS). The member confirmed that their program still supports their imports but are moving away from this practice as well.

The Committee Vice Chair stated that their OPO does packaging, but it is a strain for their staff, and they do not ask when the transplant program schedules a living donor surgery. There is not enough notice given and it is hard to predict when issues may arise or the volume of requests they may receive. A member added that it is challenging to staff for all of these unknown challenges. The Committee Vice Chair agreed with this and voiced understanding of why an OPO would decide this type of service is not a part of their core purpose and electing to opt out.

A member asked that if working towards efficiency, wouldn't it make more sense to have the transplant program do the packaging themselves? The member added that packaging can be taught, and that once training is done, it is not a hard task to do.

The Committee Chair stated that in leaning towards the safety piece of this topic, the system is monitored, built for safety, and reliable, and the shipping is only increasing for living donors. This is beginning to be a bigger issue. A member asked if this policy requires chain of custody. The Committee Chair commented that this does not require chain of custody, which could present errors that result in the loss of a living donor organ. The member reiterated that this is mainly a packaging and chain of custody issue.

The Committee Chair inquired if there are new donor clinical factors that may need to be updated. A member asked if the OPO was also responsible for travel in these instances or just packaging. Another member stated that it is a burden on OPOs, and that just like everyone in healthcare, are struggling with staffing. The member added that from a safety perspective, it makes sense to expand access to the OPTN Organ Labeling, Packaging and Tracking System.

The Committee Chair asked if OPOs could take a leading role in educating transplant programs or if it was an unpaid burden. A member stated that it would make the OPOs responsible for training transplant program staff; having OPOs responsible for transplant program requirements becomes difficult to manage.

Another member suggested the potential for a training session during regional meetings. OPOs could be used as a resource for troubleshooting. The training should come directly from the United Network for Organ Sharing (UNOS), and the responsibility would be on the transplant program members to take it back to their respective programs and reach out to the OPOs for any follow up questions.

The Committee Vice Chair commented that there are some transplant programs that use the OPTN Organ Labeling, Packaging and Tracking System to check in organs and asked who provided that education. Staff confirmed that UNOS provided education, but added that there are a variety of devices used for organ-check in. The presenter also added that organ check in is just on the website and that there is no mobile application like there is for packaging. It is not the same as what OPOs experience in using the OPTN Organ Labeling, Packaging and Tracking System.

A member asked that before the OPTN Organ Labeling, Packaging and Tracking System, OPOs hand labeled everything and, in some instances, now are still hand labeling labels. The member asked if programs could revery to hand labeling rather than switching to the OPTN Organ Labeling, Packaging and Tracking System. The member continued by stating that training can be done, but how many people would have their hand in the process. Staff stated that there have been a number of different solutions discussed, but either way, there would need to be an approved project.

The Committee Chair asked if there were any safety events. Staff stated that there has not been any information provided regarding any reports of safety events.

The Committee Vice Chair stated that a lot of transplant programs are not being supported in this way and asked how those transplant programs have managed. Staff clarified that there was a transplant hospital that had the training that volunteered to share the training. A member cautioned against changing everyone's process that may be working for other programs.

Staff clarified that looking at 2023, there were 136 different programs that recovered a living donor organ and only 45 had any form of packaging done by the OPO. About 100 of 136 of the programs do manual packaging. There are some high volumes, but there are a lot of programs that only do 1 or 2 a year.

A member commented that this issue is similar to the Committee's extra vessels discussion. Programs have had some issues with labeling, and it is not always the transplant program. The member stated that using the OPTN Organ Labeling, Packaging and Tracking System should not be an issue to adopt.

The Committee Chair stated that on one hand the process is being done successfully with no patient safety events, but on the other hand, why not provide an upgrade to promote a more powerful process. A member asked if there could be a choice and elaborated by stating for extremely low volume areas, manual labeling could be performed, but the higher volume programs could choose.

The Committee Chair suggested a potential white paper outlining best practices and allowing label access. A member stated that allowing transplant programs is the option for what works best for their

processes rather than mandate. Staff commented that for information technology (IT) resources, the recommendation would need to go through the OPTN Policy Oversight Committee (POC) for additional review.

A member asked if the National Kidney Registry (NKR) was transporting all of these. The Committee Cahir stated that this was related to some of each and that NKR is involved in many but not all. Staff added that any project and how they align with the new strategic plan should also be in consideration.

Another member stated that in thinking about workload of training that started at the beginning, is it realistic to do something in that format for this? The member pointed out that technology and training avenues have changed and asked if there may be a better pathway for providing education that does not create burden. The member suggested training being available online to lessen some of this burden. Staff commented that this would then be dedication of the programming and would still need to become a Committee project.

The Committee Chair asked if programs could access the OPTN Organ Labeling, Packaging and Tracking System now. Staff replied that currently only OPOs have access to the OPTN Organ Labeling, Packaging and Tracking System.

Staff suggested the Committee gather more information on safety data for the Committee to review further and discuss if this is a potential project to pursue. The Committee Chair suggested speaking to the NKR to see if they have logistics for transport as they would have more experience on living donor transplant.

Next steps:

The Committee will continue to discuss this potential project and determine next steps.

7. Discussion and Report Outs: New Project Ideas

The Committee discussed and identified potential new projects ideas.

Summary of discussion:

The Committee will review and further outline the potential new projects identified and determine the sequence of projects.

Group 1: Focus group on improved offer acceptance rates

The Committee Chair commented that the Task Force has worked on how to improve offer acceptance rates. One item that the workgroup has found to be manageable is to do a survey across OPOs of how they use kidney pumps (i.e. who pumps, when do they place them on a plane, how do they get them back). The idea was to examine the best practices, get the data, and put together a white paper on the state of pump use in present day and acknowledge some practices as a forward way of thinking. The Committee Chair continued to say that this is not a policy change, nor does it attribute to significant costs. This would help address harder to place kidneys and would increase acceptance. It may also include center practices like managing the pump.

The Committee Chair added that their group also considered a wide variation of use of planes for pump travels – there are so many ways to travel, and chartering flights are exceptionally expensive. There are other ways organs can be transported, that would be cheaper and more widely available. A member

added that the group also targeted standardized criteria for hard-to-place organs. The Committee Chair continued by stating that this would be a way to better understand what a medically complex organ is. There is a need to develop standard definitions.

Group 2 – Optimize Organ Use

The Vice Chair reported that this group spent time analyzing donor best practices. It would help OPOs get what they need so when a list is run, the OPOs are not being asked for additional testing and the transplant program would have some reliability about what information is available. It was suggested that a review of current policy should be done to determine whether the required testing outlined is relevant from a timing perspective.

The Vice Chair continued by stating the group discussed whether altering machine perfusion is available. Consequently, is there a way that OPOs can ensure that transplant programs can see that some devices are available. The group also talked about a bidding system for the marginal donor – instead of opting out, transplant programs would be opt in for certain patients instead of a decline system. Members of the Committee agreed with this approach, stating that this method is positively motivating, follows the final rule better, and provides a place for a first come first serve bases on an organ offer.

Group 3 – Enhancing OPTN efficiency

A member reported on their group's discussion, with a focus being from an OPO perspective, specifically on the confusion surrounding crossmatching and how it depends if multiple tissue labs are in the same DSA. Some other key concerns included having to remove restrictions from transplant programs to utilize more organs, transplant programs getting reprimanded for poor outcomes, and how to enhance OPTN efficiency.

The member continued by stating that when it pertains to organ allocation (from the perspective of transplant coordinators), there are challenges related to the various organ offers received and ability to keep track of where each organ offer is in the process. There should be more resources provided to programs that can help to better manage this and provide transparency on what is needed for transplant programs to make informed decisions. Programs put in a provisional yes and then the offer is pending and results in programs not taking action until they become primary, which delays the process.

The member continued by commenting that there can create confusion when an offer must go through multiple coordinators before getting to a surgeon. Another member added to this point by stating that AOOS is used a band aid to address this circumstance.

A member added that they were under the impression that part of the goal of offer filters is to evaluate what programs are doing (in regard to utilization of the tool) and providing outreach to help programs further in adopting the offer filters tool. When filters are not being used, this bogs down the system. A member of the committee added that sometimes filters aren't the only solution. The member continued that their program reviews all cases of non-use – sometimes offers are filtered early in allocation but the programs would have taken them later in the allocation process. Staff asked if the Committee saw any policy barriers or if the Committee felt the focus needed to be on system tools? A member answered that the focus needs to be on system tools.

The member reporting out continued by stating that the communicating donor information system has not been updated to include things such as NRP and that transplant programs and OPOs should focus on donor highlights and standardizing what is documented there. It is important to streamline how donor information is communicated.

A member suggested re-evaluating policies that may be impacting efficiency for OPOs and added that allowing transplant programs to accept two livers for one candidate was recently removed. Although the policy change was approved, it has already had implications with liver loss, meaning that it's hindering the ability to place organs. The multi-organ policy is also making allocation more complex, making the process longer, and increasing organ non-use due to challenges with timing constraints to place organs. Another member stated that more information related to machine perfusion was relevant. There are some OPOs that are pumping the livers, while other OPOs do not pump their own livers. Additionally, there are some transplant programs that use pumps and bring their own. A member stated that there is a struggle when companies are coming in to the donor operating room (OR) for the transplant program, but the recovery team is from the perfusion company. If the recovery team aren't willing to wait (i.e. if the liver is declined in the OR), having the OPOs being able to report them would be helpful. There is also a need to make sure these third parties are up to date on practices, that there are no surgical issues, and if so, they are being reported/documented appropriately. A member suggested having outside companies report to the patient safety portal and follow up with the transplant program.

Another member asked what would occur next, how an incident would be reported and how that information is shared. It presents a challenge because the use of these perfusion devices is why more DCD complex organs can be transplanted, but there's risk in the OR of losing organs due to surgical damage. The Committee agreed and suggested there being a need for oversight on third parties performing organ recovery. The Committee Chair shared that a lot of programs can't take a late decline liver. There should be education on late decline livers and a rapid system in place so that there is a place to accept these offers. There is a need for a program-level shift or standard practice to putting the organ on a pump to find a recipient. Staff added that the OPTN Kidney Transplantation Committee is currently working on defining hard-to-place kidneys and kidneys at risk of non-use. The Committee Chair commented this would be helpful to better understand the risk factors and added that there may be a parallel effort with the donors such as Hepatitis B donors because they are hard to place. The Committee Chair voiced concern for these donors and added that this is an issue for Hepatitis C donors as well.

A member added that the OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) attempted to develop an algorithm to distinguish false positives, but that worked was stopped under guidance of the Centers for Disease Control (CDC). This project may come around again, but the estimates are half of the patients under the HOPE Act are not actually infected. The Committee Chair added that HOPE Act was limiting and there is anticipation for the policy to change. A member asked if an organ was placed to a HOPE act patient, are certain centers in place that are still receiving these organs? The Committee Chair stated that the understanding was that there were centers that may. At the closure of the study, there was hope that there would be a change to the law, but that has not yet occurred. Staff added that the OPTN Executive Committee (ExCom) requested this from the secretary. The Advisory Committee on Organ Transplantation (ACOT) also recommended that kidneys not be under the required of the institutional review board (IRB) protocol.

Next steps:

The Committee will review and further outline the potential new projects identified and determine the sequence of projects.

8. Discussion: ABO Genotyping

The Committee discussed a potential new project idea regarding ABO genotyping.

There has been recent discussion about increasing potential donors that are non-A1 to help share blood type B or blood type O organs. Additionally, an American Journal of Transplantation (AJT) article[1] compared the results from the traditional subtype test which is a Lectin test that agglutinates their A1 to determine A1/A2. The deoxyribonucleic acid (DNA) testing identifies many more donors as non-A1 and could be used for blood type B or blood type O recipients. Current living donor policy doesn't specify the type of testing that one must do. The policy requires concurrent results that are the same (and cannot use subtyping). The policy was written with the Lectin methodology in mind. It was added that the OPTN Histocompatibility Committee also has interest in doing more to promote genotyping. The Committee is being asked if there should be a re-evaluation of the living donor for potential modifications that would include molecular typing.

Summary of discussion:

The Committee will review the AJT article to further discuss their recommendations on next steps during an upcoming meeting.

A member asked if this was an alternative form of typing. The Committee Chair stated that the question in mind is if genotyping would be permitted for at least one sample; the concern being what types of testing would be covered cost-wise. Staff responded that per CMS, payment is provided for one genotype in a lifetime. Also, the Histocompatibility Committee is concerned in the fact that there have not been any extensive studies on this testing method. There were some weak reactions that were not true, and they were non-A1s.

The Committee Chair commented that CMS needs to cover more testing. The Committee Chair advised that a small population would be affected, but suggested the Committee review the article for additional context and then come back to discuss and provide an recommendation.

A member commented that it would be interesting to see how many more transplants would have occurred in one blood type B and blood type O recipient versus another. The Committee Chair stated that some recipients go through paired exchange.

Staff asked if there is benefit to genotyping living donors to understand their risk of genetic end-stage renal disease (ESRD)? The Committee Chair stated that there is a current study looking at APOL1 – for that piece of this, that's being asked, there is also atypical A2S and complement disorders. There has been a movement towards typing potential living donors, whether there is a risk of graft and living

[1] Joseph A, Murray CJ, Novikov ND, Velliquette RW, Vege S, Halls JBL, Mah HH, Dellagatta JL, Comeau E, Aguad M, Kaufman RM, Olsson ML, Guleria I, Stowell SR, Milford EL, Hult AK, Yeung MY, Westhoff CM, Murphey CL, Lane WJ. ABO Genotyping finds more A_2 to B kidney transplant opportunities than lectin-based subtyping. Am J Transplant. 2023 Apr;23(4):512-519. doi: 10.1016/j.ajt.2022.12.017. Epub 2023 Jan 3. PMID: 36732087.

donor failure. There is a parallel question with race being dropped out of KDPI. One could say that there is only race in there for APOL1 – could we test for APOL1 to see if there are 1 or 2 copies of the genetic mutation. A member asked when those results will be available. The Committee Chair responded that this work is still ongoing, but the thought is that it should be within the year. The Committee Chair added that it is unknown if it makes a difference; if you don't go on to donate and are you living your life differently. There are many people with APOL1 mutations that have nothing happen. A member commented that it sounds similar to genetic testing for Type I Diabetes; it can pose questions on how a person will live their life if a precursor to a disease/disease is known ahead of time. The Committee Chair commented that this poses the question of how paternalistic we should be as a society for donors. Staff will send out the AJT article for the Committee to review to discuss their recommendations on next steps during an upcoming meeting.

Next Steps:

- Staff will send the AJT article for the Committee to review.
- The Committee will review the article and discuss their recommendations on next steps during an upcoming meeting.

Upcoming Meetings

- March 28, 2024 (teleconference)

Attendance

- **Committee Members**
  - Alden Doyle
  - Kim Koontz
  - Julie Bergin
  - Andy Bonham
  - Kaitlyn Fitzgerald
  - Sarah Koohmaraie
  - Anja DiCesaro
  - Anne Krueger
  - Jennifer Smith
  - Jillian Wojtowicz
  - Annemarie Lucas
  - Stephanie Little
  - Jami Gleason
  - Laura Huckstein
- **HRSA Representatives**
  - Jim Bowman
  - Arjun Naik
- **SRTR Staff**
  - Avery Cook
- **UNOS Staff**
  - Joann White
  - Kayla Temple
  - Susan Tlusty
  - Houlder Hudgins
  - Kaitlin Swanner
  - Betsy Gans
  - Viktoria Filatova
  - Kerrie Masten
  - Carlos Martinez
  - Lloyd Board
  - Dane Thorson
- **Additional Attendees**
  - Marie Budev
  - Ginny McBride