OPTN Operations & Safety Committee
Meeting Summary
March 23, 2023
Chicago, IL, O'Hare Hilton

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Introduction

The Operations & Safety Committee ("Committee") met in Chicago, Illinois on 03/23/2023 to discuss the following agenda items:

1. Post-Public Comment Review: Offer Filters
2. Demo/Discussion: Replacing Default Filters
3. POC Update
4. Project Update: Collect Donor Continuous Renal Replacement Therapy (CRRT), Dialysis, and Extracorporeal Membrane Oxygenation (ECMO) Data
5. Follow Up: Redefining Provisional Yes
6. Closing Remarks

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

1. Post-Public Comment Review: Offer Filters

The Committee was provided an overview of the public comment received on the Committee's *Optimizing Usage of Offer Filters* proposal.

The proposal was in response the *Optimizing Usage of Kidney Offer Filters* concept paper (August 2023), where public comment voiced support in starting with a default filter model. The proposal outlined the default filter model, exclusion criteria, and a proposed new data field for candidate exclusions of offer filters. The community was asked to provide feedback on all aspects of the proposal, but also had specific questions related to education (patient), the proposed three-month re-evaluation timeframe, and suggestions for any additional exclusion criteria and/or offer filters the Committee should consider.

There were a total of 42 comments, and presentations during all 11 regions. Overall, there was support for this proposal with some opposition to some components of the proposal. Those themes were as follows:

- Re-evaluation period
- Automation within offer filters tool
- Patient education
- (Transparency among) OPOs
- Mandatory Offer Filters
- Maintenance of transplant programs flexibility in modifying offer filters

The Committee discussed potentially modifications to proposed policy language to address public comment received.

Summary of discussion:

The Committee Chair stated that from previous discussions, the Committee discussed and compromised in setting the re-evaluation timeframe to three months. The Committee's intent was to ensure that for those programs that "opted out" of using offer filters, there would be a more consistent cadence of reviewing the tool. The Committee Chair continued by suggesting that data be available every three months for review and modifying the re-evaluation period to six months, where the transplant program would re-evaluate their offer filters. A member agreed with this and stated that having data available every three months would be helpful and that the stress of having to re-evaluate the offer filters tool every three months would be too much. It would be reasonable to act by re-evaluating the filters twice a year (every 6 months).

Another member suggested that given the variability in program size, this should be driven by number of offers rather than timeframe. The Committee Chair stated that this is reasonable but added that there should be a focus on the concerns addressed by the community for this iteration of the project and upon implementation and a review of the offer filters, could then further assess and make modifications as needed for future iterations.

UNOS staff stated that from previous Committee discussions, it appeared that the Committee agreed that picking a timeline was more easily understood. Programs would know that filters would be turned back on for everyone. Staff continued by asking if there was concern of what that threshold number of offers would be and that this may vary from one program to the other.

A member agreed with this and stated in policy development, there should be an understanding that different parts of the country and transplant programs are not the same. This then poses the question of how best to lean into supporting individual programs in being successful rather than applying a "one size fits all" approach. The Committee Chair agreed with this and stated that there are ways to accommodate this notion by monitoring data on this further. In addition to this, the offer filters tool is still voluntary in nature.

UNOS staff stated that from previous discussions on what would be a good timeline and staff driving behavior at the transplant programs (ex. staff changes). One thing to keep in mind is if you are a smaller program, that does have a staff change, do you want to wait for that program to build enough offers? That staff change could show a behavior change within a few offers in which you would want a shorter timeframe regardless. A member stated that with a default model, the offer filters could be changed at any time. UNOS staff confirm that this was true, but the OPTN would not be generating model-identified filters (which would be based on data) until a threshold is made. If basing off number of offers, there could be a difference in when the programs may be provided their information.

The member continued by stating that six months of data for one program can vary with another and that with the ability to change filters at any time, and suggested potentially giving a program the option of having filter generated every six months or after a certain number of offers. Staff clarified that there could be a hybrid where the filters could still be generated on a regular cadence, but a program may not have it applied until a certain threshold is met.

The member stated that this would be dependent on how transplant program feel of this with keeping in mind the goal of this project being to promote efficiencies with these processes. The Committee Vice Chair stated that previous discussions on the timeframe was trying to encourage transplant program usage and not wanting to have a long period where a transplant program is not using offer filters. There

was comment from public comment that voiced the burden of re-evaluating the offer filters every three months. The Vice Chair suggested that the three-month period could be for those programs that "opt out" of the offer filters and extend the re-evaluation period for those that are using the offer filters consistently.

A member stated that this may be a good option to consider and that it appears that the staff of the burden is fear of the unknown and what it may translate to in coordinator hours. The member stated that during their regional meeting presentation, a question was posed regarding when a program excludes a candidate, would this mean that the program would have to exclude them again every three months when this re-evaluation period comes around.

Another member commented by stating that a vast majority of programs are activating, deactivating, and creating filters until something is prompting the program to go back in and look at their filters. The filters currently apply to a program's entire list but not individualizing the list. The member noted that a challenge for programs is that there are some limitations to the report tool. The member continued that from experience with attempting to go back and look at program data from the last three months, there is an error message stating that the volume of data is too high.

UNOS staff stated that this was a known issue of the report and there is work being done to move this tool to the data services portal so that it would bypass this limitation. The Committee Chair stated that this should be included in the Committee's potential roll out of this project.

The Committee Chair reiterated the suggestion of having data available every three months and modifying the re-evaluation period from the proposed three months to six months as suggested by public comment. UNOS staff added that after monitoring of the default filter model, there is an opportunity to evaluate more data to determine next steps for future iterations.

The Committee Vice Chair commented that the question from the regional meeting was most likely in response to the proposed new data field that would allow transplant programs to specify if a candidate would be excluded from offer filters. This would not be included in the default, which would alleviate the burden that is perceived with this. The Committee Chair agreed with this and stated any additional work done outside of the offer filters, would not need to be redone.

UNOS staff mentioned that from the DAC presentation of the proposal, there was a comment made that in the offer filters current state, the default filters might drive conservative practice, given that the offer filters tool are built to filter right at the line where programs are accepting versus not accepting offers. In the concept paper, in the context of mandatory offer filters, there was discussion of having a buffer and asked the Committee if this should also be considered for the default filter model.

The Committee Chair stated that there is a buffer for this model and explained that the filters are designed to be outside of such that when applied, a program would not have lost any offers over the last two years. UNOS staff continued by stating that the concern was that if programs did not interact with the offer filters tool because the thought is that the filters would be re-applied based on the program's acceptance history, the program won't know about the offers they would be losing that they may have considered. UNOS staff continued to explain that if for some reason a program did not receive and offer they would have considered in the past, a year's worth of data that is being used to generate the filter, the program would not know that one if suddenly excluded if they won't they don't actually check on their filters. So the thought was that if a program decided to do nothing to their offer filters, there is a chance that a program could lose some offers the program would have accepted.

A member stated that this should be a reason for a transplant program to utilize the programs to avoid losing out on an offer. The Committee Chair added that the fear of missing out on an organ offer, which is understandable, is bogging down the system and resulting in accumulations in cold time of organs.

Another member stated that although there is some work upfront, the offer filters tool is beneficial. A member stated that the key of having transplant programs use the tool is the educational efforts in the beginning which should include information showing transplant programs what their offers currently are, what offers the program is turning down, and never accept to alleviate this fear of missing out on offers. The member then suggested that a review of programs data should be mandatory.

UNOS staff commented that currently the kidney minimum acceptance criteria has policy related to programs reviewing their data every year. It has been found that there are some programs that have never updated because there is nothing actionable that the programs can document that they have reviewed their minimum acceptance criteria. The Committee was asked in the context of offer filters, how can the review of this data be enforced?

The Committee Chair stated that as a future iteration of this offer filters model, programs can "opt out" but would need to acknowledge they reviewed their program's data and provide rationale for why they opted out of using the filters.

The Committee Chair then commented on the theme of patient education, stating that it is the Committee's job to provide education on how the system works and best practices. The Committee plan to be a part of the educational efforts for this project. The Committee Chair continued that transparency is important and suggested the approach of patients being able to see the offer acceptance rates of transplant programs or later the filters can be published so that patients are aware of what filters are being used at programs. The Committee Chair stated that it may be complex in education in understanding the actual tool itself.

A member asked how patients may be able to access Health Resources and Services Administration (HRSA) data and if this information showing the transplant rates would be enough education. The Committee Chair clarified that for education in a broad sense, the thought is that as part of the initial education, there should be some type of patient understandable metric that can be compared across programs to indicate how likely they are to get transplanted.

Another member stated that information such as a handout would be helpful in patients' learning. The member continued by stating that at their program, many of their patients do not have the internet or cell phone to look up this information or have a clear understanding of it. A member stated that one handout would not be sufficient for patients and suggested additional educational materials should be provided. The member added that from a health literacy standpoint is important and that the education that is being provided needs to be under consideration when developing these materials to help break these concepts that is comprehensive for patients to understand.

A member suggested multiple opportunities throughout a patient's visit with their physician could be helpful. The Committee Vice Chair agreed with this and stated that some of the feedback heard during public comment was around the volume of information presented to a patient and their ability to consume and comprehend what is provided. The Committee Vice Chair continued by stating that providing patients with a handout during their visit and additional information for patients to review at home would be helpful.

A member asked if policy was being included to educate patients on offer filters. Another member stated that this should not be the case because the filters are a tool for the transplant program, not the patient. The member continued by stating that patients should not be burdened or confused with

educating on tools that the transplant programs use to help in decision making. A member responded that it is commendable that there are tools that are being used to help in decision making, but patients should be a part of this decision-making process, which involves education.

Another member voiced agreement with both sides and commented that what the Committee is addressing is around a tool that enables programs to apply a decline upfront based on a transplant programs behavior or not normally accepting those offers. To the points made from the patient community's standpoint, there is a challenge of not hearing the offers that are being received and not being a part of that process. On the other hand, clinicians are enabled to make good decisions for their patients and the offer filters tool allows to put that criteria in place before the offers come. These are two separate conversations but equally important to understand.

UNOS staff clarified that developing policy language is part of this project, but these discussions are helping to inform what education is needed. A member stated that if there are certain offers that are not accepted, such as HIV or Hep C kidneys, patient should be informed of this but formal education should be needed in these decisions; this would make processes less efficient if done this way.

A member stated that offer filters are a temporary solution for what should be patient specific criteria that determine whether a patient shows up on a match run and if this cannot be achieved nationally, offer filters is a good solution. UNOS staff commented that from an education standpoint, sharing these best practices may be an approach to consider. During the collaboratives at the regional meeting the previous public comment cycle, there was good feedback and members learned things that other programs were doing and did not know were options.

The Vice Chair voiced agreement in the Committee providing education, and not a policy, as policy could be burdensome. The Committee Chair commented that the offer acceptance ratio data, as it will be a quality metric, is a way all things get distilled.

A member stated asked if potential recipients have access to declined data. Another member clarified that candidates would have access to the organ acceptance rates. A member stated that a year ago, there was a push for patients to be informed within a certain timeframe of a decline for them, which was shut down due to the burden on the transplant programs to do so. The member continued that there have been discussion around giving patients level access to the list of organs they have been offered in the past but it is unknown that there are any projects underway in moving this forward.

The Committee Chair stated support in transparency for patients, but a lot of the data would be complex for patients to understand and would require additional education. Another member stated that too much transparency could result in unintended consequences where patients would become restricted from offer they are listed for and not receive any offers. A member stated that on the other hand, this may be a push for some programs to reconsider organs they would consider for those patients, which is a component of what the goal is for the country in moving forward with transplanting these kidneys that would otherwise not be utilized.

A member asked in regards to transparency among OPOs, currently, OPOs are unable to see what programs are using filters and what filters transplant programs are using. UNOS staff clarified that OPOs can see a report to see if a transplant program has an offer filters bypass code filters but cannot see what the specific filters are or what criteria is used.

Another member commented that the term "bypass" should not be used in the context of offer filters as they are refusals by a program that exists before the offer. The member continued that the terminology of "bypass" used by OPOs means that an offer was not made by a program and the program did not have a chance to accept it. UNOS staff stated that this would be a good term, as it reflects that it is not a

refusal that counts as a refusal on a transplant program's offer acceptance ratio. The member suggested using the term "pre offer decline" and agreed that changing the term should not interfere with a transplant programs acceptance ratio, otherwise it would undermine the proposal's intent. The Committee Chair agreed with the term pre offer decline. Another member suggested using the term "filtered".

A member advocated, from an OPO standpoint, knowing what transplant programs within a donor hospitals region would be helpful because OPOs want their programs to use offer filters and it could be an opportunity to do outreach to those programs to get more information on why they may not be using the tool. UNOS staff commented that this had been discussed during public comment and there were also comments made that as offer kidney further away are allocated farther, how would this allow for that outreach? A member stated uncertainty of needing to know what filters are being used. Another member added that OPOs don't necessarily need to know what offer filters are used by transplant programs, but it would be beneficial to know which programs are using offer filters or not until there is something in place education wise.

Another member agreed with this and stated that promoting the usage of offer filters in this environment would be nice to help OPOs advocate for the usage of offer filters. UNOS staff commented that an OPTN Ethics Committee paper regarding transparency and transplant program selection that was out two public comment cycles ago recommended offer filters data should be available more broadly than just for OPOs. The Committee was asked if offer filters data should be available more publicly or not. A member stated that from an OPO perspective, did not see why this would be a problem.

A member commented that transplant programs probably do not want this information public because they would not want all of a program's filters were broadcasted. The Committee Chair stated that it may be not wanting to broadcast this information to their competitors. Another member stated that if the ability for multiple listing were eliminated, this would be something they would want to see.

The Committee Chair stated that the counterfactual of this would be the program's offer acceptance; although not the same thing, this is a distillate of their various factors in terms of how likely a program may be aggressive. The Committee Chair added to a member's earlier point of the fact that transplant programs have various tools that are to achieve an aim to balance organ acceptance.

A member commented online that viewing patient education as a burden is disheartening and that transparency requires education. Education versus overwhelming patients should not be part of the transplant process held by the transplant program. Trusting medical professionals is essential, but so is having patient being knowledgeable and engaged in the care team process. Patients deserve the right to know what's going on behind the scenes. Another member agreed with this and provided an example from their experience: a patient came in and in having a discussion with this patient, the patient had their PRA confused with the KDPI of the recipient confused with their eGFR. The member agreed that there should be transparency, but there needs to be a good way to be able to provide this information to patients without making them more confused. There are various levels of socio-economic status and education levels which is fine and transplant programs are always willing to give as much education as possible, but there are also time constraints that also need to be considered for transplant programs to decide and not lose the organ.

A member stated that when proposals include a future outlook, the focus tends to be on the future outlook and not the proposal that is moving forward which is thought to be the confusion of and concern of mandatory offer filters. The member continued by stating that it is believed that the community is in agreement in moving towards the idea of being required to using offer filters in the

future but programs will not want those filters to be dictated without flexibility. The member suggested that programs should be provided filters based on their program's behaviors and then have the ability to adjust their criteria as needed, which is ultimately what should be the goal of this tool.

The Committee reviewed suggested filters for consideration that came out of public comment as follows:

- Kidney Donor Profile Index (KDPI)/Estimated Post Transplanted Survival (EPTS)
- Size parameters (body mass index (BMI), height/weight)
- Normothermic reperfusion as a factor in addition to donation after cardiac death (DCD)
- Donor dialysis or continuous veno-venous hemofiltration (CVVH) within 24 or 48 hours of death

The Committee Chair stated that it makes sense to have more specific, granular filters, but suggested this be included in a future iteration of this project. The Committee analyzed data and decided on simple filters that are simple to understand to be applied first. At the same time, the Committee can be working on offer filters that do not allow programs to individualize.

A member asked if there were places to document information such as NRP. UNOS staff clarified that the OPTN OPO Committee had worked on a data collection project that would collect some of this information, which was just passed by the Board in December 2022. The Committee Chair stated that it does make sense to collect more granular data that could be attached to point to the exact patients or donors a program wants to include or exclude, but it should not slow down the application of this initial step the Committee is proposing.

The Committee Chair suggested the use of SRTR data as part of education for transplant programs. In real time, transplant programs may be able see a change in the system as an early indicator of predicting what a program is likely in the offers that are being received. A member agreed with this and commented that this would capture a big audience. UNOS staff asked if this information was public. The Committee Chair confirmed that this would be program specific data that is currently not public. Some members agreed with this. A member stated that this would be good data to refer to and that it is hard as a pediatric center as there are not as many offers to begin with. The Committee Chair clarified that this data should be built into the educational efforts, rather than making this mandatory, as this data is available.

Post-Public Comment (PC) Considerations

The Committee reviewed the following potential post-public comment modifications based on the public comment feedback received:

Re-evaluation Period: Based on public comment, it was suggested that the proposed three-month re-evaluation period be extended to six months. The potential modification would read as follows:

<u>New model-identified filters will be generated for each transplant program every six months.</u>

The Committee agreed with this modification. The Committee Chair commented that this would be a step that addresses the concern that was brought up in public comment and see this as an ongoing process. The Committee Vice Chair agreed with this and stated during public comment, there was praise that the Committee took action based on the feedback received from the community, which should still be considered as the Committee works to finalize this proposal.

Automatic Exclusion criteria: To avoid redundancy, the line "unless the filter is for a pediatric alone program" would be removed. The potential modification would read as follows:

All model-identified offer filters will automatically not apply to candidates with any of the following criteria at the time of the match run:

- Greater than 90% CPRA,
- 0-ABDR mismatch,
- in medically urgent status, or
- less than 18 years old~~, unless the filter is for a pediatric alone program~~

Model-identified offer filters will be applied to all adult kidney transplant programs. Pediatric alone programs may manually apply model-identified filters.

A member asked if a pediatric program had a 22-year-old patient, is the program still considered a pediatric program? The Committee Chair clarified that the program would still be considered a pediatric program. The member continued that there are some pediatric programs that do have adult patients. UNOS staff suggested including this in a frequently asked questions (FAQ) document to clarify this. Committee members agreed with this. Another member stated that at a pediatric program, they have encountered adult transplant programs not wanting to accept other pediatric patients who are up for re-transplant as well as those patients who have developmental delay; there are patients who are transplanted at pediatric programs who are older than 18 years old. The Committee agreed with this modification.

Data Collection: Feedback from the OPTN Data Advisory Committee (DAC) suggested that further modification was needed in the wording of the proposed data field. The proposed modification is as follows:

Proposed Data Element: Candidate offer filter exclusion

Location: OPTN Waiting List

Format: Choose an option for this candidate

- Apply kidney offer filter
- Do not apply kidney offer filter

Definition: This field determines whether a candidate is manually excluded from having offers filters applied for them. This is set to "Do not apply kidney offer filters" by default.

Apply kidney offer filters - this patient will only receive offers defined by the program's offer filters settings

Do not apply kidney offer filters - this patient will receive all offers regardless of program's offer filter settings

The Committee Chair clarified that whatever changes made in this field would not be affected by the application of the default filters. When the offer filters are refreshed every six months, this field would not be; the transplant program would need to manually make any changes as applicable to this field. The Vice Chair suggested this being defined.

A member stated that there should be a list of these patients excluded from offer filters for transplant programs to review in addition to any data related to the offers for that patient. The Vice Chair agreed with this and clarified that there had been discussion on this previously of being able to track this information.

UNOS staff clarified that this field would not be reset during the re-evaluation period and if a program were to determine not to apply offer filters to a candidate, it would remain as entered during the reset

period. The Committee agreed with this. Modified language will be included to specify the functionality of this data field in context of the offer functionality as discussed. The Committee Chair stated that if a transplant program were to exclude all offer filters and the patient, therefore receives an offer, and declines the offer, this would go against a program's refusal rate. A member agreed with this.

The Vice Chair asked for clarification in language around what this field would mean in not applying kidney offer filters. A member suggested rewording this to "Do not apply kidney offer filters – this patient will receive kidney offers on match runs which they appear." In other words, the member continued, if a candidate appears on a match run, and an OPO gets to them, that candidate would receive the offer.

A member asked if these modifications for the data collection, would be included in the proposal since this is currently not a field on the Waiting List. UNOS staff clarified that this would be included. The member continued by asking if there was a timeframe of when this would be added. A member stated that this would have to be passed by the OPTN Board of Directors first before implementation begins.

The member commented that in talking to transplant programs about wanting to take donors that are medically complex and apply it to a subset of their candidates they may consider more medically complex kidneys for; is there an opportunity to create a tool that opt out or filters for patients if they meet a certain criterion?

The Committee Chair stated that this could be achieved at the same end by going into the individual level if a transplant program reviews their listing and consistently review and uncheck the field as applicable.

UNOS clarified that the member was suggesting a model that is similar to offer filters, but on the patient side. The member agreed with this and added that the concept is like applying a filter that excludes candidates from needing to have the filter applied.

Another member asked on the small subset of patients (like an expedited list), a transplant program could just turn the filters off. The Committee Chair agreed with this and stated that the transplant program would need to have a system in place to review this in some sub cadence to make updates as needed to this selection (i.e., re-evaluate at annual visit).

A member stated that this would be something that would be beneficial for OPOs to know. Another member agreed with this and stated that OPOs do not necessarily know what programs would be willing to accept the offer. The member suggested there being a functionality that would allow OPOs to click on a button that would filter those patients that would accept a certain offer at a time. UNOS staff clarified that currently, if an OPO sends out a batch of offers, the offer filters are applied to the entire list. The member stated that this would be a good education point as this was not understood by them. UNOS staff agreed with added that it is beneficial for the OPOs to send out more notifications within the system. When clicking on the "Send Notification" button, the offer filters are applied as well as the latest cold ischemic time (CIT). The member agreed with this and stated that it would be nice to not have to push a button to alert OPOs of this.

Another member stated that this was the only negative feedback on usage of the offer filters so far; a number of these filters have to do with CIT and distance. The member continued by stating that even though filters are applied the first round, there are offers that come back because the offers were not cross clamped at the time of the offer. The member stated that this is something that could be improved on later and agreed that the OPOs should not have the burden of having to push an additional button and it would be nice to get to a point where the technology internally can update this information on its own.

The Committee Vice Chair commented that it would be nice for an OPO to be able to view in real time any changes that are made and that the math run updates with these changes. Members agreed with this and acknowledged that that would not be for the purposes of this project.

UNOS staff added that if offer filters function as intended with broader usage, it would be expected that there would be fewer instances of provisional yes (PY) that at entered/seen on the list. It would be interested to see any changes in PY's that are entered in and those PY's that would be filtered out.

A member asked for clarification on offer filters, specifically on "cold ischemic time at time of offer" and if this is meant by when the initial match run is sent to the program and a decision is made on if the offer is PY or if this is when an offer becomes primary. Another member clarified that this is in reference to the time the OPO clicks the button to send electronic notification. The member continued by clarifying that a program could be number 1000 PY to receive an offer. A member confirmed this was the case. The member continued to explain that if an OPO ran a match run and then six hours later the kidney was allocated and clicked to electronically notify 1-10, it will then apply the filter to the match run to those programs and candidates at the time the button was clicked to send the electronic offers. UNOS staff confirmed this was correct.

Another member asked when the OPOs are clicking this button. A member clarified stated that this is dependent on where the OPO is in the process. Another member stated that this varies among OPOs of when this electronic offer is sent out. A member agreed with this and added that the OPTN Ad Hoc Multi-Organ Transplantation (MOT) Committee is working through those scenarios where OPOs are holding organs and there needs to be coverage for OPOs for this, so they are not penalized in allocating the offers and then having to allocate it as part of an MOT offer. The member continued that it would be nice for offer filters to be applied in those instances (expedited kidney offers) as well which is not currently seen. The member continued that the biggest challenge faced by OPOs is when going to the operating room (OR) and there is interest in the offer and then in recovery, with biopsies and pumps being fine, the organs are still declined. There is a need to address provisional yes due to this because currently, PY is non-binding and nothing is usually done once this is entered. The member continued by stating that provisional yes should have been addressed first so that while this proposal was being developed, the offers would be accepted in an authentic way and could convince OPOs not to send out an overwhelming volume of offers.

A member commented online that at their program, they generate a list immediate to send cross match blood that with the new allocation system will help to determine high CPRAs; immediately meaning when serologies are back. The member further explained that their programs would generate a list, identify high CPRA candidates and then have virtual cross matches performed and then send out a cross match blood out so that programs are receiving notifications early and at least evaluating them.

Another member stated that it is in the best interest of the OPO to get offer out before recovery and that there are some instances it is probably based on donor instabilities and there needing to be a rush to the OR. A member shared an experience with an OPO that is notorious for giving last minute notification, making it difficult for their transplant programs to mobilize and procure the organs. The result is the OPO then offers the organ to a local program, with the procurement done the next day. The member continued by stating that it would be easy to make things more transparent by tracking time from when work has started on a donor, getting verification, and sending notification out. If the notification is sent two hours before the OR, there should be justification for why that is. A member stated that this information is currently available on an OPO dashboard.

There were no additional comments or questions.

<u>Next steps:</u>

- Staff will make recommended modifications as discussed by the Committee to policy language.
- The Committee will review and vote on the final policy language that will move forward to the Board during an upcoming meeting (an additional meeting in April will be scheduled).

2. Demo/Discussion: Replacing Default Filters

The Committee reviewed a demo on the functionalities of the proposed offer filters. The demo specifically related to how the refresh of the offer filters during the re-evaluation period would functionally operate.

Summary of discussion:

UNOS staff asked for clarification on what the maximum involved in the criteria within a filter. It was clarified by UNOS research staff that the numeric filters are rounded to certain intervals. For distance, it is rounded by 25 (i.e., 25, 50, 25, etc.).

A member asked how this a bottom line is determined should a certain numeric filter not be utilized. UNOS staff clarified that if a filter decreases to DCD greater than 25NM and a transplant program has never taken an offer with these criteria, the filter would then be adjusted to just filter for DCD donors.

UNOS staff reviewed a scenario where the model no longer identifies the filter. A member asked why the system would not identify any filters in this case. UNO staff clarified stated that there could be a few different reasons that a filter could no longer be recommended. it could be that a transplant program did not receive 20 offers from DCD donors so there is not enough data to justify it anymore or it could be that a transplant program turned off the filters and did a DCD transplant. The member continued by asking if a transplant program did a DCD transplant would there be some distance point that would be recommended?

The Committee Chair commented that a program would have to meet the criteria for the model-identified filters to be generated which includes the following:

- The program declined all kidney offers on at least 20 donors that met the offer filter criteria,
- The program transplanted 0 donors that met the filter criteria, and
- The kidneys they meet the filter criteria were transplanted elsewhere

The Committee Chair commented that it would be nice for transplant programs to be able to see previous filter history, whether inactive or not, so that transplant programs can evaluate program behavior. A member stated that a concern with this is that if filters were not recommended, a transplant program may think they may not need the filter. The member suggested having the capability to provide reasoning as to why a filter is not being suggested anymore.

Another member asked that when an individual patient has a filter opted out of offer filters, would this be included in the re-evaluation period of the offer filters? UNOS staff clarified that the re-evaluation period for the offer filters would not affect the candidate exclusions applied. UNOS staff further explained that transplant programs will have the ability to modify the candidate exclusions as the candidate exclusions are not identified by the model. If a candidate exclusion were modified (i.e. CPRA), that would persist from a refresh filter and not be changed.

UNOS staff asked the Committee their thoughts on what should be done with a filter if that filter was no longer recommended. The Committee Vice Chair suggested having the filter recommended to be archived and allowing the transplant program can mark it as archived. Another member suggested having the release date of the filters time stamped to be able to track these filters better. The Committee Chair also suggested that there could be an alert to the transplant program that the specific offer filter is about to be turned off and have the transplant program the ability to own the filter if they

choose to still use it, making it a program-identified filter versus a model-identified filter. This would promote ownership and stewardship of transplant program teams to evaluate and thinking about their offers with notice.

UNOS staff commented that similar feedback was received by the Transplant Administrators Committee (TAC) where it was suggested that at the re-evaluation period, there should be a notification to transplant programs of their model-identified filters, having the transplant program determine if the filters are something they would like to turn on or off. In this same context, the review could be done for those outdated offer filters and asking the transplant program to take action of whether they want to continue using the filter or not. The Committee Chair agreed with this and stated that if the program determined they would take the offer filter and customize it as their own, they would always have the filter and can modify it as they would like.

A HRSA representative asked if transplant programs would have to wait until the re-evaluation period to change the filters. UNOS staff clarified that the offer filters could be turned on and off at any time and that new filters would not be generated until the re-evaluation period every six months. The Committee Chair clarified that new filters can be made or turned off at any time. If a new surgeon joined a transplant program team, they can apply or turn off any offer filters at any time. At six months, the transplant program will need to take action to re-evaluate the filters and determine what offer filters they wish to apply or turn off.

A member asked for clarification on what was meant by a program being able to make their own filters. UNOS staff clarified that a program-identified filter allows a transplant program to freely edit their filter from within the Offer Filters manager screen. The proposed model-identified filters would not allow transplant programs the ability to modify it from offer filters; the transplant program would need to disable the offer filter and then create their own filter with the modifications.

Another member stated that in circumstances like this, there should be some level of retention of the original filter, especially if there is not enough data to refer to. The member recommended allowing the transplant program the ability to turn off the offer filters but retaining the original offer filter and having a notification that can state that due to limited data. It is not thought that transplant programs would make a dramatic change unless they had a program change themselves.

A member asked if there would be further analysis of what programs choose for filter as this progresses. UNOS research staff stated that there is interest in publishing some of this data in a manuscript for educational purposes. The Committee Chair stated that there should be monitoring of this data as done in post-implementation monitoring for any other policy proposal to help inform potential changes (if any) to future iterations of this project.

UNOS staff inquired if a transplant program were to turn off a model-identified filter but wanted to turn it back on, would they have the ability to do so prior to the re-evaluation period. UNOS research staff responded that this would need to be clarified a bit further (turning off versus deleting the offer filter) and how this may be operationalized. Turning off an offer filter would be simple in turning it back on. If a filter were deleted, it would require the transplant program to find the original filter. If the transplant program demonstrated the behavior, the filter would appear during the re-evaluation period. UNOS staff suggested including an explanation of what is the difference between deleting an offer filter or turning off an offer filter in an FAQ.

UNOS research staff continued by asking the Committee if the recommended process of adjusting the offer filters as recommended by the Committee should have policy language around this. The Committee Chair stated that this would be a type of modification. UNOS staff reviewed potential

modified policy language to reflect this discussion. The Committee agreed with the following modification:

> All programs may remove their model-identified filters or modify candidate automatic exclusion criteria of their model-identified filters. Any program may create their own program-identified filters.

There were no further comments or questions.

Next steps:

- Staff will make recommended modifications as discussed by the Committee to policy language.
- The Committee will review and vote on the final policy language that will move forward to the Board during an upcoming meeting (an additional meeting in April will be scheduled).

3. POC Update

The Vice-Chair provided an update to the Committee on the role of the Policy Oversight Committee (POC), their discussions, and subcommittee progress.

Data summary:

The POC is sponsoring two subcommittees:

Benefit Scoring Subcommittee

- This subcommittee reviews the benefit scoring system being developed by the POC. Benefit scoring aims to provide an objective metric for which policies should be prioritized.
- Progress to date includes:
    - A metric for impact
    - Reweighting values
    - Bundling project review
    - Standardizing information provided for new projects

Post-Implementation Monitoring Subcommittee

- This subcommittee reviews the post-implementation monitoring actions taken by each committee and will develop a framework by which each policy can be evaluated after implementation.
- Progress to date includes:
    - A definition for key metric and its role in policy success
    - An analysis of limitations in monitoring
    - Unintended consequences

Both subcommittees seek to refine the role of the POC when considering projects at both the project approval stage and the post-implementation monitoring stage.

Policy Priorities

The POC is also evaluating policy priorities and any updates that should be made. Current policy priorities are:

- Continuous Distribution
- Efficient Matching
- Multi-Organ Allocation

Summary of discussion:

A member felt that POC should be much more informed on the IT resource limitations, as that seemed to be the largest limitation to policy development. The Chair agreed with this, noting that benefit needed to be contrasted with cost.

A second member appreciated the bundling of projects proposed by the benefit scoring subcommittee, as they felt projects were too often reviewed in an absence of other projects competing for the same resources within the same policy development cycle. They added that the POC should consider having a method to retrospectively review previously approved projects if a cycle was over budget.

Staff clarified that OPTN Research staff have been developing key metrics in the past, but this approach would hopefully provide a more objective method to review the project post-hoc. In addition, it was encouraged that sponsoring committees review the key metric being proposed prior to project approval.

In response to the discussion regarding key metric, the Chair suggested that a measurable metric to determine the success or failure of the offer filters project could be utilization rates by programs. They noted that the current key metrics did not outline a threshold anywhere indicating the project's success or failure.

Next steps:

The Committee will review the key metric for the new project, "Donor CRRT, Dialysis, and ECMO Data Collection" when it is drafted.

4. Project Update: Collect Donor Continuous Renal Replacement Therapy (CRRT), Dialysis, and extracorporeal membrane oxygenation (ECMO) Data

The Committee was provided an update on the upcoming Collect Donor CRRT, Dialysis, and ECMO Data proposal. This new project proposes the collection on donor support therapies to promote the efficient review of organ offers from donors on CRRT or ECMO. This data would provide granular information to include in the ongoing efforts on offer filters as well as standardize the reporting of this data.

The project was recently endorsed by the DAC and will be presented to the OPTN Policy Oversight Committee (POC) for approval during their March 24th in person meeting. The project is anticipated to go out for public comment during the summer 2023 cycle and later to the Board in December 2023. The DAC would receive a presentation prior to public comment as a second check in.

Summary of discussion:

A member asked if this data collection would just include ECMO or if there would be other forms of mechanical circulatory support. UNOS staff clarified that this will be one of the components of this project that will need to be discussed to determine what would be include.

Another member stated that as the Committee, there may need to be a more overarching approach in looking at the OPTN Donor Data and Matching System and data collection. The OPTN Donor Data and Matching System has an abundance of need and there seems to be a piecemeal approach to working on this system and new data fields that are to be added. There was a project being worked on by the OPTN OPO Committee with proposed data fields and now the Committee is working on additional data to be included in the OPTN Donor Data and Matching System. The member suggested working on this in a more holistic way and that it would be nice to enter information in the Decease Donor Registration (DDR) form (which is retrospective) and it can be fed the data needed.

UNOS staff commented that there was feedback received that a potential downside approach to this project could be the rate of updating support therapies. This would require maintenance for relevancy. The Committee would need to consider how granular this data collection effort should be.

A member stated that there should be some consideration to qualify some of these therapies, like ECMO prior to donation or for the purpose of donation. The member continued by stating that they have observed kidney transplant programs declining donors that have been on ECMO, while at the same time seeing that ECMO with NRP is being used as a means of preservation which does not seem to make sense clinically. The member suggested delineating the timeframe/periods the patient is on supportive therapy and then will need to consider this in terms of NRP later on.

The Committee Chair suggested including representation from the Lung, Liver and Intestines, and Pancreas Committees on the Workgroup to discuss this project further. Those recommendations would then come back to the Committee for further review of finalization of the proposal.

A member stated that it will be good to include all organ-specific Committees because there may be instances when a transplant program receives an offer and declines, it would be helpful to have this information readily available to help transplant programs decide in an efficient way.

UNOS staff commented that AOPO and ASTS's comments during public comment called out a need for this data collection, which provides some insight of the support for this project.

There were no additional comments and questions.

Next steps:

- A call for volunteers will be announced to include representation from the following OPTN Committees to further discuss this project in a Workgroup:
    - Kidney
    - Heart
    - DAC
    - OPO
    - Liver and Intestines
    - Lung
    - Pancreas

5. Follow Up: Redefining Provisional Yes

The Committee reviewed the project "Redefine Provisional Yes: Concept Paper". This concept paper did not progress to a policy proposal due to lack of support during public comment, in part because the effort was too large. The Committee was asked to identify smaller projects that could be taken out of the project and pursued independently.

Data summary:

The Provisional Yes project sought to improve the efficiency of organ offering, review of offers, and acceptances to reduce overall allocation time. This project was also sequenced alongside a concept paper for kidney offer filters; community sentiment felt that offer filters would help address this issue

Four workgroups were identified for this meeting to consider aspects of the project. These were:

- Responsibilities of the transplant program
- Responsibilities of the OPO
- Definitions
- Time limits on offers and notifications

Summary of discussion:

The following is a summary of each of the work groups' reports to the committee.

Responsibilities of the transplant program

Members from this group felt that a significant area for development could be automated notifications and responses. However, programs should be able to customize these automated practices to best fit their program's needs. Programs also need to feel that they can trust process improvements proposed, as a member noted, pointing out the low voluntary usage of offer filters.

The group also reviewed the requirements of the tiered framework and felt that, while policy may not be the correct approach for it, the steps still needed to be taken. For example, programs should commit to notifying and prepping a patient if they receive a primary offer.

Responsibilities of the OPO

Members from this group felt that there needed to be more guardrails surrounding the notifications that programs can send, especially with kidneys. Kidneys require a binding response option pending anatomy and biopsy such that programs can feel confident in their placement prior to recovery. If a program uses this response option and later declines for a reason other than anatomy or biopsy, there should be a flag like how out-of-sequence allocation is tracked.

A second problem identified by the group was that OPOs will send too many offers on organs that should be accepted early in the match. This is being done to ensure the placement of the organ, but it results in programs not seriously evaluating the offer when they are much lower than the primary program. It was suggested that there should be a cutoff to the number of offers able to be distributed on donors of a certain good quality.

However, for organs that are more difficult to place, there needs to be a system that efficiently places them if they carry key factors identified during the pre-recovery phase. This will prevent OPOs from having to spend time offering to programs that will not consider the organ. A member noted that it is currently up to the offering OPO to determine which organs will be difficult to place, and there is no policy solution to allow for the expedited placement of kidneys. They also suggested it would be extremely beneficial if there were a way to indicate from the transplant program side to the OPO that there is a recipient their program would be willing to accept for later in the match run. The Chair added that this approach is known to work, given that it is what some OPOs are already doing outside of OPTN policy. A member inquired if the only way this would be permissible in current policy was through a variance. Staff replied that an approved variance was the only way to allocate out of sequence within policy. A member also noted that allocations out of sequence have doubled since the removal of direct service area (DSA) and region.

Staff clarified that a difficulty in developing an expedited allocation system like what was described above was that the final rule requires offers to go to candidates, rather than programs. An expedited allocation system that allows programs to flag the patients they would use it for could be considered as allocating to a program, rather than a candidate.

The group also noted that there may need to be different backup routes for offers, suggesting that backup offers could go to the closest geographic program or the closest aggressive program. In addition, they suggested that there be requirements for backup diversity, such that one program does not have five candidates backing up the same organ, creating a single point of failure.

Definitions

Members of this group felt that backup offer needs to be defined in policy. This also needs to clarify between first, second, and third backup.

The group also noted that the "tier" terminology may carry negative stigma given the new OPO performance metrics.

They suggested that programs need to be able to hold a conversation with an OPO earlier and easier when considering an organ. This would also help an OPO feel confident in the placement of their organ.

A member proposed having a definition for multi-organ acceptance. Additionally, multi-organ acceptances should have increased scrutiny when a multi-organ offer does not use one of the organs.

Another member considered that there should be more refusal codes, or that they should be reevaluated.

It was suggested that there should be standard language between "decline" and "refuse". This terminology change may drive behavior changes.

The group also proposed examining and updating the definition of provisional yes, given that it implies several actions, but none are spelled out. For example, it requires a program to have "evaluated the offer" but does not provide any definition for what "evaluated the offer" means.

Time limits on offers and notifications

Members of this group held a similar discussion considering whether there should be limits on the number of offers allowable for "good" organs. They felt that this drives the practice of not evaluating the offer and instead putting in provisional yes as a placeholder. This then drives up the overall allocation time. A member agreed that there should be a policy solution rather than relying on OPO-specific practices to identify programs they know will take hard-to-place organs.

A member from the group advocated for applying offer filters to all organs. They also noted that coordinators should receive a text message notification when their program becomes backup to facilitate the efficient review of the offer.

Another member noted that much of the current practice for medically complex organs are workarounds, which seems to entail that the system is not functioning well.

It was suggested that there be a standardization of practice around the "notify as primary" button and programs that only consider calling a program an indication of primary. Because there are multiple options, programs can waste time determining if they are primary when they receive offers.

Next steps:

Staff will organize this feedback and provide a list of potential projects based on the Committee's discussion.

6. Closing Remarks

The Chair thanked members for attending.

Summary of discussion:

There was no discussion surrounding this item.

Upcoming Meeting

- April 27, 2023 (Teleconference)

Attendance

- **Committee Members**
  - Alden Doyle
  - Kim Koontz
  - Chris Curran
  - Julie Bergin
  - Jill Campbell
  - Stephanie Little
  - Gregory Abrahamian
  - Mony Fraer
  - Norihisa Shigemura
  - Susan Stockemer
  - Laura Huckestein
  - Jennifer Smith
  - Andy Bonham
  - Jami Gleason
  - Renee Morgan
  - Jillian Wojtowicz
  - Sarah Koohmaraie
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
- **SRTR Staff**
  - Katherine Audette
- **UNOS Staff**
  - Joann White
  - Isaac Hager
  - Lauren Mauk
  - Betsy Gans
  - Carson Yost
  - Heather Carlson-Jaquez
  - Laura Schmitt
  - Kaitlin Swanner
  - Kerrie Masten
  - Carlos Martinez