OPTN Operations & Safety Committee
Meeting Summary
October 27, 2022
In Person Meeting

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

Introduction

The Operations & Safety Committee (the Committee) met in person in Richmond, VA and on 10/27/2022 to discuss the following agenda items:

1. Post-Public Comment Review: Redefining Provisional Yes and the Approach to Organ Offers
2. Update: Voluntary Usage of Offer Filters
3. Post-Public Comment Review: Optimizing Usage of Kidney Offer Filters
4. Offer Filter Enhancements
5. Review of Offer Filter Options/Building Offer Filter Model
6. Follow Up: National Academies of Sciences, Engineering, and Medicine (NASEM) Report

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

1. Post-Public Comment Review: Redefining Provisional Yes and the Approach to Organ Offers

The Committee reviewed the post-public comment on the *Redefining Provisional Yes and the Approach to Organ Offers* concept paper. The concept paper provided an update on the project's progress to date and solicited feedback on the three-tiered framework and associated responsibilities considered by the Committee.

The public comment themes and feedback are as follows:

- **Offer Filters**
  - Tier III is synonymous with offer filters
  - Offer Filters and Continuous Distribution projects should be addressed first

- **Complexities of Framework**
  - No notable difference from current organ placement practices
  - Tier III could become new provisional yes
  - Tiered concept does not necessarily address the root problem of provisional yes
  - This approach could benefit kidney offers; would not be applicable across all organs

- **Staff Burden**
  - Tiers I and II require substantial scrutiny that is typically not done until candidate is likely to receive offer
  - Tiered concept would present a burden to OPOs and slow down allocation
  - Concept presented would apply differently depending on program size

- **Late Declines**
  - Believed to be attributed to inefficiencies within the organ placement system

- Efforts should be focused on better documentation of offer process and identifying late declines/declines with no change in donor information

- **Multi-visceral placements**
  - Believed to be attributed inefficiencies within the organ placement process
  - Increase in mandatory multi-visceral placements → leads to inability to allocation more than one organ

- **Time Limits**
  - Time limits outlined for Tiers I and II may prolong the process even further
  - Transplant programs may not have the information needed to fully evaluate an offer within the timeframes outlined
  - Framework may not allow sufficient time to perform testing required (i.e., highly sensitized candidates, physical vs. virtual crossmatch)

- **Sequencing of Offers**
  - Tiered framework is more subjective for harder to place kidneys; there should be a different approach to these offers
  - Consideration of auction-style allocation
  - Consideration for batch offers

- **Compliance**
  - The tiered framework would only be effective if enforced by the OPTN
  - Accountability for transplant programs should be built into the system
  - Provisional yes decisions should be made more biding

- **Additional Tools and Considerations**
  - Support for automated solutions

Summary of discussion:

The Committee Chair commented that the Committee's work on this project and the offer filters project is focusing on making processes more efficient. The Committee Chair suggested rebranding the Redefining Provisional Yes project to the Offer Efficiency project or something that more related to what the Committee is seeking to address. Additionally, this rebranding would address the public comment received that the direction of the Provisional Yes project and the concepts presented are too complex at this time and that the first iterative step should be to address the offer filters and automated solutions within the system that would promote efficiencies. Both projects have transformed and broadened in context and is seen to include a mixture of guidance, education, and policy. The Committee Chair suggested to think about each of these categories (guidance, education, and policy) and determine what other next steps should be considered besides system enhancements.

A member stated that rebranding the project to Offer Efficiency is reasonable and added that this also includes utilization. The Committee Chair agreed with this.

A member asked for clarification on whether the overall projects were being categorized as offer efficiency. The Chair agreed with this and stated this was an idea to encompass all the Committee is working to address by increasing organ utilization, reducing cold time, and making processes more efficient for organ procurement organizations (OPOs) and transplant programs. A member agreed that the project has transformed and rebranding it as the Offer Efficiency project is fair.

The Committee Chair added that the National Academies of Sciences, Engineering, and Medicine (NASEM) report makes it clear that these types are projects need addressing. It is the responsibility as a community to make these processes as efficient as possible.

A member asked if there was any thought of getting ahead of the pump usage and how this may change the paradigm of how organs are allocated. The Committee Chair agreed with this idea and stated that there should be further consideration and discussion in the development of this project.

Another member stated that depending on how long an organ is on the pump, there should be consideration for more efficient processes for OPOs to allocate those organs. The member continued by suggesting that for those organs that are on pumps for longer durations of time, there should be a local expedited list to help in the allocation of those organs. There were comments related to these harder to place kidneys and how best to allocate them and there should be consideration of having local lists. The idea of variances or local lists may be a topic that comes back up again as a solution to allocate these organs.

The Committee Chair stated that there are circumstances where equity makes less sense because you lose organs; instead, there should be a push for efficiency in those certain instances. The Committee Chair continued by suggested allowing for local variances and have local solutions until continuous distribution is in place. Once continuous distribution is in place, there can be a determination on which approach is the more efficient placement of these organs.

A member stated that something similar to the expedited liver match run would be helpful in allocating these harder to place kidneys.

Another member stated that going back to the beginning of this project and in discussing offer filters and continuous distribution, there should still be a set of ground rules that have yet to be addressed. The member continued by stating that despite public comment opposing to the concepts presented, which is believed to be due to the complex nature of the concepts presented, there should be policy that allows OPOs and transplant programs to hold each other accountable when needed. Instead of focusing on the outliers, there should be a focus on what authentic interactions between OPOs and transplant programs that can be done prior to going into the operating room (OR) and there is no cold time regardless of organ type.

The Committee Chair added that part of the challenge in allocation is also due to programs having two offers from the same candidate. This also creates inefficiencies. UNOS staff added that there is project sponsored by the OPO Committee that will address limiting organ acceptances per candidate type. This proposal would limit to one acceptance rather than two.

There were no additional questions or discussion.

<u>Next Steps:</u>

- The Committee will address the offer filters project first by submitting a proposal for January 2023 public comment.
- The Committee's previous discussions and system enhancement recommendations are currently under review by UNOS IT.
- United Network for Organ Sharing (UNOS) IT will determine resource estimates for the recommendations provided by the Committee and categorize them to determine the sequence of the enhancements
- The Committee will be updated as planning develops

2. Update: Voluntary Usage of Offer Filters

The Committee received an overview on the current functionality of the offer filter tool. Research staff presented the update on voluntary offer filters to the Workgroup. They also conducted data analysis on whether offer filters reduce match duration and how much of an impact filters have on individual matches.

Voluntary Usage of Offer Filters

As of October 7, 2022:

- 96 programs with at least one enabled filter
- 4,874,637 Offer Filters bypasses applied
    - 19.6% of offers from all programs
    - 37.4% of offers from programs that currently have at least one enabled Offer Filter
- KI non-utilization rates pre/post Offer Filters: 27.28% (pre)→ 25.86% (post)

Summary of discussion:

Overview of Offer Filter Functionality

A member asked how the offer filters affect current metrics – would the usage of offer filters be seen as a refusal of an offer? UNOS staff clarified that the usage of offer filters would not be counted as a refusal and would not affect the current metrics that are used.

The Committee Chair stated that it does not seem to be clear among the community that the usage of offer filters is a bypass of an offer and not a refusal. UNOS staff stated that this would be helpful for future communications and education efforts.

A member stated that if the offers are bypasses and the program is conservative, it would look as though the program is accepting everything. The member questioned whether there is misrepresentation.

The Committee Vice Chair stated that this ties into a topic that was brought up of being more transparent to patients on the offer filters processes and what offers the programs are willing to accept or not. Another member stated that theoretically, if a program is not as conservative and not turning those filters on, the acceptance rate of that program should reflect this.

A member stated that these filters are similar to the waitlist criteria in some ways in that a candidate will show up on a match run but may not receive an offer based on filters applied. Patients/candidates are not aware of what the kidney acceptance criteria of programs are so this is no different from those processes. The difference being the timing at which the filters are applied and the fact that the filters are multi-factorial.

The Committee Chair stated that it is very hard to defend with the NASEM report and to the public that the Committee does not move towards a mandatory filter model. If there were a combination of factors that set a standard of how aggressive a program would be and then allowing for organ offers to naturally broaden based on acceptance behavior. This model would help to build a list of those criteria that programs are actually accepting.

The member continued that the question is how to get more adoption of filters. Hearing the feedback and then modifying the offer filters tool accordingly should help in the adoption of the offer filters tool. The member posed a question of what other elements could be adopted to create a tool transplant programs considered useful.

The Committee Chair agreed with this and suggested publishing program's offer filter data to encourage programs to adopt offer filters.

A member agreed with this and stated that the primary problem is not getting members to use the offer filters tool, but instead the variation of what filters are across surgeons at a program. If there is accountability based on published data, programs would be more likely to adopt the offer filters tool. The member continued by stating that there should be enforcement of usage of what is already programmed. Some of the filters that are available with enhancements would need endorsements from OPOs to make sure the data is captured in fields rather than attachments.

Another member asked how many transplant programs have adopted the offer filters tool. UNOS staff confirmed that there are 96 programs currently utilizing the offer filters tool. The Committee Chair commented that this is less than half of all transplant programs.

A member stated that 100 percent of organ offer utilization will not be achieved until filters are made mandatory. The Committee Chair agreed with this. The member continued that the vast majority of programs that are not utilizing the offer filters have most likely not reviewed the tool to realize the utility their program could have.

The Committee Vice Chair suggested determining which filters should be mandatory rather than making this all mandatory. A member asked if for those programs that do not use offer filters have had education on tool. The member continued by suggesting having some educational tool to help bring awareness to the tool and the benefits of utilizing it.

Another member stated that staff turnover at programs can affect the utilization of offer filters. UNOS staff stated that this was one of the aspects that the Committee would need to clarify how often filters should be refreshed.

A member stated that their program works based on one decision maker for the entire program. This is unique in comparison to other programs but has been efficient at their program.

Voluntary Offer Filter Usage

A member asked if there were any indication on the types of programs among the 96 that are utilizing the offer filters (ex. size of program). UNOS staff stated that this would need to be looked into the specifics of this further. The data looked at the programs at a regional level.

The Committee Vice Chair asked if there was any knowledge of any particular filters used more often than others. UNOS staff stated that among the components frequently used as filters are distance and cold ischemic time (CIT).

A member stated that the number of offers is not as important as time saved in organ allocation. The member suggested looking at the time of allocation on the impact of offer filters and its impact on organ allocation. The member continued by suggesting measuring this from time of cross clamp to organ placement and compare to those allocations where there are not a lot of filters used to determine if there is a reduction that can be measured. The Committee Chair agreed with this.

The Committee Chair asked if a program lost one offer a year but the organ was still placed, what would that tradeoff be. A member agreed with this and added that there are programs that feel they are missing out on offers. There is a component of this where programs are blinded by all of the offers they are hesitant in missing out on to the point that they may be missing the offers they would likely accept.

Another member stated that their program holds meeting with their surgical and quality staff, review the data from the offer filters tool (going back five years) and modify the offer filters in developing their offer filter criteria.

The Committee Chair asked for clarification on how offer filters are based on past offer acceptance if there is 100 percent of offers. UNOS staff explained that the models were trained on requiring zero acceptance but then applying those after the training period.

A member inquired if there were other recommended filters not based on program's specific previous acceptance practices but instead on filters that have been utilized by other transplant programs of similar size and characteristics that have been successful. The current filter tool is still optional. This would be a matter of making other recommendation from other programs that have utilized some filters. The member clarified that this would not necessarily mean making filters transplant programs are using visible to others.

The Committee Chair stated that in an effort to being transparent, the filters used by transplant programs should be published. The member stated that if this were done, this may discourage transplant programs from utilizing the tool. The Committee Chair stated that if mandatory, filters are applied based on behavior, which would be published.

The member continued by stating that the current offer filters can be turned on and off at will; if the data were published, it would be more static than variable. The member stated that the if the model started off as mandatory, there would be pushback from the community just like the provisional yes project.

The Committee Chair stated that in thinking about this from a patient perspective, it is hard to justify not going to a mandatory stance at some point.

A member asked if regional meetings had an impact on the usage of offer filters. UNOS staff stated that there was a slight increase but would need to follow up with the actual data to give a clear depiction.

UNOS staff continued by stating that the data being refreshed presents a three months lag, but the effort is not too strenuous due to the there being more automation in updating this information.

A member stated that any tools that can help in marketing the offer filters tool would help in encouraging utilization. The member continued that in showing the community the positive and benefits of utilization of the tool, this should help transplant programs be more willing to adapt the offer filters tool. The Committee was asked what their thoughts were on approaches that would be helpful.

A member stated that education at a program level where staff went to programs individually in person to help with education would be beneficial. Another member suggested a forum to provide education and awareness to the community. Another member agreed with performing outreach to programs individually on a one on one basis.

A member commented on data on offer filter usage could somehow be incorporated in their UNOS or Centers for Medicaid and Medicare Services (CMS) audit. Another member stated that this would not be within the purview of CMS. A member suggested UNOS reaching out to programs that do not utilize offer filters and identifying staff to discuss offer filters and providing education. A member suggested having a session or outreach done at the TMF conference. Members agreed with this

Another member stated that there are tools available now where programs have to evaluate every year such as minimum acceptance criteria. In thinking about the offer filters tool in the future, there should be consideration in incorporating this same type of evaluation process. This could be utilized at the same time as the minimum acceptance criteria.

A member agreed with this and added that the same audience would be targeted to review their minimum acceptance criteria. Re-evaluation of offer filters could be done at the same time.

Another member asked if any pediatric programs are using offer filters. UNOS staff clarified that this was topic of discussion during public comment and that it did not appear from the feedback received that those programs were utilizing the offer filters tool. The member commented that UNOS Connect is a useful tool to help provide education, especially for someone as a non-clinician.

A member stated that offers for pediatric candidates are very specific which make it challenging to apply filters for those patients. Another member agreed with this and voiced interest in understanding how offer filters would impact their kidney program's acceptance rate.

Another member stated that this project provides an opportunity to improve the offer filters. Not just the data points that can be used for filters, but also the candidate circumstance under which a program would not want the filters applied. The member emphasized that the goal of this project should be to make the tool better so members would want to use them.

There were no additional questions or discussion.

Next Steps:

The Committee will continue to monitor the usage of the voluntary kidney offer filters.

3. Post-Public Comment Review: Optimizing Usage of Kidney Offer Filters

The Committee reviewed the post-public comment on the *Optimizing Usage of Kidney Offer Filters* concept paper.

The public comment themes and feedback are as follows (those items underlined indicate those themes frequently mentioned):

- More filter options
- Patient-specific exclusion criteria
- Mandatory usage could have unintended consequences
- Offer filters are limited by retaining the ability to turn off
- Necessitates need for dynamic filter updating
- Data cohort needs to be updated at shorter intervals
- Consideration for offer filters for other organs
- More factors for multi-factorial filters
- Increased education/transparency surrounding the tool
- Should preclude redefining provisional yes
- Support for filter liberalization option #3 (generally "looser")
- Autonomy should remain with TXCs
- Programs may not use them due to difficulty in setting up filters
- COVID-19 considerations for acceptance practices data
- Send updates to programs with their own acceptance data

Summary of discussion:

The Committee Chair asked the Committee their thoughts on exclusion criteria that should be considered for the upcoming offer filters proposal. The Committee agreed that CPRA, pediatrics and medically urgent candidates.

A members suggested including wait time. The member continued to explain that it may make sense to have a filter exclusion to not apply filters if a patient has a certain wait time.

Another member commented that for the CPRA exclusion, is the assumption that this would include 0 ABDR mismatch with 100 percent CPRA. The Committee Chair agreed with this and asked the Committee if there was a certain percentage that should be considered for the CPRA exclusion criteria. The Committee agreed for 90 percent CPRA was reasonable with the caveat that this could always be modified based on public comment.

UNOS staff asked for clarification that in discussing waiting time, was this in regards to dialysis time. A member stated that this should be asked of the community. The member continued by stating that the Committee should also determine which filters are not used anymore. For example, there are filters related to designated service area (DSA), which is no longer relevant at this time and instead a filter for distance should be enough.

The Committee Vice Chair stated that there was a discussion among with the Offer Filters Workgroup on a button that could be clicked on to indicate that a patient could be excluded from filters. The Workgroup discussed that there should be a percentage of patients that a program could include and agreed that 5-10 percent of patients was reasonable. The Committee agreed that 5 percent was a good threshold. The Committee Chair clarified that this exclusion percentage minus the automatic exclusion criteria already agreed upon.

UNOS staff asked for clarification if there were any possibilities for smaller programs not being able to have the option due to their size. The Committee Chair stated that those particular instances most likely would be pediatric programs where pediatrics is a part of the automatic exclusion criteria. A member suggested the exclusion criteria being exclusive of pediatric programs or smaller programs that have less than a certain number of candidates on their waitlist.

Another member stated that right now, programs are able to edit their recommended filters. The member inquired how this would be different from what the Committee is recommending for the exclusion criteria. UNOS staff clarified that for the model proposed, the exclusions would be applied automatically; the program would be able to modify the exclusion criteria as needed. The member asked if a program already had 30 patients with a CPRA with 98 score how would this be incorporated. The Committee Chair clarified that this would not count within the 5 percent threshold, rather, the 5 percent threshold would be for any exclusions that would not be automatically excluded.

UNOS staff commented on a member's suggestion on automatic exclusions for HIV positive match runs. A member agreed with this.

The Committee Chair asked the Committee their thoughts on changing filter stringency, or how to demonstrate change in behavior for this model. The Committee Chair suggested three months. With the understanding that there is a three-month lag in data, it seems reasonable since the data would be updated quarterly.

UNOS staff asked the Committee their thoughts on stringency within the model and allowing limits to be generally looser to allow programs to show change in behavior to modify their filters. The Committee Chair agreed that this would make sense but also wanted to be mindful of the complexities this may present from public comment feedback.

The Committee Vice Chair commented that increasing the stringency of a filter and allowing programs to accept filters closer to that limit, there should be consideration in not wanting to dilute the effectiveness offer filters tool. UNOS staff clarified that the concept paper provided these stringency options for the

mandatory filter model. There were three options in making criteria looser as it pertained to distance, cold ischemic time (CIT), and all criteria within a filter.

The Committee was asked what criteria should be considered that could be made generally looser for the proposed model filter. A member commented that once the filters are updated for programs to review, there is no need to make the criteria looser. The recommended filters would be provided for the programs based on their acceptance behavior already. The member agreed that in making the filters looser, this may dilute the purpose and functionality of the filters now.

Another member suggested that creatinine should be included as a filter. The Committee Chair stated that creatinine makes sense, but when looking at the data, distance and CIT seemed to be the most frequently used filter. The member asked if this was because creatinine was not an available filter. Another member confirmed this was the case. The member continued that creatinine is important because it is at the time of offer and not at the time of match run.

A member stated that this is the distinction because creatinine on the waitlist or kidney acceptance criteria is binary. For offer filters, this is in regards to multi-variates. The member stated that the Committee should also be thinking about what options are being added to the OPTN Donor Data and Matching System that may be good as filters. The member suggested age and creatinine should be combined as a filter.

Another member agreed with this and stated that the difference is that when discussing the recommended filters, this is based on a program's historic acceptance criteria and however number of offers the program was given. The member continued by stating that it was not believed that some of the additional filters may not necessarily change or there will be enough offers to change the recommended offer filters. The additional filters will allow programs to further fine tune their offer filters.

A member asked if there was any work looking at the combination of filters being turned on and making programs aware of if a combination of filters were used what that impact would be. UNOS staff commented that the report in the Filter Manager looks at the impact of the individual filters while the Offer Explorers tool shows the aggregate.

The Committee Vice Chair mentioned that dual kidney was a topic of discussion by the Workgroup to include this as an offer filter as well. UNOS staff asked the Committee their thoughts on including dual kidney as an offer filter and if this should be the same as the single kidney criteria or something more aggressive criteria for kidney.

A member stated that the dual kidney allocation system overall is needs a drastic overhaul. Another member stated that dual kidney needs to be addressed by the Kidney and Pancreas Committees and that for it to work, there needs to be a defined set of criteria that would always be applied to a donor.

The Committee Vice Chair stated that the Committee is working on a separate allocation system for dual but there are programs that opt in and never accept dual kidneys. The question is if dual kidneys should be an offer filters where the tool would show whether or not a program has a history of accepting dual kidneys or not.

The Committee Vice Chair stated that the only contrary discussion for dual kidney was that because the current allocation system is not efficiently allocating dual kidney offers, does it negatively impact those programs that would have taken a dual kidney offer but didn't because it did not get to those programs.

A member stated that dual kidneys should be offered first for donors that meet a certain criteria on the match run before single kidney offers. The Committee Chair stated that dual kidney acceptors should be included in the 5 percent exclusion previously discussed.

Another member stated that their understanding is that the exclusion would work faster in getting to those offers a program would likely accept. A member agreed with this and stated that there is currently not a data field that specifies that an offer is dual. The Committee recommend that for the initial version of the offer filter model being proposed would include dual kidney as an exclusion criteria and will defer to the Kidney Committee to develop a criteria that would promote early decision for dual kidney offers.

A member asked, in going back to the percentage for exclusionary, if 5 percent is enough. The member suggested 10 percent. A member stated that the percentage should remain at 5 percent at this time and then have consideration for having an increase in the percentage once the Kidney Committee has further discussed and developed criteria for dual kidney.

A member stated that the dual kidney offer filter makes it seem as though it is more about the donor, rather than the candidate. The Committee Chair stated that the dual kidney filter could be layered with the exclusion percentage and other exclusions. This would push duals as separate offers earlier in the process. Another member stated that if looking at this as a tool for an offer, this could still be used. The Committee agreed with this.

Next Steps:

The Committee will continue their discussions in the development of this proposal.

4. Offer Filter Enhancements

The Committee reviewed proposed enhancements for the Offer Filters tool. This was presented by IT Staff.

The scope of the enhancements falls under five categories:

- Implementation of default filters
    - Generate new model identified filters for each kidney program
    - Automatically add proposed exclusion criteria
    - Delete any existing filters that are turned off
    - Load new recommended filters and activate
- Exclusion of specific candidates from offer filters
    - Add field to Candidate Add/Edit Waitlist page
    - Add new Waitlist report or custom report to show programs which candidates are being excluded from offer filters
- Additional candidate exclusion criteria
    - Candidate height and weight
    - Dialysis time
    - Candidate age greater than
    - EPTS
    - Candidate is medically urgent
- New donor filter criteria
    - Admission serum creatinine
    - Peak serum creatinine
    - Most recent serum creatinine at time of offer
    - Donor weight
- Additional enhancements

- Improve offer filters reporting
    - Move offer filters report to data services portal
    - Enhance kidneys bypassed by offer filters report
    - Update offer filters explorer monthly
- Warn users of overly broad filters

Summary of discussion:

The Chair asked if there was a period of time that programs would have to have filters active before being able to deactivate them. Staff replied that there was no current plan to stop programs from immediately deactivating filters once they were applied.

Staff asked if the Committee was in favor of having the model be informed by one year of data or two years of data. The Chair supported using one year of data, noting that program practice can change quickly, and one year of data would be more indicative of their actual acceptance practices; in addition, this would shift the first data set to be post-COVID. The Chair and a member was also in favor of keeping the evidence threshold at 20 donors.

A member wondered if pediatric programs would be excluded altogether from using offer filters. Staff clarified that pediatric programs would be able to use offer filters to the same extent as adult programs, but would not have model-identified filters automatically applied.

The Chair asked if programs should have a buffer amount applied to the model-identified filters. Staff noted that in the default proposal, there were no plans to include any buffer to the model-identified filter. The discussion of a buffer for the filters stemmed from the conversation on mandatory filter usage, in which a program would need a method to demonstrate a change in acceptance practices. Staff also expressed concern that adding a buffer to the filters would make them less effective in a default setting.

The Vice-Chair suggested that, in the monitoring of programs' usage of offer filters, if they repeatedly expand their filters only to have more restrictive filters applied with the refresh every three months, it would support moving to the mandatory usage of offer filters. A member also noted that this data should be presented to the program so that they become more aware of the cycle that is repeating.

Another member added that it may be beneficial for programs to expand their criteria with every application if they want to understand what is being screened or are attempting to broaden their acceptance criteria; if they accept a donor that would otherwise have been filtered, it would inform their filters for the next reapplication.

A member asked what the reasoning for deleting existing filters that are turned off was. Staff clarified that this was to ensure programs do not end up with only filters being added to their program with no "cleaning" being done to delete past model-identified filters. Additionally, the existing filters within the tool are based off of data that is approximately two years old.

Concern was expressed by a member that, if programs want to make a change in their acceptance practices, they need to be aware that their offer filters will need to be actively managed. If programs do not, there is only the possibility that their filters will remain the same or become more conservative. Multiple members of the committee agreed that there must be clear education and guidance on changing filters to match programs' desired acceptance practices.

Staff clarified that the automatically excluded candidates would not need to be manually excluded from offer filters with the candidate exclusion field as well.

A member wondered how patients would be made aware of the changes proposed, especially as the concept of filtered offers could be misconstrued without proper education. The chair suggested a number of ideas: an article on the OPTN website with information on offer filters; an informational video; educational material for patients and staff. A second member supported the latter, adding that the burden of education should not be placed on coordinators – they suggested having material available that programs can deliver to their patients at request.

Another member suggested that donor HCV status be considered as an additional donor filter criteria. The Chair supported this addition, and suggested that donor COVID status also be considered. Staff noted that donor COVID status is not a current field tracked in the OPTN Donor Data and Matching System.

It was stated that a number of the donor offer filters criteria overlap with the existing minimum acceptance criteria. A member worried that this would cause confusion if screening criteria were tracked in two separate places. They proposed having a report that detailed to a program when their minimum acceptance criteria and offer filters had differing answers (i.e. a program will consider HCV positive donors on the minimum acceptance criteria, but has an offer filter that screens off all offers from HCV positive donors).

A member asked how candidate height and weight would be used. The Chair provided the example of requiring kidneys under a certain size for candidates that were exceptionally small.

Staff asked the Committee whether they felt candidate wait time or dialysis time should be used as a filter. The Chair responded that waiting time could provide more nuance for programs while candidates can accrue waiting time prior to being listed.

The Chair asked if donor dialysis status or continuous renal replacement therapy (CRRT) was captured in the OPTN Donor Data and Matching System. Staff replied that it was not. Multiple members of the Committee expressed support for collecting that data, noting that creatinine values were not reliable unless a program knew the donor's dialysis status. Staff also clarified that the creatinine values used for filtering in offer filters were based on donor information at the time of offer, rather than the time of match run. Staff explained that the tool would prompt the user to confirm when sending out offers whether the first creatinine value entered should be used to screen based on admission serum creatinine.

A member suggested having the model use final serum creatinine once a cross-clamp time was entered into the Donor Data and Matching System. A second member replied that that may be duplicative if the most recent serum creatinine is included as a filter option; once a kidney is post cross-clamp, the most recent serum creatinine and final serum creatinine would be the same.

Another member added that being able to filer based off a donor's hemoglobin A1C status would also be useful, but they did not believe it was tracked within the Donor Data and Matching System.

It was proposed that body mass index should be included in the filters alongside height and weight to provide additional specificity for some candidates. The Chair supported this idea.

Next Steps:

Staff will present a set of final recommendations to the Committee for their proposal at the following meeting based on the Committee's discussion.

5. Review of Filter Options/Building Offer Filter Model

Staff reviewed the proposed recommendations for the offer filters tool.

- Exclusion Criteria
    - CPRA >90%
    - 0 ABDR Mismatch
    - Donor < 18 years old
    - Medically urgent
    - HIV positive ***donor*** match runs
    - Multi-Organ Transplant
- Changing Filter Stringency
    - Programs should have the ability to request removal of filters to demonstrate a change in behavior
- Mandatory Filter Usage/Usage Monitoring
- Data Services
- Education

Summary of discussion:

The Chair suggested the Kidney Review Board could review and approve filter removal requests. They also suggested that programs should be provided with a report of their acceptance practices to help inform this request.

A member considered that a report which details what the acceptance practices of other programs within the same region would be very useful; this would allow programs to compare their acceptance practices with programs that receive similar offers. The Chair supported this idea, and added that the Committee should continue to think of useful reports that can be created even through the monitoring of the proposal.

Another member asked if there was a timeline to move to mandatory, and, if so, what data should be gathered to inform the decisions that a future mandatory proposal will have to make. Staff noted that the earliest potential timeline likely for a future mandatory proposal would be approximately December 2024. This would factor in implementation time for the default model and have enough time to gather data from the default usage of offer filters. A member suggested monitoring how many programs did not modify their model-identified filters.

Staff wondered whether the report detailing acceptance practices of nearby programs should be based off of a program's region; what should the radius of this report be. The Chair and Vice-Chair were in favor of bounding it by region.

The Vice Chair asked if there were a way to estimate the change in a program's acceptance ratio by selecting a certain filter. Staff expressed hesitation at calculating that change because that ratio is calculated by SRTR rather than the OPTN.

While reviewing educational materials required, the Chair reiterated the need for patient-specific resources. They clarified that these should be materials provided to transplant programs that they can distribute for patients such that the burden of patient education is not on the transplant coordinators.

A member asked how filters would be incrementally scaled once a program did demonstrate a change in behavior. Staff affirmed that there would be increments that the filters would move across, but those increments were not finalized.

Another member asked whether there would be collaboration with the Centers for Medicare and Medicaid (CMS) on the monitoring of the proposal; they noted that, if the proposal works as intended, programs would be accepting more medically complex organs kidneys because they have less cold ischemic time. This would align with CMS's initiative to have program's accept more medically complex organs. Staff replied that this was not currently being considered.

A member asked which OPTN Committee was responsible for reviewing trends in discard rates. The Chair responded that it was either the organ-specific committee, if it was only related to one organ, or the Operations & Safety Committee if it was in aggregate. The member wondered if there were a way to identify which organs are currently being discarded that would have been used if they had been immediately offered to a different program. They suggested a project for the Committee could be to identify characteristics of those organs.

It was also suggested that the Committee could consider a project on setting time limits for when an OPO can move to the operating room in order to allow for adequate time for programs to realistically consider the offer. A member was hesitant to ascribe limits on that time because of the variability in donors.

Next Steps:

Staff will include the Committee's feedback in their draft proposal for Committee review.

6. Follow Up: NASEM Report

The Chair provided a brief overview of the overlap between Committee work and the National Academy of Science, Engineering, and Mathematics Report on the state of organ transplantation.

Summary of discussion:

The Chair noted that there was significant overlap between the work of the Committee and the areas that the NASEM report suggested for improvement; they added that the increased usage of offer filters was a specific recommendation from the report.

Next Steps:

Staff will let the Committee know of NASEM report alignment for future projects.

Upcoming Meetings

- November 16, 2022 (teleconference)
- December 14, 2022 (teleconference)

Attendance

- **Committee Members**
  - Alden Doyle
  - Kim Koontz
  - Chris Curran
  - Susan Stockemer
  - Julie Bergin
  - Audrey Kleet
  - Jill Campbell
  - Mony Fraer
  - Norihisa Shigemura
  - Paige Oberle
  - Sarah Koohmaraie
  - Stephanie Little
  - Laura Huckestein
  - Jillian Wojtowicz
  - Greg Abrahamian
  - Andy Bonham
  - Jami Gleason
  - Renee Morgan
  - Melissa Parente
- **HRSA Representatives**
  - Edna Dumas
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Joann White
  - Isaac Hager
  - Rob McTier
  - Carlos Martinez
  - Kerrie Masten
  - Kieran McMahon
  - Susan Tlusty