OPTN

Briefing to the OPTN Board of Directors on

Optimizing Usage of Offer Filters

OPTN Operations and Safety Committee

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Optimizing Usage of Offer Filters

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Executive Summary

Note: *Offer filters referenced in this paper are referring exclusively to kidney offer filters.*

The Offer Filters Project allows kidney transplant programs to create multi-factorial offer filters to filter off their organ offers more precisely. The goal of the Offer Filters Project is to increase the number of transplants by getting to organ offer acceptance faster. It aims to reduce the number of unwanted organ offers that organ procurement organizations (OPOs) need to make and that kidney transplant programs need to respond to; it also seeks to decrease allocation time and increase organ acceptance, particularly for medically complex organs. This project has progressed through several phases, starting with an initial pilot in June 2019, a phase two in 2020, the voluntary rollout in January 2022 to all kidney programs, and a concept paper in August 2022[1].

The feedback received in past iterations and requests for feedback informed the OPTN Operations and Safety Committee ("Committee") on this proposal that includes a default filter model (an "opt-out" system, rather than the existing "opt-in" system), additional offer filter and exclusion criteria, and a new data field that will allow transplant programs to specify if a candidate would be excluded from all offer filters. The system would use an algorithm to identify filters informed by a transplant program's past acceptance behavior and enable filters that would automatically filter out kidney-alone offers from donors that met the identified criteria. This will streamline the allocation process by decreasing the amount of time spent reviewing unwanted offers, thereby increasing the efficiency of organ offer evaluation.

There was overall support for the proposal, with concerns voiced for some components of the proposal that were considered and addressed by the Committee. The Committee plans to closely monitor the progress of the proposed default filter model to help inform future offer filter policies.

[1] *Optimizing Usage of Kidney Offer Filters Concept Paper,* OPTN Operations and Safety Committee, August 2022.

Purpose

The Operations and Safety Committee ("Committee") has embarked on several projects aimed at improving processes and increasing the efficient use of organ offers and acceptances, and ultimately reducing overall organ allocation time. Organ offer filters, which focus initially on kidney allocation, provide kidney transplant programs with a tool to better filter kidney offers using data-driven decisions.

Offer filters have been recommended from several sources.[2] [3] [4] These filters would help increase the efficiency of the allocation process, promote the use of medically complex organs, and reduce the overall organ allocation time. Programs that have used organ offer filters in the voluntary setting have not seen a decline in overall acceptance rates but have received fewer offers[5]. The Committee proposes instituting model-identified offer filters in a default format. Offer filters will provide transplant programs with a data-based tool to drive acceptance decisions. By changing the format of offer filters from "opt-in" to "opt-out", offer filters can increase the efficiency of allocation and decrease the amount of time required for an organ to be offered to a program that will consider it.

Furthermore, when an organ procurement organization (OPO) offers a medically complex organ to kidney transplant programs that have not historically accepted similar quality organs, it results in an increase in effort for both the OPO and the transplant program. These "unnecessary" offers also increase the overall time required to allocate, which in turn increases the chances that an organ will not be used for transplant. The need for an increase in efficiency on match runs can be seen through the rate of kidneys being recovered and not transplanted, which is over 20 percent.[6] By changing the default status of a kidney transplant program's offer filters from "off" to "on", kidney offers will more frequently go to transplant programs that have a legitimate chance of accepting the organ.

The proposed default offer filters model will utilize model-identified offer filters. A model-identified offer filter is generated based on a transplant program's previous kidney offer acceptance behavior. These filters would then be applied automatically to a program every six months. In the default filter model, programs will have the ability to remove ("opt-out of") their model-identified filters if they do not wish to have offer filters applied at their transplant program. Programs will also maintain the ability to modify or remove any program-identified filter.

Background

This proposal was informed by a concept paper[7] that sought feedback from the community on whether offer filters should be implemented in a "default" format, wherein a program retains its ability to remove or modify filters, or a mandatory format, in which applied filters cannot be modified by the transplant program. The Committee also took into consideration the recommendations outlined in the

[2] National Research Council. 2022. *Realizing the Promise of Equity in the Organ Transplantation System*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26364.
[3] Concepcion, BP, Harhay, M, Ruterbories, J, et al. Current landscape of kidney allocation: Organ procurement organization perspectives. *Clin Transplant*. 2023;e14925. https://doi.org/10.1111/ctr.14925
[4] Garrett R. Roll, Ryutaro Hirose, Toward a more efficient organ placement system (and defeating FOMO), American Journal of Transplantation, Volume 22, Issue 6, 2022, Pages 1511-1512, ISSN 1600-6135, https://doi.org/10.1111/ajt.17004.
[5] *Optimizing Usage of Kidney Offer Filters Concept Paper,* OPTN Operations and Safety Committee, August 2022.
[6] https://optn.transplant.hrsa.gov/media/z0ohhcut/data_report_kidney_full_20211008_1_508_compliant.pdf
[7] *Optimizing Usage of Kidney Offer Filters Concept Paper,* OPTN Operations and Safety Committee, August 2022.

National Academies of Sciences, Engineering, and Medicine (NASEM) report.[8,9] The Committee's efforts on this proposal is in alignment with Recommendation 9 of the report that states the following:

> **Recommendation 9:** ***Make it easier for transplant centers to say "yes" to organ offers.***
>
> The OPTN should enhance organ allocation and distribution policies and processes to reduce non-use of deceased donor organs and make it easier for transplant centers to say "yes" to organ offers. To improve the organ offer process, the OPTN should do the following:
>
> - Require the use of more refined filters for transplant centers to indicate their preferences for which kidneys will be accepted, if offered. The filters should especially focus on determining transplant center willingness to accept medically complex kidneys, akin to what is done in the UK's Kidney Fast Track Scheme.

When allocating donor organs, it is paramount that a match between a candidate and recipient be found within the quickest amount of time. However, due to the continuously increasing number of organs recovered, as well as the diverse acceptance practices across transplant programs, some organ offers are extended to programs that may have never considered organs with similar clinical or donor characteristics. The use of offer filters is one strategy to ensure that OPOs allocate in the most efficient manner, and transplant programs only receive offers that they would legitimately consider.

The offer filters tool was developed and tested in a two-phase pilot before being released nationally for all kidney transplant programs.

The initial pilot (Phase I) was launched in June of 2019 and allowed the 29 participating kidney transplant programs to select filters for their programs. This did not filter offers, but instead allowed the filter information to be displayed when a transplant program received a kidney offer. For the pilot, kidney programs selected from the set of model-identified filters and their own custom filters, but received all offers they selected filters for. The pilot measured the impact (number of offers and donors filtered) and allocation risk (accepted offers that would have been filtered) had the filters been in effect.

Phase II of the Offer Filters Pilot Project was held from August to December 2020. The number of participants increased from 29 to 34 kidney transplant programs. Among the 34 participating kidney transplant programs, 26 programs elected to activate one or more filters to filter offers. These model-identified filters were determined by using 2018-2019 acceptance data and included donor profiles for kidney offers from at least 20 donors without any acceptances. Additionally, kidney transplant programs had the ability to apply additional filters to meet the needs of their individual programs and candidates. The results from the pilot "demonstrated the potential for multifactorial filters to reduce unwanted organ offers and the willingness of centers to turn these filters on for bypassing."[10]

After Phase II, the national rollout for the voluntary usage of offer filters was implemented on January 27, 2022. The national rollout allowed kidney transplant programs to utilize existing features of the offer filters tooling at their own discretion.

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[8] National Research Council. 2022. *Realizing the Promise of Equity in the Organ Transplantation System*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26364.

[9] OPTN Operations and Safety Committee, 2022, July 28. Operations and Safety Committee Meeting Summary

[10] Toll A, McGehee H, McTier R, Stewart D. Kidney Programs Can Filter Off a Majority of Their Unwanted Organ Offers without Harming Transplant Volumes [abstract]. Am J Transplant. 2021; 21 (suppl 3). https://atcmeetingabstracts.com/abstract/kidney-programs-can-filter-off-a-majority-of-their-unwanted-organ-offers-without-harming-transplant-volumes/. Accessed June 7, 2022

Voluntary Usage

As part of the national rollout portion of offer filters, kidney transplant programs were able to utilize existing tooling and analyze updated data to determine which offer filters could benefit their program. The goal was to allow kidney transplant programs to create multi-factorial offer filters to filter off their organ offers more precisely, but at their own discretion. Offer filters tooling within the OPTN Donor Data and Match System identified filters that each program could utilize to increase efficiency in the system. The parameters used for establishing the model-identified offer filters include:

- Kidney offers from the past 2 years
- Only donors that were eventually accepted
- Only offers up to and including the final offer acceptance
- Must filter at least 20 donors
- Must have zero acceptances
- No candidate specific parameters included

The model-identified filters could be enabled as-is or disabled at any time and adjusted with additional donor factors or candidate exclusion criteria. Transplant programs could create their own program-identified filters that can be adjusted or disabled at any time. or adjusted with additional donor factors or candidate exclusion criteria.

As of March 31, 2023:

- Number of kidney programs who have accessed offer filters: 186
- Number of kidney programs that have turned on at least one filter: 125
- Number of filters that have been turned on: 612
- Percentage of offers that have been filtered: 23.6% of all offers; 37.6% of offers to programs with at least one filter enabled
- The kidney non-utilization rate is higher in the post-Offer Filters era (Pre Offer Filters = 24.7%, Post Offer Filters = 26.8%; p = .01)
- Since the national rollout, change in time between first organ offer notification and time of acceptance: 36 minute increase
- Since the national rollout, change in cold ischemia time: 12 minute increase
- Since the national rollout, change in overall transplant volume: 11.6% increase

The Committee has emphasized and continues to discuss the importance of bringing awareness and providing education on the offer filters and offer filters explorer tools to promote usage of the voluntary offer filters.

Optimizing Usage

The use of offer filters is one of many strategies for increasing the efficiency of organ placement. Efficiency can be diminished when OPOs are offering medically complex organs to kidney transplant programs that have not historically accepted such organs. These “unnecessary offers” take time and increase the chances that an organ will not be used for transplant. This can also lead to kidneys being recovered and not transplanted as the kidney non-utilization rate continues to be over 20 percent.[11] As

[11] https://optn.transplant.hrsa.gov/media/z0ohhcut/data_report_kidney_full_20211008_1_508_compliant.pdf

Roll and Hirose noted in their February 2022 editorial in the American Journal of Transplantation, "there are many potential reasons why kidney transplant programs resist tightening their filters to make them more restrictive."[12] However, if kidney transplant programs continue to receive offers that they would never accept, OPOs use up valuable time and resources to make these unnecessary offers. These efforts could instead be focused on making offers to kidney transplant programs that will seriously consider the offers.

After the voluntary national rollout of offer filters, the Committee has worked to identify strategies for increasing awareness and usage of offer filters. This included educational offerings, such as virtual webinars, and interactive collaborative sessions during regional meetings. Additionally, the Committee discussed options to update the offer filters system to increase its overall benefit and presented those options in the August 2022 *Optimizing Usage of Kidney Offer Filters Concept Paper*[13].

Proposal for Board Consideration

The Committee is proposing a default offer filter model which will have the OPTN Computer System automatically enable model-identified filters for kidney transplant programs by default instead of having programs opt-in to enable them. The model-identified filters would be identified using the same methodology that was previously described and is strictly based on each transplant program's donor acceptance and transplant data.

The kidney transplant programs would have the ability to remove the model-identified offer filter(s) or create and adjust their own program-identified offer filter(s) to meet the needs of their patients and program. Kidney programs will be required to re-evaluate their filters every six months. A new set of model-identified filters will be generated during this re-evaluation period to best reflect the most recent acceptance practices of the kidney transplant program. Programs only performing pediatric transplants will not have offer filters automatically enabled, but these programs may manually apply model-identified filters.

The model currently generates filters based on the following criteria:

- Kidney offer type (single, dual, en bloc)
- Donor type (brain dead or DCD)
- Offer is after cross-clamp
- Cold ischemic time at time of offer
- Warm ischemic time
- Donor has risk factors for blood-borne disease transmission
- Donor history of hypertension
- Donor history of diabetes
- Donor age
- Distance from the donor hospital to the transplant hospital
- KDPI
- Percent glomerular sclerosis

[12] Roll, G.R. and Hirose, R. (2022), Toward a more efficient organ placement system (and defeating FOMO). Am J Transplant. https://doi.org/10.1111/ajt.17004

[13] *Optimizing Usage of Kidney Offer Filters Concept Paper,* OPTN Operations and Safety Committee, August 2022.

The Committee propose the following criteria to be added to the model:[14]

- Donor weight
- Donor body mass index (BMI)
- Donor positive Hepatitis B core antibody test
- Donor positive Hepatitis B nucleic acid test
- Donor positive Hepatitis C antibody test
- Donor positive Hepatitis C nucleic acid test
- Donor serum creatinine at time of offer
- Donor admission serum creatinine
- Donor peak serum creatinine

The offer filters are based on individual kidney transplant programs data, as outlined in **Figure 5**. Model-identified filters are recommended based on the kidney transplant program's acceptance practices. Filters would be able to be adjusted based on a transplant program's discretion.

Figure 5: Evidence Thresholds for Offer Filters

Kidney offers from the past **1 year**
Only donors that were eventually transplanted
Only offers up to and including final offer acceptance
Must filter at least **20** donors
Must have 0 transplants
No candidate parameters included

In addition to the model-identified filters, the proposal seeks to enhance a program's usage of offer filters by enhancing current functionality, updating existing data sets and filter options, and increasing education available. Many of these considerations were informed by feedback to the offer filters concept paper[15] and fall broadly under the following five categories:

[14] OPTN Operations and Safety Committee, 2022, October 27. Operations and Safety Committee Meeting Summary
[15] *Optimizing Usage of Kidney Offer Filters Concept Paper,* OPTN Operations and Safety Committee, August 2022.

Exclusion Criteria

In order to ensure that no candidate is filtered-off of an offer that a program may have considered due to candidate-specific criteria, the Committee has identified candidate groups that will not have model-identified filters automatically applied to their offers. Offer filters will allow programs to exclude candidates based on one or more of the following criteria:

- Candidate age
- Candidate cPRA
- Candidate 0 ABDR mismatch with the donor
- Candidate blood type
- Candidate match score
- Candidate height
- Candidate weight
- Candidate waiting time
- Candidate EPTS score
- Multi-organ transplant candidates

Automatic Exclusion Criteria

Exclusion criteria will be added to the model-identified default filters created by the system. Candidates with the following criteria will not have filters applied:

- Calculated Panel Reactive Antibodies (CPRA) > 90%
- 0 ABDR Mismatch with the donor
- Candidate age < 18
- Medically Urgent

Programs will be able to modify the candidate exclusion criteria on the default filters. In the same approach as mentioned above, these exclusions would not be automatically enabled for pediatric-alone programs.

The exclusion criteria listed below are optional and available for programs to enable for increased availability of offers for the identified candidate groups. By default, these will not be enabled, but transplant programs will be able to enable or disable these exclusions at their discretion from the Offer Filters Explorer tool. These candidate groups are:

- Candidate height or weight greater than or less than an identified amount
- Candidate waiting time greater than an identified amount
- Candidate EPTS score
- Candidate is waiting for a multi-organ transplant

The system will have alerts within the system to let programs know if an exclusion criteria appears too broad. Additionally, the Committee will monitor whether programs are excluding a large percentage of their candidates.

Additional Exclusion Criteria

The Committee considered additional exclusion criteria separate from the above mentioned. The Committee proposes that offer filters cannot be applied to kidney match runs in which the donor is HIV positive. The Committee discussed that these matches are relatively small and offer filters could impact the ability to successfully place those donor organs.[16]

Changing Default Filters

Within the default filter model, programs can remove their model-identified filters or modify automatic exclusion criteria of their model-identified filters at any time. If further customization is needed, any program may create their own program-identified filters. To increase or decrease offers filtered, therefore, programs may update their offer filters manually at their own discretion.

Data Services & Evaluation

A consistent theme among feedback from the concept paper was increasing transparency around offer filters data. Specifically, a program's acceptance data should be provided to that program on a regular cadence such that they can review their program's acceptance practices. In addition, programs will be able to evaluate the filters used within 250 NM of their transplant program. This data would not identify individual program data, but instead provide an overview of the filters' impact within a program's 250NM allocation circle.

Additionally, when an update happens within the offer filters tool, programs will be alerted that their filters have changed. This will happen with each update to a program's model-identified filter.

Proposed New Data Field

This proposal also includes the addition of a new data field that would allow transplant programs the ability to specify if a candidate would be excluded from all offer filters. **Appendix A** outlines the data field that would be included to the OPTN Waiting List.

Overall Sentiment from Public Comment

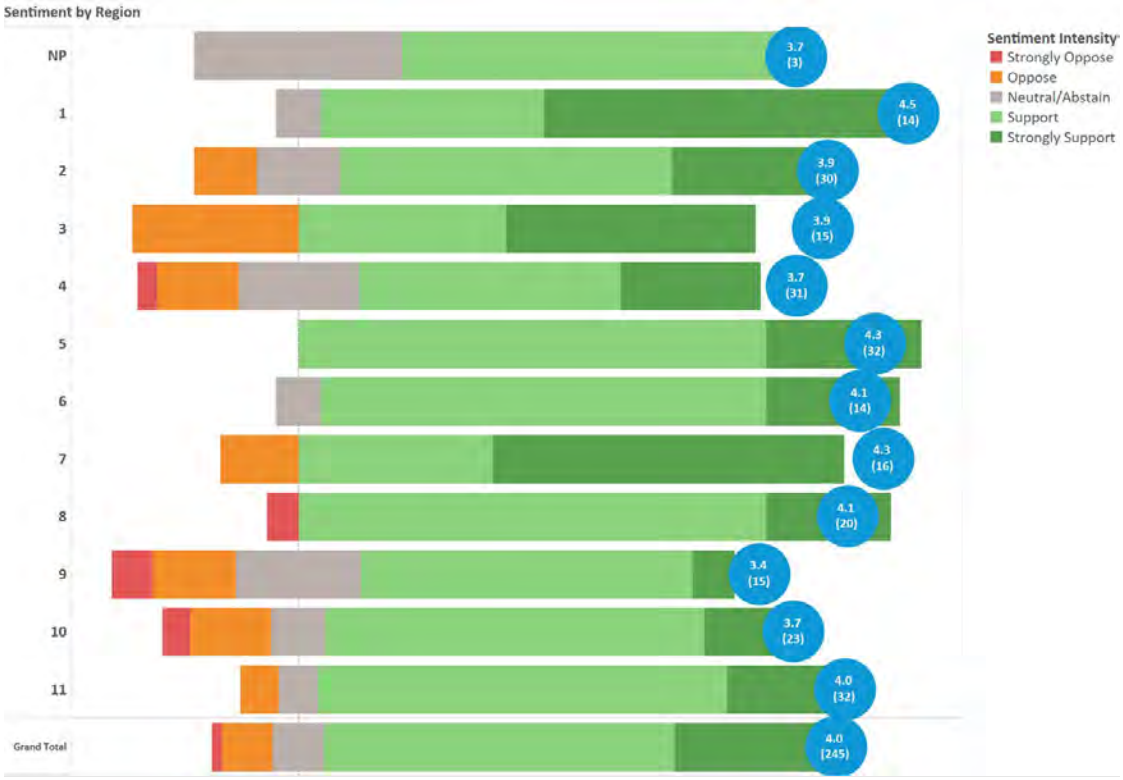
This proposal was issued for public comment from January 19, 2023 to March 18, 2023. Committee members presented the proposal to eight other OPTN Committees and to all eleven OPTN regions for feedback, and a video presentation describing the proposal was posted to the OPTN website. Eight professional organizations as well as several transplant programs, OPOs, and individuals provided written public comment.

The proposal was on the discussion agenda for the OPTN regional meetings. All eleven regions and public comment indicated general support with some opposition to some components of the proposal. Further detail on the feedback and the Committee's changes to the proposal are summarized later in this document.

[16] OPTN Operations and Safety Committee, 2022, October 27. Operations and Safety Committee Meeting Summary

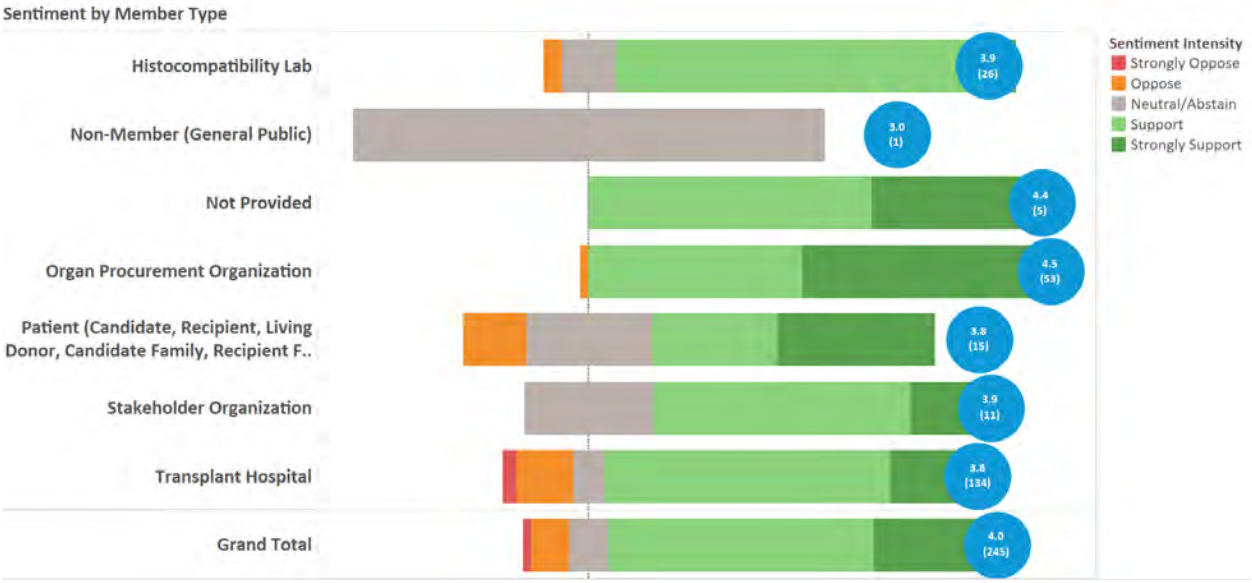
Figure 1 illustrates the sentiment votes for the proposal at the regional meetings. Red represents strong opposition, orange represents general opposition, gray represents neutral sentiment or abstentions, light green represents general support, and dark green represents strong support. The "NP" bar represents votes that did not indicate a state/location. The score (indicated by the blue figure at the end of each bar) is calculated using a scale of 1-5. For example, a "strongly oppose" comment would receive a score of one, "oppose" would receive a two, "neutral/abstain" would receive a three, "support" would receive a four, and finally, a "strongly support" would receive a five.

Figure 1: Sentiment at Regional Meetings



There was overall support across member types as shown below in **Figure 2**. The scores were calculated in the same manner as Figure 1. There was some opposition to the proposal from histocompatibility lab, organ procurement organization (OPO), patient, and transplant hospital members. Further detail on the feedback and the Committee's changes to the proposal are summarized later in this document.

Figure 2: Sentiment by Member Type



In addition to the sentiment score, items out for public comment also provide the opportunity for respondents to submit a substantive written comment. Responses are submitted by members of the public at large, as well as on behalf of regions and Committees.

Commenters covered several topics, including the following main themes. Each theme is described based on the feedback provided and, where able, excerpts from relevant comments are included.

- Re-evaluation period (timeframe)
- Patient education
- OPOs (transparency with)
- Flexibility among transplant program usage of offer filters tool
- Mandatory Offer Filters
- Automation within offer filters tool

Re-evaluation period (timeframe)

The re-evaluation period was one of the most common themes throughout the regional meetings and online submissions on the OPTN website. The proposal asked the community for feedback on the proposed three-month re-evaluation period. There was consensus among commenters that a three-month re-evaluation period was too short of a timeframe to provide sufficient time to demonstrate any changes in behavior.

Additionally, commenters voiced concern of staff burden in having to do a full evaluation of the offer filters every three months. Commenters suggested extending the re-evaluation period to every six months. Some comments suggested a three-month re-evaluation period for those programs who do not use the offer filters to encourage consistent review of the tool and allowing more flexibility to those programs that manage their filters well and have strong offer acceptance outcomes.

In response to the public comment, the Committee decided to modify the previously proposed three-month re-evaluation period to six months (as mentioned in the previous section).

Patient education

Education was another common theme, specifically as it pertains to transparency among patients. In general, there was agreement that patient education was important, however, there were some differences in opinion in what information would be most valuable for patients.

The OPTN Patient Affairs Committee (PAC) voiced the importance of transparency among patients and their transplant programs (transplant coordinators and physicians). PAC members also commented that "patient education must be ongoing, as candidates can be overwhelmed by information at the beginning of their transplant journey". Another comment by the National Kidney Foundation suggested that "a conversation about organ offer filters can occur during the evaluation process and be communicated to the patient in the listing letter patients receive when they become active on the transplant waitlist."

Some commenters voiced some reservation to the complexities of providing education on the specific tools used to enhance the organ offer process and cautioned how this may impede transplant surgeon's clinical decisions and program behaviors. The American Society of Transplant Surgeons (ASTS) commented that, "a complicating factor in education is that the patient likely has little control over these filters, particularly if filters become mandatory", and that "it should be clear that this proposal does not offer the patient individual selection of which filters will apply to them."

Other comments reflected that education and messaging on the offer filters tool should be carefully considered and suggested the focus being on transplant rates and offer acceptance rates, rather than on specific organ offers.

There was also a comment that education on offer filters should be mandatory for transplant programs and that transplant programs should review their program's data consistently and use this information to broaden their acceptance criteria and improve access to transplant for their candidates. The OPTN Membership and Professional Standards Committee (MPSC) suggested "connecting the offer filters with the new offer acceptance ratio metric to show that programs may not have been flagged for low acceptance ratios if they were using offer filters".

The Committee will work to develop various educational offerings with consideration to these comments.

OPOs (transparency with)

There were a few comments related to transparency among the OPOs on the offer filters tool and having accessibility to review what offer filters are being used by transplant programs. Commenters mentioned that this transparency gives OPOs the opportunity to bypass disinterested programs and place organs more efficiently.

The Committee will monitor and continue discussions on determining what information may be helpful for OPOs to advocate the usage of the offer filters tool. The Committee will consider educational offerings that will help OPOs gain a better understanding of the offer filters tool.

Flexibility among transplant program usage of offer filters tool

There were several comments encouraging the maintenance of transplant programs' flexibility in their usage of the offer filters and allowing programs to turn offer filters off for specific recipients to address any patient specific needs.

The Committee determined the proposed default filter model provides flexibility that would allow transplant programs to enable and/or disable the offer filters at any time. The Committee highlighted the inclusion of automatic exclusions, and the addition of a proposed new data field that allows for further specificity for patients to be excluded from all offer filters.

Mandatory Offer Filters

There were some comments raised that warranted clarification that what is currently being proposed by the Committee is a default filter option and not a mandatory filter model. There were some commenters voicing concern that should offer filters become mandatory, this would result in the tool becoming too stringent and consequently become a disservice to patients.

There were several comments in general support of a future iteration of the offer filters tool being mandated. The Association of Organ Procurement Organizations (AOPO) voiced concern that the potential "opt-out" by transplant programs could undermine the policy goals of efficient allocation and increased utilization" as "the policy will continue to rely on each individual transplant programs' willingness to use the filters, with no incentive to participate or consequence for opting out". There were several comments recommending that the Committee/OPTN develop a timeline for adoption of a policy for mandatory offer filters.

Based on the feedback from the Committee's *Optimizing Usage of Kidney Offer Filters* concept paper[17], the Committee decided to begin with the default filter model. The Committee will monitor utilization of the default filter model to help inform potential future offer filter policies.

Automation within offer filters tool

In response to the staff burden of re-evaluating offer filters, members of the OPTN Transplant Coordinators Committee (TCC) suggested consideration for automations within the system that could aid in the evaluation of offers. There was one suggestion of the creation of a report on the types of offers accepted or missed by transplant programs. There was another suggestion of allowing transplant programs the ability to select yes or no to Donation after Cardiac Death (DCD) donors and that the ability to apply a combination of filters at the candidate level, such as age or distance for DCD would help to enhance the offer filters tool.

The Committee will monitor utilization of the default filter model to help inform potential future offer filter policies.

[17] *Optimizing Usage of Kidney Offer Filters Concept Paper,* OPTN Operations and Safety Committee, August 2022.

Suggested Filters for Consideration

Commenters covered several topics, including the following main themes. Each theme is described based on the feedback provided and, where able, excerpts from relevant comments are included.

- Kidney Donor Profile Index (KDPI)/Estimated Post Transplant 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 agreed that more specific, granular data as suggested would be helpful, but decided that the on the application of simple filters with the first iteration of the filter model. This proposal allows programs to create their own program-identified filters which will be monitored and help to inform additional filters.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits the following proposal under the authority of the National Organ Transplant Act (NOTA), which states the OPTN shall establish "a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list,"[18] as well as the OPTN Final Rule, which states “transplant programs shall establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated.”[19] This proposal will enhance offer filters to more efficiently match organs to individuals who are likely to accept the organ, informed by the established acceptance criteria of the transplant program.

OPTN Strategic Plan

This proposal aligns with the OPTN Strategic Goal to increase the number of transplants.[20] One of the initiatives within this goal is to “Pursue policies and system tools that promote system efficiency and increase organ utilization” and, more specifically, “expand the use of offer filters to reduce unwanted offers and increase efficient placement.” As noted earlier, this proposal will enhance the offer filters tool by developing a process that will require transplant programs to continuously review, track and manage the offer filters tool and in turn will increase the efficiency of organ placement.

Implementation Considerations

This proposal will be implemented once the existing offer filters tools and models can be updated to include the proposed filter options and new data cohort as described in the previous sections.

[18] 42 U.S.C. §274(b)(2)(A)(ii)
[19] 42 CFR 121.6(c)
[20] https://optn.transplant.hrsa.gov/about/strategic-plan/goal-1/

Histocompatibility Laboratories

Operational Considerations

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Fiscal Impact

There is no impact on Histocompatibility Laboratories.

Organ Procurement Organizations

Operational Considerations

Organ procurement organization staff may require education on the impact of offer filters. Additionally, there may be some changes to the OPTN Donor Data and Matching System workflow that OPOs use when making kidney offers. There are no required changes for OPOs.

Fiscal Impact

The proposal should not require added resources by OPOs, or substantial increases in existing resources. Like the transplant hospital impact, the proposal has the potential to decrease cost by reducing the amount of time OPOs spend making offers to transplant hospitals that do not typically accept organs from certain donors.

Transplant Programs

Operational Considerations

This proposal will require transplant hospitals to become familiar with the offer filters tool and staff to review, track and manage offer filters. Transplant hospital staff may require education on the impact of offer filters.

Transplant programs will not be required to perform any action prior to implementation but will receive more information on implementation deadlines and suggested transition procedures following approval.

Fiscal Impact

The proposal is not expected to have a substantial fiscal impact on transplant hospitals. This will require extra time for staff to review, track and manage offer filters; particularly, transplant hospitals not currently utilizing offer filters or smaller programs with limited resources. Using offer filters can decrease costs by reducing the amount of time transplant hospital staff spend responding to and screening organ offers. The use of periodic reports will be needed to ensure that transplant hospitals evaluate their filters periodically as outlined in policy.

OPTN

Operational Considerations

This proposal requires submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through the Office of Management and Budget (OMB) approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995, which may impact the implementation timeline.

The proposed field in the OPTN Waiting List (**Appendix A**) will not require individual approval by OMB but will be reviewed in aggregate with all other data fields in the OPTN Waiting List pending approval by OMB.

There is no anticipated impact on operations affecting the OPTN.

Resource Estimates

The OPTN contractor estimates 3,740 hours for implementation. Implementation will involve updates to the OPTN Computer System to include adding additional donor criteria and candidate exclusions, applying automatic candidate exclusions on model filters, updating the ability to exclude specific candidates from being included in offer filters, and preventing filters from running on HIV positive donor matches and implementation of a 6-month refresh process. In addition, this effort will require research effort for model-identified filter generation, as well as education, training, and communication efforts about the changes.

The OPTN contractor estimates 590 hours for ongoing support. Ongoing support will involve answering member questions, routine monitoring, and providing updated and accessible information for members to evaluate the impact of offer filters used.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program."[21] This proposal will not change the current routine monitoring of OPTN members. The OPTN will continue to review deceased donor match runs that result in a transplanted organ to ensure that organs have been allocated according to OPTN policy and will continue to investigate potential policy violations.

[21] 42 CFR §121.8(a)(7).

Policy Evaluation

Key metric: The percent of adult kidney programs that have had at least one filter (model-identified or program-identified) enabled for 80 of the previous 90 days. Target threshold: at least 85%.

In addition to the key metric, the following metrics will be evaluated weekly. “Hard-to-place" donors are defined as donors where kidney offers were sent to over 100 candidates before the final acceptance.

1. Number and percent of offers that were filtered (all donors and “hard-to-place donor”)
2. Number and percent of donors that were filtered (all donors and “hard-to-place donor”)
3. Number of model-identified filters that were disabled
4. Transplant volumes pre/post
5. Percent change in transplant volume pre/post
6. Non-use rates pre/post
7. Average cold time pre/post (all donors and “hard-to-place donor”)
8. Time from allocation initiation to acceptance pre/post (all donors and “hard-to-place donor”)
9. Program offer acceptance ratios (observed to expected ratios) reported in PSRs produced by the SRTR (evaluated upon PSR release).
10. Percent of Offers Actually Filtered vs Percent of Offers Predicted to Filter During Modeling
11. Percent of waitlist registrations that are opted out of all offer filters. This will be monitored per program and across all programs.

Conclusion

Improving the efficiency of organ placement is vital to ensuring that the right organs get to the right patients in a timely manner. Organ offer filters provide an important tool for transplant programs to screen-off unnecessary organ offers and allows them to create multi-factorial offer filters to more precisely filter their organ offers to ensure they only receive the offers they want to receive. Both OPOs and transplant hospitals benefit from the use of offer filters, as it will more efficiently allow organ offers to get to the transplant hospitals with a history of accepting organ offers from donors with certain characteristics.

This proposal is the first phase in a potential transition to a mandatory offer filters model. The Committee will closely monitor the progress of the default filter model to help inform future offer filter policies. The Committee plans to develop offer filter models across all organs and will work to sequence this project's timeline upon evaluating the kidney offer filter model.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1.2 Definitions

Model-identified offer filter

A recommended offer filter generated based on a transplant program's previous organ offer acceptance.

5.3.H Kidney Offer Filters

The OPTN generates model-identified offer filters for all kidney transplant programs based off of a program's transplantation behavior within the most recently available 365 days of data. New model-identified filters will be generated and enabled for each transplant program every six months. A model-identified offer filter is generated for a program if *all* of the following criteria are met:

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

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

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

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

Model-identified and program-identified offer filters will not be applied to kidney match runs from an HIV positive donor.

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Proposed Modification to OPTN Data Collection

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Additional Data Element Proposed	Location	Format
Candidate offer filter exclusion	OPTN Waiting List	Choose an option for this candidate: • Apply kidney offer filters • Do not apply kidney offer filters

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Appendix A: Proposed Data Definition

Candidate offer filter exclusion – This field determines whether a candidate is manually excluded from having offers filters applied for them. This is set to “Apply kidney offer filters” by default. This field will not be reset in the re-evaluation period of the offer filters.

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

Appendix B: Offer Filters Design

Offer filters allow transplant hospitals to enter multi-factorial criteria to filter offers more precisely. For example, a kidney program could have a filter that combines organ quality and distance from the donor as shown below:

- Kidney Donor Profile Index (KDPI) greater than 50%
- AND distance greater than 250 nautical miles
- AND donor age greater than 60 years

Additionally, a kidney program could also add additional filters for post-recovery offers as shown below:

- IF offer is after cross clamp
- AND distance is greater than 500 nautical miles

Offer filters are managed at the program level, so they generally apply to all candidates at a kidney transplant program. Kidney transplant programs can apply a filter, but exempt certain types of patients, to ensure they still receive such offers.

For example, the following filter exempts higher priority candidates such as high-calculated panel reactive antibody (CPRA) and 0 ABDR mismatch candidates:

- KDPI greater than 50%
- AND distance greater than 250 nautical miles (NM)
- AND donor age greater than 60 years
- **UNLESS candidate CPRA exceeds 90% OR candidate and donor are a 0 ABDR mismatch**

Offer filters currently allow users to exclude candidates based upon candidate age, CPRA, 0 ABDR mismatch, candidate blood type and candidate score on the kidney match.

The OPTN Donor Data and Matching System will apply offer filters each time the OPO sends out electronic organ offers.

Figure 1 outlines the offer filters concept and how it currently functions within the OPTN Donor Data and Matching System.

Figure 1: Offer Filters Concept

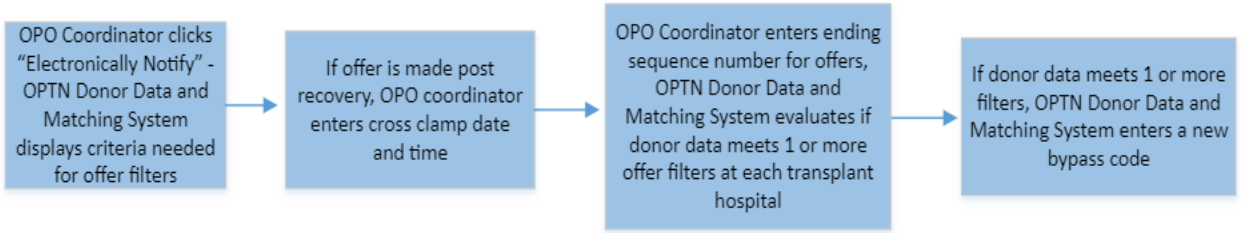
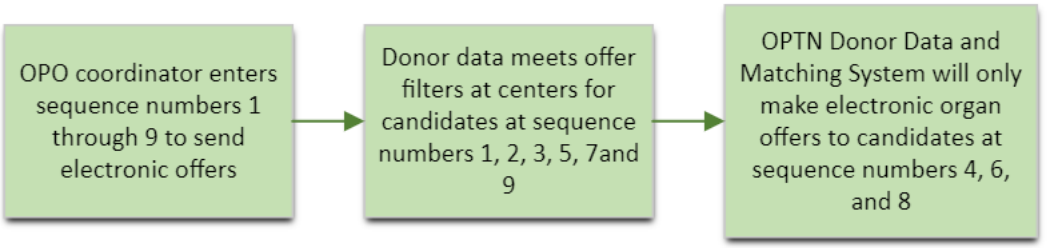


Figure 2 provides an example of how offer filters would filter offers. In this example, the donor data meets Offer Filters requirements at centers for candidates at sequence number 1, 2, 3, 5, 7 and 9. So

the OPTN Donor Data and Matching System entered Offer Filters bypass codes for sequence numbers 1, 2, 3, 5, 7, and 9; and only made electronic organ offers to candidates at sequence number 4, 6, and 8.

Figure 2: Example of Bypassed Offers



There are various tools available to kidney transplant programs to assist with managing offer filters:

- *Offer filters explorer* – a tool for viewing the impacts of potential filters on historical offer data. Offer filters explorer also allows kidney transplant programs to access their model-identified filters. These were developed by applying data science to identify consistent organ offer refusal patterns for individual kidney transplant programs.

- *Offer filters manager* – an application that controls and monitors filters that will be used to screen actual organ offers. This application allows kidney transplant programs to turn filters on or off, edit existing filters, and add custom filters.

- *Offer filter reports* – allows transplant kidney transplant programs to view the impact that filters are having on the kidney offers their program is receiving.

It should be noted that the offer filters criteria differs from the donor minimum acceptance criteria entered in the OPTN Waiting List on a candidate record. The donor acceptance criteria are applied as screening when an organ procurement organization (OPO) runs a match, which could be early in the allocation process and well before the donor enters the operating room for organ recovery. When screening occurs, a candidate does not appear on the match run. After the match has been generated, offer filters are applied to potential transplant recipients at the time the OPO makes an offer and updated with each subsequent offer. This (the amount of time an organ spends being preserved after recovery from the donor) to be used for filtering when an offer is made.

Development of Model-Identified Filters

For the offer filter pilot projects, model-identified filters were created as a starting point for kidney transplant programs to evaluate organ offers and acceptance practices. The offer filters model was developed based on individual kidney transplant program's historical kidney offers and identifies potentially effective offer filters. Kidney transplant programs can use the model-identified filters to better understand their organ offer acceptance practices to inform creating more precise screening criteria.

The model only considers offers from donors that were eventually accepted by another kidney transplant program. Model-identified filters must screen off at least 20 donors with no acceptances from kidney transplant programs in the past 2 years.

Parameters

The parameters used for identifying the model-identified offer filters includes:

- Kidney offers from the past 2 years
- Only donors that were eventually accepted
- Only offers up to and including the final offer acceptance
- Must filter at least 20 donors
- Must have zero acceptances
- No candidate parameters included

Summary of Offer Filters Identified

To prepare for the national rollout of the offer filters tool in January 2022, model-identified filters were generated in October 2021 using offer acceptance data from offers received between 7/1/2019 and 6/30/2021. The offer filters model-identified 560 filters in total. The most impactful filter in terms of number of donors affected was a single filter impacting 543 donors. In other words, the model-identified a filter for which the program had declined all organ offers from 543 donors over 2 years. The range of donors impacted across all model-identified filters is shown in **Figure 3**.

Figure 3: Model-Identified Filters[22]

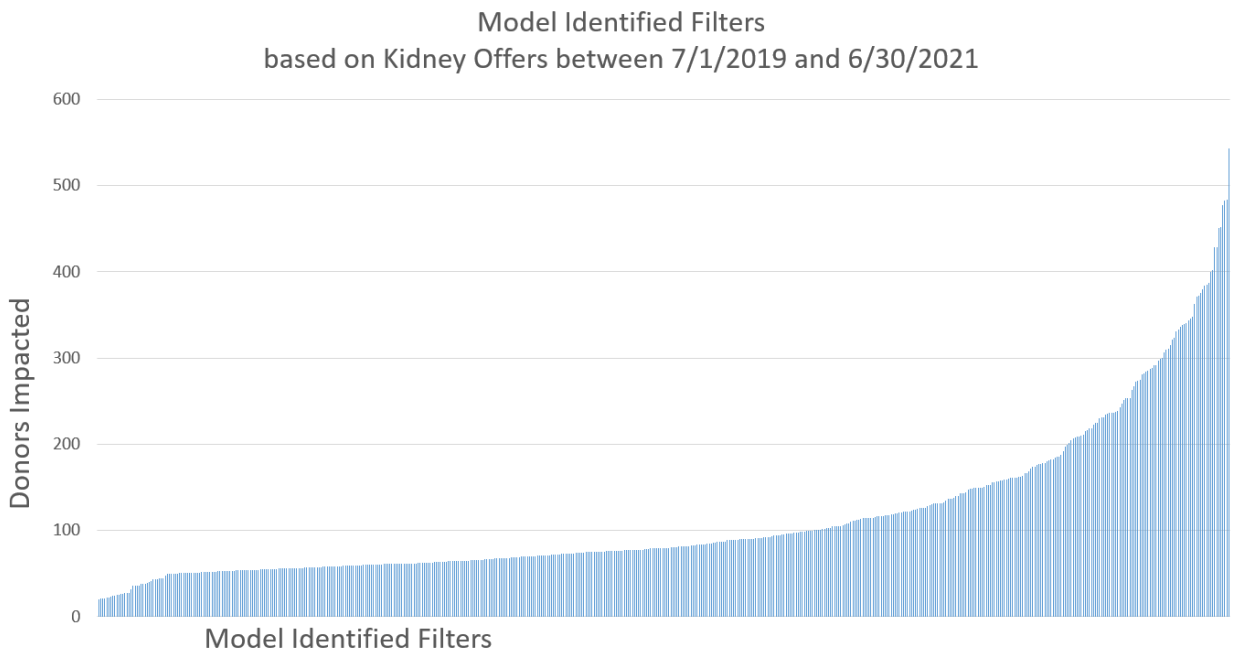


Figure 4 shows the filter criteria with the highest number and percentage of filters during the pilot program based on kidney offers between 7/1/2019 and 6/30/2021.

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[22] OPTN Operations and Safety Committee, 2022, May 20. Mandatory Offer Filters Workgroup Meeting Summary

Figure 4: Filter Components[23]

All Filters (>20 Donors Filtered)			Filters with >100 Donors Filtered During Training		
Filter Criteria	**N. Filters**	**% Filters**	**Filter Criteria**	**N. Filters**	**% Filters**
Distance	218	38.93%	Distance	98	46.67%
DSA	179	31.96%	DSA	84	40.00%
KDPI	175	31.25%	KDPI	70	33.33%
Clamp Timing	164	29.29%	Clamp Timing	70	33.33%
Min Age	122	21.79%	Min Age	41	19.52%
Cold Ischemic Time (CIT)	92	16.43%	Cold Ischemic Time (CIT)	37	17.62%
Hypertension	77	13.75%	Hypertension	17	8.10%
DCD	70	12.50%	DCD	16	7.62%
Risk Factors	37	6.61%	Risk Factors	4	1.90%
Diabetes	31	5.54%	Diabetes	1	0.48%
Max Age	7	1.25%	Max Age	0	0.00%

[23] OPTN Operations and Safety Committee. 2021, Dec. 13. Mandatory Offer Filters Workgroup Meeting Summary