

Public Comment Proposal

Optimizing Usage of Kidney Offer Filters

OPTN Operations and Safety Committee

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Optimizing Usage of Kidney Offer Filters

Affected Policies: 5.3.H: Kidney Offer Filters
Sponsoring Committee: Operations and Safety
Public Comment Period: January 19, 2023 – March 15, 2023

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. 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 2022¹. 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.

The OPTN Operations and Safety Committee proposes optimizing the usage of offer filters by standardizing their use in an “opt-out” system, rather than their existing “opt-in” system. The system would use an algorithm to identify filters informed by a transplant program’s past acceptance behavior and enable filters that would automatically bypass 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.

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 is focused initially on kidney allocation, will provide kidney transplant programs with a tool to better bypass kidney offers using data-driven decisions.

When an 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.² 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. The model-identified offer filters are recommended offer filters generated based on a transplant program’s previous organ offer acceptance behavior. In the default filter model, programs will have the ability to modify or remove (“opt-out of”) their model-identified filters if they do not wish to have offer filters applied at their transplant program. The filters applied to a transplant program will be based off of a program’s past acceptance behavior, with a re-evaluation and reapplication of the filters every 3 months.³

Background

This proposal was informed by a concept paper⁴ 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 National Academies of Sciences, Engineering, and Medicine (NASEM) report.^{5,6} The Committee’s efforts on this proposal is in alignment with Recommendation 9 of the report that states that 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 nonuse 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.

² https://optn.transplant.hrsa.gov/media/z0ohhcut/data_report_kidney_full_20211008_1_508_compliant.pdf

³ OPTN Operations and Safety Committee, 2022, October 27. Operations and Safety Committee Meeting Summary

⁴ *Optimizing Usage of Kidney Offer Filters Concept Paper*, OPTN Operations and Safety Committee, August 2022.

⁵ 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>.

⁶ OPTN Operations and Safety Committee, 2022, July 28. Operations and Safety Committee Meeting Summary

After reviewing feedback from the community in response to the concept paper, the Committee proposes implementing offer filters in the default format. This format is described as default, and not mandatory, because they are automatically applied but programs do maintain the ability to modify or remove (“opt-out”). The offer filters tool allows kidney transplant programs to apply program-specific, custom-designed, multi-factorial filters to bypass donor offers that they do not want to receive.⁷ The tool was developed and tested in a two-phase pilot before being released nationally for all kidney transplant programs.

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, 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 is 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 run, offer filters are applied to potential transplant recipients at the time the OPO makes an offer which allows for the most up-to-date information, including such vital information as cold ischemic time (the amount of time an organ spends being preserved after recovery from the donor) when an offer is made.

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 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 bypass offers. These model-identified filters were determined by using 2018-2019 acceptance data and included donor profiles for

⁷ Finnie, J. & Moriarty, S. “Better organ offer screening”, <https://unos.org/news/innovation/reducing-unwanted-organ-offers/>.

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.”⁸

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.

Offer Filters Concept

Offer filters allow transplant hospitals to enter multi-factorial criteria in order to bypass 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 kidney 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 so 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.

⁸ 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

Figure 1: Offer Filters Concept

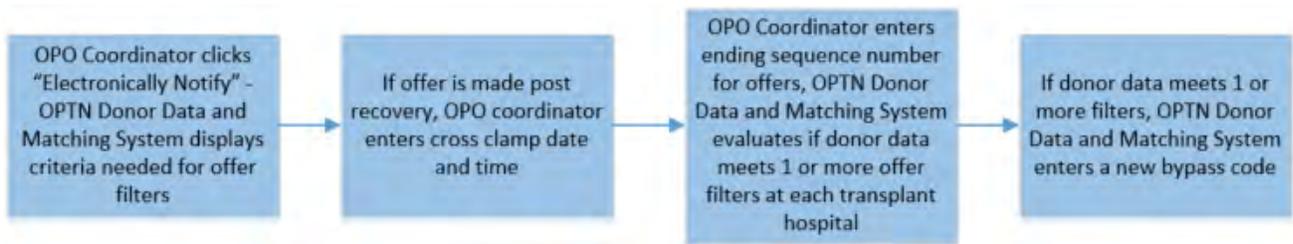
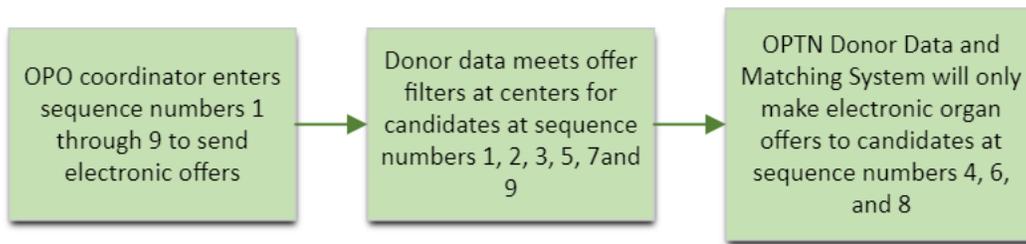


Figure 2 provides an example of how offer filters would bypass offers. In this example, the donor data meets Offer Filters requirements at centers for candidates at sequence number 1, 2, 3, 5, 7 and 9. So the OPTN Donor Data and Matching System entered bypass codes for sequence numbers 1, 2, 3, 5, 7, and 9; and only made electronic organ offers to candidates at sequence number 4, 6, and 8.

Figure 2: Example of Bypassed Offers



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 Filters⁹

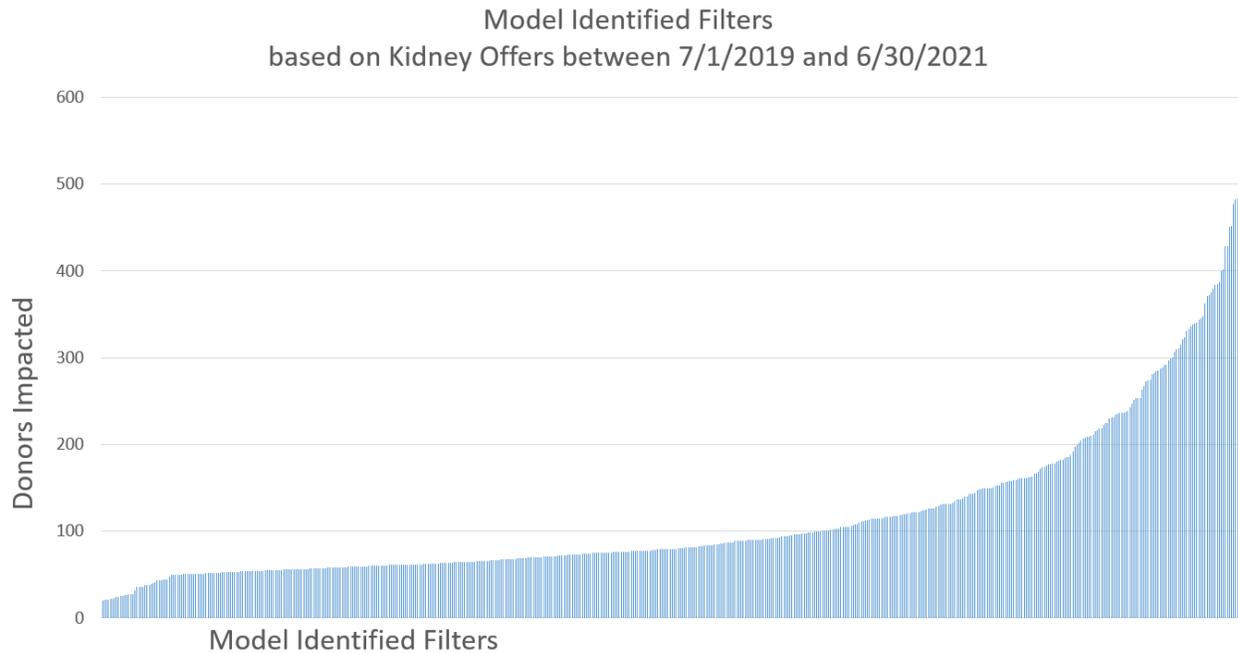


Figure 4 shows the filter criteria with the highest number and percentage of filters during the pilot program based on kidney offers between 7/1/2019 and 6/30/2021.

Figure 4: Filter Components¹⁰

Filter Components					
All Filters (>20 Donors Filtered)			Filters with >100 Donors Filtered During Training		
<u>Filter Criteria</u>	<u>N. Filters</u>	<u>% Filters</u>	<u>Filter Criteria</u>	<u>N. Filters</u>	<u>% Filters</u>
Distance	218	38.93%	Distance	98	46.67%
DSA	179	31.96%	DSA	84	40.00%

⁹ OPTN Operations and Safety Committee, 2022, May 20. Mandatory Offer Filters Workgroup Meeting Summary

¹⁰ OPTN Operations and Safety Committee. 2021, Dec. 13. Mandatory Offer Filters Workgroup Meeting Summary

Filter Components					
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%

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 adjusted with additional donor factors or candidate exclusion criteria. Both model identified and custom filters can be adjusted or disabled entirely at any time.

As of October 7, 2022:

- Number of kidney programs who have accessed offer filters: 143
- Number of kidney programs that have turned on at least one filter: 96
- Number of filters that have been turned on: 409
- Percentage of offers that have been filtered: 19.6% of all offers; 37.4% of offers to programs with at least one filter enabled
- The kidney non-utilization rate is lower in the post-Offer Filters era (Pre Offer Filters = 26.7%, Post Offer Filters = 25.5%; $p = .01$)
- Since the national rollout, change in time between first organ offer notification and time of acceptance: 1.9 hour decrease
- Since the national rollout, change in cold ischemia time: 8.4 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 in an effort 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. As 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.”¹¹ However, if kidney transplant programs continue to receive offers that they would never accept, OPOs use up valuable time and resources making unnecessary offers. These efforts could instead be focused on making offers to kidney transplant programs that will seriously consider the offers. This can also lead to kidneys being recovered and not transplanted as the kidney non-utilization rate continues to be over 20 percent.¹²

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 including webinars and interactive 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.

Overview of Proposal

Default Offer Filter Model

The Committee proposes a default offer filter model which will have the system automatically enable model-identified filters for kidney transplant programs by default instead of having programs opt-in to enable them. The kidney program would not receive offers from donors that meet these default filter criteria unless they specifically opt-out and disable the filter(s). 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. After implementation of the default filters, kidney transplant programs would have the ability to adjust and, if necessary, remove their model-identified offer filter criteria, at their discretion, to meet the needs of their patients and updates to their program’s acceptance criteria, staffing, and practices. A new set of default filters will be generated every three months 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)

¹¹ 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>

¹² https://optn.transplant.hrsa.gov/media/z0ohhcut/data_report_kidney_full_20211008_1_508_compliant.pdf

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

- 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

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 and fall broadly under the following five categories:

¹⁴ OPTN Operations and Safety Committee, 2022, October 27. Operations and Safety Committee Meeting Summary

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 O 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%
- O 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 added to the Offer Filters Manager to let programs know if a filter will impact greater than 20% of their waitlisted candidates. The Committee is considering additional alerts within the system to let programs know if an exclusion criteria could also be too broad. Additionally, the Committee will monitor whether programs are excluding a large percentage of their candidates.

Additional Exclusion Criteria Considerations

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.¹⁵

The Committee requests feedback on whether there should be a maximum allowable number of candidates from one transplant program able to be excluded from offer filters through this method.

Changing Default Filters

Within the default filter model, programs will have the ability to modify or remove filters at any time. In order 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.

Education

In order to encourage the effective usage of offer filters, the Committee has considered a number of educational offerings to inform programs of upcoming changes. More broadly, however, the Committee recognizes that this change to offer filters needs to be disseminated across a wide spectrum of audiences: transplant programs, OPOs, patients, and any organization that assists in organ allocation. As such, the Committee is considering a diverse spread of educational opportunities.

The Committee will develop a video walkthrough on the step-by-step usage of offer filters that guide a user through editing existing filters and developing new ones. In conjunction, peer-to-peer webinars led by programs that have had success in using voluntary offer filters will be held to share best practices, effective custom filters, and the impact that filters have had on their program. Finally, the Committee will be engaging with larger platforms to determine if presentations can be held to demonstrate both the effect offer filters can have as well as an analysis of offer filters data.

In addition, the OPTN will engage patients by creating a brochure for transplant programs to share with their candidates which explains the functionality of offer filters and their impact on allocation efficiency.

¹⁵ OPTN Operations and Safety Committee, 2022, October 27. Operations and Safety Committee Meeting Summary

The Committee requests feedback on any additional educational opportunities that should be considered.

Mandatory Filter Usage

Following feedback from public comment on the offer filters concept paper, the Committee has identified the implementation of mandatory filters as a possible progression once data can be gathered about default filter usage.

Mandatory filters would remove a transplant program's ability to modify or remove model-identified filters. Mandatory filter implementation would also require separate considerations for filter stringency and the opportunity for programs to demonstrate a change in behavior. This proposal does not address mandatory filter considerations, which were presented in the concept paper.¹⁶

After the implementation of default offer filters, the Committee will monitor behavioral changes based on offer filter usage, the impact of the system enhancements to the offer filters tool, and acceptance, allocation duration, and kidney utilization data to inform mandatory offer filter discussions.

NOTA and Final Rule Analysis

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,"¹⁷ 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."¹⁸ 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.

Implementation Considerations

Member and OPTN Operations

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 Default Offer Filter Model section above.

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.

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.

¹⁶ *Optimizing Usage of Kidney Offer Filters Concept Paper*, OPTN Operations and Safety Committee, August 2022

¹⁷ 42 U.S.C. §274(b)(2)(A)(ii)

¹⁸ 42 CFR 121.6(c)

Operations affecting Histocompatibility Laboratories

There is no anticipated impact on histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

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.

Operations affecting Transplant Hospitals

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. There are no required changes for transplant programs.

Operations affecting the OPTN

This proposal requires the 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 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.

There is no anticipated impact on operations affecting the OPTN.

Potential Impact on Select Patient Populations

There is no impact on select patient populations. The Committee has taken steps to protect certain patients from over-filtering by default with the inclusion of exclusion criteria as mentioned in previous sections.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

There is no impact on Histocompatibility Laboratories.

Projected Impact on Organ Procurement Organizations

The proposal should not require new resources by OPOs, or substantial increases in existing resources. Similar to 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.

Projected Impact on Transplant Hospitals

The proposal is not expected to have a substantial fiscal impact on transplant hospitals. This will require additional time for staff to review, track and manage offer filters; in particular, those transplant hospitals not currently utilizing offer filters or smaller programs with limited resources. The use of offer

filters has the potential to decrease cost 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.

Projected Impact on the OPTN

A Medium IT implementation effort, estimated at 3210 hours, includes updates to the current offer filters tool to enable filters to automatically be turned on. Additionally, the automatic exclusion criteria will need to be programmed as outlined in previous sections.

Research anticipates a Medium effort, estimated at 580 hours in model-identified filter generation, 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.”¹⁹ 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.

Policy Evaluation

The following metrics will be evaluated weekly.

1. Number and percent of offers that were bypassed
2. Number and percent of donors that were bypassed
3. Number of model-identified filters that were disabled
4. Number of model-identified filters that were modified
5. Number and percent of offers bypassed for offer filters
6. Transplant volumes pre/post
7. Percent change in transplant volume pre/post
8. Average cold time pre/post
9. Time from allocation initiation to acceptance pre/post
10. Program offer acceptance ratios (observed to expected ratios) reported in PSRs produced by the SRTR (evaluated upon PSR release).

¹⁹ 42 CFR §121.8(a)(7).

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 the timeline of this project upon the evaluation of the kidney offer filter model.

Considerations for the Community

In reviewing this proposal, readers are encouraged to provide feedback on all aspects of the paper, and to consider the following questions:

- What other educational considerations would be helpful for patients to understand processes related to offer filters?
- Is three months a sufficient re-evaluation period of the offer filters? If not, what timeframe would be most appropriate?
- Are there other automatic exclusions not mentioned that should be considered? Are there additional filter options not mentioned that should be considered?

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 **1.2** **Definitions**

2

3

4 **Model-identified offer filter**

5

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

8

9 **5.3.H** **Kidney Offer Filters**

10

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

15

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

19

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

22

- 23 ○ Greater than 90% CPRA,
- 24 ○ 0-ABDR mismatch,
- 25 ○ in medically urgent status, or
- 26 ○ less than 18 years old, unless the filter is for a pediatric alone program

27

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

30

31 All programs may modify or remove their model-identified filters. Any program may create their
32 own program-identified filters.

33

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

36

#

Appendix A: Data Collection

Proposed Data Element	Location	Format	Definition
Exclude this candidate from all offer filters?	OPTN Waiting List	Yes or No	This field determines whether a candidate is manually excluded from having offers filtered for them. This is set to No by default.

#