OPTN

Concept Paper

Optimizing Usage of Kidney Offer Filters

OPTN Operations and Safety Committee

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Optimizing Usage of Kidney Offer Filters

Sponsoring Committee: *Operations and Safety*
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Executive Summary

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

This concept paper provides an update to the community about the ongoing work on kidney offer filters, and seeks to increase community awareness on the benefit of offer filters usage within the OPTN Donor Data and Match System. Most importantly, however, this paper seeks to gain community feedback on potential options to increase utilization and system benefit of kidney offer filters. This concept paper provides an overview of the offer filters concept, data from the pilot program and voluntary rollout, and solicits feedback from the community in an effort to increase the usage of offer filters across the country. This document will provide several options for consideration by the transplant community. This is the next step towards developing national policies and requirements for the usage of offer filters.

The Offer Filters Project has progressed through several phases, starting with an initial pilot in June 2019, a phase two in 2020, and most recently, the voluntary rollout in January 2022 to all kidney programs. 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, as well as decrease cold time and increase organ acceptance, particularly for harder-to-place organs. The Offer Filters Project allows kidney transplant programs to create multi-factorial offer filters to filter off their organ offers more precisely.

This document is not a proposal, but instead a concept paper that seeks to develop a solution to optimize the usage of kidney offer filters. The feedback received will be used to develop a future proposal that would support the OPTN strategic goal of increasing the number of transplants and promoting efficient donor and recipient matching. The Committee requests feedback on all concepts presented in this paper as well as specific input outlined in further detail that can be found in the Community Feedback section of this document.

Background

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 screen kidney offers using data-driven decisions.

It should be noted that the offer filters criteria differs from the donor 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 . Offer filters are applied 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.

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.[1] 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.

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 actively screen 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-derived 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. 26 of the 34 participating kidney transplant 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 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

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[1] Finnie, J. & Moriarty, S. "Better organ offer screening", https://unos.org/news/innovation/reducing-unwanted-organ-offers/.

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."[2]

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 screen 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
- AND donor age greater than 60 years
- **UNLESS candidate CPRA exceeds 90% OR candidate and donor are a 0 ABDR mismatch**

Offer filters currently allows 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.

[2] 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 1 flow: OPO Coordinator clicks "Electronically Notify" - OPTN Donor Data and Matching System displays criteria needed for offer filters → If offer is made post recovery, OPO coordinator enters cross clamp date and time → OPO Coordinator enters ending sequence number for offers, OPTN Donor Data and Matching System evaluates if donor data meets 1 or more offer filters at each transplant hospital → If donor data meets 1 or more filters, OPTN Donor Data and Matching System enters a new bypass code
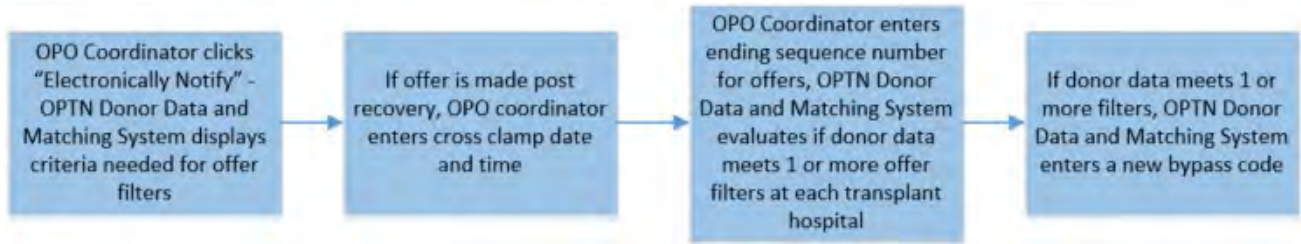
Figure 2 provides an example of how offer filters would bypass offers. In this example, the donor data meets Offer Filters at centers for candidates at sequence number 1, 2, 3, 5, 7 and 9. So the OPTN Donor Data and Matching System entered bypass codes for sequence numbers 1, 2, 3, 5, 7, and 9; and only made electronic organ offers to candidates at sequence number 4, 6, and 8.

Figure 2: Example of Bypassed Offers

Figure 2 flow: OPO coordinator enters sequence numbers 1 through 9 → Donor data meets offer filters at centers for candidates at sequence numbers 1, 2, 3, 5, 7and 9 → OPTN Donor Data and Matching System will only make electronic organ offers to candidates at sequence numbers 4, 6, and 8
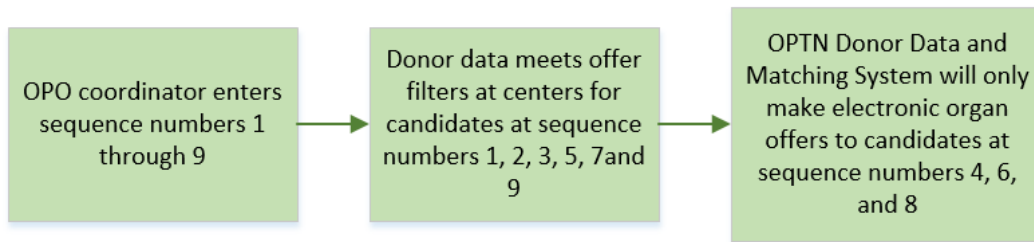
Development of Model Identified Filters

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 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. 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

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 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**.
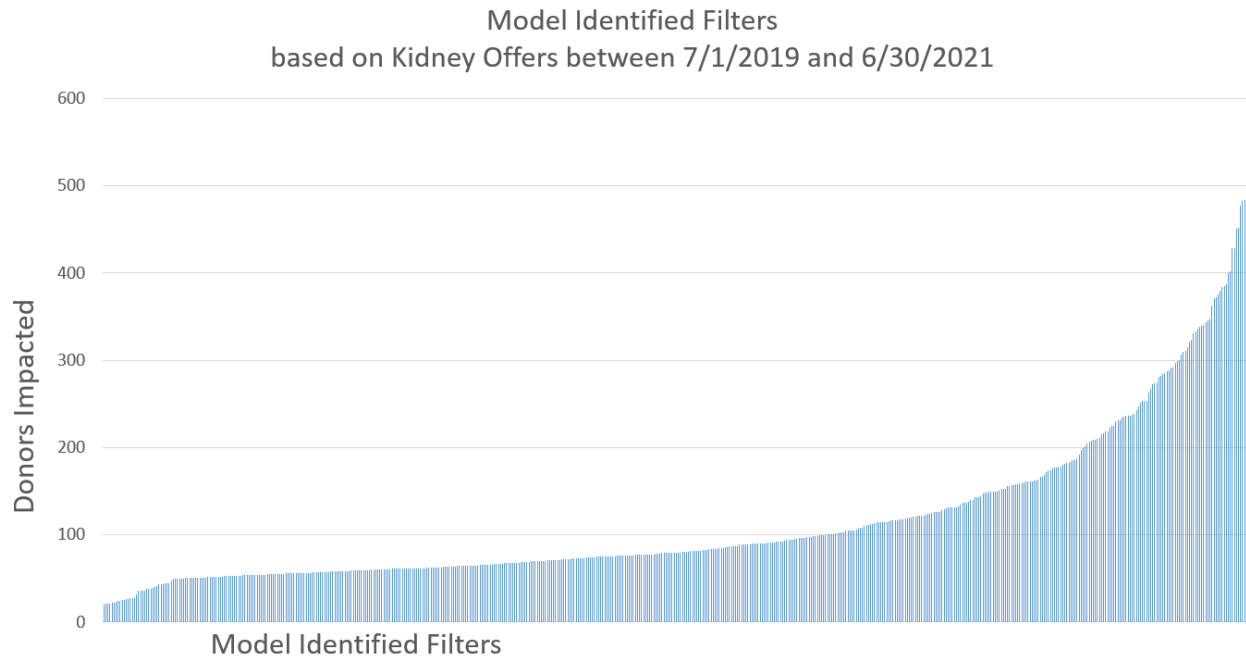
Figure 3: Model Identified Filters[3]

Model Identified Filters
based on Kidney Offers between 7/1/2019 and 6/30/2021

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

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Figure 4: Filter Components[4]

Filter Components					
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%

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 June 24, 2022:
- Number of kidney programs who have accessed offer filters: 143
- Number of kidney programs that have turned on at least one filter: 79
- Number of filters that have been turned on: 341
- Percentage of offers that have been filtered: 18.2% of all offers; 36.6% of offers to programs with at least one filter enabled

- 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 CIT: 8.4 minute increase
- Since the national rollout, change in transplant volume: 14.2% increase

The Committee will continue monitoring the usage of the voluntary offer filters. The Workgroup has emphasized 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 marginal 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."[5] 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.[6]

After the voluntary national rollout of offer filters, the Committee has worked to identify strategies for increasing awareness and usage of offer filters. This includes educational offers such as webinars as well as interactive sessions during regional meetings. Additionally, the Committee has discussed options to update the offer filters system to increase its overall benefit. Multiple options have been proposed:

Option 1 – Default Offer Filters

One option for consideration is to have the system automatically enable model identified filters by default instead of having kidney transplant 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 periodically generated to best reflect the most recent acceptance practices of the kidney transplant program.

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[4] OPTN Operations and Safety Committee. 2021, Dec. 13. Mandatory Offer Filters Workgroup Meeting Summary
[5] 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
[6] https://optn.transplant.hrsa.gov/media/z0ohhcut/data_report_kidney_full_20211008_1_508_compliant.pdf

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Option 2 – Mandatory Offer Filters

Another approach would be to apply the model identified filters on match runs for kidney transplant programs based on previous organ offer acceptance/refusal behavior, without granting transplant programs the ability to adjust or remove these model identified filters. As with the default offer filters, these filters are based on individual kidney transplant programs data, as outlined in **Figure 5**. There would be a pathway for kidney transplant programs to demonstrate a change in behavior (acceptance practices) in order to adjust the model identified filters. Any change to these filters would be strictly data driven based on actual acceptance practices. Filters would not be able to be adjusted based on a transplant program's discretion, but instead would only be updated by the system, as driven by data compiled from actual acceptance/refusal behavior.

Figure 5: Evidence Thresholds for Mandatory Offer Filters

Kidney offers from the past **2 years**
Only donors that were eventually **accepted**
Only offers up to and including final offer acceptance
Must filter at least **20** donors
Must have 0 **acceptances**
No candidate parameters included

The Committee discussed strategies to continue to utilize required data-driven filters, but in a way that allows space for evolving acceptance criteria, staffing, and practices. This includes three options: increased distance, cold ischemic time, or a series of select filters. These would make the mandatory filters less restrictive and provide a pathway for kidney transplant programs to show a change in acceptance behavior. The Committee is seeking feedback from the community about this approach to less restrictive mandatory offer filters.

The model identified filters describe offers that a kidney program has not been accepting. If the system simply activates the model identified filters then it could lock in past behavior. In order to provide a pathway to show a change in acceptance behavior, the system could make the mandatory filter less restrictive than the model identified filters.

For example, if model identified the following filter for center EEEE:
- Donor KDPI exceeds 40% AND Donor type is DCD

Then the system could add a distance criteria to the mandatory filter to make it less restrictive:
- Donor KPDI exceeds 40% and Donor type is DCD
- AND distance exceeds 250 nautical miles

The model identified "mandatory filter" would allow the program to receive higher KDPI DCD donors from nearby donor hospitals.

The Committee considered three ways that we could make the mandatory filters less restrictive.

Figure 6 shows how donor hospital distance could be used to make the mandatory filters less restrictive.

Figure 6: Offers That Are Far Away (Option 1)[7]

Center	Donors impacted over 2 years	Model Identified Filter	Mandatory Filter
AAAA	483	Distance exceeds 325 nm AND Offer timing is post-cross clamp	Distance exceeds 575 nm AND Offer timing is post-cross clamp
BBBB	384	Donor KDPI exceeds 15% AND Offer timing is post-cross clamp	Donor KDPI exceeds 15% AND Offer timing is post-cross clamp AND Distance exceeds 250 nm
CCCC	331	Distance exceeds 125 nm AND CIT at time of offer exceeds 5 hours AND Donor age greater than 15 years	Distance exceeds 375 nm AND CIT at time of offer exceeds 5 hours AND Donor age greater than 15 years
DDDD	297	Distance exceeds 200 nm AND Donor KDPI exceeds 35% AND Donor has any history of hypertension	Distance exceeds 450 nm AND Donor KDPI exceeds 35% AND Donor has any history of hypertension
EEEE	167	Donor KDPI exceeds 40% AND Donor type is DCD	Donor KDPI exceeds 40% AND Donor type is DCD AND Distance exceeds 250 nm

Figure 7 shows how the system could use cold ischemic time at time of offer to make the mandatory filter less restrictive.

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[7] OPTN Operations and Safety Committee. 2022, May 23. Mandatory Offer Filters Workgroup Meeting Summary.

Figure 7: CIT at Time of Offer (Option 2)[8]

Center	Donors impacted over 2 years	Model Identified Filter	Mandatory Filter
AAAA	483	Distance exceeds 325 nm AND Offer timing is post-cross clamp	Distance exceeds 325 nm AND CIT at time of offer exceeds 5 hours
BBBB	384	Donor KDPI exceeds 15% AND Offer timing is post-cross clamp	Donor KDPI exceeds 15% AND CIT at time of offer exceeds 5 hours
CCCC	331	Distance exceeds 125 nm AND CIT at time of offer exceeds 5 hours AND Donor age greater than 15 years	Distance exceeds 125 nm AND CIT at time of offer exceeds 10 hours AND Donor age greater than 15 years
DDDD	297	Distance exceeds 200 nm AND Donor KDPI exceeds 35% AND Donor has any history of hypertension	No additional CIT added since the model identified filter does not include CIT
EEEE	167	Donor KDPI exceeds 40% AND Donor type is DCD	No additional CIT added since the model identified filter does not include CIT

Figure 8 shows how we could adjust each filter criteria to make it less restrictive.

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[8] OPTN Operations and Safety Committee. 2022, May 23. Mandatory Offer Filters Workgroup Meeting Summary.

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Figure 8: Adjust Each Criteria (Option 3)[9]

| Center	Donors impacted over 2 years	Model Identified Filter	Mandatory Filter
AAAA	483	Distance exceeds 325 nm AND Offer timing is post-cross clamp	Distance exceeds 575 nm AND CIT at time of offer exceeds 5 hours
BBBB	384	Donor KDPI exceeds 15% AND Offer timing is post-cross clamp	Donor KDPI exceeds 20% AND CIT at time of offer exceeds 5 hours
CCCC	331	Distance exceeds 125 nm AND CIT at time of offer exceeds 5 hours AND Donor age greater than 15 years	Distance exceeds 375 nm AND CIT at time of offer exceeds 10 hours AND Donor age greater than 20 years
DDDD	297	Distance exceeds 200 nm AND Donor KDPI exceeds 35% AND Donor has any history of hypertension	Distance exceeds 450 nm AND Donor KDPI exceeds 40% AND Donor exceeds 5 years of hypertension
EEEE	167	Donor KDPI exceeds 40% AND Donor type is DCD	Donor KDPI exceeds 45% AND Donor type is DCD AND Distance exceeds 250 nm

Additional Considerations

Evidence Threshold - Number of Donors Impacted

Both the default and mandatory offer filters could be implemented along with stricter evidence thresholds such as the number of donors impacted. **Figure 9** shows the hypothetical impact on offer volume if all kidney programs turned on their model identified filters starting on July 1, 2021 (the day after the 2-year date to identify filters) up to June 17, 2022. With the minimum evidence threshold of 20 donors impacted, then 32.39% of all offers would have been bypassed including 2.63% of offers that were accepted. If only filters with an evidence threshold of at least 100 donors were enabled, then 21.34% of all offers would have been bypassed including 1.23% of accepted offers. Additional percentages are shown for 200, 300, and 400 donor thresholds.

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[9] OPTN Operations and Safety Committee. 2022, May 23. Mandatory Offer Filters Workgroup Meeting Summary.

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Figure 9: Offers that would have been bypassed if all kidney programs enabled model identified filters
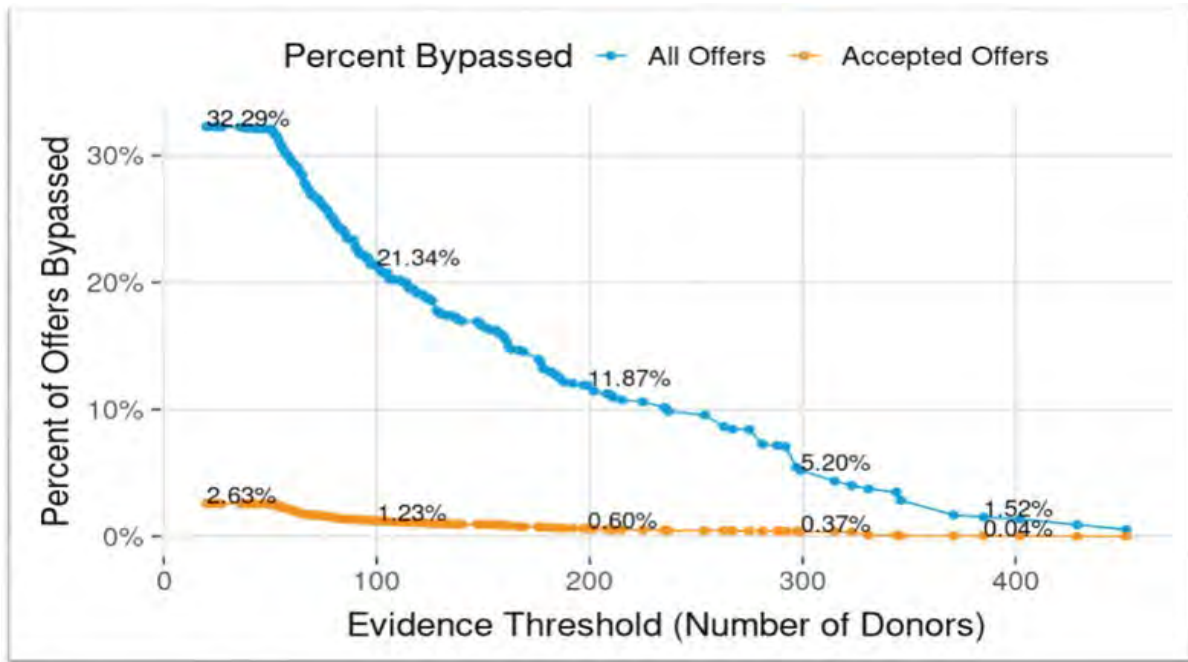
Potentially, both default and mandatory offer filters could be implemented only using filters that impact a minimum number of donors.

Excluded Candidates

One approach to alleviating some of the concerns with automatically applying model identified filters is to always exclude certain types of candidates. This could potentially include the following candidates: 0 ABDR mismatches, CPRA exceeding 97%, and pediatric candidates. The Committee is seeking input from the community on these considerations.

Voluntary Usage Monitoring

The Committee will continue to monitor the current offer filters voluntary usage data intended to help committees, stakeholders, and researchers answer the following questions:

- How effective are offer filters at filtering out offers and donors?
- Are offer filters affecting transplant volumes?
- Are offer filters improving allocation efficiency and/or cold time?
- How are centers engaging with offer filters? Are filters being turned on? Do centers create their own filters and/or use the model-identified filters?
- How accurate and useful are the model-identified filters?

This information will also help the Committee evaluate the use of offer filters in order to determine next steps, including the development of future policies to address the use of offer filters.

The following metrics will be calculated per center and aggregated for an overall national metric. Some of these items compare metrics before and after the implementation of voluntary offer filters in order to compare pre and post implementation:

1. Number and percent of offers that were bypassed
2. Number and percent of donors that were bypassed
3. Number of filters that were model identified
4. Number of filters that were model identified AND turned on
5. Number of custom filters turned on (i.e. filters that were not model identified)
6. Number and percent of offers bypassed with model identified filters
7. Number and percent of offers bypassed with custom filters
8. Number of bypassed organs that had no acceptances at any centers
9. Percent of Offers Actually Bypassed vs Percent of Offers Predicted to Bypass During Modeling
10. Percent of filters with each component i.e. percent of filters with a distance component, percent of filters with a KDPI component, etc.
11. Transplant volumes pre/post
12. Percent change in transplant volume pre/post
13. Average cold time pre/post
14. Time from allocation initiation to acceptance pre/post
15. Number and percent of offers/donors that would be bypassed if all transplant hospitals turned on their model identified filters
    o What percent of accepted donors would have been bypassed?

Re-evaluation Period

The Committee has discussed several options for when to update the models for the offer filters. This includes every six months or yearly. The Committee is seeking input from the community.

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 establish medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs"[10], as well as the OPTN Final Rule, which states the OPTN "shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[11] Offer filters would be electronically programmed in the OPTN Computer System and would allow transplant programs to report their organ acceptance criteria to the OPTN in a more efficient and effective manner.

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.

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[10] 42 U.S.C. §274(b)(2)(A)(ii)
[11] 42 CFR § 121.8(a)

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This concept paper highlights the current work on offer filters and seeks input from the transplant community on various topics. This feedback will be used to further refine offer filters and help inform future requirements for the use of offer filters.

Considerations for the Community

In addition to the specific questions below, the Committee is seeking feedback on all aspects of kidney offer filters to help inform the development of a future policy proposal.

- Should OPTN policy promote increased filter use? If so, which option outlined in the concept paper do you support?

- What is the appropriate threshold for applying a filter?

- Should the filter be mandatory? If so, can a program request removal under certain circumstances?

- Should the filter be removable by the program? If so, should the filter reset if the center continues to decline the organs?

- Should certain hard to match candidates never be subject to having offers filtered?

- How often should the acceptance data be re-evaluated for transplant programs in order to adjust the model identified offer filters?