March 15, 2023

Jerry McCauley, MD
President
Organ Procurement and Transplantation Network
Thomas Jefferson University Hospital
111 South Jefferson Street
Philadelphia, PA 19107

Alden M. Doyle, MD
Chair
Organ Procurement and Transplantation Network
Operations and Safety Committee
University of Virginia Health Sciences Center
4th Floor
1300 Jefferson Park Ave.
Charlottesville, VA 22903

RE: Public Comment Proposal: Optimizing Usage of Kidney Offer Filters

Dear Dr. McCauley and Dr. Doyle:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to respond to provide comment regarding the Organ Procurement and Transplantation Network (OPTN) public comment proposal "Optimizing Usage of Kidney Offer Filters."

Maximizing patients' access to kidney transplant—and ensuring that access is equitably available to all patients—is of utmost priority for ASN. The society stands ready to work with OPTN, and the OPTN Operations and Safety Committee, to achieve this goal. As ample research demonstrates, many aspects of our nation's kidney health ecosystem, including those related to kidney transplantation, are not equitably available to all patients. Significant disparities in transplant access and outcomes exist along racial/ethnic, socioeconomic, geographic, gender, and other lines, and ASN is dedicated to addressing these gaps and increasing health equity.

Ample research also demonstrates that there is significant untapped potential to maximize the use of procured organs to increase survival and quality of life for people with kidney failure, particularly as compared to dialysis.[i, ii] As this proposal outlines, two critically important aspects of increasing organ use are minimizing cold ischemia time and expediting organ placement—among other crucial policy and practice changes outside the scope of this proposal.[iii] Accordingly, ASN perceives numerous potentially positive outcomes deriving from this proposal, if finalized. As outlined, increasing the use of model-identified filters may:

- Decrease the number of offers programs must dedicate time and resources considering and responding to (sparing their time for other patient care-related activities)
- Decrease the amount of time organ procurement organizations (OPOs) must spend working to place an organ (allowing them to focus resources on other efforts, such as working with donor families and procuring other organs in their service areas)
- Decrease the "time to yes," by ensuring offers are made only to programs with a reasonable likelihood of accepting them based on demonstrated program expertise and risk tolerance levels
- Decrease the number of instances of the perception that sometimes that if numerous other transplant centers have already rejected an organ, there must be something "wrong" with it (particularly given that data demonstrate that is most often a false perception[iv])
- Decrease the overall United States organ nonuse rate
- Decrease the overall time to allocate an organ, better preserving its integrity
- Increase, as a result of the six above outcomes, patient access to kidney transplantation—the ultimate goal

Each of the above effects are highly relevant, particularly considering their influence on end-goal of increasing patients' access to kidney transplantation. For all these reasons, ASN believes this proposal has merit. The society also believes are several unintended consequences that may occur because of its implementation as currently proposed, described below, that give the society pause in supporting this proposal outright. Because the proposal does a thorough job of describing the potential positive effects, this response focuses on the potential unintended consequences (and ASN's recommendations to avert them to the degree possible) summarized below:

- Impede patients' agency to select a program whose organ offer acceptance practices are in alignment with their individual care goals
    - **ASN Recommendation 1:** Ensure transparency regarding organ offer filters in patient-friendly formats
    - **ASN Recommendation 2:** Invest in patient education efforts and tools to support informed program selection, such as a patient matching clearinghouse

- Become *de facto* mandatory if programs are not understanding or availing themselves of the flexibilities offered (as proposed) at this stage
    - **ASN Recommendation 3:** Develop educational materials as well as an active monitoring effort to understand program decision-making about filters at this stage
    - **ASN Recommendation 4:** Address the effect of filters on offers made to surgeons whose risk tolerances may vary within a program in the committee's next report

- Hinder program evolution and deepen divides in patient access
    - **ASN Recommendation 5:** Monitor (and share) the data to understand the effects of this policy on program behavior and patient access

- Homogenize the capabilities and risk tolerances of the next generation of trainees
    - **ASN Recommendation 6:** Monitor and forecast the degree to which this policy could result in overall less-risk averse transplant health professionals

ASN recognizes that the Committee has considered many of these potential downsides in its deliberations in drafting this proposal and in earlier phases of this effort but urges that OPTN dedicate more time to mitigating them before moving forward. The society underscores the need to continue keep these issues top-of-mind, monitor the data regarding the effects of these changes, and engage stakeholders during rollout and before moving onto the next planned phase of this process—mandatory filter adoption. Kindly note that the terms "bypass filters" and "organ acceptance filters" are used interchangeably in this response.

Patient awareness and transparency ASN's most significant concern with the proposal is that patients evaluating transplant centers and seeking one that will be a good match for their individual needs and preferences will be unable to discern the implications of a given center's use of organ offer acceptance filters. The society recognizes that the proposal includes exclusion criteria that would mean certain patients (e.g. highly sensitized with a PRA > 90, pediatric patients, etc.) would still receive offers that would otherwise be filtered out for other patients wait-listed at the center—and that centers could set or tweak a variety of exclusion criteria listed on page 11.

However, studies indicate that patients' most important priorities related to kidney transplant are "waitlist factors (including ease of getting onto the waitlist and waitlist time)"…a surrogate for prioritization of overall likelihood of transplantation."[v], [vi] Already under the current system with limited use of bypass filters, it can be very difficult—and in some cases impossible—from the patient's or the general nephrologist's point of view to ascertain which programs have attributes that would make that particular program a good fit based on that patient's unique needs. Indeed, at many transplant centers, it is not possible to ascertain what a program can or will do on behalf of a given patient until that patient has been accepted into the program. These challenges, and some potential policy solutions, were explored in the 2022 OPTN white paper "*Transparency in Program Selection."* [vii]

The proposal to use model-identified filters that reflect centers' own recent behavior means that in theory in many cases, patients would not be substantially less likely to receive an organ at a center under the proposed opt-out filter system than they would have without the opt-out system, based on the center's own expertise and risk tolerance. However, the establishment of an official policy implementing blanket opt-out filters—as opposed to leaving the choice up to the on-call surgeon's decisions—substantially increases the onus of the kidney health ecosystem (particularly on transplant centers) to both inform and educate patients about the effect of those filters on their specific likelihood of receiving a transplant at a given program, based on their individual characteristics and preferences.

While the proposal asserts that "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," ASN would counter with the assertion that *every* patient is potentially affected by the use of bypass filters, depending on their individual care goals and preferences.

It is imperative that OPTN develop a uniform, patient-friendly mechanism to describe not only what offer filters are, but specifically how they are being used at each program, and how that might affect the number and type of organs that might be offered to a patient wait-listed at that program. ASN appreciates that the proposal suggests that "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," but firmly believes much

greater transparency paired with substantially more patient-tailored education efforts must go much further than a brochure. Importantly, patient education should be individualized, interactive, and include context regarding patient survival with "marginal" kidneys that might be filtered out as compared to patient survival on dialysis based on a given center's bypass filter settings.

In the past, ASN has urged that each center be required to report on its organ offer acceptance rates both with *and without* bypass filters, in a patient-friendly, web-based manner. This recommendation would become all the more important in the context of adoption of the proposed "out-out" system of organ offer acceptance filters.

In an ideal world, we could benefit from the advantages offered by opt-out bypass filters while ensuring patient understanding and choice. One policy approach that may foster that goal is the creation of a centralized, national online clearinghouse would help match patients with transplant programs. The clearinghouse would upload information from electronic health records (EHRs) for prospective patients, compare that with transplant centers' baseline criteria for accepting patients, and suggest likely matches. Germane to the conversation about organ offer acceptance filters, the clearinghouse could also contain information from OPTN regarding current center bypass filters. The inclusion of this data in this patient-friendly format would help assuage concerns about patient understanding of the effect of bypass filters on their odds of receiving a kidney transplant as they work to select a center. In addition, the clearinghouse would:

- Create a pathway to transplant for many patients for whom one does not presently exist.
- Decrease redundancy and administrative/paperwork burden (such as nephrology care teams or patients having one-off interfaces sharing the same information with multiple transplant centers to attempt to identify a good fit).
- Reduce transplant coordinator effort (such as fielding many one-off interactions regarding patients who may or may not be a good fit).
- Increase transplant center transparency to better understand—and improve—patients' access to transplant nationwide.

Pioneering research funded by the Agency for Healthcare Research and Quality (AHRQ) aims to help empower patients with more of this type of information, but this effort remains in its infancy. Eventually, this AHRQ proof-of-concept platform could be expanded into a nationwide matching clearinghouse to help patients identify the transplant center(s) that are the optimal fit, including integration with EHRs at dialysis facilities, nephrology clinics, and transplant centers nationwide.

In addition to empowering patients to go to centers whose organ offer acceptance practices match their care goals, a clearinghouse may also shape transplant centers' own behavior patterns to be more open to accepting more types of organs if patients vote with their feet to work with programs shown to have more open organ offer acceptance filters.

Opt-out versus mandatory ASN appreciates that this stage of the proposed plan permits centers to opt-out of the use of filters. The society also appreciates that OPTN has planned educational efforts to help centers understand how the new filters may affect them as well as how to create additional exceptions and to opt-out. However, in some instances, an opt-out program becomes a de facto mandatory program (and the burden of reviewing them every three months would be significant). ASN encourages OPTN to closely monitor and report on how

many centers are making changes and opting out, and if possible, to conduct some qualitative research with transplant center staff to understand how they are thinking about using the options available to them. It will be important to understand the extent to which centers are exercising the flexibility afforded to them at this stage—and why or why not—as OPTN considers moving onto the mandatory filter adoption stage.

Related, it is well-documented that organ offer acceptance practices vary not only from center to center, but from surgeon to surgeon within a center. Depending on who is on call to make the decision at the time an organ offer is made today, the organ may be accepted or declined for a wait-listed patient. One concern ASN has is that at programs with significant variation between surgeons—or with one more aggressive surgeon (e.g. willing to accept more marginal kidneys) among three less aggressive surgeons—the filters might force the more aggressive surgeon to the lower common denominator of only being offered "higher quality" kidneys—translating in longer wait times for patients at the program. ASN realizes that the use of model-identified filters would mirror centers' own practices, but requests that the committee address the effect of filters on offers made to surgeons whose risk tolerances may vary within a program in its next report.

Hinder program evolution and deepen divides in patient access Again, appreciating that programs do technically have the option to opt-out of filter use altogether, or to make certain modifications, ASN is concerned that the "opt-out" or mandatory use of filters may make it more difficult for programs to change their behavior and become more willing to accept "less perfect" kidneys—organs that would still benefit their wait-listed kidney patients, particularly as compared to outcomes on dialysis. Over time, this could result in a calcification of center practices at the moment in time when the opt-out or mandatory system is implemented, at the expense of patients' access to more marginal kidneys (that would benefit them as compared to waiting for the type of kidney the center has historically accepted, and which are offered through their bypass filter settings). It is crucial to watch for inadvertent separation of centers into conservative and aggressive centers, with the divide being only expanded over time.

This "trapped in amber" effect could inadvertently impede programs' evolution to accept more marginal kidneys, as it is often easier to stick with the status quo than to take action to accept more risk—particularly in the current regulatory environment. (ASN has also made many recommendations to CMS and HRSA regarding steps that can and should be taken to alter the regulatory environment to make it easier for programs to assume more risk than at present, though that is of course outside the scope of this proposal.) The most likely way to change a center's organ offer acceptance practices would potentially be through the recruitment of a new surgeon(s) who are more comfortable with saying yes to more marginal kidneys. Over time, however, one could envision a scenario where patients in some regions of the country—where programs have a history of accepting higher KDPI and other more marginal kidneys—have better odds of getting access to a transplant quickly—and people who live in places with historically less aggressive acceptance practices do not. While this dynamic is not dissimilar to the disparate wait times currently seen in different geographies, it would not be a desirable outcome to perpetuate in another form.

Accordingly, if OPTN moves forward with this proposal, ASN **urges close monitoring of data to understand its effects on program behavior and patient access and to strongly consider not implementing the envisioned mandatory phase of this effort.**

Necessity of preserving multiple listing This proposal from the OPTN Operations and Safety Committee was made available for public comment at the same time as a white paper from the OPTN Ethics Committee, which proposed eliminating most patients' option to list at more than

one transplant center (*White Paper: Ethical Evaluation of Multiple Listing).*[viii] If OPTN moves forward with the opt-in system of organ offer acceptance filters—and *especially* if OPTN moves forward with the mandatory system of organ offer acceptance filters—it is all the more imperative that OPTN **not finalize** the proposal to limit patients to just one center. Patients whose individual goal is to receive an organ quickly should not be forced to select just one center that has been mandated to bypass organ offers that might have been a good fit based on their preferences. While ASN recognizes that centers would have some control over exceptions settings, the potential for these two policies to restrict patient autonomy in conjunction with one another appears too great to outweigh any potential upsides they may each offer.

Homogenize the capabilities and risk tolerances of the next generation of trainees Should programs begin to sort into a smaller number of "more aggressive" and larger number of "less aggressive" groups in terms of organ acceptance risk tolerance as filters roll out, some trainees will emerge with a high degree of confidence accepting higher-risk kidneys and others less so. Over time, if the number of transplant centers that are "less aggressive" significantly outweighs the number of centers that are "more aggressive," the next generation of trainees may overall be less capable of accepting higher-risk kidneys—and in disseminating higher-risk tolerances at programs nationwide. To a degree, this dynamic already exists: trainees mirror the environment in which they trained. But, it would be important to monitor and forecast the degree to which this trend could accelerate under opt-in or mandatory organ offer acceptance filters.

On the other hand, transplant centers that have a reputation as possessing the unique expertise or risk tolerance to accept less-perfect kidneys would be well-positioned to recruit the best of the best trainees—potentially creating a behavioral economics incentive for programs to embrace more risk. Overall, ASN urges OPTN to monitor potential effects of any future use of opt-in or mandatory organ offer acceptance filters on the workforce.

Opportunities to address other influences on organ nonuse rates The reasons that more than 25% of procured kidneys are currently not used are complex and multifactorial. As bypass filters are considered as one tool in the toolbox to increase usage rates, ASN also bears in mind there are also many other opportunities that should be pursued, including the two examples described below.

Developing more and better validated predictive tools to offer transplant surgeons and other members of the transplant team to inform their thought processes and decision-making in accepting or declining organ offers on behalf of their patients could enable more organ use. Having these more of these kinds of tools widely available to complement the currently-used tools could help alleviate the overall organ shortage, as it could enable some centers that are currently more risk-averse to say yes to some organs they currently decline by having a higher degree of confidence that the outcomes would be good (preventing discards of some organs that would benefit patients otherwise facing dialysis). Ideally, any tool(s) developed to along these limes could also integrate patient-specific preferences generated from validated shared decision-making tool(s).

It is imperative that every element of the kidney health ecosystem move away from the current emphasis on one-year outcomes metrics, which incentivize centers to be more risk-averse in their organ offer acceptance practices than is ideal from a patient access perspective. ASN has commented on this imperative in numerous other settings, as have many researchers in widely available peer-reviewed literature.[ix], [x], [xi], [xii]

Conclusion

The emphasis in the draft report on post-implementation monitoring is heartening, and ASN encourages OPTN to share as much data (ideally, all the data described on page 15) with the community as possible. This investment in transparency will go a long way towards ensuring public trust and buy-in for any next steps in the use of bypass filters—as well as influence ASN's future position regarding further rollout of this policy. **At present, the society has some reservations regarding the implementation of opt-out filters and maintains serious concerns regarding an eventual move to adoption of mandatory filters.**

While this letter has focused largely on potential unintended consequences of the proposal, the society also acknowledges that there would be unintended consequences of *not* taking steps that achieve the vital goals of increasing organ utilization, speeding time to offer acceptance, allowing stakeholders to dedicate time to making or considering organ offers, as well as other aspects of the process that ultimately influence patients' likelihood of receiving a kidney transplant. ASN affirms that these are important objectives for the kidney health ecosystem to achieve on behalf of patients. Accordingly, these comments are offered in the spirit of collaboration and in the hope they will be useful to the committee and to OPTN as the next steps to achieve these important goals are considered.

In sum, ASN appreciates OPTN's and the committee's dedication to reducing organ nonuse, speeding time to allocation, and helping more patients receive a kidney transplant, and is grateful for the opportunity to provide input on this proposal. ASN also acknowledges that many other simultaneous changes to the current kidney health ecosystem must occur urgently to achieve the goal of maximizing access to transplant and ensuring that access is equitable. The society stands ready to work with OPTN and the committee on the many recommendations included in this letter as well as towards other shared goals. Please contact ASN Strategic Policy Advisor Rachel Meyer at rmeyer@asn-online.org with any questions or to discuss this letter in more detail.

Sincerely,

Michelle A. Josephson, MD, FASN
President

---

[i] Clin J Am Soc Nephrol 13: 118–127, 2018. doi: https://doi.org/10.2215/CJN.06550617

[ii] Survival Benefit of First Single-Organ Deceased Donor Kidney Transplantation Compared With Long-term Dialysis Across Ages in Transplant-Eligible Patients With Kidney Failure https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2797181

[iii] 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.

[iv] Clin J Am Soc Nephrol 13: 118–127, 2018. doi: https://doi.org/10.2215/CJN.06550617

[v] Am J Transplant. 2018 November ; 18(11): 2781–2790. doi:10.1111/ajt.14985.

[vi] https://pubmed.ncbi.nlm.nih.gov/29945305/

vii https://optn.transplant.hrsa.gov/media/rsvlz4gc/transparency-in-program-selection_ethics_pc-summer-2022.pdf

[viii] https://optn.transplant.hrsa.gov/media/l5odohtm/ethical-evaluation_multiple-listing_white-paper_ethics_pc-winter-2023.pdf
[ix] https://www.asn-online.org/policy/webdocs/ASNfinalMay23RFIOPTNContract_(002).pdf
[x] https://www.asn-online.org/policy/webdocs/ASNTxRFIFinal2.1.22.pdf
[xi] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4186511/
[xii] https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.15394