

The American Society of Transplantation responded to fifteen public comment proposals released for comment on August 3, 2022. The responses below were entered on the OPTN website on September 27, 2022, after seeking input from the communities of practice, the OPTN/UNOS Policy Committee, and the Board of Directors.

1. Transparency in Program Selection

The American Society of Transplantation (AST) offers the following comments for consideration in response to the white paper distributed for public comment, “Transparency in Program Selection:”

- In general, transparency and sharing of transplant program selection criteria to the public is important.
- This paper aligns with various other OPTN projects to increase transparency, equality, and efforts to reduce organ discards, and with the recent NASEM Report. The proposal once implemented will allow patients to navigate the listing process at different transplant centers and choose the ones they think would provide them the best chance to be transplanted. Patients have the right to understand their realistic chances of getting a transplant and not just getting listed at a transplant center, and the white paper will facilitate this process by establishing the ethical principles that support center practices to become more transparent and provide their listing criteria with regards to BMI, frailty, sensitization, and alcohol use. The other factors that might be important for the patients in selecting a program are center’s policies on substance abuse, prior non-compliance, type of insurance, sickle cell disease, hypercoagulability disorders, incarceration/probation status etc. Centers must use every opportunity to educate the dialysis centers, referring nephrologists, and community about their listing practices to improve the trust between them. Being honest and transparent about their practices will encourage centers to undertake process improvement and ask for more resources, if necessary, from the hospital to transplant patients with complicated issues.
- It is important to recognize the selection of transplant candidates is quite nuanced, and many times involve details of their candidacy that cannot be easily delineated. These decisions often take detailed committee discussions, and the community should not risk oversimplifying this process.
- It is of utmost importance that this white paper recognizes that transplant centers must work to ensure institutional racism does not play a role in preventing access to transplant in historically underrepresented groups. Additionally, programs must be sensitive that not all candidates have a legitimate choice, due to geography, insurance, etc. A particular concern projected is in the presentation of selection criteria and data, and the potential for it to inadvertently be communicated in a manner that discourages potential candidates from seeking transplantation.
- Health literacy may also be an important factor to consider with relation to data/information presentation for public consumption and measures should be taken to ensure the language/format utilized is easily understood by all patients. In the case of pediatric transplantation centers, it is also important to consider the developmental appropriateness of presenting this data/information, adjusted for consumption by parents and pediatric patients.
- Information described in the examples provided in the proposal could lead to extensive requests for information that may be difficult not only to understand but also to provide information towards on an ongoing basis. A plan for funding or assistance may need to be implemented to ensure programs are successfully able to fulfill these recommendations.

- For reasons raised and acknowledged in the document, the AST notes that excessive information is not necessarily benign and must be carefully presented to meet the appropriate goal of transparency for the benefit of patients. Excess data, even for a transplant professional themselves seeking an organ, are too dense to be actionable.
- The AST cautions pursuing policy development in this area given an additional burden for programs. While improving transparency as a step towards access, it is also important to concurrently address the root problems of social injustice and the lack of access to needed care. The AST would highly recommend that alternative avenues to the development of patient facing materials be championed either by the OPTN or the SRTR. This seems most reasonable particularly in light of the fact that both organizations have ready access to data that would address many of the topics that patients reported wanting to learn more about but which are not currently included in the program specific reports. The AST would support either organization in the development of more comprehensive program specific reports as we agree that context is important, particularly concerning outcomes.
- Many of the examples of patient requested information noted in Table 1-1 are valid points for marketing and public relations and may in fact strengthen both the program's reputation and the patient-provider relationship. For example, a patient may feel a greater sense of trust if they ask and are answered how many years the center has been performing transplants, the medical and surgical teams' training and years of experience, what innovation is being driven by the program, acceptance practices, transplant rates, and subsequently, more details regarding outcomes beyond the 1-year patient and graft survival rates. However, mandating that a center provides this information prior to the initiation of the evaluation risks undermining the natural development of a solid patient-provider relationship. Patients must have the opportunity to assess the provider (or team) willingness to include them in the decision-making process, to provide them with information that uniquely interests them and to explore their goals of care together. Simply overwhelming a patient with a list of facts is not patient-centered care or supportive of autonomy.

2. Modify Heart Policy to Address Patient Safety Following Device Recall

The American Society of Transplantation provides the following comments for consideration in response to the questions posed in the proposal:

Should the approved emergency policy changes be considered for permanent policy by the OPTN Board of Directors?

Yes, a permanent policy would support a transplant program's ability to protect the safety of its patients.

What, if any, data analyses, peer-reviewed literature, or evidence-based medical judgments, provide evidence demonstrating that a patient with FDA-recalled heart device should be assigned to adult heart status 2 or adult heart status 3 by policy criteria, rather than a candidate's transplant physician determining whether assignment to status 1, 2, or 3 by exception is appropriate?

Currently, there is a lack of available evidence (i.e., waiting list mortality analysis) to support adult heart status 2 or 3 for patients listed under FDA-recalled heart device support. Therefore, prioritizing listing status should be maintained by appropriate, device recall-specific exception.

Is 14 days the appropriate amount of time for an extension of the assignment by exception? Why or why not?

Those patients carry high risk of serious pump malfunction, severe injury, or death; therefore, 14 days is an appropriate time for initial assignment and extension for a device recall-specific exception.

In addition to the Member Compliance and Policy Evaluation actions identified in the proposal, what other actions can be taken to ensure the new exception pathway is only used for appropriate purposes as intended by the Heart Committee?

Initial requests, as well as any subsequent extensions, should be reviewed by adult heart regional review boards for approval.

Are there any types of implanted devices that could be subject to a FDA device recall that should not qualify under the policy modifications? Describe why.

Any FDA-approved implanted LVAD device subject to an FDA device recall should be included.

Are the proposed data element and the associated data definition clear and understandable?
Yes

Are the acceptable forms of documentation regarding the recall of the device identified in the proposal widely available? Yes

3. Continuous Distribution of Kidneys and Pancreata Update

The American Society of Transplantation (AST) generally supports the concepts reviewed in this paper. This paper aligns with the recent National Academy of Science, Engineering, and Medicine (NASEM) report, "Realizing the Promise of Equity in the Organ Transplantation System," and the AST agrees a flexible and uniform approach to organ allocation that is driven by machine learning algorithms and historical data is needed. The AST offers the following comments for consideration as this work continues:

- The community should have confidence in the ability of the models to reliably and reproducibly predict actual allocation outcomes based on weighting of different variables. C-stats of these models should be provided; if actual outcomes cannot be reliably modeled, the rest of this discussion is theoretical. See also <https://pubmed.ncbi.nlm.nih.gov/19392985/>.
- This proposal would benefit from a monitoring plan, including a data analysis schedule, specific metrics, and more information about how this model will adapt and be adjusted over time.
- Hard to place, dual, and *en-bloc* kidneys should be allocated in a way to decrease cold ischemic time and preferentially offered to the centers with history of accepting such organs. The "preferential status" can be changed every 6 months based on center behaviors.
- We support the mirror approach to longevity matching in continuous distribution.
- We agree with the re-evaluation of how much waiting time should be weighted in the new framework.

- In general, we support the idea of waiting time inversion but this needs to be studied further and more granular data is needed to fully assess the impact.
- Addressing racial, geographic, and other inequities is of paramount importance. Mechanisms aimed at improving access and outcomes for currently disadvantaged populations should be a focus and included in early iterations of this project.

4. Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations

The American Society of Transplantation (AST) offers the following comments in response to the proposal, “Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations:”

- The proposal provides examples of 4 candidates: candidates A (not accruing waiting time), B (accruing waiting time), C (accruing waiting time as of registration date), and D (accruing waiting with dialysis criteria). In each example, a transplant center may increase the candidate’s accrued wait time by submitting documentation of an earlier qualifying date by race-neutral eGFR. The verbiage can be simplified by stating that for all candidates the new qualifying wait time starts whenever the race-neutral eGFR was/is 20 or less, irrespective of dialysis status.
- The AST strongly recommends all kidney programs review available data for each of its listed candidates to assess if their accrued wait time would be positively impacted by utilization of a race-neutral eGFR calculation. We also suggest that this policy modification be applicable to candidates registered after July 27, 2022, if they are subsequently found to have data supporting an earlier qualifying date. The OPTN should review these changes in a year to determine if they should be extended, expanded upon, or ended.

The AST recognizes the pros and cons of the one-year timeline currently proposed for programs to address this policy change. While there is a desire to quickly submit the wait time modification for each candidate impacted, imposing a shorter time period for addressing it may place undue burden on programs in a time where staffing and data entry challenges could make this difficult depending upon the number of candidates impacted. Shortening this time period could lead to some candidates not receiving this benefit and even potential compliance issues that could impact overall access to care in the long term. The one-year window seems to be a reasonable goal to allow for each program to comprehensively review its often lengthy kidney waiting list and relevant data to determine which candidates are impacted and make the appropriate changes needed. There is also value to leaving this waiting time modification open indefinitely for those pre-emptively referred for transplant who were impacted by the use of a race-based calculation of eGFR. The AST is not aware of any reason why any candidate found to be impacted by this would be excluded from this waiting time modification in the future. While awareness and education regarding the removal of this practice is underway, there is still opportunity for this to impact candidates at day 366 and beyond.

- There could be opportunity for recognizing programs who complete this request in a shorter time, including a letter of recognition and thanks from the OPTN or HRSA.
- This proposal does not specify requirements or recommendations for notifying patients they have been affected by race-independent eGFRs or provide guidance on how to provide such notifications. Increasing the transparency in the policy change for patients and the

impact it may have on their waiting time is necessary to empower patients and allow them to become more active participants in their care.

- Concerns were raised that these proposed changes may be difficult to implement, impose a significant burden on transplant centers, and may create medical legal issues.

5. Update Kidney Paired Donation Policy

The American Society of Transplantation (AST) generally supports the changes outlined in the public comment proposal, "Update Kidney Paired Donation Policy." We offer the following comments for consideration:

- The AST agrees with setting a 60-day deadline from the time of match offer to transplant surgery. As identified by the committee, this reduces the risk of the exchange breaking while providing enough time for centers to facilitate the transplant. Deadlines are appropriate to improve program efficiency, but language should be changed to "should" instead of "must" when referring to the timing of recovery and transplant surgery.
- Two business days to provide a provisional response is appropriate; shorter time may be challenging for the lower volume programs with less personnel.
- Extension requests may be minimized by registering transplant candidates and donors after the complete evaluation and only if they are ready to proceed with transplant. We suggest that the committee explore the use of system alerts, liaison communications, and automated emails as reminders of an outstanding offer. Reminders should be throughout the day and then programs can be alerted to an expiring offer. The incentive is for programs to respond quickly on behalf of their patients. Punitive measures are used by other registries but there is no greater penalty than a lost opportunity for a patient.
- Expanded language regarding financial risk and potential resources available to defray donation related costs, as well as increasing bridge donors autonomy, is appropriate.
- The AST recommends that clinical donor information/evaluation records and images be made available to the receiving centers at the time of preliminary offer so that transplant teams can make a quick but informed decision. This avoids late declines due to donor anatomy, etc., which reduces the efficiency of the KPD process. We think this can be accomplished within the 2-business day deadline for a preliminary response.
- The AST agrees with the OPTN committee's proposal to shorten the final acceptance/refusal to 10 days.
- The AST agrees with the committee that breaking exchanges due to administrative reasons is unfair for the patient and granting automatic extension in case of non-response from participating centers is reasonable. We recommend that the committee consider specifying a maximum duration for extension (e.g., 60 days) and a maximum number of extension requests. This will prevent overuse and aligns with the overarching goal of making the KPD process more efficient.
- The AST agrees with aligning the OPTN KPDP informed consent with OPTN Policy 14.3.
- The AST agrees that transplant programs should obtain a signature from bridge donors confirming consent and a period of willingness to become a bridge donor. Although donors are allowed to drop-out of the process at any time, this gives the bridge donor more autonomy.

- There is agreement that bridge donors should be consulted about informed consent and the estimated period of willingness to be a bridge donor; however, there were differing perspectives on whether the bridge donor's signature should be required. It was suggested that a signature may be interpreted as a binding agreement, and not altruistic and voluntary. Instead, an alternative recommendation is for transplant programs to confirm assessment of and education to the donor on bridge donation and document these conversations occurred.
- The AST recommends requiring transplant centers to disclose the presence of multiple KPD programs in the country, including the OPTN KPDPP. This will allow donor-candidate pairs to explore all their options, including multi-listing, to gain access to different KPD programs (included in 13.4.C the last statement).
- The AST urges the committee to consider a policy for requirements for testing active pairs/donors. Many offers are declined or not viable because patient testing is outdated. Instituting a requirement for patients active in the registry to be clinically ready and suitable for transplantation and donation would result in increased registry efficiency and decrease time to transplant/donation.

6. Continued Review of National Liver Review Board (NLRB) Guidance

The American Society of Transplantation generally supports the changes outlined in the proposal, "Continued Review of National Liver Review Board (NLRB) Guidance." We offer the following comments for consideration:

- Changes to the hepatic adenoma policy are long overdue, and there is broad support for the changes, some of which allow granting of exception points *before* the development of malignancy.
- Agree with Budd-Chiari changes, but programs should provide greater granularity and detail to the severity of the hepatic decompensation.

7. Review of Liver and Intestines Variances in OPTN Policy

The American Society of Transplantation generally supports the changes included in the proposal, "Review of Liver and Intestines Variances in OPTN Policy."

8. Continuous Distribution of Livers and Intestines Concept Paper

The American Society of Transplantation (AST) generally supports the approaches outlined in the Continuous Distribution of Livers and Intestines Concept Paper. The AST offers the following comments for consideration as this work continues:

- An ideal continuous score-based allocation model must balance not only consideration of waitlist mortality, but also maximize post-transplant outcomes, ensure equitable access to liver transplantation, and consider placement logistics and efficiency.
- If frailty is included as a factor, it must be objectively measured and included in both urgency and post-transplant survival estimates.
- Optimized prediction of mortality (OPOM) may be superior to MELD/PELD but requires further liver transplant community review. Additionally, it is not known how alterations to MELD (e.g., MELD 3.0) may perform compared to OPOM.

- Regarding candidate biology:
 - ABO compatible blood types should be ranked equally once a threshold medical urgency is reached.
 - To allow for equitable transplantation, donor-recipient size matching is imperative to ensure smaller adults have the same access to transplantation as larger adults. Again, using a medical urgency threshold, smaller candidates could be prioritized to the smaller donor
 - It is reasonable to offer additional points to surgically complex or retransplant patients, especially if the candidate initially received a marginal graft.
 - Because of the uncertainty in the current usage of HLA sensitization in listing practices and the impact of HLA sensitization in liver transplant outcomes, additional study is necessary to establish the benefit of including HLA sensitization in continuous distribution for isolated liver allocation.
- Regarding patient access:
 - The AST supports increasing priority to liver-intestine candidates and recommends reviewing waitlist mortality data to inform whether other multi-organ liver candidates should also receive increased priority.
 - Pediatric patients should continue to receive priority, and the OPTN should use factors other than age as a proxy to incorporate this priority. The OPTN must evaluate any proposed policy changes to demonstrate a negative impact to pediatric patients is unanticipated.
 - The AST supports priority for candidates who have been prior living donors.
 - Prioritizing candidates able to accept a split liver would result in better organ utilization assuming there would be a safety net in place in the rare event retransplant is needed.

9. Update Data Collection for Lung Mortality Models

The American Society of Transplantation (AST) offers the following comments in response to the proposal “Update Data Collection for Lung Mortality Models:”

- The AST supports improving the models but we are concerned the proposed approach will not accomplish the stated goals. Unless power analysis demonstrates that sufficient, unbiased data can be collected within 1-2 years of implementation, the AST recommends leveraging EHRs for retrospective data collection to accomplish the same goals.
- The AST is reluctant to support new data collection without some consideration about whether the data elements could be transmitted automatically through an interface. Ideally, data would be collected without additional work for transplant centers.
- Some of the proposed data elements, particularly “exacerbations,” are somewhat subjective. The OPTN should provide evidence-based definitions to describe what is expected for providing these data.
- The AST recommends data collection, including donor characteristics, that adequately capture elements to assess pre- and post-mortality for elderly lung candidates.

10. Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution

The American Society of Transplantation (AST) generally supports the changes included in the proposal “Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous

Distribution,” and offers the following comments for consideration:

- The AST recommends modifying language in the proposal to ensure that the pediatric representatives on the Review Board have real and contemporary pediatric experience (i.e., at least 5 pediatric transplants in the last 5 years) and at least one of the members has experience with infant lung transplant. There are specific nuances between adult and pediatric patients, especially infants, and adequate representation is necessary to protect this vulnerable population.
- The committee should provide guidance on requesting priority 1 equivalent score for pediatric candidates in the new allocation system to help appropriately refine the individual’s priority score.
- Making the Chair a voting member further ensures a peer reviewed approach to these requests.
- Additional guidance on concomitant lung disease such as combined pulmonary fibrosis emphysema (CPFE) and the addition of obstructive sleep apnea (OSA) would be helpful to objectively prioritize these patients.
- The AST agrees that a quorum of review board members should be required to deny or accept an exception request; however, it would be important to consider a majority minimum to make a peer reviewed decision. For example, greater than 50 percent of assigned reviewers, greater than five reviewers- instead of a majority, which in some instances could be one reviewer due to the lack of response from other reviewers.
- The appeals process is clearly outlined in this new proposal.
- Under the new system, all active transplant programs can have primary and alternative representation on the Lung Review Board allowing for a diversified approach on multiple aspects, including geographic and ethical considerations. The overlap of the terms of representation between old and new members allows ongoing expert and dynamic ideas. The AST does not think active lung transplant programs will encounter any barriers to participate in the new Lung Review Board or using the updated exceptions process. Ineligibility to participate due to the programs inactive status may be an obvious barrier.
- The OPTN should provide information about candidates that are currently listed to support transplant programs in submitting a fair score request.

11. Update Multi-Organ Allocation for Continuous Distribution of Lungs

The American Society of Transplantation (AST) offers the following comments for consideration in response to the proposal “Update Multi-Organ Allocation for Continuous Distribution of Lungs:”

- There has been a dramatic increase in multi-organ transplants including kidneys over the past 10 years, including lung-kidney multi-organ transplants, typically utilizing high-quality kidneys in patients that often have very limited life expectancy and that could otherwise provide great life expectancy benefit to young, kidney-only candidates with long waiting times. The AST recommends the final proposal also include monitoring the usage and outcomes of lung-kidney transplants to assess whether medical eligibility criteria should be developed in the future, similarly to what has been done with liver-kidney.
- More recent data presented by UNOS reflect that the score threshold of 28 only captured 75% of lung multi-organ candidates. With these updated data, the score of 25 did increase

this to 95% of transplants currently being performed and this was the intent of the Lung Committee. It also appears probable that a threshold of 25 will more likely capture those candidates whose severity of illness the other organ is driving, and who might otherwise have to wait until offers are being made to that respective organ match run, effectively reducing the time to placement. The AST supports and agrees with this adjustment as it will maintain this access at the same rate as in the LAS for these candidates.

- In lung, as in all other organs, multi-organ combinations are often challenging. Often, this is because of different protocols between organs and different scoring systems. We believe that when continuous distribution is implemented across all organs, it may be less complicated and more efficient as the strategy will be similar. When creating the composite allocation score for solid organs after the lung composite allocation score is accepted and implemented, it will be beneficial to align each organ with the same process as much as possible. The OPTN will also need to consider triple plus organ combinations and how those should be prioritized in allocation, particularly considering that it may not be the heart or lung driving the patient's severity of illness but the liver. A more complex algorithm may be needed to ensure those candidates are not unintentionally disadvantaged.

12. Enhancements to OPTN Donor Data and Matching System Clinical Data Collection

The American Society of Transplantation (AST) supports the addition of the data fields and data definitions included in the public comment proposal, "Enhancements to OPTN Donor Data and Matching System Clinical Data Collection." Additionally, the AST recommends including the following, reported in minutes and seconds:

- Explant time for each organ procured
- Time from incision to organ flush with preservative solution
- Time from flush with preservative solution to placement on a perfusion device.

13. Redefining Provisional Yes and the Approach to Organ Offers

The American Society of Transplantation (AST) offers the following comments in response to the concept paper "Redefining Provisional Yes and the Approach to Organ Offers:"

- The AST has significant concerns that, without creating parallel allocation processes to improve efficiency, the concepts outlined in this paper will add significant complexity without achieving the stated goal of expediting organ placement. It is not clear how these changes would be operationalized or whether the changes outlined in the concept paper will result in unintended consequences that could diminish rather than improve the efficiency of organ placement.
- The AST recommends that the OPTN implement changes ultimately resulting from the "Optimizing Usage of Kidney Offer Filters" concept paper first, before approving any changes to provisional yes policy. To improve efficiency as much as possible, objective "internal refusal reasons" envisioned in this paper to comprise the Tier III decision making criteria should be incorporated into the organ specific offer filter criteria as well. If or when provisional yes policy changes are implemented, Tier III decision making behavior could inform future changes to offer filters.
- The proposed chat feature and ability of programs to view their sequence if the intended organ is part of a multi-organ offer would be a welcomed change and could be implemented prior to or independent of changes to provisional yes policy.

- As allocation progresses, to remain in a position to accept an offer, transplant centers must provide increased specificity regarding what is needed to make a final decision. This prompts a few questions and concerns:
 - More detail is needed about how the “tier” system will work. i.e., will centers be notified that they are now in a higher tier and be required to enter additional information?
 - How will the current practice of potential recipient blood being sent out to OPOs for highly sensitized patients be considered? We believe it should be maintained and centers should not be penalized for this practice.
 - For this practice to work, centers should be expected to confirm a candidate's medical suitability no later than Tier II to ensure that there have been no interval changes that would lead to organ decline.
- For Tier II, OPOs should not be constrained to a single offer per organ. Regarding the number of Tier III notifications that could be sent down a match run, consider using the mean Number of Programs Needed until Final Acceptor on Each Match by Organ Type across All OPOs (Table 1 in the concept paper). Currently, OPOs determine how many centers to offer an organ on the match run.
- The functionality to remove a transplant program from a match run if the organ is declined by the program for quality should be implemented with the exception that a marginal donor may be declined for one candidate but may be suitable for an alternate candidate further down the list.
- It is important that a tiered match run maintains priority for dual organ candidates per OPTN allocation criteria.
- The number of offers that proceed to a “Tier I” should be limited to primary and back up offer. Otherwise, patients will be notified of organs that will never come to them. Consider additional offers for marginal, DCD, high KDPI, etc. organs.
- Programs should be held accountable for provisionally accepting organs that are later declined based on information provided initially. These avoidable late declines should be reported and routinely reviewed, and if a trend is identified, subject to a quality improvement process.
- In response to specific questions posed in the paper, the following feedback was provided:

What should happen if the first program refuses the organ offer (in Tier I)?

The organ should be offered to candidates listed at the next center with one exception. If an organ is declined for quality for one candidate (e.g., a pediatric patient), it very well may be suitable for an alternate candidate further down the list. The system should allow for patient-level decision-making while improving efficiency by allowing the OPO to move on to candidates at another center quickly when an organ will be declined for all candidates by the first program. Consider organ quality decline process that automatically allows a program to differentiate whether a decline is for all versus for one patient.

What information should OPOs be required to complete for a Tier III offer evaluation?

With broader sharing, a greater level of standardization between OPOs should be a priority. This includes standardizing to the extent feasible the donor data that is available at offer such as imaging, hemodynamics, and neurological status for DCD donors.

Are there tools that should be considered that could help facilitate this three-tiered model?

Current real-time donor data including hemodynamics (pressors), ventilatory status, blood and urine results, and access to imaging. Each match run should also include how many different programs are ahead of a potential transplant recipient, in addition to providing each individual candidate's ranking. As an example, the likelihood of receiving an organ is different if there are 50 potential transplant recipients from one program ahead of your patient versus 50 potential transplant recipients from 10 different programs; additional information to assess this during organ allocation would be helpful.

Are the requirements within each tier reasonable?

Tier III will become the provisional yes and accepted offers will likely increase. Ideally, virtual crossmatch information will be available at the time the Tier III offer is made.

Should OPOs limit offers based on tiers? Should this be based on the number of organ offer responses that are confirmed?

This is a must and should be implemented independently of this proposal. The number of offers is currently determined by OPOs but should be based on an algorithm that incorporates the likelihood of acceptance based on donor and organ factors. Harder to place organ offers could have a different and larger limitation that is organ specific (the data provided show differences between kidney and liver).

Should there be expectations outlined that are specific to offers sent pre- and post-recovery?

Exceptions may be needed for dual organ offers, sensitized patients, and DCD cases.

Do you agree with the recommended thresholds for each tier?

These thresholds will require careful review for each organ type. The tier thresholds should not be left up to the individual OPO. There is too much variability. Thresholds may differ between organs.

What threshold should be considered for Tier III for when should a program receive the initial notification?

The number of programs needed until a final acceptor on each match by organ across all OPOs (Table 1) is a good starting point.

Do you agree with the recommendations on time limits on offers for Tier I and Tier II?

Members expressed support for the proposed time frames for Tier I and Tier II. Strictly enforcing the time limit will significantly improve the current process.

Should there be different considerations for offers sent pre- and post-recovery? If so, what should those considerations be?

Yes, time limits should be modified for offers post-recovery as any delay at that time will prolong the ischemia time and can lead to non-utilization of an organ. Approaching these scenarios similarly could result in the discard of organs allocated post-recovery that could otherwise be transplanted.

Should there be a time limit for Tier III to respond to a notification on an organ offer?

Yes, this would facilitate efficient organ allocation.

14. Optimizing Usage of Kidney Offer Filters

The American Society of Transplantation (AST) generally supports the approaches outlined in this concept paper, ideally using “Option 1 - Default Offer Filters.” The AST offers the following comments for consideration as this work continues:

- Filters have the potential to increase kidney placement efficiency and utilization. Programs need the ability to modify their filters, thus, the default option is the preferred model. The challenge will be who makes these decisions, who enacts them in UNet, and how to adjust for each patient. It will be critical that the OPTN creates a process and tools that are easy to implement and allow for dynamic, smooth changes to filters in the future.
- Certain hard to match candidates should never be subjected to having offers filtered. It will be important that the filters include mechanisms that allow programs to make adjustments easily so hard to match candidates receive appropriate offers.
- Regarding the evaluation of acceptance data, members provided varied responses ranging from every six months to biannually. Program acceptance behavior evaluation frequency should also consider program size/annual number of transplants.
- All filters should be utilized and monitored. If a program continues to decline particular organ offers based on their settings, then the program should be notified that the setting will be adjusted unless they take a different action.
- Based on data in the concept paper, there are still a significant number of programs that haven't accessed or utilized the offer filter data or input filters for their programs which indicates something at the center level need to be done. Please consider sending programs individual evaluations as a start.
- The AST recommends that the OPTN implement changes in this concept paper first, before approving any changes to provisional yes policy. To improve efficiency as much as possible, objective "internal refusal reasons" envisioned to comprise the Tier III decision making criteria in the concept paper, “Redefining Provisional Yes and the Approach to Organ Offers,” should be incorporated into the organ specific offer filter criteria as well. If or when provisional yes policy proposal is implemented, Tier III decision making behavior could inform future changes to offer filters.
- The AST recommends that programs are transparent with patients about their usage of offer filters.

15. Apply Transplant Notification Requirements for VCA Program Inactivation

The American Society of Transplantation generally supports the changes outlined in the public comment proposal, “Apply Transplant Notification Requirements for VCA Program Inactivation.”