

Concept Paper

Redefining Provisional Yes and the Approach to Organ Offers

OPTN Operations and Safety Committee

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Redefining Provisional Yes and the Approach to Organ Offers

Sponsoring Committee: Operations and Safety
Public Comment Period: August 3, 2022 – September 28, 2022

Executive Summary

The OPTN Operations and Safety Committee (the Committee) is charged with improving the quality, safety, and efficiency of the organ donation and transplantation system. This concept paper provides an update on the ongoing work of the Committee in redefining provisional yes and the approach to organ offers. Current OPTN policy defines provisional yes as when the transplant hospital notifies the OPTN or the host OPO that they have evaluated the offer and are interested in accepting the organ or receiving more information about the organ.¹ The Committee discussed the cyclical issue of organ procurement organizations (OPOs) sending out organ offers to ensure organ placement and transplant programs being overwhelmed with the amount of organ offers they receive². In response, the use of provisional yes no longer serves the system in the intent it was established, and contributes to inefficiencies within organ offer, review, and acceptance processes.

This document is not a proposal, but instead a concept paper that seeks to develop a solution that includes a tiered framework that will standardize organ offer, review and acceptance practices, and outline associated member responsibilities. 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.

¹ OPTN Policy 1.2: *Definitions*

² OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.



Background

The Operations and Safety Committee (“Committee”) pursues projects aimed to improve processes and increase the efficiency of organ offer, review, and acceptance, and reduce overall organ allocation time. The provisional yes project first began with the OPTN Policy Oversight Committee’s (POC) establishment of the Provisional Yes Workgroup in April 2020³ to address strategic priorities approved by the OPTN Board of Directors at the December 2019 Board meeting.⁴

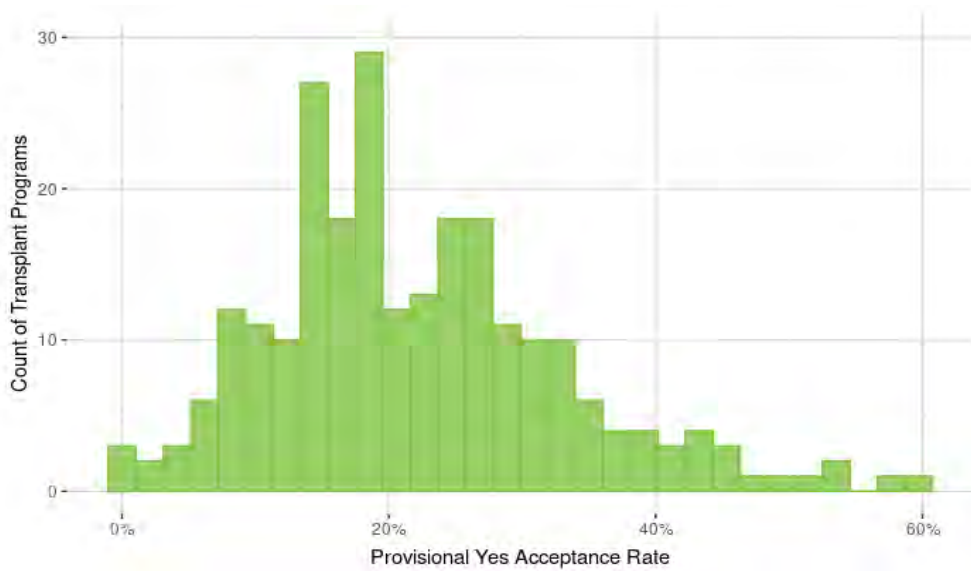
The Provisional Yes Workgroup was tasked with evaluating the provisional yes system by identifying the advantages, disadvantages, and scope of the problem.⁵ The Provisional Yes Workgroup considered current research around acceptance practices and their efficacy in terms of organ placement. The data reviewed at that time are summarized in the following data requests:

Data Request 1: Provisional Yes Acceptance Rate

The first data request used a cohort that considered all match runs with an acceptance from kidney donors that had at least one kidney match run between January 1, 2015 and December 31, 2019. The data request sought to determine both the number of donors for which the program entered a provisional yes response for at least one candidate, and the provisional yes acceptance rate; defined as the percent of these donors for which a program accepted an organ.⁶

The data (**Figure1**) demonstrated that provisional yes acceptance rates for transplant programs were distributed around 20 percent. While there are some programs below 10 percent, there are fewer programs above 40 percent.

Figure 1. Provisional Yes rates for Transplant Program⁷



³ OPTN Policy Oversight Committee. 2020, April 23. Policy Oversight Committee Meeting Summary.

⁴ OPTN Board of Directors. 2019, December 3. Board of Directors, Resolution 12, Meeting Summary.

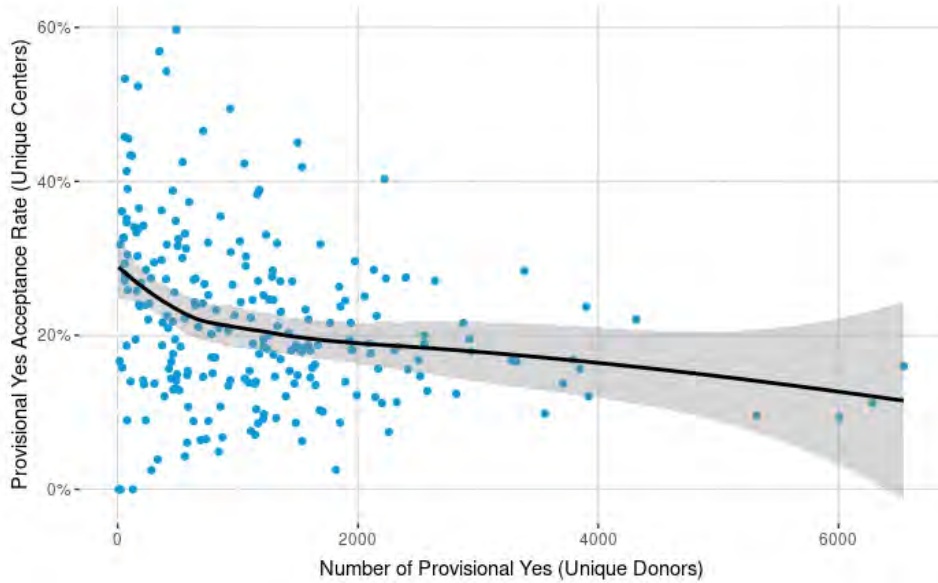
⁵ OPTN Policy Oversight Committee. 2020, May 27. Provisional Yes Workgroup Meeting Summary.

⁶ OPTN Policy Oversight Committee. 2021, September 1. Provisional Yes Workgroup Meeting Summary.

⁷ OPTN Policy Oversight Committee. 2021, September 1. Provisional Yes Workgroup Meeting Summary.

Although larger programs (Number of Provisional Yes > 2000) showed to be more tightly distributed in the 10% to 30% range, there was no clear trend to indicate that smaller-volume programs have different acceptance rates than larger-volume centers (**Figure 2**).

Figure 2. Relationship between Number of Provisional Yes and Provisional Yes Rate⁸



Data Request 2: Organ Procurement Organization (OPO) Notification Analysis

The second data request used a cohort that considered all kidney, liver, and lung match runs with an acceptance for donors that had at least one match run between January 1, 2015 and December 31, 2019. The data compared the number of programs it took to place an organ (“Needed”) versus the number of programs that were electronically notified about the organ (“Notified”), for a given donor. The terms “needed” and “notified” programs within a match run were defined as follows:⁹

- A program is counted as **needed** if there was an electronic notification sent to that program at a sequence number at or before the sequence number of the final acceptor in a match.
- A program is counted as **notified** if an electronic notification was sent to that program at any point in a match. The **difference** is calculated as the number of programs notified minus the number of programs needed.

The data (**Table 1**) showed that the number of centers needed to complete a match run varied by OPO and organ type, with kidney match runs, on average, requiring more centers needed compared to liver or lung. The variability between OPOs was large and presented a strong impact of outliers when looking at the distribution (25th to 75th percentiles) of centers needed.

⁸ OPTN Policy Oversight Committee. 2021, September 1. Provisional Yes Workgroup Meeting Summary.

⁹ OPTN Policy Oversight Committee. 2021, September 1. Provisional Yes Workgroup Meeting Summary.

Table 1. Distribution of Number of Programs Needed until Final Acceptor on Each Match by Organ Type across All OPOs¹⁰

Organ	N. Matches	Centers Needed						
		Mean	Std. Dev.	Min	25%	50%	75%	Max
Kidney	43,914	7.3	13.0	1	2	3	7	177
Liver	38,926	4.6	6.5	1	2	3	5	102
Lung	11,894	4.5	5.3	1	1	2	6	54

This data request also compared the differences (# programs notified - # of programs needed) by organ type and easier- versus harder-to-place status. The terms “easier-to-place” and “harder-to-place” were defined as follows:

- For a given OPO and organ type, we define a match run to be **easier-to-place** if the number of centers needed is less than or equal to the 25th percentile of the number of programs needed across all match runs for that OPO and organ type.
- Similarly, for each OPO and organ type, we define a match run to be **harder-to-place** if the number of programs needed is greater than or equal to the 75th percentile of the number of programs needed across all match runs for that OPO and organ type.

When contrasting easier-to-place versus harder-to-place match runs, the data showed the largest variability in kidney and liver match runs. Easier-to-place livers had a higher difference indicating more programs were notified than was needed relative to harder-to-place liver match runs (**Table 2**). Kidney match runs exhibited the inverse relationship where easier-to-place match runs had a lower average difference suggesting there were fewer additional centers notified. There was little variability for lung match runs.

Table 2. Average Differences (# Programs Notified - # Programs Needed) By Organ Type and Easier- vs Harder-to-place Status¹¹

Organ	Overall		Easier-to-place		Harder-to-place	
	Mean Difference	Standard Deviation	Mean Difference	Standard Deviation	Mean Difference	Standard Deviation
Kidney	6.1	15.2	5.2	13.1	8.1	18.5
Liver	4.1	5.0	4.9	4.6	3.4	5.6
Lung	4.0	4.8	3.9	4.1	3.8	5.1

¹⁰ OPTN Policy Oversight Committee. 2021, September 1. Provisional Yes Workgroup Meeting Summary.

¹¹ OPTN Policy Oversight Committee. 2021, September 1. Provisional Yes Workgroup Meeting Summary.

Provisional Yes Workgroup Recommendation

The Provisional Yes Workgroup discussed and assessed current practices when accepting and responding to organ offers within a provisional yes system and determined there were multiple focus points within the current system that could be improved. There were two project recommendations the group considered related to limiting the number of offers that are sent by OPOs and limiting the number of provisional yes responses that programs can enter.¹² At the time, the Provisional Yes Workgroup determined not to pursue these recommendations due to complexities related to behavioral incentives within the system for both OPOs and transplant programs, and unintended consequences that could result in an increase in inefficiencies.¹³

The group developed the following recommendations that were then taken to the Committee for review and further development:

- **Increase offer filters** – enabling multi-criteria filters for programs to be bypassed on donor offers they do not want to receive.
- **Develop a dynamic match run** – explore the details of active screening with a dynamic match run such as adapting the system to screen off programs whose acceptance criteria would preclude accepting the organ in real-time as new information is entered. Therefore, increasing efficiency and expediting the organ placement process.

Upon receiving the Provisional Yes Workgroup’s assessment, the Committee created a new workgroup to further address the efficiency recommendations and move proposals forward for approval. This workgroup, titled the Match Run Rules Workgroup (“the Workgroup”), is comprised of members from the OPTN Operations and Safety Committee, OPTN Transplant Administrators Committee, OPTN Transplant Coordinators Committee, OPTN Organ Procurement Organization Committee, OPTN Patient Affairs Committee, OPTN Liver and Intestine Transplantation Committee, and the OPTN Membership and Professional Standards Committee (MPSC).

The Workgroup began discussions and outlining of the project in December 2020. In considering the dynamic match run recommendation, the Workgroup started by identifying specific areas within the OPTN Donor Data and Matching System that help guide decision-making and could be improved upon.¹⁴ The Workgroup identified inefficiencies within provisional yes and suggested focusing on redefining provisional yes to standardize processes and the responsibilities of members.¹⁵

Due to the broad nature of the topics, the Workgroup developed a phased approach to this project, with the first phase outlined as follows:¹⁶

- Phase I: Develop framework/standardization of processes
 - Project 1
 - Redefine provisional yes
 - Limit the amount of organ offers sent out to manage offer overburden
 - Determine the appropriate time limits for organ offers
 - Project 2

¹² OPTN Policy Oversight Committee. 2020, October 6. Provisional Yes Workgroup Meeting Summary.

¹³ OPTN Policy Oversight Committee. 2020, October 14. Policy Oversight Committee Meeting Summary.

¹⁴ OPTN Operations and Safety Committee. 2021, February 18. Match Run Rules Workgroup Meeting Summary.

¹⁵ OPTN Operations and Safety Committee. 2021, February 18. Match Run Rules Workgroup Meeting Summary.

¹⁶ OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.

- Optimizing usage of offer filters

For the purposes of this concept paper, the focus will be on Project 1 and the discussions related to the development of the redefining provisional yes project. The Committee’s Optimizing Usage of Offer Filters project (Project 2) is addressed in a separate concept paper that is also available for public comment, titled “Optimizing Usage of Kidney Offer Filters.”

Project Plan

The Workgroup outlined the project’s objective to improve processes to increase the efficiency of the organ offer, review, and acceptance system and reduce overall organ allocation time. The Workgroup’s discussions included:

- Redefining provisional yes and associated member responsibilities
- Reviewing and considering the number of organ offers sent
- Modifying organ offer time limits with system enforcement
- Modifying organ offer notifications

This concept paper details the Workgroup’s discussions related to the organ offer and acceptance system, creating a tiered approach, and formalizing associated member responsibilities. Additionally, the Workgroup discussed other components that could help support efficiency within the organ offer, review, and acceptance system, such as potentially limiting the volume of organ offers, modifying organ offer time limits associated with receiving organ offers, and modifying how the system manages organ offer notifications.

The Workgroup presented the concepts outlined below to the Committee. The Committee voted in support of recommending the concept paper be sent out for public comment.

Progress So Far

The Workgroup began by defining the challenges related to provisional yes that contributed to inefficiencies in the organ offer and acceptance processes. The Workgroup identified the biggest challenge as being cyclical in nature: organ procurement organizations (OPOs) send out organ offers to ensure organ placement, and transplant programs become overwhelmed with the amount of organ offers they receive¹⁷. Transplant programs enter provisional yes in an effort to more appropriately manage the number of offers they receive. OPOs send a high number of offers due to the high number of provisional yes responses, which do not result in final acceptance (as shown in **Figure 1**). Thus, these two factors compound each other and result in provisional yes not serving the system in the intent it was established.¹⁸

The Workgroup also discussed the variations of informal definitions and expectations of provisional yes across transplant programs. This variation in practice, with few formal expectations outlined within OPTN policy, results in provisional yes entries that hold no obligation or responsibility for transplant programs¹⁹.

¹⁷ OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.

¹⁸ OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.

¹⁹ OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.

After much discussion, a three-tiered approach was developed with associated requirements for transplant programs. Rather than a simple, single provisional yes response, with no associated responsibilities, each tier would represent the various stages of communication and responsibilities necessary between OPOs and transplant programs within the organ offer process.²⁰ The Workgroup discussed the various changes that occur over the course of organ allocation and suggested different expectations be considered for offers that are sent prior to recovery and post recovery.²¹ The Committee asks for feedback on those requirements.

The Workgroup reviewed the results of the previously summarized Provisional Yes Workgroup data request.²² Upon their review, the Workgroup discussed the variation among transplant programs with regards to who reviews and responds to the organ offers. They noted that in some cases, it may be responses directly from transplant program staff, and in other cases, business (third party) contractors. The discussions reviewed how this variation could be attributed to the number of declines observed throughout allocation.²³

The Workgroup modified the data request to look at the difference in provisional yes to no (refusal) conversion rates based on if the initial responder is part of the transplant program or contracted from a third-party contractor. Additionally, the Workgroup wanted to evaluate if time of day had an impact on provisional yes usage. The Workgroup developed a modeling request that applied the following modifications to all three of the previously summarized Provisional Yes Workgroup data requests:²⁴

1. Provisional yes to acceptance conversion rates,
2. Number of transplant programs notified, and
3. Provisional yes conversion rates by transplant program affiliation:
 - a. Do not exclude offers after the final acceptor. Include any offer with a response from the transplant program (provisional yes, acceptance, or decline)
 - b. Do not obscure organ procurement organization (OPO) codes
 - c. Stratify results by day/night to assess if time of day has an impact on provisional yes usage
 - d. Cohort: organ-specific. Use a pre/post circles policy cohort for each organ

The results of the modified data request were reviewed by the Workgroup and are summarized below.

Figure 3 shows the provisional yes (PY) to no (N) conversion rate ranges between 68 – 78 percent across organ types, with the exception of Intestine, which is likely due to a small sample size.

²⁰ OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.

²¹ OPTN Operations and Safety Committee. 2022, May 19. Match Run Rules Workgroup Meeting Summary.

²² OPTN Operations and Safety Committee. 2021, August 19. Match Run Rules Workgroup Meeting Summary.

²³ OPTN Operations and Safety Committee. 2022, January 20. Match Run Rules Workgroup Meeting Summary.

²⁴ OPTN Operations and Safety Committee. 2022, January 20. Match Run Rules Workgroup Meeting Summary.

Figure 3. PY to N Conversion Rates by Initial Responder Type



In evaluating the PY to N conversion rates by organ offer acceptance status, **Figure 4** shows that although the absolute conversion rates vary based on the offer position in the match (e.g. before or after the final acceptance), the trends between personnel from the transplant program versus personnel from the third party contractors were consistent.

Figure 4. PY to N Conversion Rates by Organ Offer Acceptance Status²⁵

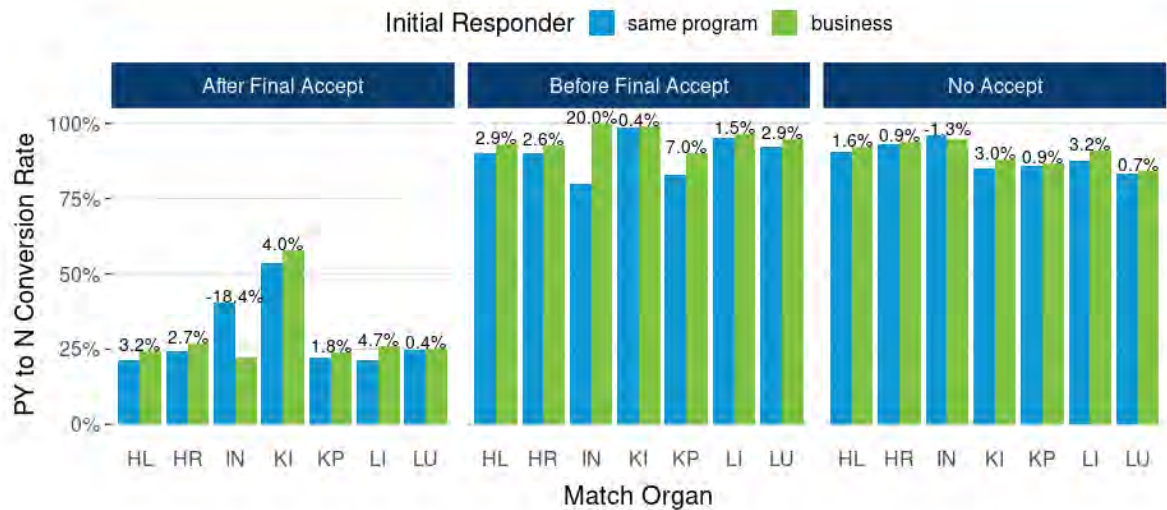
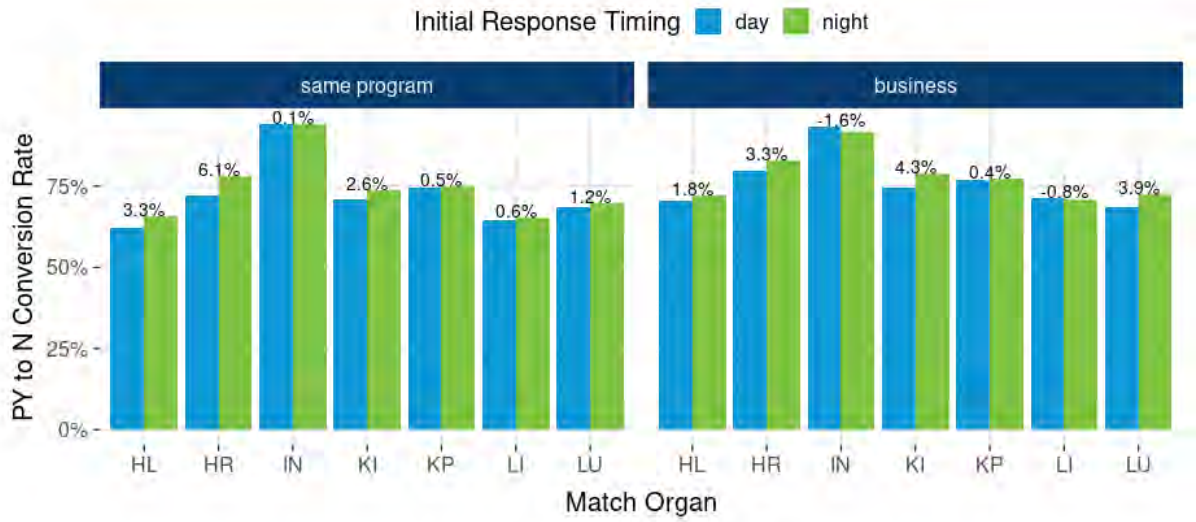


Figure 5 shows a slight increase in provisional yes to refusal conversion rate from day to night.

²⁵ OPTN Operations and Safety Committee. 2022, April 21. Match Run Rules Workgroup Meeting Summary.

Figure 5. PY to N Conversion Rates by Timing (Day vs Night) of the Initial Response²⁶



In looking at PY to N conversion rates pre- and post-removal of donation service areas (DSA) as the primary geographical boundary, the PY to N conversion rates were observed to be higher post-removal of DSA as seen in **Figure 6**.

Figure 6. Program PY to N Conversion Rates by Era²⁷



The Workgroup concluded that these results supported their previous discussions on the inefficiencies observed in the usage of Provisional Yes.²⁸

²⁶ OPTN Operations and Safety Committee. 2022, April 21. Match Run Rules Workgroup Meeting Summary.

²⁷ OPTN Operations and Safety Committee. 2022, April 21. Match Run Rules Workgroup Meeting Summary.

²⁸ OPTN Operations and Safety Committee. 2022, April 21. Match Run Rules Workgroup Meeting Summary.

The Workgroup developed a tiered approach to refine the organ offer, review, and acceptance system.²⁹ The Workgroup also discussed on the need to outline and define specific requirements of transplant programs within policy to help standardize organ offer and acceptance practices and develop a system that promotes accountability among programs.³⁰ The framework and the associated requirements are outlined in further detail in the next section.

Tiered Framework

A three-tiered approach would eliminate provisional yes and instead provide a framework that would reflect the responsibilities of transplant programs within each step of the organ offer, review, and acceptance system. Within each tier, transplant programs would need to complete outlined requirements before advancing to the next tier in the organ evaluation process. As a transplant program advances to each tier, requirements would become more rigorous as a program nears closer to the final acceptance of an organ.³¹ In contrast, the Workgroup also discussed and acknowledged that the suggested time requirements for organ offer evaluation and OPO organ offer limits (the number of offers that can be sent at a given time) would need to be addressed. This would be necessary to manage transplant program burden and efficiency when managing organ offers. It is of note that the tiered framework and associated program expectations are conceptual in nature. The Committee seeks feedback from the community on the suggested thresholds outlined below.

Figure 7 outlines the idea of the three-tiered approach with potential associated responsibilities. Each tier, by order of phase (when the initial offer is sent (Tier III) to when the evaluation process is complete and the transplant program is assigned a primary and/or back up offer (Tier I) and a final decision on acceptance or refusal of offer is needed), are outlined in further detail below.

²⁹ OPTN Operations and Safety Committee. 2021, October 15. OPTN Operations and Safety Committee Meeting Summary.

³⁰ OPTN Operations and Safety Committee. 2021, March 18. Match Run Rules Workgroup Meeting Summary.

³¹ OPTN Operations and Safety Committee. 2021, November 18. Match Run Rules Workgroup Meeting Summary.

Figure 7. Tiered Framework and Program Expectations

Tier III	Tier II	Tier I
Transplant programs evaluate organ offers to see if the offer immediately meets any of their program’s refusal reasons	Transplant programs evaluate organ offers to see if the offer immediately meets any of their program’s refusal reasons	Transplant programs evaluate organ offers to see if the offer immediately meets any of their program’s refusal reasons
	Transplant programs assess candidate’s medical suitability	Transplant programs assess candidate’s medical suitability
	Transplant programs notify OPOs of any additional information needed for testing or evaluation	Transplant programs notify OPOs of any additional information needed for testing or evaluation
		Transplant programs assess histocompatibility
		Transplant programs confirm candidate availability for transplant

Tier III

Tier III refers to a transplant program’s initial review of an organ offer. Transplant programs will review and determine if an offer immediately meets any of their internal refusal reasons. The Workgroup acknowledged the need to streamline communications within the system to limit the amount of notifications transplant programs receive and in an attempt to address this, the Workgroup discussed Tier III be based on communications within the match run to notify a transplant program of an offer when they reach a certain point on the match run. The match run would not be inundated with provisional yes entries because there would also be minimum responsibilities on all transplant programs receiving Tier III offers. This would limit notifications only to those transplant programs that fall within this threshold to receive an organ offer and provide a response for their candidates at a program level.³² The Workgroup discussed the potential of allowing programs to evaluate and provide a response for other candidates within their program that immediately meets any of their program’s refusal reasons. This would not make any changes within the match run, but instead, limit the number of notifications received by a program on the same offer they have already responded to in an effort to get the offer to a program that would be more likely to accept the offer. The Workgroup will continue to discuss the logistics of how this may be operationalized. The Committee seeks feedback from the community regarding the number of Tier III notifications that could be sent down a match run, before an offer to a program too far down the match becomes unnecessary.

³² OPTN Operations and Safety Committee. 2022, May 19. Match Run Rules Workgroup Meeting Summary.

The Workgroup acknowledges the potential complexity of accurately defining each tier as organ placement progresses and transplant programs decline offers. The Workgroup also discussed and acknowledged that the suggested time and organ offer limits within Tiers I and II (further described below) may need to vary by organ type and quality, which also could result in significant complexity.

Tier II

Tier II refers to the review/evaluation of the organ offer. The transplant program will review the organ offer per the outlined Tier II requirements and must notify the host OPO of any additional information needed to inform the program's decision on an organ offer.

The Workgroup discussed that the time limit for review and acceptance of organ offers should mirror current policy, giving the transplant program for the initial primary potential transplant recipient one hour to respond to the host OPO with an organ offer acceptance or organ offer refusal. All subsequent offers would allow 30 minutes to respond to the host OPO with an organ offer acceptance or organ offer refusal.^{33 34}

Additionally, the Workgroup discussed that within Tier II, one offer would be sent out for each available organ, resulting in additional back up organ offers to be prepared in the case of a Tier I offer refusal. For situations in which two organs can be offered, such as kidney or lung, the Workgroup agreed that there would be an offer for each organ within a set (totaling two offers).³⁵

The Workgroup acknowledged consideration for time limit on offers and organ offer limits may differ for organ offers sent pre-recovery versus post-recovery. The Workgroup discussed the need to potentially increase the limit of organ offers sent within Tier I and Tier II if an organ offer is sent post-recovery due to the concern of ischemic time and inability to place the organ under the outlined time limits.³⁶

Tier I

Tier I refers to the transplant program finalizing their organ evaluation requirements, receiving a primary or first back up offer for a specific candidate, and providing a final response to the organ offer (acceptance or refusal). The Workgroup discussed that the time limit for review and acceptance of organ offers should mirror current policy, which gives the transplant program for the initial primary potential transplant recipient one hour to respond to the host OPO with an organ offer acceptance or organ offer refusal. All subsequent offers would be given 30 minutes to respond to the host OPO with an organ offer acceptance or organ offer refusal (this would also include those programs that move from Tier II to Tier I).^{37, 38}

Additionally, the Workgroup discussed that within Tier I, there should be one offer sent out for each organ for primary and back up offers. For situations in which two organs can be offered, such as kidney

³³ OPTN Operations and Safety Committee. 2022, May 19. Match Run Rules Workgroup Meeting Summary.

³⁴ OPTN Policy 5.6.B: *Time Limit for Review and Acceptance of Organ Offers*.

³⁵ OPTN Operations and Safety Committee. 2022, May 19. Match Run Rules Workgroup Meeting Summary.

³⁶ OPTN Operations and Safety Committee. 2022, May 19. Match Run Rules Workgroup Meeting Summary.

³⁷ OPTN Operations and Safety Committee. 2022, May 19. Match Run Rules Workgroup Meeting Summary.

³⁸ OPTN Policy 5.6.B: *Time Limit for Review and Acceptance of Organ Offers*.

or lung, the Workgroup agreed that there would be an offer for each organ within a set (totaling two offers).³⁹

Transplant Program Requirements

During the Workgroup’s discussions, there was agreement on the need to potentially define or outline specific expectations of members within policy to help standardize and develop a system that promotes accountability among programs.⁴⁰ Transplant programs would have associated responsibilities within each tier of the tiered framework.

As mentioned in the previous section, the Workgroup agreed that there should be a level of reasonable requirements outlined for transplant programs within each tier. These requirements would need to be completed in order to advance to the next tier. Transplant programs in Tier III will have associated responsibilities as well, although fewer than Tier I and Tier II. Those requirements, by order of phase (when the initial offer is sent (Tier III) to when the evaluation process is complete and the transplant program is assigned a primary and/or back up offer (Tier I) and a final decision on acceptance or refusal of offer is needed), are outlined below. The requirements outlined are not limited to any additional review or evaluation efforts the transplant programs wish to perform.

Initial Review of the Organ Offer (Tier III Requirements)

Transplant programs evaluate organ offers to see if the offer immediately meets any of their program’s refusal reasons

A central responsibility of organ offer review, regardless of tier or place on the match, is for transplant programs to analyze whether the offer immediately meets any of the transplant program’s refusal reasons or “rule-out criteria.” The Workgroup emphasizes this initial review of refusal reasons is integral to efficient organ review and acceptance processes.

When a transplant program initially receives the organ offer in Tier III, the transplant program must evaluate deceased donor organ offers for program-specific absolute refusal criteria. This information includes, but is not limited to:

- An assessment of *all* donor information included in *Policy 2.11 Required Deceased Donor Information*, as well as
- Organ-specific information contained within *Policy 2.11.A Required Information for Deceased Kidney Donors*, *Policy 2.11.B Required Information for Deceased Liver Donors*, *Policy 2.11.C Required Information for Deceased Heart Donors*, *Policy 2.11.D Required Information for Deceased Lung Donors*, *Policy 2.11.E Required Information for Deceased Pancreas Donors*

The transplant program would be expected to provide a response indicating their interest in the offer or refusal of the offer. The Workgroup acknowledges the benefit of offer filters as this tool would help with this requirement by allowing transplant programs to apply program-specific, custom-designed, multi-criteria filters to filter out donor offers that they do not want to receive.⁴¹ Currently, offer filters are of voluntary use. The Committee is currently working on a project that will consider mandatory usage of offer filters and is further detailed in a separate concept paper that is out for public comment. Increased

³⁹ OPTN Operations and Safety Committee. 2022, May 19. Match Run Rules Workgroup Meeting Summary.

⁴⁰ March 18, 2021 OPTN Operations and Safety Committee Match Run Rules Workgroup, meeting summary.

⁴¹ Finnie, J. & Moriarty, S. “Better organ offer screening”, <https://unos.org/news/innovation/reducing-unwanted-organ-offers/>.

usage of offer filters may decrease the need for transplant programs to have to evaluate their program's refusal reasons or "rule-out" criteria altogether, as they would not be inundated with offers they know their program would not accept.

Review/Evaluation of the Organ Offer (Tier II Requirements)

In addition to the Tier III requirement as outlined above, a Tier II transplant program must also complete the following requirements:

Transplant programs assess candidate's medical suitability

Once the transplant program enters Tier II, the transplant program must assess and confirm the medical suitability of the candidate for the offered organ. The Workgroup discussed and agreed on the importance of identifying a decision-maker to help in the evaluation process.⁴² The Workgroup discussed that the candidate's medical suitability should be confirmed by a qualified physician and includes, but is not limited to:

- Blood type
- Blood subtype, when used for allocation
- Donor height
- Donor weight
- Infectious disease test results
- For HIV positive deceased donors, the OPO and transplant hospital must also:
 - Verify that the potential recipient is registered as an HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.7.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs*
 - Meet the requirements in *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*

Transplant programs notify OPOs of any additional information needed for testing or evaluation

The Workgroup discussed challenges that may be faced if there is a lack of information. Various nuances within the evaluation process lead to an increased workload for transplant programs. Additionally, the Workgroup discussed the importance of transparency among OPOs and transplant programs.⁴³ Upon reviewing the organ offer, transplant programs must report to the OPOs any additional information needed to help the transplant program make an informed decision on the organ offer.

Final Review and Decision on Organ Offer (Tier I Requirements)

Tier I would include the completion of all requirements as outlined above for Tier II and Tier III and the following two additional requirements:

Transplant programs assess histocompatibility

⁴² OPTN Operations and Safety Committee. 2021, November 18. Match Run Rules Workgroup Meeting Summary.

⁴³ OPTN Operations and Safety Committee. 2021, August 19. Match Run Rules Workgroup Meeting Summary.

The transplant program would be expected to assess and confirm the suitability of the candidate's and deceased donor's histocompatibility. This information must be confirmed by a qualified physician.⁴⁴

The Workgroup asserts that assessing histocompatibility is important for the efficiency of the organ offer and acceptance practices and acknowledges differences in this assessment based on the donor organ being offered.⁴⁵ The Committee does not seek to dictate specific steps that transplant programs must take, but seeks to emphasize that assessment of histocompatibility is important for transplant candidates who are sensitized, or who have had a sensitizing event. The Workgroup discussed considerations in OPOs sending specimen samples to transplant programs to perform a cross match, but acknowledge that this may not always be feasible for OPOs to do.⁴⁶ The Committee has discussed some considerations needed for histocompatibility assessment, such as virtual crossmatching, but requests further input to understand the associated workload and ensure the feasibility of such a responsibility. Additionally, the Committee seeks to understand when it is practicable for OPOs to send specimens to requesting transplant programs.⁴⁷

Transplant programs confirm candidate availability for transplant

In addition to confirming candidate availability, the transplant program should ensure the candidate is medically suitable for transplant surgery, including an assessment of the individual's medical record.

The Workgroup has discussed in depth the various aspects of requiring transplant programs to confirm a transplant candidate's availability. For example, the Workgroup felt that transplant programs should not confirm candidate availability until they enter Tier I and are a primary or back up offer.⁴⁸ Some considerations regarding candidate availability are as follows:⁴⁹

- Can the transplant candidate get to the hospital?
- How far away is the candidate from the hospital?
- Is the transplant candidate already admitted to the hospital?

The Workgroup specifically seeks feedback from the patient community in order to ensure the appropriateness of establishing a formal expectation such as this.

Additional Considerations

OPO Requirements

The Committee understands that with the tiered framework and associated requirements of transplant programs, this would also require a re-evaluation of current OPO requirements. The Committee asks for feedback on the requirements of OPOs within the tiered framework:

Transparency within the Match Run

The Workgroup discussed potential functionalities within the match run that could help provide transparency between transplant programs and OPOs. The Workgroup discussed challenges transplant

⁴⁴ OPTN Operations and Safety Committee. 2021, November 18. Match Run Rules Workgroup Meeting Summary.

⁴⁵ OPTN Operations and Safety Committee. 2021, August 19. Match Run Rules Workgroup Meeting Summary.

⁴⁶ OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.

⁴⁷ OPTN Operations and Safety Committee. 2021, November 18. Match Run Rules Workgroup Meeting Summary.

⁴⁸ OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.

⁴⁹ OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.

programs may face in adequately assessing organ offers due to a need for additional information from the OPO. The Workgroup suggested that within the tiered framework, there would be the ability for transplant programs to communicate within the system what additional information is needed by the OPO to help complete the organ offer evaluation and ultimately come to an informed decision on the offer.⁵⁰ The Workgroup has discussed this potentially being a chat feature or notification field within the system, but continues to discuss how this may be operationalized.

The Workgroup also suggested allowing transplant programs the ability to view what sequence they fall in on the match run related to the sequencing of transplant programs. The Workgroup discussed how this capability could provide valuable information, for example, if a transplant program declines an offer for one candidate due to quality, that program most likely would decline for all candidates within their program. Currently, there is a feature on the mobile platform for the OPTN Donor Data and Matching System that allows transplant programs to view the sequencing of candidates and transplant programs. The Workgroup suggested expanding this feature to the desktop application.⁵¹

Additionally, the Workgroup discussed an additional feature within the OPTN Donor Data and Matching System that would alert programs on specific match runs if there is a multi-organ transplant priority. It was further explained that the first candidate on the match run is not necessarily the first due to multi-organ transplant considerations. This enhancement could help provide transparency for transplant programs.⁵² The Committee asks for any additional input on tools that should be considered and could potentially help facilitate the tiered framework.

Re-evaluating definitions related to provisional yes

The Workgroup reviewed and discussed current definitions in OPTN policy related to organ offer, review, and acceptances. With the development of the tiered framework, the Workgroup acknowledged that provisional yes would no longer be relevant and therefore discussed the removal of this term. The Committee asks for additional feedback on these suggested definitions:

Initial notification – OPO notification to transplant program of a candidate. This could refer to any of the tiers where a program receives its initial notification for an organ offer.

Back-up notification – OPO notification to transplant program candidate in preparation for a potential primary offer. This notification is specific to Tier II offers and Tier I back up offers.

Back-up acceptance – Transplant program has evaluated the offer and assessed the candidate’s medical suitability (Tier II). Additionally, for Tier I back up acceptance, a transplant program has assessed histocompatibility and confirmed the candidate’s availability for transplant. In both Tier I and Tier II. Transplant programs are to notify OPOs of any additional information needed in their evaluation process of the organ offer(s).

Primary offer notification – OPO notification to transplant program candidate of primary offer.

⁵⁰ OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.

⁵¹ OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.

⁵² OPTN Operations and Safety Committee. 2021, July 29. Match Run Rules Workgroup Meeting Summary.

Primary offer acceptance – Transplant program has assessed initial histocompatibility and has confirmed candidate availability and suitability. An accepted primary offer is an agreement between the OPO and the transplant program of the organ acceptance, pending review of organ anatomy (and cross match, if applicable). This would be specific to Tier I offers.

NOTA and Final Rule Analysis

The Committee submits the following concept paper under the authority of the National Organ Transplantation Act, which states, “The Organ Procurement and Transplantation Network shall... (A) establish... (ii) a national system... to match organs and individuals included in the list...”⁵³, and the OPTN Final Rule, which states, “A transplant program shall either accept or refuse the offered organ for the designated potential recipient within such time as the OPTN may prescribe.”⁵⁴ This concept paper describes how the OPTN is considering developing policies that may prescribe the time and manner in which a transplant program must respond to an organ offer using the OPTN computer system.

Conclusion

The Committee agrees that the standardization of provisional yes offers is essential in increasing efficiency and expediting the organ placement process. The Committee will continue its work to develop a process that will be both transparent and efficient while also outlining and defining the roles and responsibilities of transplant programs and OPOs.

Considerations for the Community

In addition to the specific questions below, the Committee asks for feedback on all aspects of the framework presented as well as any additional considerations to help inform the Committee in the development of a future policy proposal.

Tiered Framework

- What should happen if the first program refuses the organ offer (in Tier I)?
- What information should OPOs be required to complete for a Tier III offer evaluation?
- Are there tools that should be considered that could help facilitate this three-tiered model?

Associated Requirements within Tiers

- Are the requirements within each tier reasonable?
- Should OPOs limit offers based on tiers? Should this be based on the number of organ offer responses that are confirmed?
- Should there be expectations outlined that are specific to offers sent pre- and post-recovery?

Tier Thresholds (number of offers sent)

- Do you agree with the recommended thresholds for each tier?
- What threshold should be considered for Tier III for when should a program receive the initial notification?

⁵³ 42 USC §274(b)(2)(A)(ii)

⁵⁴ 42 C.F.R. §121.7(b)(4)

Time Limit on Offers

- Do you agree with the recommendations on time limits on offers for Tier I and Tier II?
- Should there be different considerations for offers sent pre- and post-recovery? If so, what should those considerations be?
- Should there be a time limit for Tier III to respond to a notification on an organ offer?