Expedited Placement Protocol Proposal

Accelerated Placement of Hard-to-Place Kidneys

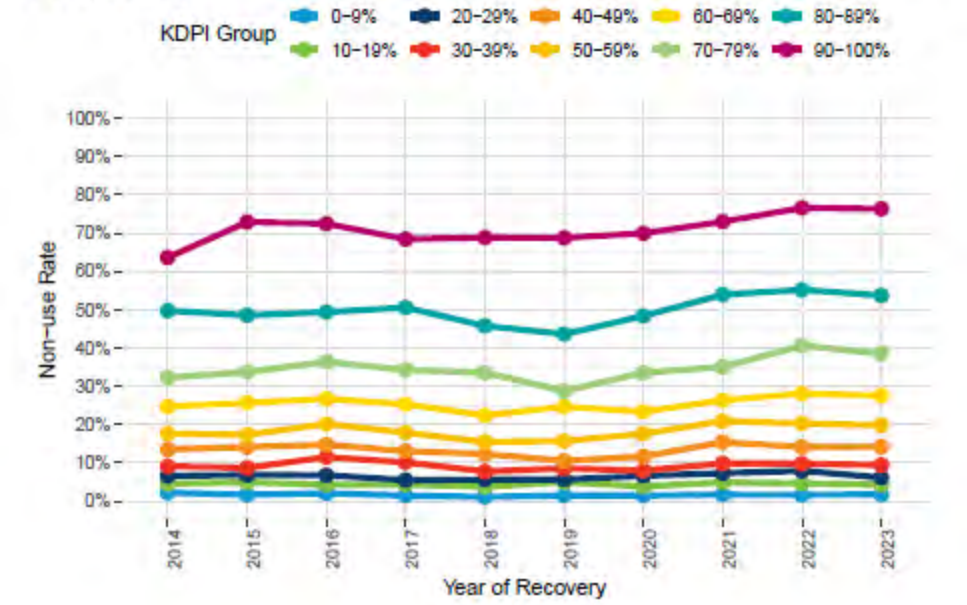
Submitting Organization/Individual: *OPTN Expeditious Task Force Rescue Pathways Work Group*
Public Feedback Period: *May 15, 2024 – May 30, 2024*

Background

The OPTN Kidney Committee developed a comprehensive report on deceased donor kidney non-use[1] that was shared with and reviewed by the Expeditious Task Force. KDPI 86-100% kidneys are widely recognized as more marginal kidneys and have the highest deceased donor kidney non-use rate. In 2023, 3,869 (71.9%) KDPI 86-100% kidneys were recovered for transplant and not used. However, high rates of non-use are not exclusive to the 86-100% kidneys. Breaking out 2023 non-use rates by deciles, KDPI 90-100% kidneys had highest non-use rate (76.3%) followed by KDPI 80-90% KDPI kidneys (53.7%) and finally KDPI 70-80% kidneys (38.5%). Figure 3 in the OPTN Kidney Committee data request shows a drop off in the non-use rate for KDPI <70% kidneys that falls in line with national non-use rate of 27%, or lower. Compared to the national 2023 non-use rate of 27%, it's clear that KDPI 70%+ kidneys are harder to place. These data helped drive the Expeditious Task Force Expedited Placement Work Group's decision to develop a protocol to expedite KDPI 75%+ kidneys, because the Work Group wanted to design a protocol that limited eligible organs to those at the greatest risk for non-use

[1] OPTN Kidney Committee. Hard to Place Kidneys Data Request, February 1 2024, Pages 15-21.

Figure 3: Non-use Rate of Deceased Donor Kidneys Recovered in the United States by Recovery Year and KDPI Deciles



Overview of Protocol

This pre cross clamp placement of KDPI 75-100% kidneys PDSA will pair participating Organ Procurement Organizations (OPOs) with a number of kidney transplant programs who have agreed to utilize a number of >75% KDPI kidneys. The goal is to offer kidneys with as little cold ischemic time as possible to patients ready and willing to accept >75% KDPI kidneys. Additionally, the Work Group designed the protocol to protect the ability of the highest priority candidates to receive these offers and to provide an opportunity for kidney transplant programs that do not routinely accept >75% KDPI kidneys to increase their acceptance and provide additional opportunities for patients at those programs.

Selecting OPO and Transplant Program Participants

This protocol will include no more than five OPO participants who will be selected by the Rescue Pathways Workgroup with the goal of balancing factors including geographic location and population density. The Rescue Pathways Workgroup will work with each participating OPO to identify a unique list of kidney transplant programs willing to participate in the protocol and to be paired with the OPO. These programs will be known as the OPO's "Target List". The Target List will not be based on a single transplant program characteristic. Instead, each Target List should include kidney transplant programs with reasonable travel arrangements, when factoring in the transportation modalities used in the area and acceptable pump times, to minimize cold ischemic time. Because the protocol aims to test whether kidney transplant program acceptance for KDPI 75+ offers improves with a reduction in cold ischemic time, each Target List should also include at least one kidney transplant program that does not have a history of frequently accepting KDPI 75+ offers. The size of each OPO's Target List and the location of the Target List programs in relation to the OPO may vary.

Length of the Protocol

As required by OPTN Policy 5.4.G Open Variance for Expedited Placement, the protocol will run for no more than 6 months, unless amended by the OPTN Executive Committee, and the protocol will expire if any of the specific conditions for monitoring metrics outlined in OPTN Policy 5.4.G Open Variance for Expedited Placement occur.

The protocol will run for at least 60 days. The Rescue Pathways Workgroup will determine whether to continue the protocol after 60 days based on the amount of data available and feedback from participating OPOs and kidney transplant programs.

Executing the Protocol

Participating OPOs may not use this protocol to offer kidneys from any pediatric donors. Participating OPOs must first make offers to candidates falling in the specified high priority classifications outlined below, including to pediatric candidates.

Before cross clamp, the OPO must first offer Kidneys from Deceased Donors with KDPI scores greater than 75% through high priority classifications 1-26 in OPTN *Policy 8.4.K Allocation of Kidneys from Deceased Donors with KDPI scores Greater than or Equal to 35% but Less than or Equal to 85%* (Sequence C), which includes high CPRA, 0-ABDR, mismatch, medically urgent, and safety net candidates. Kidneys from Deceased Donors with KDPI Scores Greater than 85% must be offered through high priority classifications 1-19 according to OPTN *Policy 8.4.L Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%* (Sequence D), which also includes high CPRA, 0-ABDR, mismatch, medically urgent, and safety net candidates.

No less than two hours before operating room (OR) time, the OPO will notify the Target List programs of the donor. The notification can be made using the modality the OPO and programs deem most efficient (examples include email, text, or third-party notification system). This Target List notification may be done in parallel with the high priority classification system notices. These Target List notifications are considered back up offers.

After cross clamp, the OPO will notify the Target List programs with anatomy and biopsy results, as appropriate. The Target List programs will then have 30 minutes to submit two potential transplant recipients listed on the match run who are suitable for and ready for transplant. Once the OPO completes allocation through the high priority classifications specified above, the OPO will allocate to the list of potential transplant candidates submitted by the Target List programs, based on sequence number. The Target List program will have 30 minutes to indicate final acceptance. The OPO will track notifications times throughout the process and submit this information to the OPTN contractor.

Protocol allocation is considered ended if there are no Target List potential transplant recipients submitted, or all high priority classification offers, and all submitted Target List potential transplant recipients decline the offer.

OPO and Transplant Program Responsibilities

Participating transplant programs will be expected to:

- set a goal to transplant a certain percentage of offers received through the protocol,
- actively identify and support patients likely to receive offers to promote transplant readiness,
- expeditiously evaluate pre-cross clamp notifications from the OPO and identify no more than two potential transplant candidates suitable and ready for transplant,
- quickly review and accept kidneys offers after final receipt of all recovery information,
- participate in meetings at least once per month to review the results of the protocol, and
- report information to OPOs and the OPTN contractor as required, including:
    - consistent with the OPTN Final Rule, any time the program transplants an organ allocated through the protocol into a candidate other than the one to whom the organ was allocated to avoid organ wastage.

Participating OPOs will be expected to:

- provide consistent donor and organ information,
- develop plans to promote direct and expeditious communication with participating transplant programs,
- develop plans to expeditiously transport kidneys to the participating programs,
- participate in meetings at least once per month review the results of the protocol, and
- report information to the OPTN contractor including but not limited to:
    - the date, time, and match run when they initiate the protocol,
    - the outcome of each attempt (no recipient identified, recipient identified but not transplanted, recipient identified and transplanted),
    - the list of potential transplant recipients submitted for each donor by the Target List of patients suitable and ready for transplant,
    - the modality of communication between the OPO and transplant programs for donor notification and offer notification, and
    - the timing of the donor notification and offer notification.

NOTA and Final Rule Analysis

The Taskforce submits this protocol for consideration under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the OPTN to "establish…medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria."[2] The OPTN Final Rule states the OPTN "shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[3] The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement; … (8) Shall not be based on the candidate's

[2] 42 U.S.C. § 274(b)(2)(B).
[3] 42 C.F.R. § 121.4(a)(1).

place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."[4]

This protocol aligns with 42 CFR 121.8(g) which sets standards for OPTN variances. As explained above, this variance includes a research and analysis plan, includes relevant data collection, and is time limited. Additionally, this protocol:

- **Is based on sound medical judgement**[5] because the thresholds were set after an evaluation of drop off the non-use rate of kidneys for different KDPIs.
- **Seeks to achieve the best use of donated organs**[6] and is **designed to avoid wasting organs**[7] by seeking to increase the utilization of kidneys at high risk of non-utilization.
- **Promotes the efficient management of organ placement**[8] by seeking to offer kidneys at a high risk of non-utilization to programs and candidates more likely to benefit from those offers.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[9] and this protocol is specific to kidneys.[10]

Although the protocol outlined above addresses certain aspects of the Final Rule listed above, the Taskforce does not expect impacts on the following aspects of the Final Rule:

- Is designed to avoid futile transplants[11]
- Is designed to … promote patient access to transplantation[12]

[4] 42 C.F.R. § 121.8(a).
[5] 42 C.F.R. § 121.8(a)(1).
[6] 42 C.F.R. § 121.8(a)(2).
[7] 42 C.F.R. § 121.8(a)(5).
[8] Id.
[9] 42 C.F.R. § 121.8(a)(3).
[10] 42 C.F.R. § 121.8(a)(4).
[11] Id.
[12] Id.

High Level Monitoring Plan:

Two types of monitoring will accompany the protocol:

Stopping Rules

Short report examining proportion of transplants to females, non-white and pediatric candidates among participating OPOs per policy 5.4.G

- **Timing:** Weekly
- **Posting** to TF Sharepoint site
- **Subgroup of TF expedited placement WG will regularly Review** and provide recommendations to Excomm

Protocol Specific Reporting

In-depth monitoring of the success and potential unintended consequences of each protocol

- **Timing:** Every other week for 2 months and monthly after
- **Posting:**
  - TF, KI, OPO Sharepoint sites
  - Presented to committees upon request
  - Monthly monitoring report posted to OPTN website
- **Subgroup of TF expedited placement WG will regularly review** and provide recommendations to Excomm

Protocol Specific Monitoring Plan:

Research Questions:

1. How often is the expedited placement protocol used?
2. What is the impact of the protocol on system efficiency, particularly non-use?
3. Were there any impacts to equity in access to transplant?

What will be monitored?

- Metrics will be broken into 4 sections:
  - (1) National metrics (involving all OPOs, not just those in the protocol)
  - Protocol specific metrics (among participating OPOs and TXHs)
    - (2) Usage of the protocol
    - (3) Impacts on Efficiency
    - (4) Impacts on Equity
- Monitoring metrics will be shown for each participating OPO and transplant hospital (TXH), as appropriate, and in aggregate. Therefore, OPOs and TXHs participating in the protocol will be identified in the monitoring report.
- All metrics will be calculated and shown for the subset of kidneys that qualify for expedited placement under the protocol (here, 75-100 KDPI kidneys)
- All metrics are pending sufficient sample size

National Metrics (these metrics will be for all OPOs in and not included in the protocol)	
N/% KDPI 75-100 KI alone transplants overall and by • Age (ped/adult) • CPRA • Race/ethnicity • Sex • Qualifying time • ABO	*How did the protocol impact these subpopulations? Was there any impact on their access to transplant?*
N/% KDPI 75-100 KI alone transplants inside/outside 250NM circle	*Did the protocol improve efficiency by allocating organs closer to the donor hospital?*
Distribution of KDPI 75-100 KI alone transplants by distance	*Did the protocol improve efficiency by allocating organs closer to the donor hospital?*
National non-use rate among KDPI 75-100 KIs	*Did the protocol reduce the national non-use rate?*
Median cold ischemic time among KDPI 75-100 KI alone transplants	*Did the protocol reduce national CIT?*
Protocol Specific Metrics (among participating OPOs)	
Protocol usage among organs eligible for protocols (only for post implementation)	
N/% KDPI 75-100 KIs where protocol expedited placement was attempted	*For how many KIs 75-100 KDPI, was expedited placement attempted?*
N/% KIs where protocol expedited placement resulted in final acceptance	*How many organs were successfully placed through protocol?*
N/% organs where protocol expedited placement resulted in transplant overall and by: • DCD • Uncontrolled DCD • Pumping • NRP*	*Were organs placed but not accepted? i.e. did the protocol solve one problem but exacerbate another (late declines)*
Distribution of KDPI for KIs where protocol expedited placement occurred among KDPI 75-100 KIs eligible for protocol	*Are OPOs only attempting expedited placement for a*

	subset of eligible organs?
N/% transplanted protocol expedited KIs by KDPI (75-80,80-85,85-90,90-95,95-100)	*Is the protocol more successful among a subset of eligible organs?*
N/% of protocol expedited match runs where non-protocol specific expedited placement bypass codes (861,862,863, 799) were also used	*Are OPOs mixing protocol specific and non-protocol expedited placement?*
Impact on Efficiency Metrics will compare OPOs in and not in the protocol in addition to pre and post comparison for OPOs in the protocol	
Number of TXHs electronically notified on expedited protocol specific versus non expedited matches	*Does the expedited protocol reduce offer burden?*
Number of candidates electronically notified on expedited protocol specific versus non expedited matches	*Does the expedited protocol reduce offer burden?*
N/% organs AOOS (via bypass codes 861, 862, 863 and 799) through non-approved protocols	*Does the protocol reduce AOOS not approved under the protocol?*
Non-use rate and number of non-used kidneys overall and by • DCD • Uncontrolled DCD • Pumping • NRP*	*Did the protocol reduce non-use?*
Cold ischemic time at transplant for transplanted organs	*Did the protocol reduce cold ischemic time?*
Time from first electronic offer to final acceptance	*Did the protocol reduce the amount of time it takes to place an organ?*
Impact on Equity Recipients of protocol expedited organs These metrics will be calculated for participating OPOs before and after the protocol is implemented *** Examples of tables for the following metrics are shown, below	
Distribution of KI KDPI 75-100 transplants by recipient factors including: • Age (ped/adult) • CPRA • Race/ethnicity • Sex	*Has the protocol resulted in changes in the distribution of who is receiving transplants as a*

• Dialysis Time • ABO • Inside/outside 250 NM circle *** See example table below	*result of the expedited process?*
Summary of candidates bypassed • % Inside/outside priority classifications • Age • CPRA Compared to candidates bypassed as a result of non-protocol AOOS via bypass codes *** See example table below	*How far are participating OPOs deviating from the match run? What percent of all candidates before the final acceptor not in priority classifications are not getting an offer?*

** NRP is not reported to the OPTN; NRP will be inferred and defined as greater than 30 minutes between declaration of death and cross clamp for DCD donors; Source: https://www.srtr.org/tools/donation-and-transplant-system-explorer/

*** Example table(s) for monitoring equity in access to transplant for the protocol provided on following pages

Table 1. **EXAMPLE** of a table showing the distribution of KDPI 75-100 kidneys allocated in sequence (AIS), allocated out of sequence (AOOS; defined by use of bypass codes), and allocated according to the expeditious task force protocol (defined by use of protocol specific bypass code); **Dummy data are presented in the table for demonstration purposes only and are not reflective of actual trends;**

EXAMPLE Summary: Recipients of kidneys allocated through the protocol are more likely to be older, have a lower CPRA and less dialysis time than recipients of AIS kidneys. While kidneys AOOS are more likely to go to white non-hispanic and male recipients, kidneys allocated through the protocol look very similar in race/ethnicity, sex and blood type to recipients of kidneys allocated through standard, in-sequence allocation. **Dummy data are presented in the table for demonstration purposes only and are not reflective of actual trends;**

Transplant Recipient Characteristics	**AIS (n=450)**	**Non-protocol approved AOOS (n=250)**	**Protocol (n=175)**
	N(%) or Median (Q1, Q3)		
Age (years)	55 (45, 63)	60 (52, 77)	70 (60, 75)
CPRA	50 (40, 60)	15 (10, 20)	30 (20, 40)
Dialysis Time (years)	4.0 (1.5, 5)	2.0 (1.2, 4.7)	1.7 (1.5, 2.4)
Race/ Ethnicity			
White Non-Hispanic	148 (33%)	100 (40%)	53 (30%)
Black Non-Hispanic	162 (36%)	75 (30%)	57 (33%)
Hispanic Latino	95 (21%)	43 (17%)	40 (23%)
Asian Non-Hispanic	31 (7%)	25 (10%)	17 (10%)
American Indian/Alaska Native, Non-Hispanic	5(1%)	3(1%)	4(2%)
Native Hawaiian/other Pacific Islander	2 (0.5%)	1 (0.5%)	1 (0.5%)
Multiracial, Non-Hispanic	7 (1.5%)	3 (1.5%)	3 (1.5%)
Blood Type			
A	157 (35%)	100 (40%)	61 (35%)
AB	22 (5%)	18 (7%)	11 (6%)
B	68 (15%)	38 (15%)	25 (14%)
O	203 (45%)	94 (38%)	78 (45%)
Male sex at birth	270 (60%)	175 (70%)	96 (55%)
Inside Priority Classifications	45 (10%)	5 (2%)	7 (4%)

AIS = Allocated in Sequence; AOOS = Allocated out of Sequence; Protocol = Allocated through Expedited placement protocol, policy 5.4.G; **Dummy data are presented in the table for demonstration purposes only and are not reflective of actual trends;**

Table 2. **EXAMPLE** of a table of candidates bypassed under AOOS and under the approved expedited protocol; **Dummy data are presented in the table for demonstration purposes only and are not reflective of actual trends;**

EXAMPLE Summary: When KDPI 75-100% kidneys are AOOS under non-protocol approved pathways, a median of 60% of candidates in priority classifications are bypassed. Under the protocol approved expedited placement pathway, only 2% of pediatric candidates were bypassed. Although pediatrics and high CPRA candidates are not in priority classifications we also show the percent of these candidates that were bypassed under non-protocol approved AOOS and under the protocol approved expedited placement. A median of 25% of pediatric candidates and a median of 10% of high CPRA candidates were bypassed under non-protocol approved AOOS. A similar but slightly smaller percent of pediatric and high CPRA candidates were bypassed under protocol approved expedited placement. For context, we also show the percent of match runs where these types of candidates appear on that match run and ever accepted a KDPI 75-100% kidney. Although candidates in priority classifications, pediatric and high CPRA candidates are bypassed through AOOS and sometimes, through the protocol, these candidates rarely accept these organs. **Dummy data are presented in the table for demonstration purposes only and are not reflective of actual trends;**

	Candidates Bypassed (Median % (Q1, Q3))		KDPI 75-100 KIs ever accepted (Median % (Q1, Q3))
Recipient Characteristic	**Non-protocol approved AOOS**	**Protocol**	
Inside Priority Classification	60% (45%, 100%)	2% (0%, 3%)	10% (6%, 12%)
Pediatric	25% (13%, 33%)	20% (10%, 23%)	4% (0%, 6)
CPRA	10% (7%, 14%)	7% (4%, 13%)	2% (0%, 4%)

Dummy data are presented in the table for demonstration purposes only and are not reflective of actual trends;