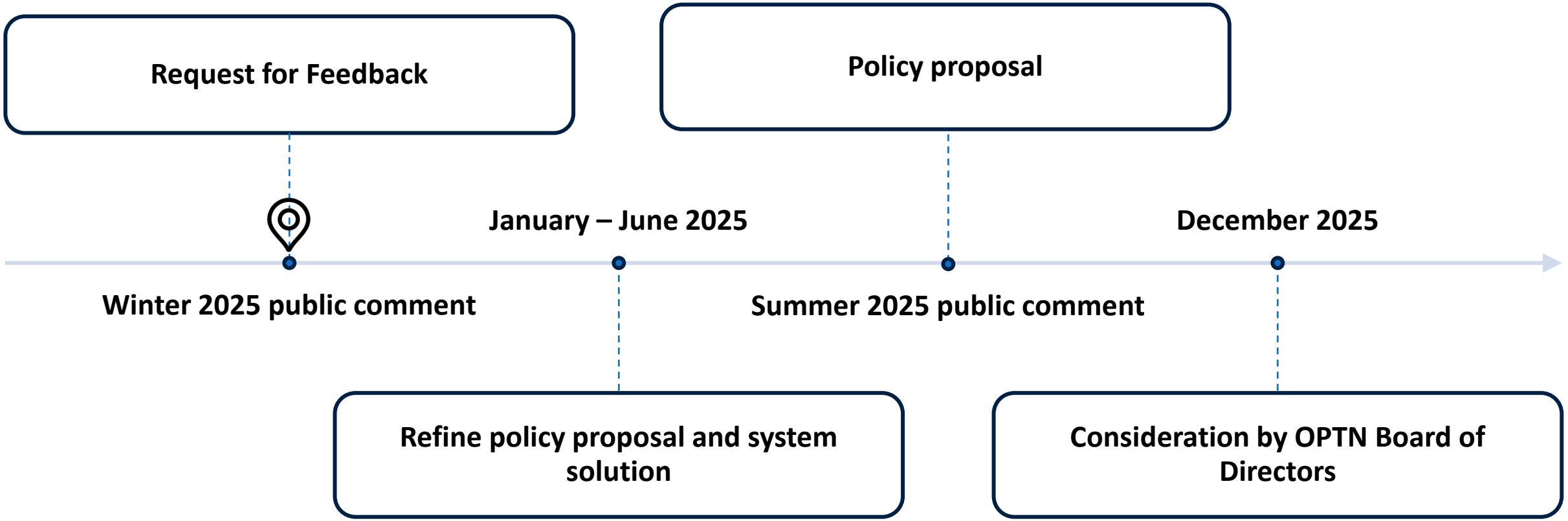
Request for Feedback: Establish Comprehensive Multi-Organ Allocation Policy

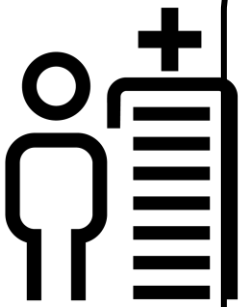
OPTN Ad Hoc Multi-Organ Transplantation Committee

Opportunities for community input

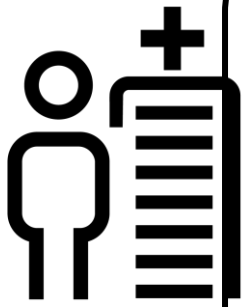


What challenges does this project address?

Two candidates need a liver



Candidate A is an adult Heart Status 3 candidate who is also registered for a liver. The candidate is supported by a mechanical circulatory support device (MCSD) and has been hospitalized for bleeding several times.

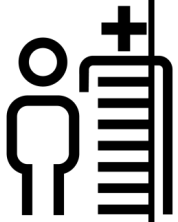


Candidate B is an adult Liver Status 1A candidate. The candidate is not expected to live for more than a week and there are no life sustaining technologies available.

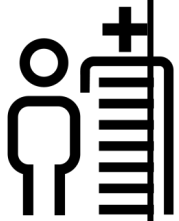
Current policy does not direct which candidate should receive priority for the liver – right now, it depends which organ match run is used first

What challenges does this project address ?

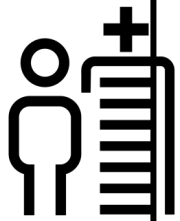
Three candidates need a kidney



Candidate A is an adult liver candidate with a model for end stage liver disease (MELD) score of 38 who is also eligible for a kidney.



Candidate B is an adult kidney-pancreas candidate with a calculated panel reactive antibody (CPRA) score ≥ 80%.



Candidate C is an adult kidney candidate with CPRA = 100%.

Current policy requires that offers be made to Candidate A and Candidate B before Candidate C. It does not direct whether Candidate A or B should receive priority.

What is the purpose of this project?

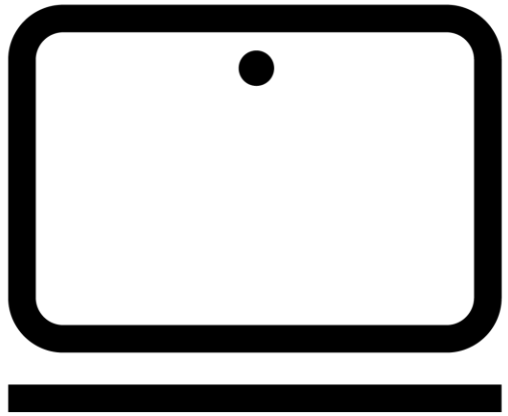
- The upcoming policy proposal aims to promote **equity** in access to transplant and to facilitate **consistent** and **efficient** allocation
- It will **standardize** the order in which OPOs work through match runs for highly prioritized candidate groups

How would allocation work in practice?

- The upcoming policy proposal will standardize allocation for donors with more than one organ available by inserting **multi-organ allocation tables** in policy
  - The allocation tables include approximately 50 high priority candidate groups across all organ types
- The OPO will enter donor information, run the applicable matches, and the system will generate a **donor-specific allocation plan** based on the applicable allocation table
  - As allocation progresses, the allocation plan will track allocation progress

A system solution to guide allocation

- Initial feedback from OPOs:
  - Differing OPO-specific allocation practices
  - Laborious efforts to create allocation plans
  - Recognition that allocation practices are non-linear
  - Need for policy and system solutions that reduce complexity
  - Requests for system-level guidance specific to each donor
  - Identification of potential contingencies that should be considered



The MOT Committee has requested development of a system solution to help guide the user through the proposed multi-organ allocation tables, with the goal of streamlining the allocation process.

Policy tables for multi-organ allocation

Organ	Class.	Description
LI	1	Status 1A within 500NM
HR	1	Adult Status 1 or Pediatric Status 1A within 500NM
HR	2	
LI	2	Status 1B within 500NM
~~LI~~	~~3~~	Status 1A (HI/PR)
~~LI~~	~~4~~	Status 1B (HI/PR)
HR	3	Adult Status 2 within 500NM
~~HR~~	~~4~~	
LU	-	Composite Allocation Score TBD
KI	1	CPRA = 100% within 250NM
KI	2	
KI	3	CPRA = 100%, nation
KI	4	
KI	5	Prior living donors within 250NM

Organ	Class.	Description
~~LI~~	~~5~~	MELD/PELD of at least 37 within 150NM
~~LI~~	~~6~~	
~~LI~~	~~7~~	MELD/PELD of at least 37 within 250NM
~~LI~~	~~8~~	
~~LI~~	~~9~~	MELD/PELD of at least 37 within 500NM
~~LI~~	~~10~~	
~~LI~~	~~11~~	MELD/PELD of at least 37 (HI/PR)
LI	12	
IN	1	Status 1 within 500NM
~~IN~~	~~2~~	
~~IN~~	~~3~~	Status 1, nation
~~IN~~	~~4~~	
LU	-	Composite Allocation Score TBD
P or KP	1	CPRA ≥ 80% within 250NM
~~P or KP~~	~~2~~	

Example of allocation based on proposed *Allocation Table for DBD donors aged 18-69 years with KDPI 0-34%*

Policy tables to standardize allocation

Organ classification and description
Liver Class 1: Status 1A (adult and pediatric); 500NM
Heart Class 1: Adult Status 1 or Pediatric Status 1A; 500NM
Heart Class 2: Adult Status 1 or Ped Status 1A; 500NM
Liver Class 2: Status 1B; 500NM
Liver Class 3: Status 1A; HI or PR
Liver Class 4: Status 1B; HI or PR
Heart Class 3: Adult Status 2; 500NM
Heart Class 4: Adult Status 2; 500NM
Lung: Composite Allocation Score (CAS) to be determined
Kidney Class 1: 0-ABDR mismatch; CPRA = 100%; 250NM
Kidney Class 2: CPRA equal to 100%; 250NM
Kidney Class 3: 0-ABDR mismatch; CPRA = 100%; nation
Kidney Class 4: CPRA equal to 100%; nation
Kidney Class 5: Prior living donor; 250NM
Liver Class 5: MELD/PELD of at least 37; 150NM
Liver Class 6: MELD/PELD of at least 37; 150 NM
Liver Class 7: MELD/PELD of at least 37; 250NM
Liver Class 8: MELD/PELD of at least 37; 250NM
Liver Class 9: MELD/PELD of at least 37; 500NM
Liver Class 10: MELD/PELD of at least 37; 500NM

Liver Class 11: MELD/PELD of at least 37; HI or PR
Liver Class 12: MELD/PELD of at least 37; HI or PR
Intestine Class 1: Status 1; 500NM
Intestine Class 2: Status 1; 500NM
Intestine Class 3: Status 1; nation
Intestine Class 4: Status 1; nation
Lung: Composite Allocation Score TBD
Pancreas or K/P Class 1: 0-ABDR mismatch; CPRA ≥ 80%; 250NM
Pancreas or K/P Class 2: CPRA ≥ 80%; 250NM
Heart Class 5: Adult Status 3 or Pediatric Status 1B; 250NM
Heart Class 6: Adult Status 3 or Pediatric Status 1B; 250NM
Pancreas or K/P Class 3: 0-ABDR mismatch; CPRA ≥ 80%; nation
Pancreas or K/P Classification 4: 250NM
Kidney Class 6: Registered prior to 18 years old; 250NM
Kidney Class 7: Medically Urgent; 250NM
Kidney Class 8: 0-ABDR mismatch; CPRA equal to 99%; 250NM
Kidney Class 9: CPRA equal to 99%; 250NM
Kidney Class 10: 0-ABDR mismatch; CPRA equal to 98%; 250NM
Kidney Class 11: CPRA equal to 98%; 250NM

Liver Class 13: MELD/PELD of at least 33; 150NM
Liver Class 14: MELD/PELD of at least 33; 150NM
Liver Class 15: MELD/PELD of at least 33; 250NM
Liver Class 16: MELD/PELD of at least 33; 250NM
Liver Class 17: MELD/PELD of at least 33; 500NM
Liver Class 18: MELD/PELD of at least 33; 500NM
Liver Class 19: MELD/PELD of at least 30; O donor; O or B cand.; 150NM
Liver Class 20: MELD/PELD of at least 29; O donor; O cand.; 150NM
Liver Class 21: MELD/PELD of at least 29; non-O donor; any cand.; 150NM
Liver Class 22: MELD/PELD of at least 30; O donor; O or B cand.; 250NM
Liver Class 23: MELD/PELD of at least 29; O donor; O cand.; 250NM
Liver Class 24: MELD/PELD of at least 29; non-O donor; any cand.; 250NM
Liver Class 25: MELD/PELD of at least 30; O donor; O or B cand.; 500NM
Liver Class 26: MELD/PELD of at least 29; O donor; O cand.; 500NM
Liver Class 27: MELD/PELD of at least 29; O donor; O cand.; 500NM

Proposed allocation table for DBD donors aged 18-69 years with KDPI 0-34%

The details – classifications in the tables

- The multi-organ allocation tables incorporate classifications in existing organ-specific policies
  - For example, the order of heart classifications within the multi-organ allocation tables follows existing heart policy
  - The upcoming policy proposal *would not* change the order of priority set in organ-specific policies

Examples of organ-specific tables incorporated into the multi-organ allocation tables

6.6.D Allocation of Hearts from Donors at Least 18 years Old

Hearts from deceased donors at least 18 years old are allocated to candidates according to *Table 6-7* below.

Table 6-7: Allocation of Hearts from Deceased Donors At Least 18 Years Old

Classification	Candidates that are within the	And registered at a transplant hospital that is at or within this distance from the donor hospital
1	Adult status 1 or pediatric status 1A and primary blood type match with the donor	500NM
2	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	500NM

Table 8-7: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal To 20%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any

The details – Lung CAS thresholds

- As lungs are allocated through a continuous distribution system, the MOT Committee established a Lung Multi-Organ Workgroup to consider how to incorporate lung composite allocation scores (CAS) into the proposed framework
  - The Request for Feedback includes the following lung CAS threshold options for community feedback

Lower lung CAS threshold
- Non-O donor – 30
- O donor – 34

Higher lung CAS threshold
- Non-O donor – 31
- O donor – 35

The details – donors

- Six multi-organ allocation tables included in the Request for Feedback
  - Different tables are necessary because the proposal incorporates organ-specific allocation policies, which prioritize allocation differently depending on donor characteristics, such as donor age and KDPI
- The six tables cover approximately 96% of donors to multi-organ recipients between July 2021 and December 2023

Table 1: Six multi-organ donor tables recommended for inclusion in the policy proposal

Donor group	% of donors to multi-organ recipients	Comments
DBD donors aged 18-69, KDPI 0-34%	65%	Highest percentage of donations to multi-organ recipients
DBD donors aged 18-69, KDPI 35-85%	15%	Second highest percentage of donations to multi-organ recipients
DCD donors aged 18+, KDPI 0-34%	4%	Likely growing percentage of donations to multi-organ recipients
DBD donors aged 11-17, KDPI 0-34%	10%	Third highest percentage of donations to multi-organ recipients
DBD donors aged <11, KDPI 0-34% with liver and intestine available	1%	Important donor group for pediatric multivisceral candidates
DBD donors aged <11, KDPI 35-85% with liver and intestine available	1%	Important donor group for pediatric multivisceral candidates

Table shows percent of donors to multi-organ recipients between July 2021 and December 2023. Per OPTN data as of July 26, 2024. Data are subject to change based on future submission or correction.

The details – candidates

- Each multi-organ allocation table include approximately 50 high priority candidate groups across all organ types
- Rationale for the recommended order of priority is based largely on medical urgency, considering access to life sustaining technologies
  - For example, the Committee recommends that Liver Classification 1 candidates (Status 1A within 500NM) receive the highest priority because they are not expected to survive more than seven days without transplant, and they do not have access to life sustaining technologies

Figure 5: Placement of Liver Classification 1

Organ	Class.	Description
LI	1	Status 1A within 500NM
HR	1	Adult Status 1 or Pediatric Status 1A within 500NM
HR	2	

The details – candidates

- Some candidate groups are prioritized to promote access to transplantation
  - For example, the Committee recommends that highly sensitized kidney candidates in Classifications 1-4 (CPRA = 100%, nation) are placed directly below the most medically urgent liver, heart, and lung candidates

Figure 6: Placement of Kidney Class. 1-5 in Table for DBD donors aged 18-69, KDPI 0-34%

Organ	Class.	Description
LU	-	Composite Allocation Score TBD
KI	1	CPRA equal to 100% within 250NM
KI	2	
KI	3	CPRA equal to 100%, nation
KI	4	
KI	5	Prior living donors within 250NM
LI	5	MELD/PELD of at least 37 within 150NM
LI	6	

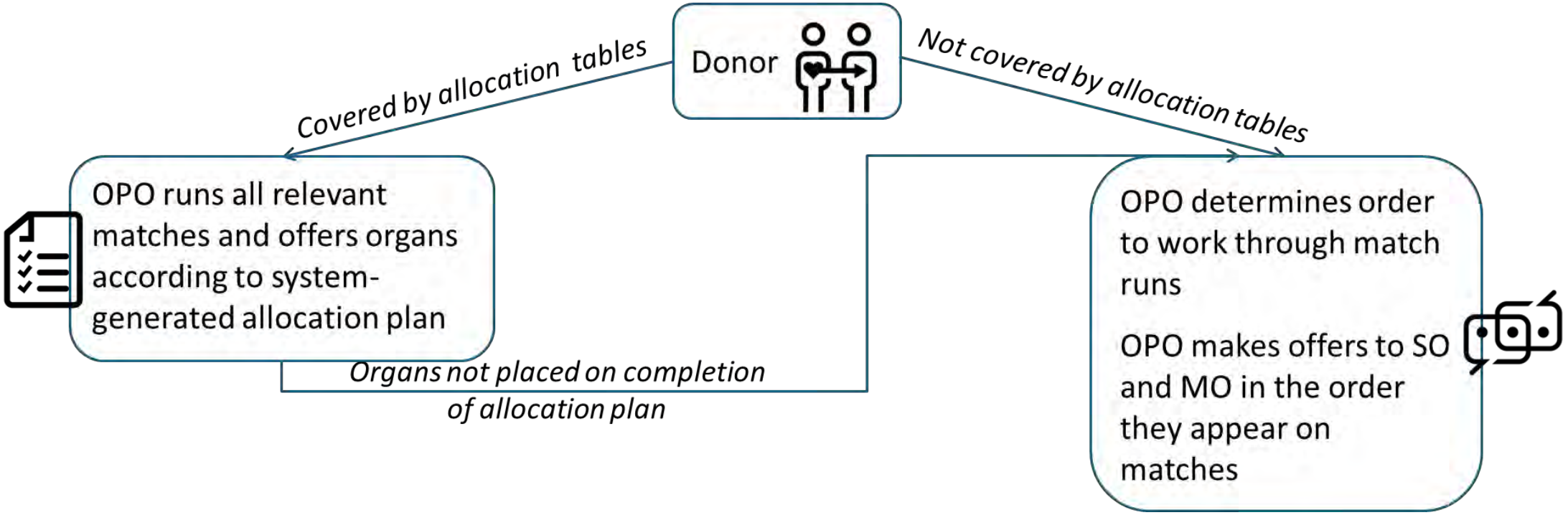
The details – candidates (cont.)

- Some candidate groups are prioritized to avoid organ non-utilization
  - For example, the Committee recommends that highly sensitized kidney-pancreas candidates in Classifications 1-2 (CPRA ≥ 80% within 250NM) are placed above Heart Classifications 5-6 (Adult Status 3 and Pediatric Status 1B within 250NM) so that kidney-pancreas candidates in those classifications could receive offers before heart-kidney candidates in Classifications 5-6

Placement of P and KP Class. 1-2 in Table for DBD donors aged 18-69, KDPI 0-34%

Organ	Class.	Description
P or KP	1	CPRA greater than or equal to 80% within 250NM
P or KP	2	
HR	5	Adult Status 3 or Pediatric Status 1B within 250NM
HR	6	

The details – offers not covered by allocation tables



The details – multi-organ offers and eligibility

Opportunity to establish policies directing the match runs from which multi-organ offers can be made

Table 2: Multi-organ offers from the heart, lung, and liver match runs

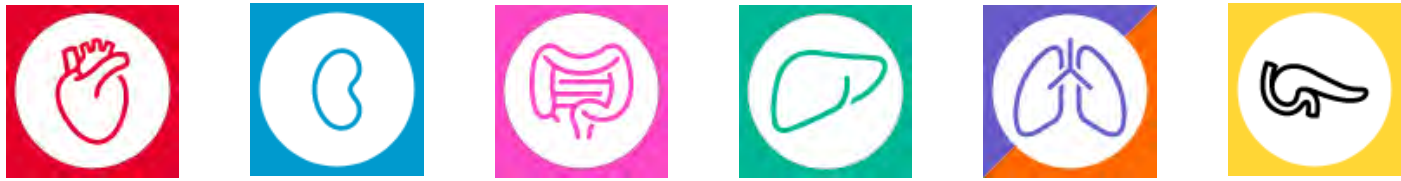
Primary organ/ match run	Other organs offered from the match	Eligibility criteria
Heart	All other organs	• Incorporate existing eligibility criteria for Heart-Lung, Heart-Liver, Heart-Kidney
Lung	All other organs	• Incorporate existing eligibility criteria for Heart-Lung, Lung-Liver, Lung-Kidney
Liver	All other organs	• Incorporate existing eligibility criteria for Lung-Liver • Develop criteria for Heart-Liver and Lung-Liver offers from the liver match run

Table 3: Multivisceral offers from the liver, intestine, kidney, pancreas, and KP match runs

Primary organ/ match run	Other organs offered from the match
Liver	All abdominal organs
Intestine, kidney, pancreas, kidney-pancreas	All abdominal organs except livers

The MOT Committee's approach

- Determining the order of priority among different organ groups is complex and challenging work
- A diverse group working together to strengthen the system as a whole
- While there may not be a "perfect" solution, the MOT Committee believes that standardization will improve allocation overall



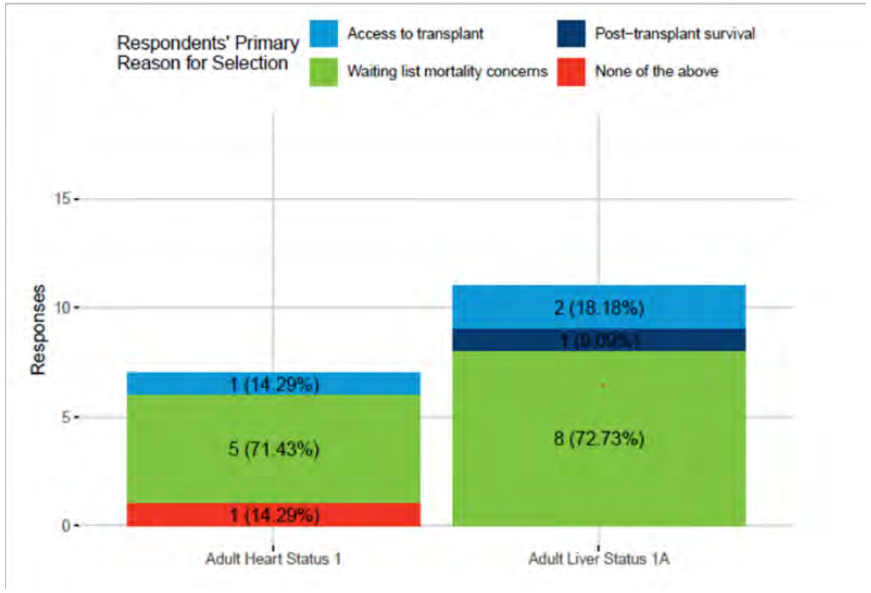
Values Prioritization Exercise (VPE)

- 20 current and past MOT Committee members participated in a VPE to help build clinical consensus on organ allocation priorities across match runs
- Participants compared 16 sets of candidates and determined which candidate should receive priority

Figure 1: Example VPE comparison: Adult Heart Status 1 compared to Adult Liver Status 1A

Attribute	Candidate A	Candidate B
Organ Registration(s)	Heart-Liver	Liver
Medical Urgency	HR Status 1	LI Status 1A
Sensitization	-	-
Candidate Age Group	Adult	Adult
Prior Living Donor	-	-
Distance	250NM	300NM
Blood Type	B	B

Figure 2: Example VPE result, broken down by respondents' primary reasons for selection



Data requests

- Data requested by the MOT Committee:
  - Candidate Waitlist Mortality and Outcomes
  - Post-transplant Survival
  - Candidate Access and Time without an Offer
  - Match Run Efficiency

Key data points and the Committee's rationale for prioritization decisions are included in the Request for Feedback

Organ classification	Median appearances	Median waitlist survival	Median post-tx survival	Median time without offer	Percent without offer	Rational for placement
Liver Class 1: Status 1A (adult and pediatric); 500NM	0	94.3	86.8	2	14	Medical urgency. No life-sustaining technology.
Heart Class 1: Adult Status 1 or Pediatric Status 1A; 500NM	1	85.1	90.3	12	26	Medical urgency.
Heart Class 2: Adult Status 1 or Ped Status 1A; 500NM	0	85.1	91.3	34	80	
Liver Class 2: Status 1B; 500NM	0	94.8	88.1	3	8	Medical urgency. Pediatric access to transplant.
Liver Class 3: Status 1A; HI or PR	0	94.3	81.1	2	10	
Liver Class 4: Status 1B; HI or PR	0	94.8	93.7	--	--	

Frequently asked questions

What are the key differences between current multi-organ policies and the upcoming policy proposal *Establish Comprehensive Multi-Organ Allocation Policy?*

Why are there so many multi-organ allocation tables?

The upcoming policy proposal seems complex – how would it help streamline allocation?

How would the upcoming policy proposal impact patients and donor families?

Can the OPTN develop a single match run for each donor?

How would the upcoming policy proposal help make allocation fairer?

What do you think?

- Does the community support the standardization of allocation order across match runs?
- Do the proposed tables cover appropriate donor and candidate groups?
- Do the proposed tables appropriately prioritize candidate groups?
- Should multi-organ offers be available from all match runs?
- Is the lung composite allocation score (CAS) appropriately incorporated?
- What potential barriers to operationalization and implementation challenges does the community anticipate?
- Does the proposed policy allow sufficient flexibility to maximize organ utilization?

Provide Feedback

Submit public comments on the OPTN website:

- January 21, 2025 – March 19, 2025
- optn.transplant.hrsa.gov

Additional questions about this Request for Feedback?

- Please contact Sarah Roache: Sarah.Roache@unos.org