

OPTN Committee Data Analysis Request Form

DHHS Contract #234-2005-370011C
Task 1.s., Item 23

Date Form Submitted to HRSA: July 19, 2018

Requesting Committee: Liver and Intestinal Organ Transplantation Committee

Date Committee Met: July 10, 2018

Date of Next Meeting: July 19, 2018

OPTN staff member referring Committee's requests: Samantha M. Noreen, Ph.D.

Chair Approval? Yes

ANALYSES REQUESTED:

• Descriptive Statistical Requests (responsibility of OPTN contractor)

- None

• Inferential Statistical Requests (responsibility of SRTR contractor)

Data Request 1: Provide LSAM data on revised proposals for liver redistribution

Background: On June 25, 2018 the OPTN Board of Directors directed the Liver and Intestinal Organ Transplantation Committee ("the Committee") to propose changes to policy removing any reference to DSA and Region as units of allocation in response to a critical comment submitted to the Secretary of Health and Human Services on May 30, 2018. The OPTN has committed to a multi-step plan to eliminate the use of DSAs in liver distribution in a deliberative manner and within a timeframe that will reduce the likelihood of unintended consequences.

Towards the goal of utmost compliance with the Final Rule, the Committee has discussed options for a revised allocation proposal that will reduce disparities in access to liver transplants, as well as decrease potential unintended consequences of an expedited policy change. The OPTN Final Rule requires that organ allocation policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required by" the OPTN Final Rule. (42 CFR 121.8(a)(8).) Furthermore, the OPTN Final Rule states that "Allocation policies shall be designed to achieve equitable allocation of organs among patients ... [by] (3) Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency." (42. CFR 121.8(b).) Consistent with these requirements, the Committee has discussed limitations on the feasibility of national organ distribution. Committee members have stated that there are improved outcomes for livers with lower cold ischemic time (CIT). CIT increases as the distance between the donor hospital and transplant hospital increase. This relationship and the desire to decrease CIT justifies a local priority due to the need to "achieve the best use of donated organs." (42 CFR 121.8(a)(2).) Furthermore, committee members have noted that liver surgeons often times travel to participate in organ procurement efforts. Therefore, organ offers that require additional travel time result in more surgeons away from the hospital and unavailable to perform transplants. This justifies a local priority due to the need "to promote the efficient management of organ placement." (42 CFR 121.8(a)(5).)

The two agreed-upon options to consider moving forward are outlined below, as Allocation Framework 1 and Allocation Framework 2. The goal of modeling both allocation frameworks is to compare these two proposals and inform the choice of the final policy proposal for a special public comment period, to begin October 8, 2018, prior to the December 2018 Board of Directors meeting.

The request laid out below will aid the Committee in their recommendation to the Board of Directors regarding the most appropriate policy that should be adopted.

Strategic Goal or Committee Project Addressed: Evaluate outcomes associated with the removal of DSA and Region as units of allocation. The project is in alignment with the strategic goal to improve equity in access to transplants.

Request: Using the most recently available LSAM version and data, model the distribution systems outlined below as **Allocation Framework 1** and **Allocation Framework 2**.

Allocation Framework 1: Acuity Circles

Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Livers from non-DCD deceased donors at least 18 years old and less than 70 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	[500/600]nm	Adult or pediatric status 1A
2	[500/600]nm	Pediatric status 1B
3	150nm	MELD or PELD of at least 37
4	[250/300]nm	MELD or PELD of at least 37
5	[500/600]nm	MELD or PELD of at least 37
6	150nm	MELD or PELD of at least 33
7	[250/300]nm	MELD or PELD of at least 33
8	[500/600]nm	MELD or PELD of at least 33
9	150nm	MELD or PELD of at least 29
10	[250/300]nm	MELD or PELD of at least 29
11	[500/600]nm	MELD or PELD of at least 29
12	150nm	MELD or PELD of at least 15
13	[250/300]nm	MELD or PELD of at least 15
14	[500/600]nm	MELD or PELD of at least 15
15	National	Adult or Pediatric Status 1A
16	National	Pediatric Status 1B
17	National	MELD or PELD of at least 15
18	150nm	MELD or PELD less than 15
19	[250/300]nm	MELD or PELD less than 15
20	[500/600]nm	MELD or PELD less than 15
21	National	MELD or PELD less than 15

Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Livers from non-DCD deceased donors 11 to 17 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	[500/600]nm	Pediatric status 1A
2	[500/600]nm	Adult status 1A
3	[500/600]nm	Pediatric status 1B
4	[500/600]nm	Any PELD
5	[500/600]nm	Any MELD and 12 to 17 years old
6	Nation	Pediatric status 1A
7	Nation	Adult status 1A
8	Nation	Pediatric status 1B
9	Nation	Any PELD
10	Nation	Any MELD and 12 to 17 years old
11	[500/600]nm	Any MELD and at least 18 years old
12	Nation	Any MELD and at least 18 years old

Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Livers from non-DCD donors less than 11 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	[500/600]nm	Pediatric status 1A
2	Nation	Pediatric status 1A and 0 to 11 years old
3	[500/600]nm	Adult status 1A
4	[500/600]nm	Pediatric status 1B
5	[500/600]nm	Any PELD
6	[500/600]nm	Any MELD and 12 to 17 years old
7	Nation	Pediatric status 1A and 12 to 17 years old
8	Nation	Adult status 1A
9	Nation	Pediatric status 1B and 0 to 17 years old
10	Nation	Any PELD
11	Nation	Any MELD and 12 to 17 years old
12	[500/600]nm	Any MELD and at least 18 years old
13	Nation	Any MELD and at least 18 years old

Allocation of Livers from DCD Donors or Donors at Least 70 Years Old

Livers from DCD donors or donors at least 70 years old are allocated to candidates according to the table below:

Allocation of Livers from DCD Donors or Donors at Least 70 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	[500/600]nm	Adult or Pediatric status 1A
2	[500/600]nm	Pediatric status 1B
3	150nm	MELD or PELD of at least 15
4	[250/300]nm	MELD or PELD of at least 15
5	[500/600]nm	MELD or PELD of at least 15
6	Nation	Adult or Pediatric status 1A
7	Nation	Pediatric status 1B
8	Nation	MELD or PELD of at least 15
9	150nm	MELD or PELD less than 15
10	[250/300]nm	MELD or PELD less than 15
11	[500/600]nm	MELD or PELD less than 15
12	Nation	MELD or PELD less than 15

- **Simulation 1A** will use the distances 150nm, 250nm, and 500nm, respectively. Exception scores assigned following previously modeled redistribution proposals (current implemented policy).
- **Simulation 1B** will use the distances 150nm, 300nm, and 600nm, respectively. Exception scores assigned following previously modeled redistribution proposals (current implemented policy).

Allocation Framework 2: Broader 2-Circle Distribution

Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Livers from non-DCD deceased donors at least 18 years old and less than 70 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	500nm	Adult or pediatric status 1A
2	500nm	Pediatric status 1B
3	250nm	MELD or PELD of at least [35/32]
4	150nm	MELD or PELD of at least 15
5	250nm	MELD or PELD of at least 15
6	500nm	MELD or PELD of at least 15
7	National	Adult or Pediatric Status 1A
8	National	Pediatric Status 1B
9	National	MELD or PELD of at least 15
10	150nm	MELD or PELD less than 15
11	250nm	MELD or PELD less than 15
12	500nm	MELD or PELD less than 15
13	National	MELD or PELD less than 15

Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Livers from non-DCD deceased donors 11 to 17 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	500nm	Pediatric status 1A
2	500nm	Adult status 1A
3	500nm	Pediatric status 1B
4	500nm	Any PELD
5	500nm	Any MELD and 12 to 17 years old
6	Nation	Pediatric status 1A
7	Nation	Adult status 1A
8	Nation	Pediatric status 1B
9	Nation	Any PELD
10	Nation	Any MELD and 12 to 17 years old
11	500nm	Any MELD and at least 18 years old
12	Nation	Any MELD and at least 18 years old

Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Livers from non-DCD donors less than 11 years old are allocated to candidates according to the table below:

Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	500nm	Pediatric status 1A
2	Nation	Pediatric status 1A and 0 to 11 years old
3	500nm	Adult status 1A
4	500nm	Pediatric status 1B
5	500nm	Any PELD
6	500nm	Any MELD and 12 to 17 years old
7	Nation	Pediatric status 1A and 12 to 17 years old
8	Nation	Adult status 1A
9	Nation	Pediatric status 1B and 0 to 17 years old
10	Nation	Any PELD
11	Nation	Any MELD and 12 to 17 years old
12	500nm	Any MELD and at least 18 years old
13	Nation	Any MELD and at least 18 years old

Allocation of Livers from DCD Donors or Donors at Least 70 Years Old

Livers from DCD donors or donors at least 70 years old are allocated to candidates according to the table below:

Allocation of Livers from DCD Donors or Donors at Least 70 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	500nm	Adult or Pediatric status 1A
2	500nm	Pediatric status 1B
3	150nm	MELD or PELD of at least 15
4	500nm	MELD or PELD of at least 15
5	Nation	Adult or Pediatric status 1A
6	Nation	Pediatric status 1B
7	Nation	MELD or PELD of at least 15
8	150nm	MELD or PELD less than 15
9	500nm	MELD or PELD less than 15
10	Nation	MELD or PELD less than 15

- **Simulation 2A** will use the MELD/PELD score thresholds of **35**, such that the sharing threshold is a MELD or PELD score of at least 35 (“Share 35”). Exception scores assigned following previously modeled redistribution proposals (current implemented policy).
- **Simulation 2B** will use the MELD/PELD score thresholds of **32**, such that the sharing threshold is a MELD or PELD score of at least 32 (“Share 32”). Exception scores assigned following previously modeled redistribution proposals (current implemented policy).

Based on the above frameworks, provide the following metrics. Relevant metrics will be stratified by all candidates, non-exception candidates, HCC candidates, and other exceptions. Metrics to be assessed for the overall population (nationwide) include:

1. Median MELD/PELD score at transplant (MMaT)**
2. Variance in the median MELD/PELD score at transplant**
3. Counts of transplants**
4. Transplant rates**
5. Variance in transplant rates
6. Counts of waiting list deaths**
7. Waitlist mortality rates**
8. Variance in waiting list mortality rates
9. Post-transplant patient survival**
10. Median transport distance**
11. Median transport time**
12. Percent of organs flown for transport**

** *These metrics can be prioritized for initial results for **both** allocation frameworks, others can be provided in a following report if necessary.*

Relevant metrics will be displayed in maps by DSA and tables provided in an appendix for DSA level results for:

- Median MELD/PELD score at transplant
- Counts of transplants
- Transplant rates
- Counts of waiting list deaths
- Waiting list mortality rates
- Percent of organs flown for transplant (recovered in DSA, flown out)
- Percent of organs flown for transplant (transplanted in DSA, flown in)

Items 1 – 9 should also be assessed by the following subgroup populations:

- OPTN Region: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11^{^^}
- Age: pediatric (under 18 at listing) and adult (18+ at listing)^{^^}
- Sex: female and male^{^^}
- Race/ethnicity: African American, Asian/Pacific Islander, Caucasian, Hispanic^{^^}
- MELD/PELD group: < 15, 15-24, 25-28, 29-31, 32-34, 35+ (includes Status 1s)^{^^}
- Exception status: No exceptions, HCC exception, Other exception^{^^}
- Urbanicity: urban vs rural, based on RUCA codes (Individually, and grouped by metropolitan vs micropolitan + small town + rural)
- Insurance status: public and private
- Cumulative Community Risk Score (CCRS) grouped in units of 10 (0-10, 11-20, 21-30, 31-40)

Items 10 – 12 should also be assessed by the following subgroup populations:

- OPTN Region: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11^{^^}
- MELD/PELD group: < 15, 15-24, 25-28, 29-31, 32-34, 35+ (includes Status 1s)^{^^}

^{^^} *These subgroup populations can be prioritized for initial results for **both** allocation frameworks, others can be provided in a following report if necessary.*