Final Report

OPTN Liver & Intestinal Transplantation Committee

Descriptive Data Request

Out-of-the-Gate Monitoring of Liver and Intestine Acuity Circle Allocation, 3 Month Report Removal of DSA and Region as Units of Allocation

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Purpose

The purpose of this report is to provide an early look at high-level metrics revealing the performance of the system and any potential consequences of the that may require changes to policy, programming, or clinical practice. It contains information for responding to the media, general public, and transplant community in the 3 month period following implementation. This report, performed on behalf of the Organ Procurement and Transplantation Network (OPTN) Liver and Intestinal Transplantation Committee, will be followed by further reports at approximately 6 months, 9 months, 1 year, and 2 years post-implementation. The OPTN will respond to further requests by the Committee as well as relay appropriate requests to the Scientific Registry of Transplant Recipients (SRTR) related to these changes.

Monitoring Plan

The changes implemented on February 04, 2020 continue to be monitored on a weekly basis to understand potential affects of the COVID-19 pandemic on monitoring this policy change. Weeks will be defined as spanning from Tuesday through Monday, to align with the weekday of the policy implementation. Monitoring will focus on changes in the match process, waiting list population, liver transplant recipient population as counts only, and deceased donor utilization. Specifically the by-week analysis will provide comparisons pre- and post-policy implementation and include:

- Changes in the number of livers and intestines recovered and transplanted
- Impact on the national liver discard rate and utilization rate
- Changes in the median allocation Model for End-Stage Liver Disease (MELD) or Pediatric End-Stage Liver Disease (PELD) score at transplant
- Changes in the distance (in nautical miles, NM) from the donor hospital to the transplant center for deceased donor liver and intestine transplants
- Impact on the number of liver and intestine candidates removed from the waiting list by reported removal reason
- Changes in the sequence number of the liver transplant recipient
- Changes in the time from an Organ Procurement Organization's (OPO) first electronic notification of an offer to cross clamp for deceased donor livers

Executive Summary

This report serves as an early look at high-level metrics to evaluate any early indications that the policy may be trending towards achieving intended goals, as well as to evaluation potential intended and unintended consequences of the liver and intestine policy changes. Metrics are constrained to data points that are reliably available while allowing for the data submission lags allowed in OPTN policy in this report.

In all figures, tables, and values broken out by-week, the COVID-19 pandemic is labeled. The World Health Organization (WHO) declared this a pandemic on March 11, 2020 and a national state of emergency was declared in the US on March 13, 2020. This report contains approximately 7 weeks in the Post (02/04/2020-04/27/2020) era making the true impact of this policy change challenging to determine.

The metrics presented here, based on early post-implementation data, suggest no apparent national changes during the post-policy period compared to similar pre-policy periods with respect to the number of deceased donor livers being recovered, number of deceased donor liver transplants, discard and utilization rates, and removals from the waiting list due to too sick to transplant or death. Also, the match process does not show any early indications of disturbance. Data to date do suggest an increase in distance and non-local sharing, as well as larger proportions of higher-MELD/PELD score candidates receiving transplants. However, it is difficult to determine what are policy-related impacts versus COVID-19 impacts at this time. The system will continue to be monitored closely

and metrics and trends will continue to be added as more time and data accrue. Future analyses will also consider comparisons to expected trends and directions from SRTR modeling results.

Cohorts

The cohort examined contains three periods to review 12 full weeks of data after the liver policy change, and two comparison periods.

- The first pre-policy era is from Tuesday, February 05, 2019 to Monday, April 29, 2019, referred to as "Pre (02/05/2019-04/29/2019)" era, to consider seasonal changes.
- The second pre-policy era is from Tuesday, November 12, 2019 to Monday, February 03, 2020, referred to as "Pre (11/12/2019-02/03/2020)" era.
- The time period beginning upon implementation of the policy change is from Tuesday, February 04, 2020 to Monday, April 27, 2020, referred to as "Post (02/04/2020-04/27/2020)" era.

The data sets listed below, each for the time periods previously specified, are used in the descriptive tables and graphs in this report:

- Candidates ever waiting on the waiting list for a liver transplant
- Candidates ever waiting on the waiting list for an intestine transplant
- Candidates that received a liver transplant
- Candidates that received an intestine transplant
- Candidates that received a simultaneous liver-kidney transplant
- All liver donors from which at least one liver was recovered for the purpose of transplantation
- All intestine donors from which at least one intestine was recovered for the purpose of transplantation
- Liver match runs

The following results are presented by week. As data accumulate, data will be shown more in aggregate versus on a weekly basis. This analysis is based on OPTN data as of June 19, 2020 and is subject to change based on any future data submission or correction.

Analysis by Week

Liver

The number of new liver waiting list registrations added, as well as livers recovered for the purpose of transplantation and liver transplant recipients, were being monitored by week. While each of these measures customarily varies week to week, trends shown are in line with historical data on the liver allocation system. Of note, approximately 7 weeks in the post-policy era include effects of the COVID-19 pandemic.





* National state of emergency in US due to COVID–19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the number within each week, and then averaging across all weeks in the era.

The average number of new registrations added to the liver waiting list per week was 260.1 in the Pre (02/05/2019-04/29/2019) era, 242.5 in the Pre (11/12/2019-02/03/2020) era, and 254.6 in the Post (02/04/2020-04/27/2020) era.



Figure 2. Number of Liver Donors Recovered by Week

* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the number within each week, and then averaging across all weeks in the era.

The mean number of livers recovered per week was 178.1 in the Pre (02/05/2019-04/29/2019) era, 173.8 in the Pre (11/12/2019-02/03/2020) era, and 167.6 in the Post (02/04/2020-04/27/2020) era.



Figure 3. Number of Liver Donors Recovered by OPO

* Note that the Post (02/04/2020-04/27/2020) Era contains weeks during the COVID-19 pandemic.

Any points along the diagonal dashed line indicate no changes in the absolute number of deceased liver donors recovered by an Organ Procurement Organization (OPO), pre- to post-policy. Points that fall above the diagonal represent OPOs that recovered more deceased liver donors post-policy compared to pre-policy. Points that fall below the diagonal represent OPOs that recovered fewer liver donors post-policy compared to pre-policy.

The gray shaded region represents a 95% confidence ellipse, assuming a multivariate t-distribution, around_half_up the data points. While this is not a true statistical test of a hypothesis that there was a significant change in the number of liver donors recovered, it provides some context as to how often and where OPOs that may fall outside of the rest of the group may be.

The majority of OPOs recovered similar number of livers Pre (02/05/2019-04/29/2019) and Post (02/04/2020-04/27/2020) policy, overall. A Spearman's rank correlation (rho) is provided to measure the strength and direction of the monotonic, not necessarily linear, relationship between the number of deceased liver donors recovered by OPO pre- and post-policy. There is a strong positive, monotonic relationship between these two measures.

Figure 4 shows the national discard rate (the percentage of deceased donors for which the liver was recovered for the purposes of transplant but not transplanted, out of all deceased liver donors) by week.





* National state of emergency in US due to COVID–19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the discard rate within each week, and then averaging across all weeks in the era.

The average percent of livers recovered for transplant and not transplanted per week was 8.2% for the Pre (02/05/2019-04/29/2019) era, 11.1% in the Pre (11/12/2019-02/03/2020) era, and 9.1% in the Post (02/04/2020-04/27/2020) era.



Figure 5. Number of Deceased Donor Livers Recovered by Era, DSA of Recovery, and Transplant Status

* Note that the Post (02/04/2020-04/27/2020) Era contains weeks during the COVID-19 pandemic.

The average percent of livers recovered for transplant and not transplanted across DSAs was 9.8% for the Pre (02/05/2019-04/29/2019) era, 12.7% for the Pre (11/12/2019-02/03/2020) era and 10.2% for the Post (02/04/2020-04/27/2020) era.

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The figure below shows the national utilization rate (the percentage of deceased donors with a liver transplanted, out of all deceased organ donors) by week.





* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the utilization rate within each week, and then averaging across all weeks in the era.

The average utilization rate per week was 72.8% for the Pre (02/05/2019-04/29/2019) era, 65.5% in the Pre (11/12/2019-02/03/2020) era, and 68.8% in the Post (02/04/2020-04/27/2020) era.



Figure 7. Number of Deceased Donor Liver Transplants by Week

The mean number of deceased donor liver transplants per week was 165.9 in the Pre (02/05/2019-04/29/2019) era, 155.8 in the Pre (11/12/2019-02/03/2020) era, and 153.3 in the Post (02/04/2020-04/27/2020) era.

There were 1991 total deceased donor liver transplants in the Pre (02/05/2019-04/29/2019) era, 1869 in the Pre (11/12/2019-02/03/2020) era, and 1839 in the Post (02/04/2020-04/27/2020) era.

^{*} National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the number within each week, and then averaging across all weeks in the era.

In both the pre- and post- implementation era, the majority of liver transplant recipients were adults (age 18 years and older at transplant). There was no observable change in the number of pediatric (age less than 12 years at transplant) deceased donor liver transplant recipients, and a slight increase in the pediatric (age 12-17 years at transplant) deceased donor liver transplant recipients.





* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020.

Table 1. Deceased Donor Liver Transplants by Era and Age Group

Age Group	Pre (02/05/2019-04/29/2019)	Pre (11/12/2019-02/03/2020)	Post (02/04/2020-04/27/2020)
Pediatric (age 0-11 years)	102 (5.1%)	76 (4.1%)	75 (4.1%)
Pediatric (age 12-17 years)	19 (1.0%)	18 (1.0%)	26 (1.4%)
Adult (age 18+ years)	1870 (93.9%)	1775 (95.0%)	1738 (94.5%)
Total	1991 (100.0%)	1869 (100.0%)	1839 (100.0%)



Figure 9. Number of Deceased Donor Liver Transplants by Donor DCD Status and Week

* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020.

The average percent of liver transplants from DCD donors per week was 8.4% in the Pre (02/05/2019-04/29/2019) era, 9.3% in the Pre (11/12/2019-02/03/2020) era and 10.7% in the Post (02/04/2020-04/27/2020) era.



The average number of DCD transplants across DSAs was 4.6 for the Pre (02/05/2019-04/29/2019) era, 4.7, for the Pre (11/12/2019-02/03/2020) era, and 4.7 for the Post (02/04/2020-04/27/2020) era.





There has been an observable increase in the deceased donor liver transplant recipients without exception at time of transplant post-policy compared to pre-policy. This should be viewed keeping in mind that the National Liver Review Board (NLRB) policy and associated exception-related scoring policies also changed with the implementation of acuity circles. As of February 04, 2020, the median MELD at transplant calculation changed, to a basis of transplants within 250 nautical miles (NM) of each transplant program from a basis of transplants within the same donation service area (DSA) of each transplant program Pre (11/12/2019-02/03/2020) policy. Prior to that, exception scores were not standardized in policy and were adjudicated by Regional Review Boards (RRB) in the Pre (02/05/2019-04/29/2019) policy.





* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020.

** Navy solid lines are computed by calculating the number within each week and subgroup, and then averaging across all weeks in the era and subgroup.

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Exception Status	Pre (02/05/2019-04/29/2019)	Pre (11/12/2019-02/03/2020)	Post (02/04/2020-04/27/2020)
No Exception	1394 (70.0%)	1443 (77.2%)	1488 (80.9%)
HCC Exception	312 (15.7%)	273 (14.6%)	223 (12.1%)
Non-HCC Exception	285 (14.3%)	153 (8.2%)	128 (7.0%)
Total	1991 (100.0%)	1869 (100.0%)	1839 (100.0%)

Table 2. Deceased Donor Liver Transplants by Era and Exception Status

There are observable differences in the number of deceased donor liver transplants within each OPTN region. Thus far, region 3 has experienced the largest decrease in number of transplants from both pre-policy periods. Regions 1 and 7 have experienced the largest increases from both pre-policy periods. Region 5 experienced a decrease in number of transplants from the pre-policy period one year prior, but an increase from the immediately preceding pre-policy period.



Figure 12. Number of Deceased Donor Liver Transplants by OPTN Region and Era

* Note that the Post (02/04/2020-04/27/2020) Era contains weeks during the COVID-19 pandemic.



Figure 13. Number of Deceased Donor Liver Transplants by Transplant Program

* There was 1 program that is not included due to new activation after the pre era. ** Note that the Post (02/04/2020–04/27/2020) Era contains weeks during the COVID–19 pandemic.

Any points along the diagonal dashed line indicate no changes in the absolute number of deceased donor liver transplants by program, pre- to post-policy. Points that fall above the diagonal represent programs that performed more deceased donor liver transplants post-policy compared to pre-policy. Points that fall below the diagonal represent programs that performed fewer deceased donor liver transplants post-policy.

The gray shaded region represents a 95% confidence ellipse, assuming a multivariate t-distribution, around the data points. While this is not a true statistical test of a hypothesis that there was a significant change in the number of deceased donor liver transplants performed, it provides some context as to how often and where programs that may fall outside of the rest of the group may be.

The majority of programs performed similar number of deceased donor liver transplants Pre (02/05/2019-04/29/2019) and Post (02/04/2020-04/27/2020) policy, overall. A Spearman's rank correlation (rho) is provided to measure the strength and direction of the monotonic, not necessarily linear, relationship between the number of deceased donor liver transplants by program pre- and post-policy. There is a strong positive, monotonic relationship between these two measures.

In the figure below, the number of transplants per week is displayed by allocation MELD or PELD score or Status at transplant. Similar percentages of Status 1 and allocation score 37 and higher transplants occurred preand post-policy. Higher percentages of transplants with allocation scores between 29-36, in addition to a lower percentage between 15-28, occurred post-policy.





* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the number within each week and subgroup, and then averaging across all weeks in the era and subgroup.

Score or Status Group	Pre (02/05/2019-04/29/2019)	Pre (11/12/2019-02/03/2020)	Post (02/04/2020-04/27/2020)
Status 1	96 (4.8%)	87 (4.7%)	77 (4.2%)
M/P 37+	341 (17.1%)	302 (16.2%)	299 (16.3%)
M/P 33-36	253 (12.7%)	154 (8.2%)	233 (12.7%)
M/P 29-32	362 (18.2%)	302 (16.2%)	398 (21.6%)
M/P 15-28	877 (44.0%)	967 (51.7%)	766 (41.7%)
M/P < 15	62 (3.1%)	57 (3.0%)	66 (3.6%)
Total	1991 (100.0%)	1869 (100.0%)	1839 (100.0%)

Table 3. Deceased Donor Liv	er Transplants by Era and MELD	or PELD Score/Status Group

It was of interest to determine whether there was a change in the median MELD or PELD score at transplant with the change in units of allocation. It was hypothesized that there would be an increase in the median MELD or PELD score at transplant immediately following the policy change, implying an influx of high MELD or PELD candidates receiving transplants. The figure below shows the median MELD or PELD score at transplant for deceased donor liver transplant recipients by week. This excludes any Status 1A or Status 1B deceased donor liver transplants.





* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020.

** Excludes Status 1 Transplants.

*** Dots indicate median score each week. Error bars indicate the 10th and 90th percentiles of scores each week.

The ranges of allocation MELD or PELD score at transplant do not seem to be changing, and the overall median score was 29 in the Pre (02/05/2019-04/29/2019) era, 27 in the Pre (11/12/2019-02/03/2020) era and 29 in the Post (02/04/2020-04/27/2020) era. The median MELD or PELD at transplant by week does fluctuate noticeably, partly due to small sample sizes.

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This variation in median MELD or PELD at transplant is also evident across DSAs during all policy eras. However, it is beginning to appear that median transplant scores within DSAs are moving away from extreme differences and towards more similar median scores from DSA to DSA.

Figure 16. Median Deceased Donor Liver Recipient Allocation MELD or PELD Score at Transplant by Era and DSA of Transplant Center



Post (02/04/2020-04/27/2020)



Since the allocation change removed donation service area (DSA) and region as units of allocation and now uses 150, 250, and 500 NM radii-circles around the donor hospital of the potential liver donor, the distance that livers travel between donor hospital and transplant hospital is being monitored. The figure below depicts the average distance from donor hospital to transplant hospital for all liver transplants by week, with error bars indicating the 10th and 90th percentiles.





* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the mean distance within each week, and then averaging across all weeks in the era. *** Dots indicate average distance each week. Error bars indicate the 10th and 90th percentiles of distance each week.

The mean distance was 162.4 NM in the Pre (02/05/2019-04/29/2019) era, 158.9 NM in the Pre (11/12/2019-02/03/2020) era, and 206.7 NM in the Post (02/04/2020-04/27/2020) era.

Similarly, the figure below summarizes the percent of deceased donor liver transplants that traveled further than 150 NM, outside the first unit of allocation post-policy change.



Figure 18. Percent of Deceased Donor Liver Transplants that Traveled Further than 150 NM by Week

* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the percent within each week, and then averaging across all weeks in the era.

The mean percent of transplants that traveled over 150 NM per week was 34.9% for the Pre (02/05/2019-04/29/2019) era, 33.8% in the Pre (11/12/2019-02/03/2020) era, and 49.3% in the Post (02/04/2020-04/27/2020) era.



Figure 19. Percent of Deceased Donor Liver Transplants that Occurred Within Same DSA as Donor Hospital by Week

* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the percent within each week, and then averaging across all weeks in the era.

Approximately 62.8% of deceased donor liver transplants in the Pre (02/05/2019-04/29/2019) era were at a transplant hospital within the DSA of the recovery hospital. In the Pre (11/12/2019-02/03/2020) era, approximately 65% and Post (02/04/2020-04/27/2020) era approximately 35.7% were at a transplant hospital within the DSA of the recovery hospital.

Understanding the relationship between the share types (local, regional, national) used in allocation during the pre-policy and the distance groups used in allocation post-policy was important to review.





* Note that the Post (02/04/2020-04/27/2020) Era contains weeks during the COVID-19 pandemic.

While just under two-thirds of liver transplants were local in the Pre (02/05/2019-04/29/2019) and Pre (11/12/2019-02/03/2020) eras, this dropped to approximately one-third during the Post (02/04/2020-04/27/2020) era. There are fairly equal percentages of liver transplants in the local, regional, and national share types during the Post (02/04/2020-04/27/2020) era.

During the Post (02/04/2020-04/27/2020) era, there have been decreases in liver transplants occurring within 150 NM or over 500 NM from the donor hospital. There has been a subsequent increase in the liver transplants occurring over 150 NM, but within 500 NM of the donor hospital as well.

Table 4. Deceased Donor Liver Transplants by Era and Donor Share Type

Donor Share Type	Pre (02/05/2019-04/29/2019)	Pre (11/12/2019-02/03/2020)	Post (02/04/2020-04/27/2020)
Local	1251 (62.8%)	1215 (65.0%)	657 (35.7%)
Regional	623 (31.3%)	543 (29.1%)	598 (32.5%)
National	117 (5.9%)	111 (5.9%)	584 (31.8%)
Total	1991 (100.0%)	1869 (100.0%)	1839 (100.0%)

Table 5. Deceased Donor Liver Transplants by Era and Classification Distance

Classification Distance	Pre (02/05/2019-04/29/2019)	Pre (11/12/2019-02/03/2020)	Post (02/04/2020-04/27/2020)
0-150 NM	1296 (65.1%)	1238 (66.2%)	933 (50.7%)
>150-250 NM	262 (13.2%)	253 (13.5%)	324 (17.6%)
>250-500 NM	282 (14.2%)	240 (12.8%)	498 (27.1%)
>500 NM	151 (7.6%)	138 (7.4%)	84 (4.6%)
Total	1991 (100.0%)	1869 (100.0%)	1839 (100.0%)



The average percent of transplants occurring within the recovering DSA, across DSAs, was 65.4% for Pre (02/05/2019-04/29/2019), 66.3% for Pre (11/12/2019-02/03/2020) and 36.8% for Post (02/04/2020-04/27/2020).



Figure 21. Number of Deceased Donor Liver Transplants by Era, DSA of Transplant Center, and Donor Share Type

Changes in the number of liver candidates who were removed due to death or too sick to transplant were also summarized.





* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020.

** Navy solid lines are computed by calculating the number within each week, and then averaging across all weeks in the era.

The average number of candidates removed from the waiting list due to for too sick to transplant or death was 47.5 for the Pre (02/05/2019-04/29/2019) era, 47.5 in the Pre (11/12/2019-02/03/2020) era, and 45.3 in the Post (02/04/2020-04/27/2020) era, per week.





* Note that the Post (02/04/2020-04/27/2020) Era contains weeks during the COVID-19 pandemic.

The average number of waitlist removals, across DSAs, was 47.5 for the Pre (02/05/2019-04/29/2019) era, 47.5 for the Pre (11/12/2019-02/03/2020) era, and 45.3 for the Post (02/04/2020-04/27/2020) era.

ССОБ-ОРТ ЕLEM-ОРТ ЕLEM-ОРТ ЕLEM-ОРТ ЕLUF-101 ЕLUF-101 ЕLUF-001 IAOP-007 IAOP-007 ILIP-007 IAOP-007 MORC-007 MORC-

Pre (11/12/2019-02/03/2020)

DSA of Transplant Center

Pre (02/05/2019-04/29/2019)

ALOB-OP1 AROR-OP1 AZOB-OP1 CADN-OP1 CADN-OP1 CAOP-OP1

Era

CASD-I01 CORS-OP1

16 14

WIDN-OP1 WIUW-I01

VATB-OP

Post (02/04/2020-04/27/2020)

3

To summarize the match process, the median sequence number of deceased donor liver transplant recipients was also reviewed. This does not represent the final acceptor offer number outright, as OPOs have up to 30 days to close matches so final acceptor of some matches may not yet be available. As such, we present the sequence number of the deceased donor liver transplant recipient, with the caveat that there may be circumstances in which that patient was not the final acceptor on the match.



Figure 24. Distribution of Sequence Number of Deceased Donor Liver Transplant Recipients by Week

* National state of emergency in US due to COVID–19 pandemic declared week of March 13, 2020. ** Dots indicate median sequence number each week. Error bars indicate the 10th and 90th percentiles of sequence number each week.

The 90th percentile or upper end of the error bars was included to capture the sequence number for conceivably difficult livers to place. The median sequence number overall was 5 in the Pre (02/05/2019-04/29/2019) era, 6 in the Pre (11/12/2019-02/03/2020) era and 10 in the Post (02/04/2020-04/27/2020) era.

Future analyses will be able to determine whether the median offer number of the final acceptor has increased. Similarly, the mean time from first electronic offer from an OPO to cross clamp was summarized for deceased liver donors.



Figure 25. Distribution of Time from First Electronic Offer to Cross Clamp for Deceased Liver Donors by Week

* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020.

** Navy solid lines are computed by calculating the mean time within each week, and then averaging across all weeks in the era. *** Dots indicate average time each week. Error bars indicate the 10th and 90th percentiles of time each week.

The average time from first electronic offer to cross clamp per week was 21.8 hours in the Pre (02/05/2019-04/29/2019) era, 23 hours in the Pre (11/12/2019-02/03/2020) era and 24.6 hours in the Post (02/04/2020-04/27/2020) era, implying no early change.

Simultaneous Liver Kidney

Figure 26. Distribution of Distance from Donor Hospital to Transplant Hospital for Deceased Donor Simulateous Liver-Kidney Transplants by Week



* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the mean distance within each week, and then averaging across all

weeks in the era. *** Dots indicate average distance each week. Error bars indicate the 10th and 90th percentiles of distance each week.

The mean distance was 147.4 NM in the Pre (02/05/2019-04/29/2019) era, 128.7 NM in the Pre (11/12/2019-02/03/2020) era, and 192.3 NM in the Post (02/04/2020-04/27/2020) era.



Figure 27. Number of Deceased Donor Simultaneous Liver-Kidney Transplants by Week

* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the number within each week, and then averaging across all weeks in the era.

The mean number of SLK Transplants was 13 in the Pre (02/05/2019-04/29/2019) era, 16 in the Pre (11/12/2019-02/03/2020) era, and 14 in the Post (02/04/2020-04/27/2020) era.

Intestine

Similar trends with comparisons to historical data on the intestine allocation system were also monitored below.





* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020.

** Navy solid lines are computed by calculating the number within each week, and then averaging across all weeks in the era.

The average number of new registrations added to the intestine waiting list per week was 2 in the Pre (02/05/2019-04/29/2019) era, 2 in the Pre (11/12/2019-02/03/2020) era, and 3 in the Post (02/04/2020-04/27/2020) era.



Figure 29. Number of Intestine Donors Recovered by Week

* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the number within each week, and then averaging across all weeks in the era.

The mean number of intestines recovered per week was 1 in the Pre (02/05/2019-04/29/2019) era, 2 in the Pre (11/12/2019-02/03/2020) era, and 1 in the Post (02/04/2020-04/27/2020) era.



Figure 30. Number of Deceased Donor Intestine Transplants by Week

* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020.

** Navy solid lines are computed by calculating the number within each week, and then averaging across all weeks in the e

The mean number of deceased donor intestine transplants per week was 1 in the Pre (02/05/2019-04/29/2019) era, 2 in the Pre (11/12/2019-02/03/2020) era, and 1 in the Post (02/04/2020-04/27/2020) era.

There were 14 total deceased donor intestine transplants in the Pre (02/05/2019-04/29/2019) era, 20 in the Pre (11/12/2019-02/03/2020) era, and 15 in the Post (02/04/2020-04/27/2020) era.



Figure 31. Percent of Deceased Donor Intestine Transplants that Traveled Further than 150 NM by Week

* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the percent within each week, and then averaging across all weeks in the era.

The mean percent of transplants that traveled over 150 NM per week was 79.2% for the Pre (02/05/2019-04/29/2019) era, 40.3% in the Pre (11/12/2019-02/03/2020) era, and 60.4% in the Post (02/04/2020-04/27/2020) era.



Figure 32. Percent of Deceased Donor Intestine Transplants that Occurred Within Same DSA as Donor Hospital by Week

* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020. ** Navy solid lines are computed by calculating the percent within each week, and then averaging across all weeks in the era.

Approximately 7.1% of deceased donor intestine transplants in the Pre (02/05/2019-04/29/2019) era were at a transplant hospital within the DSA of the recovery hospital. In the Pre (11/12/2019-02/03/2020) era, approximately 15% and Post (02/04/2020-04/27/2020) era approximately 13.3% were at a transplant hospital within the DSA of the recovery hospital.

Changes in the number of intestine candidates who were removed due to death or too sick to transplant are summarized below.



Figure 33. Number of Intestine Candidates Removed Due To Death or Too Sick to Transplant by Week

* National state of emergency in US due to COVID-19 pandemic declared week of March 13, 2020.

** Navy solid lines are computed by calculating the number within each week, and then averaging across all weeks in the era.

There were few candidates removed from the waiting list due to for too sick to transplant or death in a given week or policy era.

Conclusion

This report serves as an early look at high-level metrics to evaluate any early indications that the policy may be trending towards achieving intended goals, as well as to evaluation potential intended and unintended consequences of the liver and intestine policy changes implemented on February 04, 2020. At this point, metrics are still constrained to data points that are reliably available while allowing for data submission lags in OPTN policy.

These early metrics have begun to reveal some potential national changes compared to the pre-periods with respect to data trends. As noted throughout this report, the COVID-19 pandemic is a major confounder and makes interpretation of these data challenging, if not impossible for some metrics. There have been no discernible changes in liver discard rates. There have been a lower percentage of deceased donor transplant recipients with exceptions compared to pre-periods, as well as less variable median scores at transplant by DSA - both intended outcomes of the allocation and National Liver Review Board (NLRB) policies. As intended, an increased percentage of transplant recipients had MELD or PELD scores 29-36 while a decreased percentage of transplant programs, approximately equal proportions of transplants occurred within local, regional, and national share types. Most transplants still occurred within 150 NM of donor hospitals; however, this percentage decreased with a corresponding increase in transplants occurring within 150-250 NM and 250-500 NM.

There were no apparent national changes in other metrics for livers that can be untangled from potential impacts of COVID-19 pandemic. Additionally, there have been no apparent national changes for intestines with respect to data trends. Average distance of SLK transplants increased in the post-policy period, but there was no change in the number of SLK transplants, compared to the pre-policy periods.

The impact of the COVID-19 pandemic will continue to be monitored. It will be many months before the true impact of this policy change can be accurately realized. However, the system will continue to be monitored closely and metrics and trends will continue to be added as more time and data accrue. Future reports will contain more comprehensive analyses of the waiting list cohort, transplant recipient cohort and utilization as more data are available for analyses.

The next comprehensive report on this policy change will be available fall 2020, after approximately 6 months of data have been collected and compiled.