Final Report

OPTN Liver & Intestinal Transplantation Committee | Descriptive Data Request

Out-of-the-Gate Monitoring of Liver and Intestine Acuity Circle Allocation, 1 Month Report
Removal of DSA and Region as Units of Allocation

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Contents

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 6 month period following implementation. This report serves as a precursor to the more extensive analyses that will be performed on behalf of the Organ Procurement and Transplantation Network (OPTN) Liver and Intestinal Transplantation Committee at approximately 3 months, 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

Until sufficient data has been collected to monitor liver and intestine allocations by month, the changes implemented on February 04, 2020 will be monitored on a weekly basis. 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
- 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.

These early metrics suggest no apparent 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. 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 analyses will also consider comparisons to expected trends and directions from SRTR modeling results.

Cohorts

The cohort examined contains three periods to reivew 4 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, March 04, 2019, referred to as "Pre (2/05/2019-3/04/2019)" era, to consider seasonal changes.
- The second pre-policy era is from Tuesday, January 07, 2020 to Monday, February 03, 2020, referred to as "Pre (1/07/2020-2/03/2020)" era.
- The time period beginning upon implementation of the policy change is from Tuesday, February 04, 2020 to Monday, March 02, 2020, referred to as "Post (2/04/2020-3/02/2020)" 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 that received a liver transplant
- All liver donors from which at least one liver 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 March 13, 2020 and is subject to change based on any future data submission or correction.**

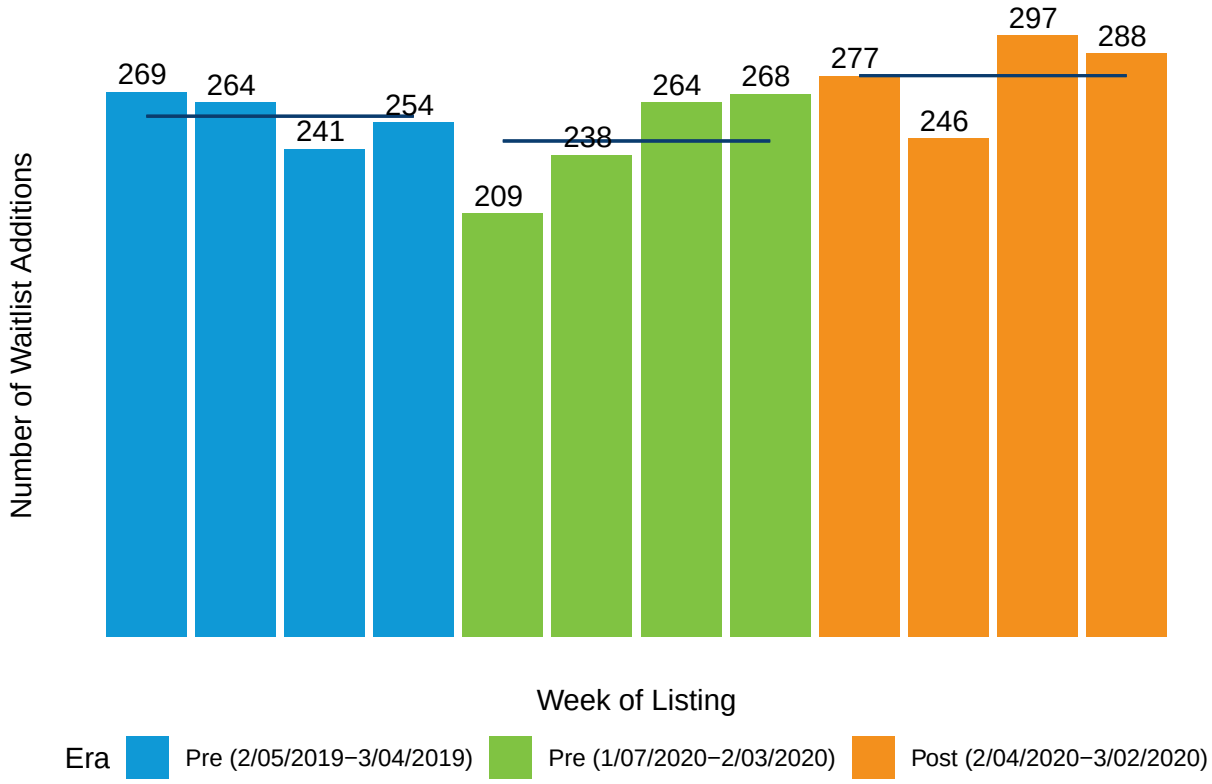
Analysis by Week

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 beginning Tuesday, January 14, 2020 and ending Monday, March 02, 2020.

While each of these measures customarily varies week to week, trends shown are in line with historical data on the liver allocation system.

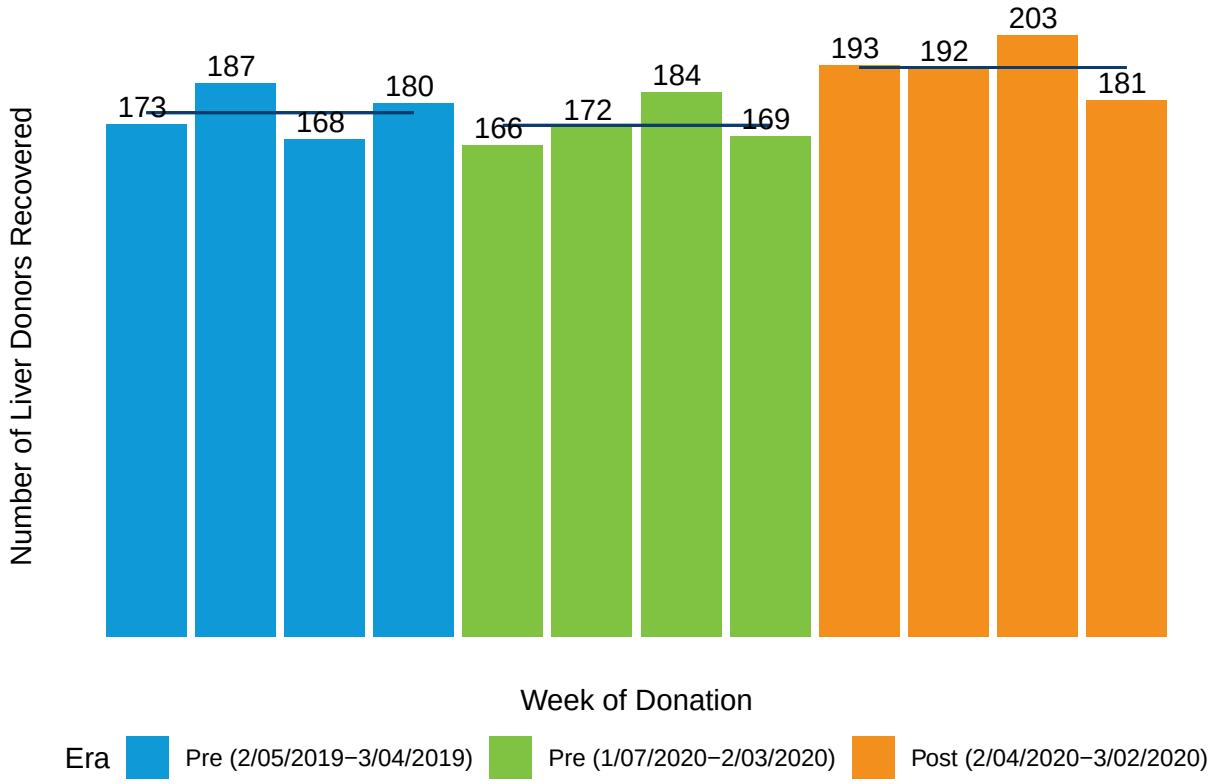
Figure 1. Number of Registrations Added to Liver Waiting List by Week



* 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 257 in the Pre (2/05/2019-3/04/2019) era, 245 in the Pre (1/07/2020-2/03/2020) era, and 277 in the Post (2/04/2020-3/02/2020) era.

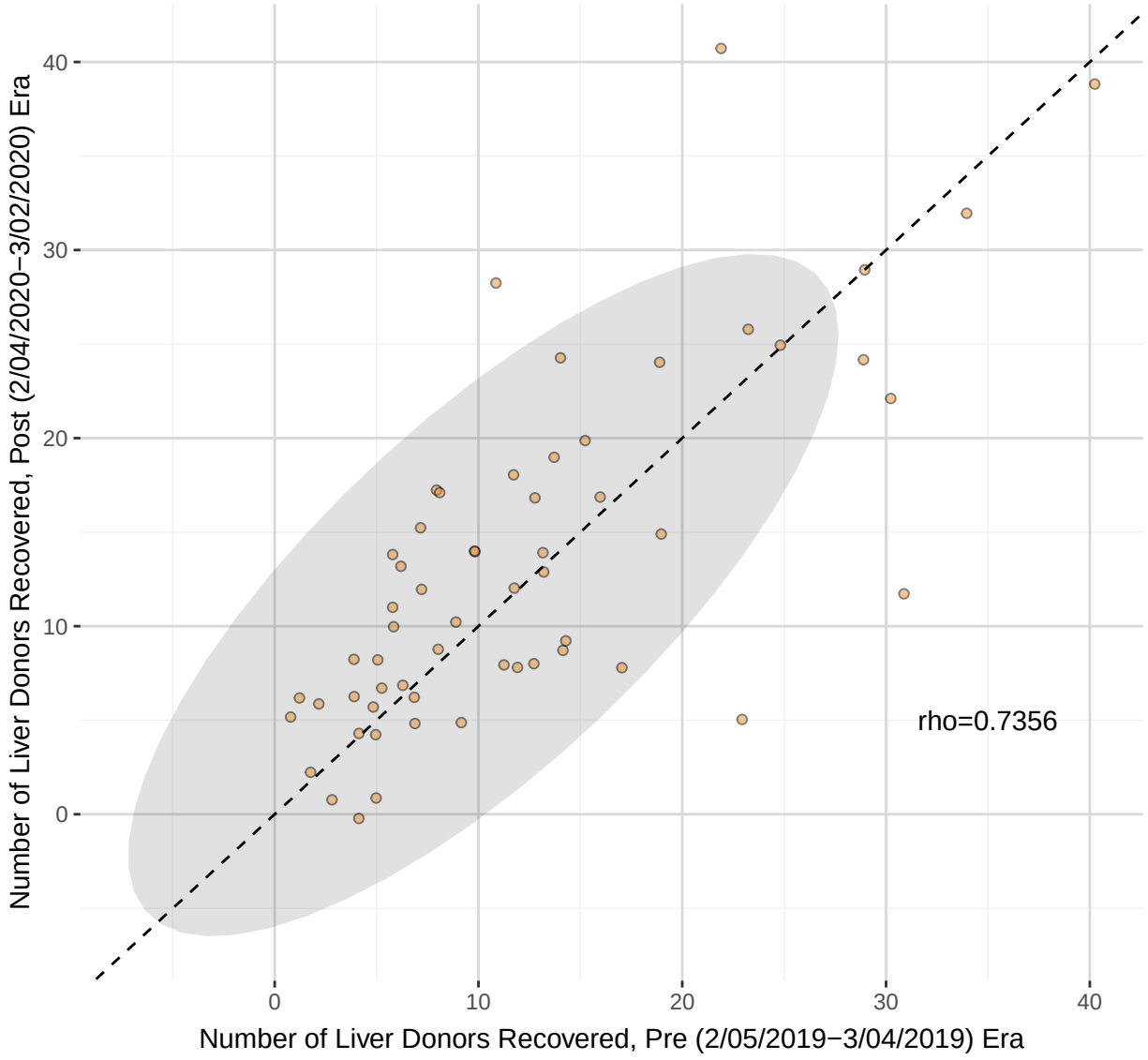
Figure 2. Number of Liver Donors Recovered by Week



* 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 177 in the Pre (2/05/2019-3/04/2019) era, 173 in the Pre (1/07/2020-2/03/2020) era, and 192 in the Post (2/04/2020-3/02/2020) era.

Figure 3. Number of Liver Donors Recovered by OPO



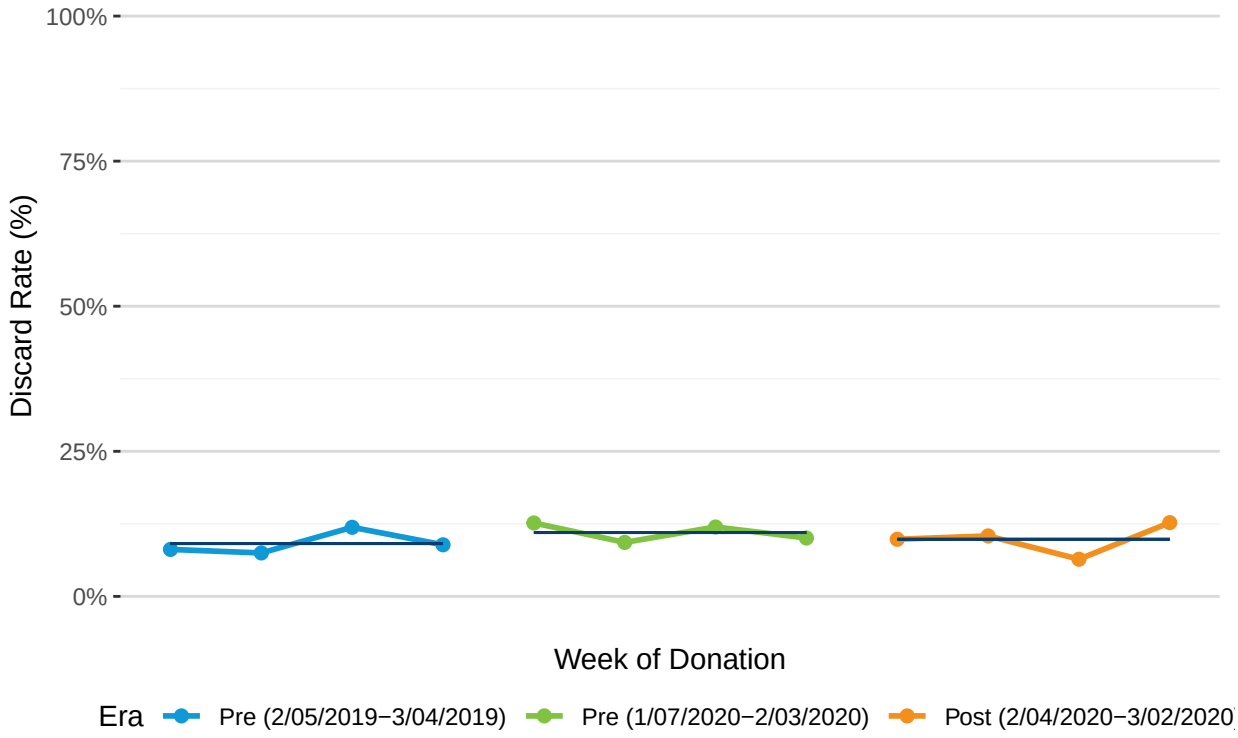
Any points along the diagonal dashed line indicate no changes in the absolute number of deceased liver donors recovered by an Organ Procurement Organization (OPO), pre- to post-policy. Points that fall above the diagonal represent OPOs that recovered more deceased liver donors post-policy compared to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

The grey 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 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 (2/05/2019-3/04/2019) and Post (2/04/2020-3/02/2020) 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.

Figure 4. Liver Discard Rate by Week

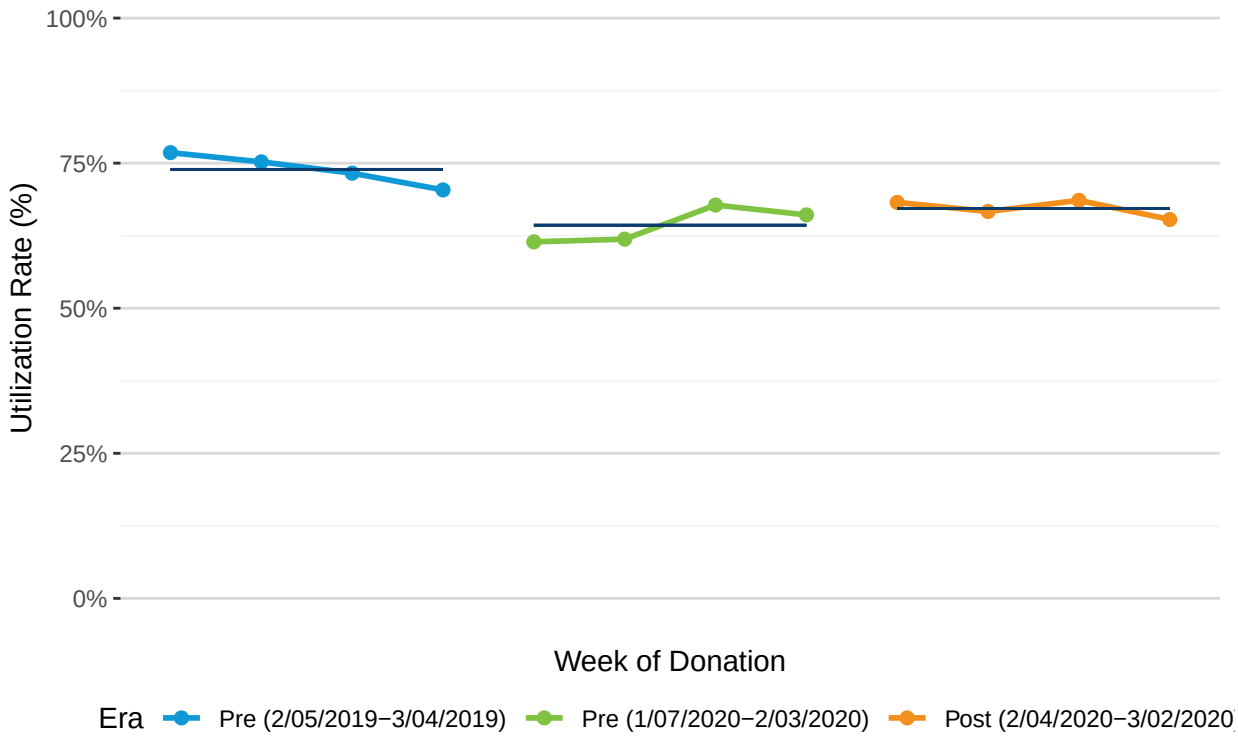


* Navy solid lines are computed by calculating the mean discard rate within each week, and then averaging across all weeks in the era.

The average discard rate per week was 9.1% for the Pre (2/05/2019-3/04/2019) era, 11% in the Pre (1/07/2020-2/03/2020) era, and 9.8% in the Post (2/04/2020-3/02/2020) era.

Figure 5 shows the national utilization rate (the percentage of deceased donors with a liver transplanted, out of all deceased organ donors) by week.

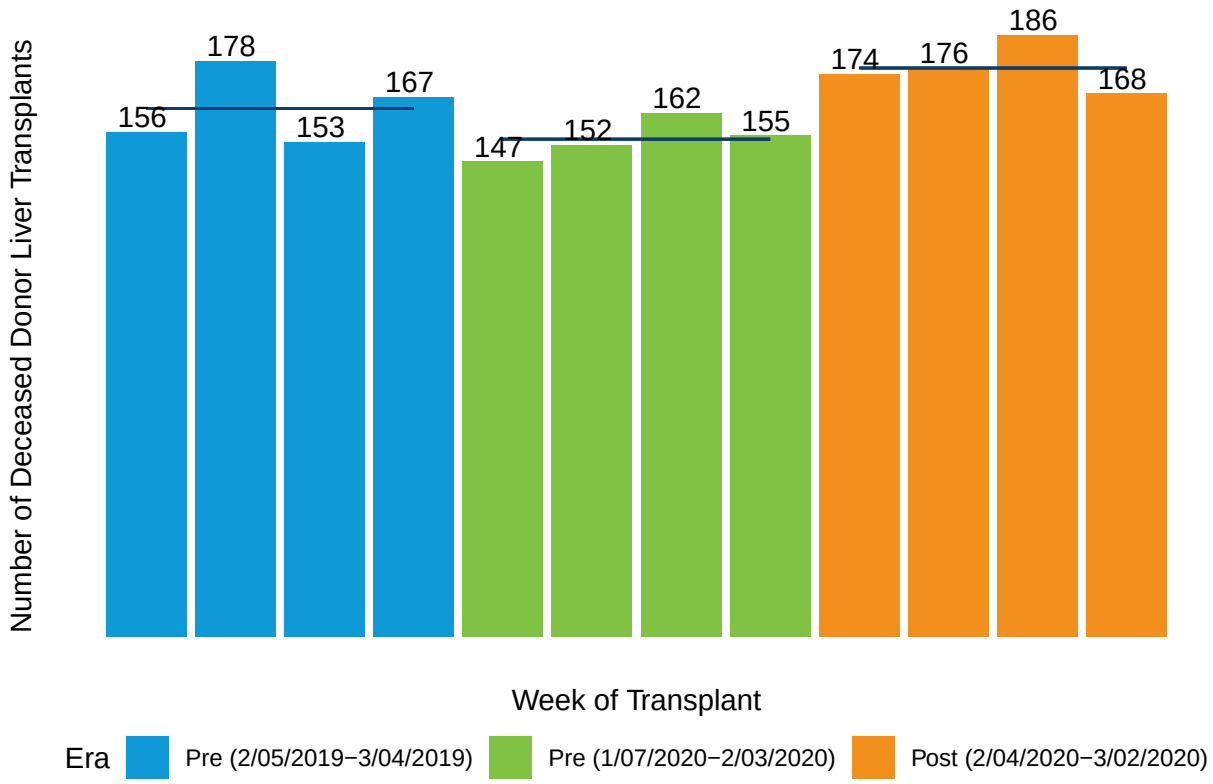
Figure 5. Liver Utilization Rate by Week



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

The average utilization rate per week was 73.9% for the Pre (2/05/2019-3/04/2019) era, 64.3% in the Pre (1/07/2020-2/03/2020) era, and 67.2% in the Post (2/04/2020-3/02/2020) era.

Figure 6. Number of Deceased Donor Liver Transplants by Week

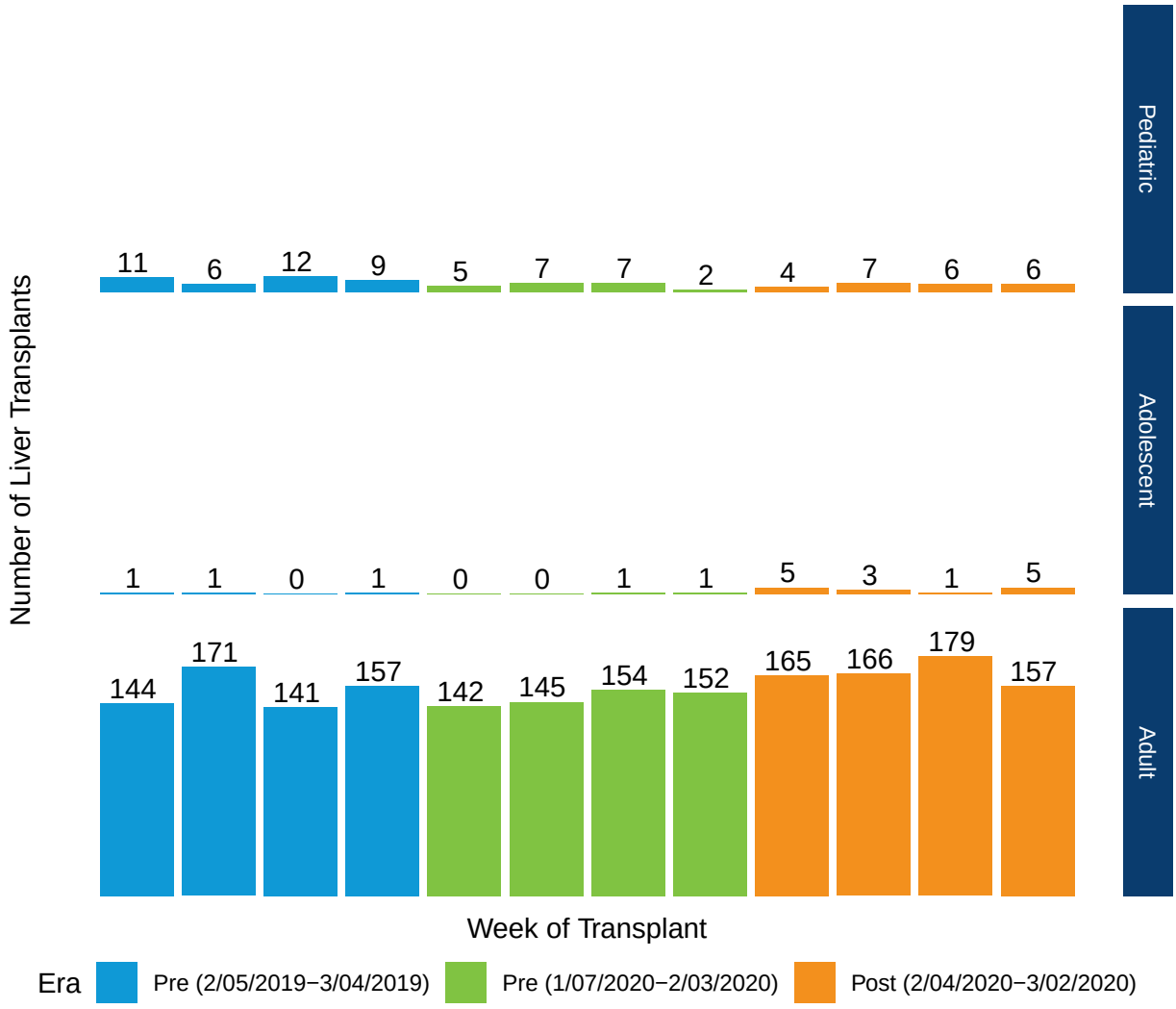


* Navy solid lines are computed by calculating the number within each week, and then averaging across all weeks in the era.

The mean number of deceased donor liver transplants per week was 164 in the Pre (2/05/2019-3/04/2019) era, 154 in the Pre (1/07/2020-2/03/2020) era, and 176 in the Post (2/04/2020-3/02/2020) era. There were 654 total deceased donor liver transplants in the Pre (2/05/2019-3/04/2019) era, 616 in the Pre (1/07/2020-2/03/2020) era, and 704 in the Post (2/04/2020-3/02/2020) era.

In Figure 7 and Table 1, deceased donor liver transplant recipients are summarized by age group. 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 adolescent (age 12-17 years at transplant) deceased donor liver transplant recipients.

Figure 7. Number of Deceased Donor Liver Transplants by Age and Week



* 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.

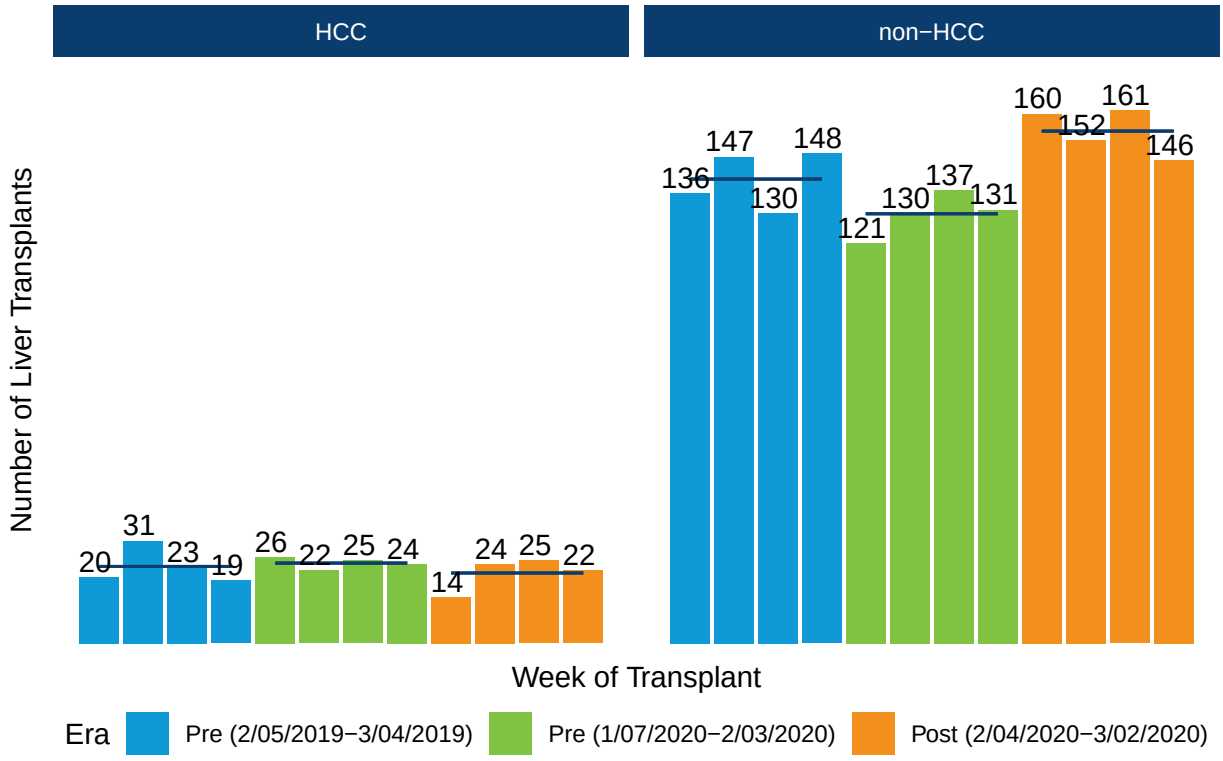
Table 1. Percentage of Deceased Donor Liver Transplants in each Age Group by Week

Age	Pre (2/05/2019-3/04/2019)	Pre (1/07/2020-2/03/2020)	Post (2/04/2020-3/02/2020)
Pediatric	5.8 %	3.4 %	3.3 %
Adolescent	0.5 %	0.3 %	2.0 %
Adult	93.7 %	96.3 %	94.7 %

Here we compare the number of deceased donor liver transplant recipients with a hepatocellular carcinoma (HCC) exception at time of transplant, to those deceased donor liver transplant recipients that did not have an HCC exception at time of transplant between eras. Note that the group of recipients that did not have an HCC exception at time of transplant contains those recipients with no type of exception, as well as those with a non-HCC related exception.

There has been an observable increase in the deceased donor liver transplant recipients without HCC 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 (1/07/2020-2/03/2020) policy. Prior to that, exception scores were not standardized in policy and were adjudicated by Regional Review Boards (RRB) in the Pre (2/05/2019-3/02/2019) policy.

Figure 8. Number of Deceased Donor Liver Transplants by HCC Exception Status and Week

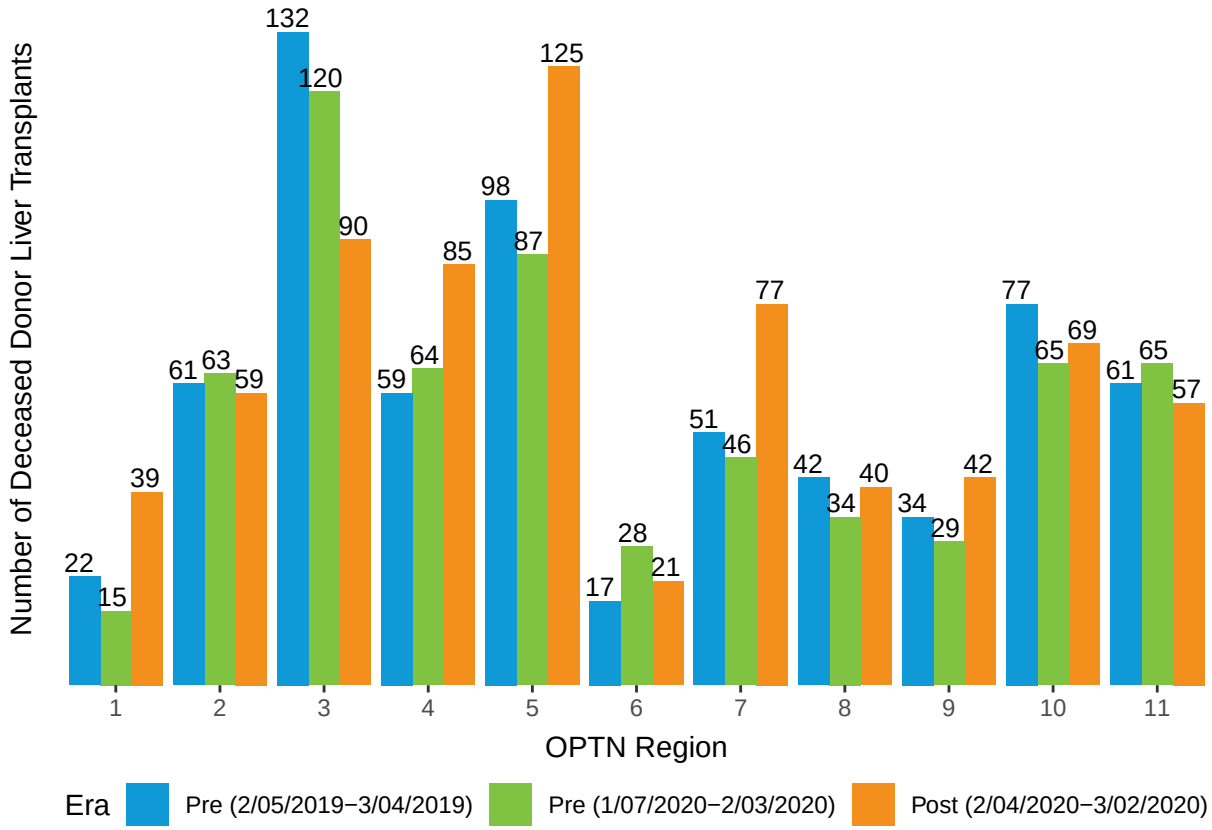


* Navy solid lines are computed by calculating the number within each week and subgroup, and then averaging across all weeks in the era and subgroup.

Table 2. Percentage of Deceased Donor Liver Transplants by HCC Exception Status and Week

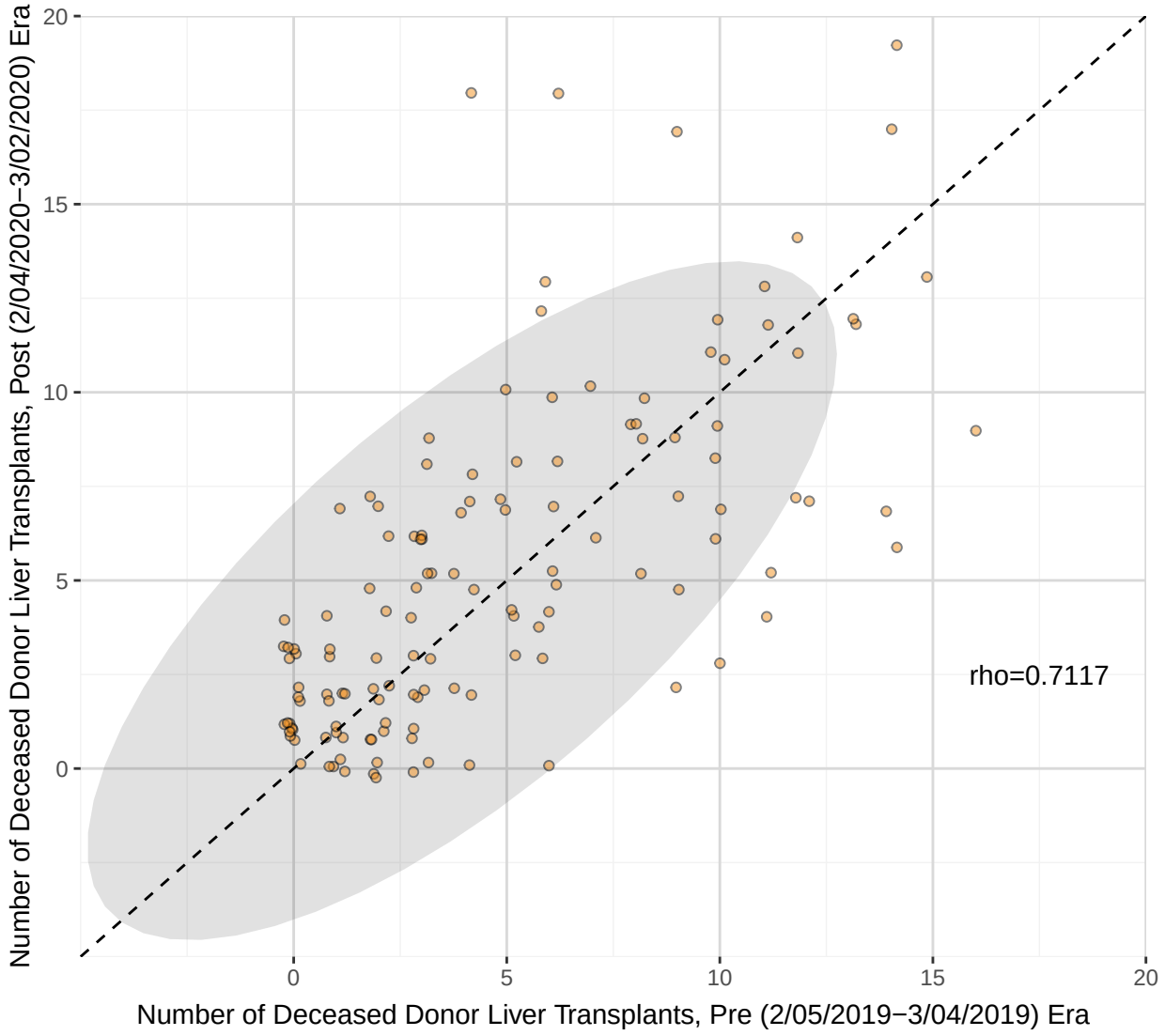
HCC Exception Status	Pre (2/05/2019-3/04/2019)	Pre (1/07/2020-2/03/2020)	Post (2/04/2020-3/02/2020)
HCC	14.2 %	15.7 %	12.1 %
non-HCC	85.8 %	84.3 %	87.9 %

Figure 9. Number of Deceased Donor Liver Transplants by OPTN Region



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, while regions 5 and 7 have experienced the largest increases.

Figure 10. 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.

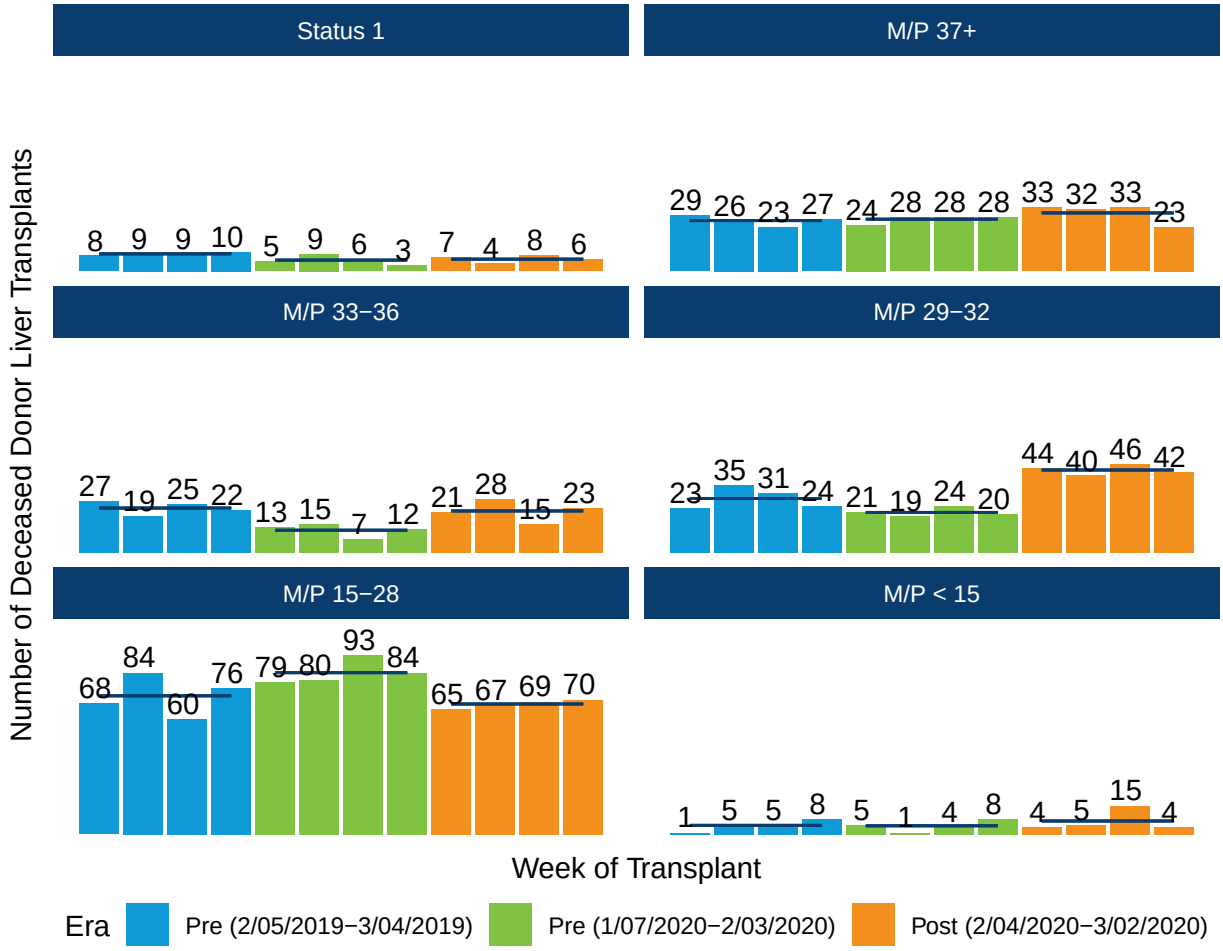
Any points along the diagonal dashed line indicate no changes in the absolute number of deceased donor liver transplants by program, pre- to post-policy. Points that fall above the diagonal represent programs that performed more deceased donor liver transplants post-policy compared to pre-policy. Points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

The grey 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 (2/05/2019-3/04/2019) and Post (2/04/2020-3/02/2020) 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 Figure 11, 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 pre- and post-policy. Higher percentages of transplants with allocation scores between 29-36, in addition to a lower percentage between 15-28, occurred post-policy.

Figure 11. Number of Deceased Donor Liver Transplants by MELD or PELD Score or Status and Week



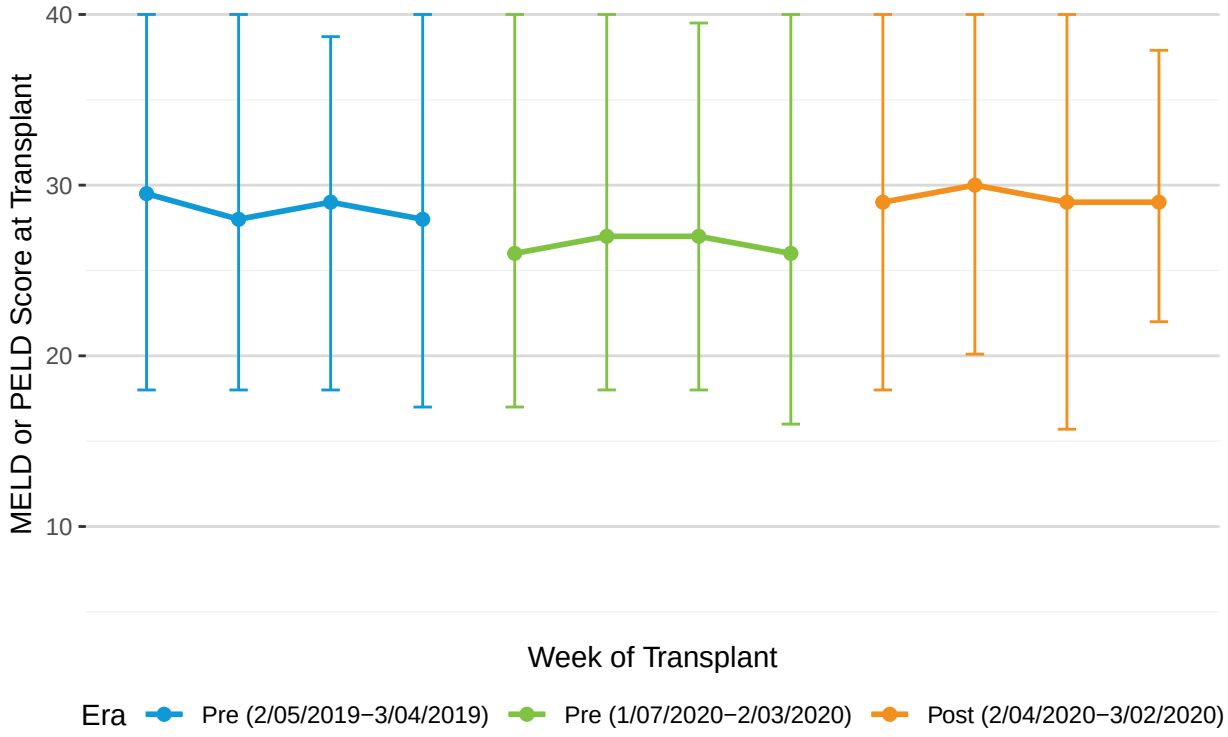
* Navy solid lines are computed by calculating the number within each week and subgroup, and then averaging across all weeks in the era and subgroup.

Table 3. Percentage of Deceased Donor Liver Transplants in each MELD or PELD Score or Status Group

MELD or PELD Score Group	Pre (2/05/2019-3/04/2019)	Pre (1/07/2020-2/03/2020)	Post (2/04/2020-3/02/2020)
Status 1	5.5 %	3.7 %	3.6 %
M/P 37+	16.1 %	17.5 %	17.2 %
M/P 33-36	14.2 %	7.6 %	12.4 %
M/P 29-32	17.3 %	13.6 %	24.4 %
M/P 15-28	44.0 %	54.5 %	38.5 %
M/P < 15	2.9 %	2.9 %	4.0 %

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. Figure 10 shows the median MELD or PELD score at transplant for deceased donor liver transplant recipients by week. The error bars indicate the 10th and 90th percentiles for each week. This excludes any Status 1A or Status 1B deceased donor liver transplants.

Figure 12. Distribution of Deceased Donor Liver Recipient Allocation MELD or PELD Score at Transplant by Week

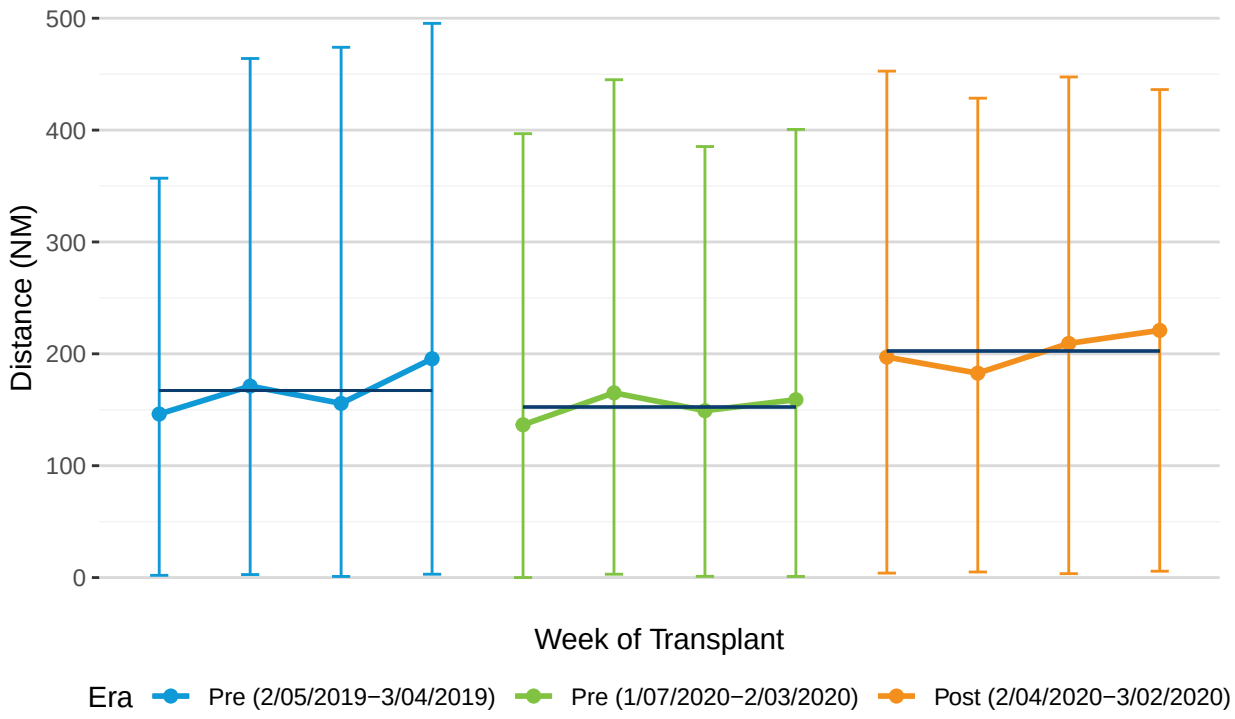


* Excludes Status 1 Transplants.
** Dots indicate median score each week. Error bars indicate the 10th and 90th percentiles of scores each week.

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 (2/05/2019-3/04/2019) era, 27 in the Pre (1/07/2020-2/03/2020) era and 29 in the Post (2/04/2020-3/02/2020) era. The median MELD or PELD at transplant by week does fluctuate noticeably, partly due to small sample sizes. However, further data and monitoring will be needed to determine if the median MELD or PELD score at transplant is significantly higher in the post-era.

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. Figure 13 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.

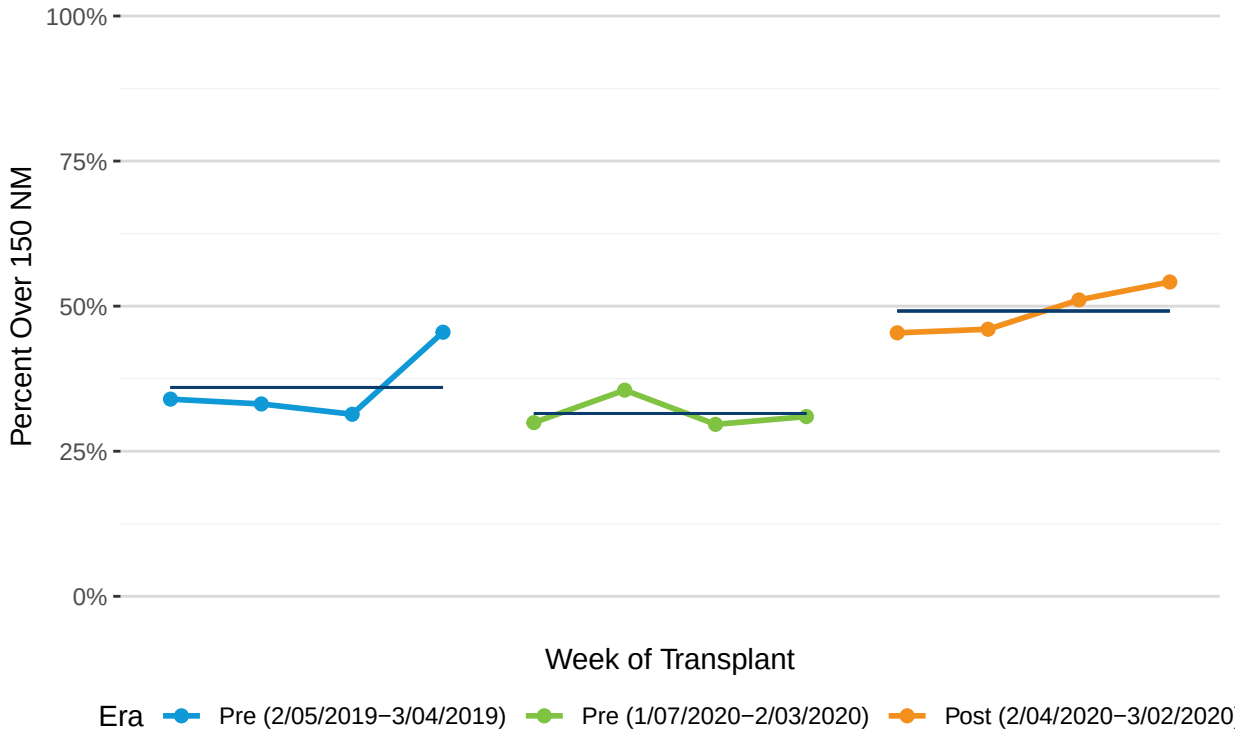
Figure 13. Distribution of Distance from Donor Hospital to Transplant Hospital for Deceased Donor Liver Transplants by Week



* 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 167 NM in the Pre (2/05/2019-3/04/2019) era, 152 NM in the Pre (1/07/2020-2/03/2020) era, and 203 NM in the Post (2/04/2020-3/02/2020) era. Similarly, Figure 14 summarizes the percent of deceased donor liver transplants that traveled further than 150 NM, outside the first unit of allocation post-policy change.

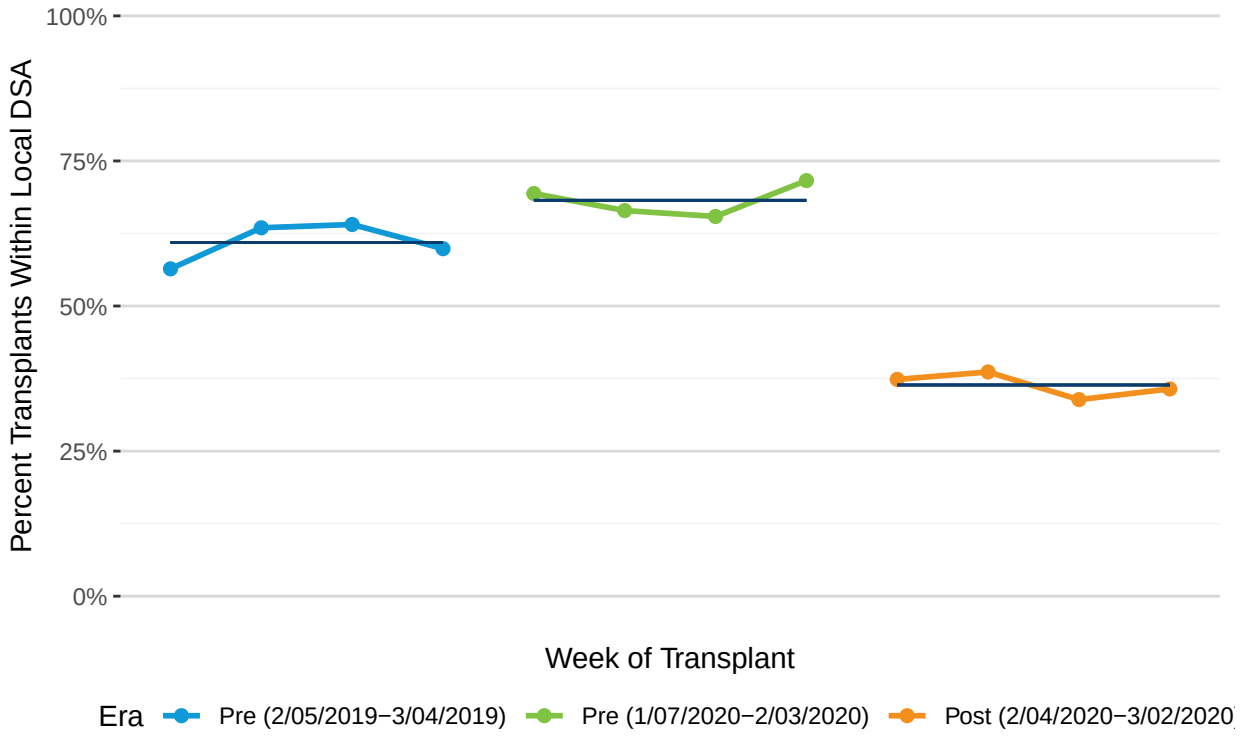
Figure 14. Percent of Deceased Donor Liver Transplants that Traveled Further than 150 NM by Week



* 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 36% for the Pre (2/05/2019-3/04/2019) era, 31.5% in the Pre (1/07/2020-2/03/2020) era, and 49.2% in the Post (2/04/2020-3/02/2020) era.

Figure 15. Percent of Deceased Donor Liver Transplants that Occurred Within Same DSA as Donor Hospital by Week

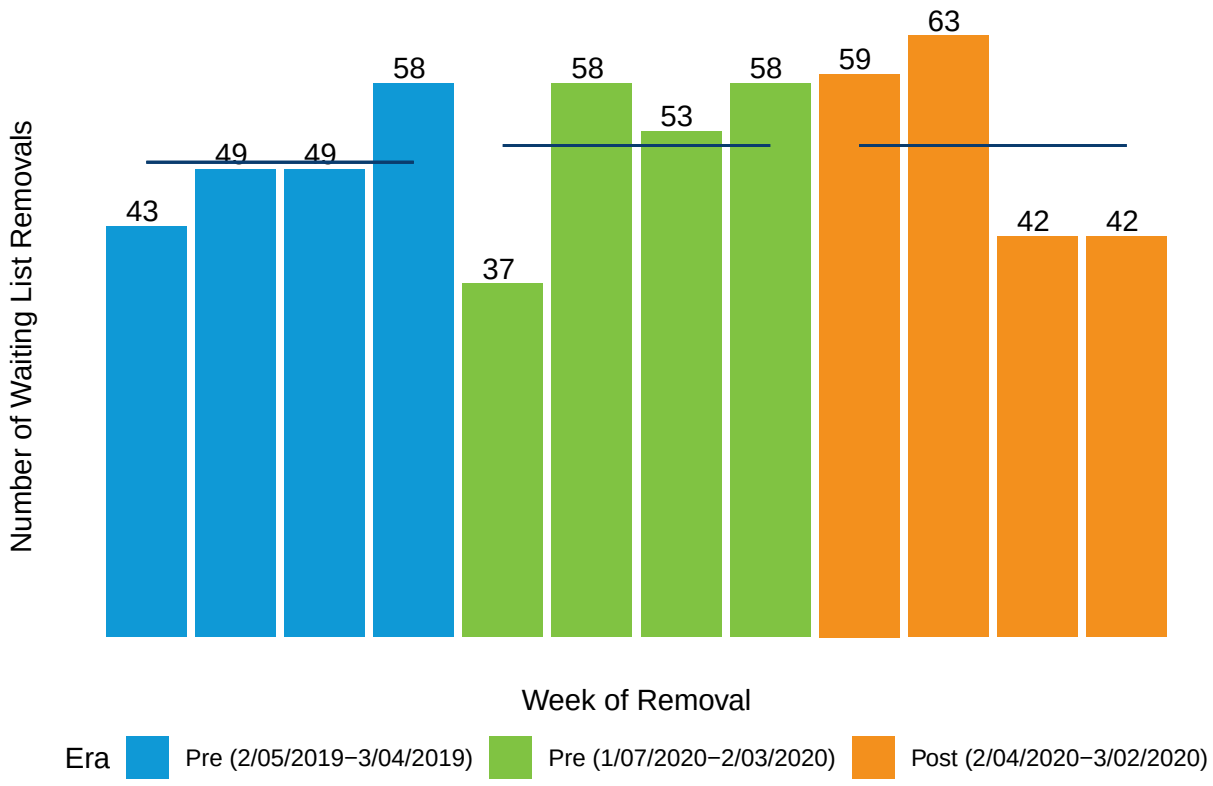


* Navy solid lines are computed by calculating the percent within each week, and then averaging across all weeks in the era.

Approximately 36.4% of deceased donor liver transplants in the Post (2/04/2020-3/02/2020) era were at a transplant hospital within the DSA of the recovery hospital. In the Pre (2/05/2019-3/04/2019) era, approximately 61% and Pre (1/07/2020-2/03/2020) era approximately 68.2% were at a transplant hospital within the DSA of the recovery hospital.

Changes in the number of liver candidates who were removed due to death or too sick to transplant are summarized in Figure 16.

Figure 16. Number of Liver Candidates Removed Due To Death or Too Sick to Transplant by Week

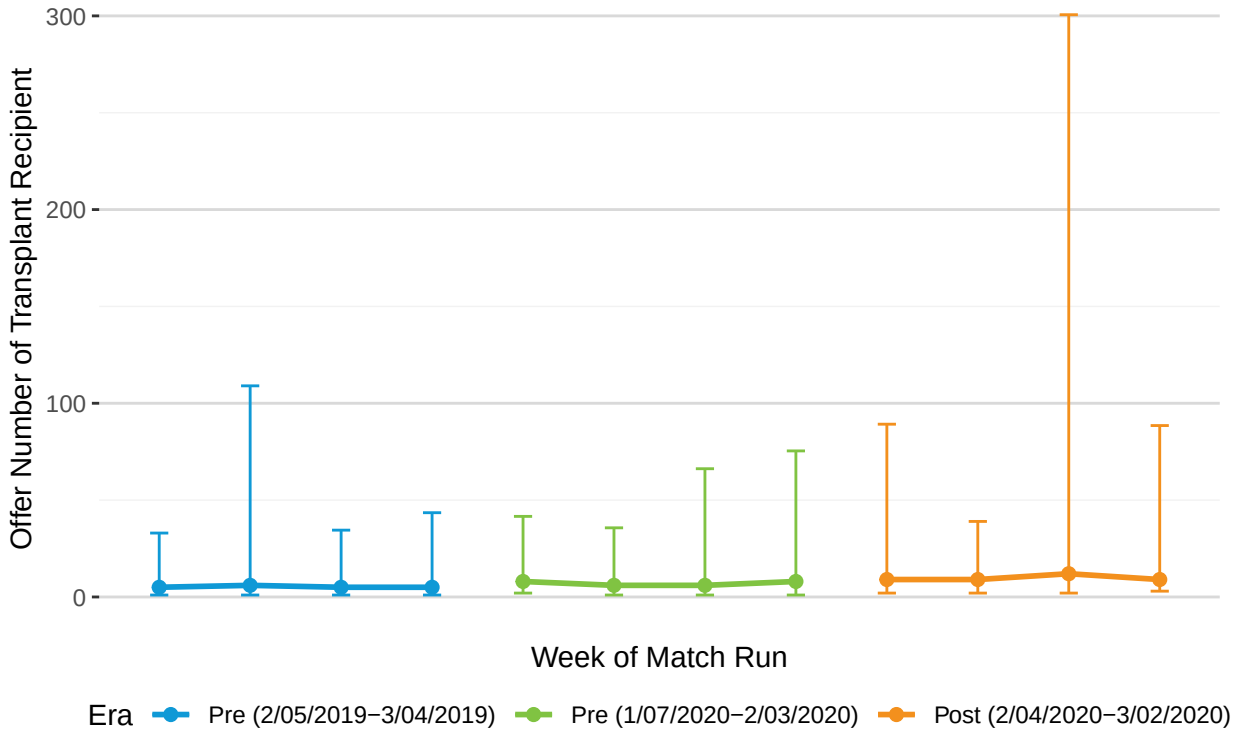


* Navy solid lines are computed by calculating the number within each week, and then averaging across all weeks in the era.

The average number of candidates removed from the waiting list due to for too sick to transplant or death, represented by the navy lines in Figure 16, was 50 for the Pre (2/05/2019-3/04/2019) era, 52 in the Pre (1/07/2020-2/03/2020) era, and 52 in the Post (2/04/2020-3/02/2020) era, per week.

To summarize the match process, Figure 17 shows the median sequence number of deceased donor liver transplant recipients. 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.

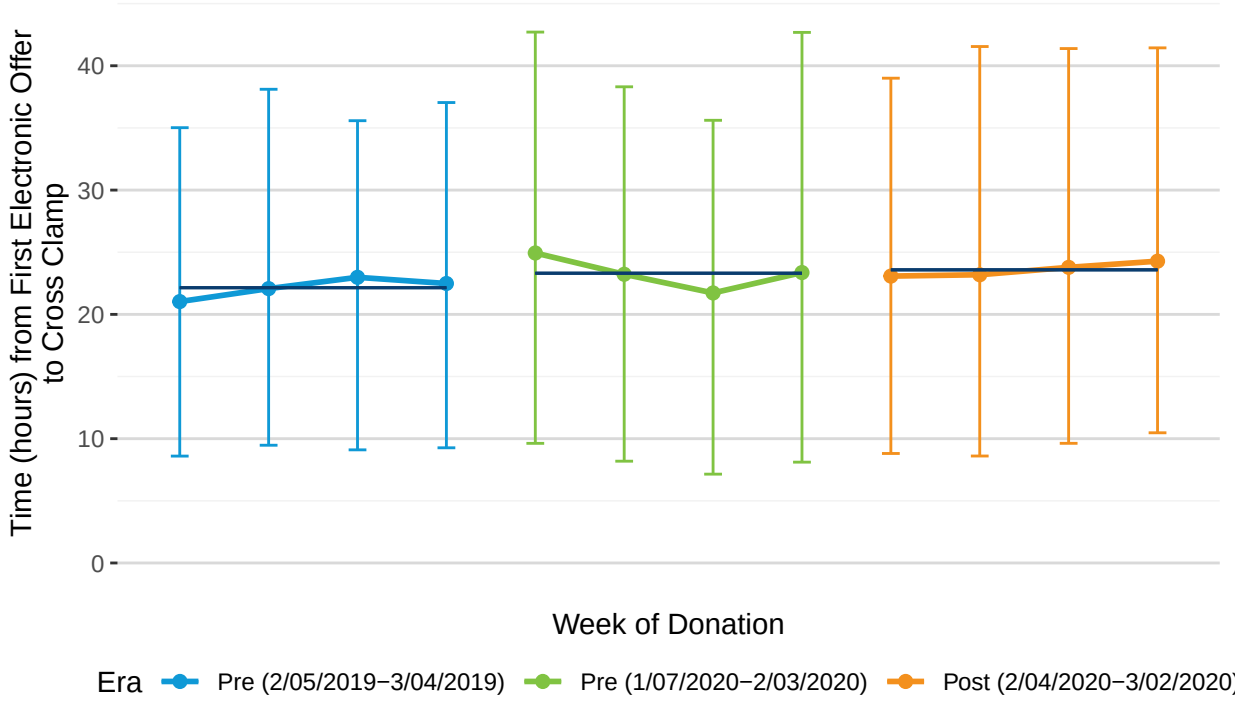
Figure 17. Distribution of Sequence Number of Deceased Donor Liver Transplant Recipients



* 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 (2/05/2019-3/04/2019) era, 7 in the Pre (1/07/2020-2/03/2020) era and 9 in the Post (2/04/2020-3/02/2020) era. Future analyses will be able to determine whether the median offer number of the final acceptor has increased. Similarly, Figure 18 summarizes the mean time from first electronic offer from an OPO to cross clamp for deceased liver donors.

Figure 18. Distribution of Time from First Electronic Offer to Cross Clamp for Deceased Liver Donors



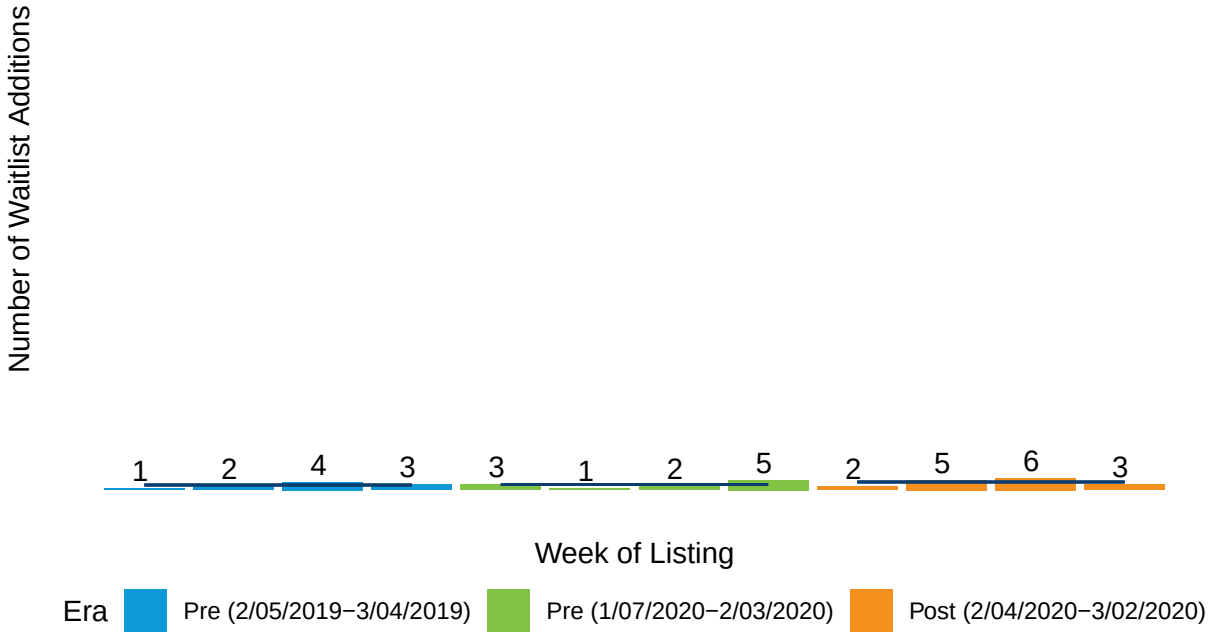
* Navy solid lines are computed by calculating the mean time within each week, and then averaging across all weeks in the era.
** Dots indicate average time each week. Error bars indicate the 10th and 90th percentiles of time each week.

The average time from first electronic offer to cross clamp per week was 22.1 hours in the Pre (2/05/2019-3/04/2019) era, 23.3 hours in the Pre (1/07/2020-2/03/2020) era and 23.6 hours in the Post (2/04/2020-3/02/2020) era, implying no early change.

Intestine

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

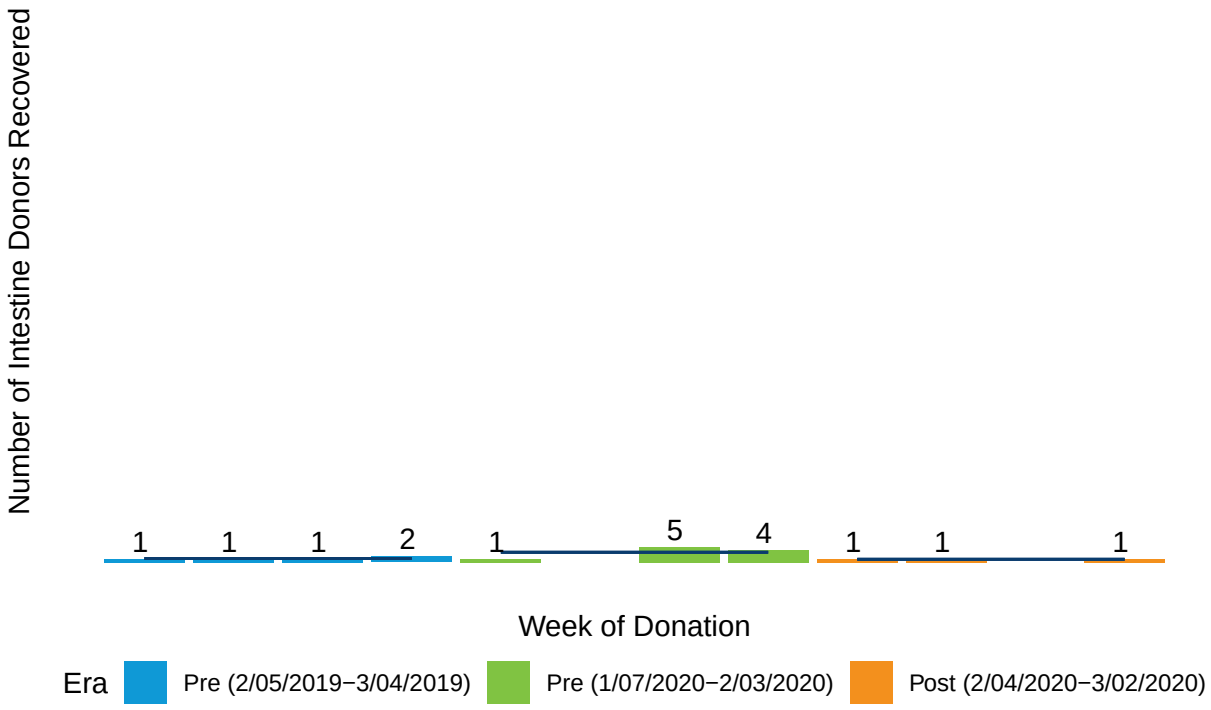
Figure 19. Number of Registrations Added to Intestine Waiting List by Week



* 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 (2/05/2019-3/04/2019) era, 3 in the Pre (1/07/2020-2/03/2020) era, and 4 in the Post (2/04/2020-3/02/2020) era.

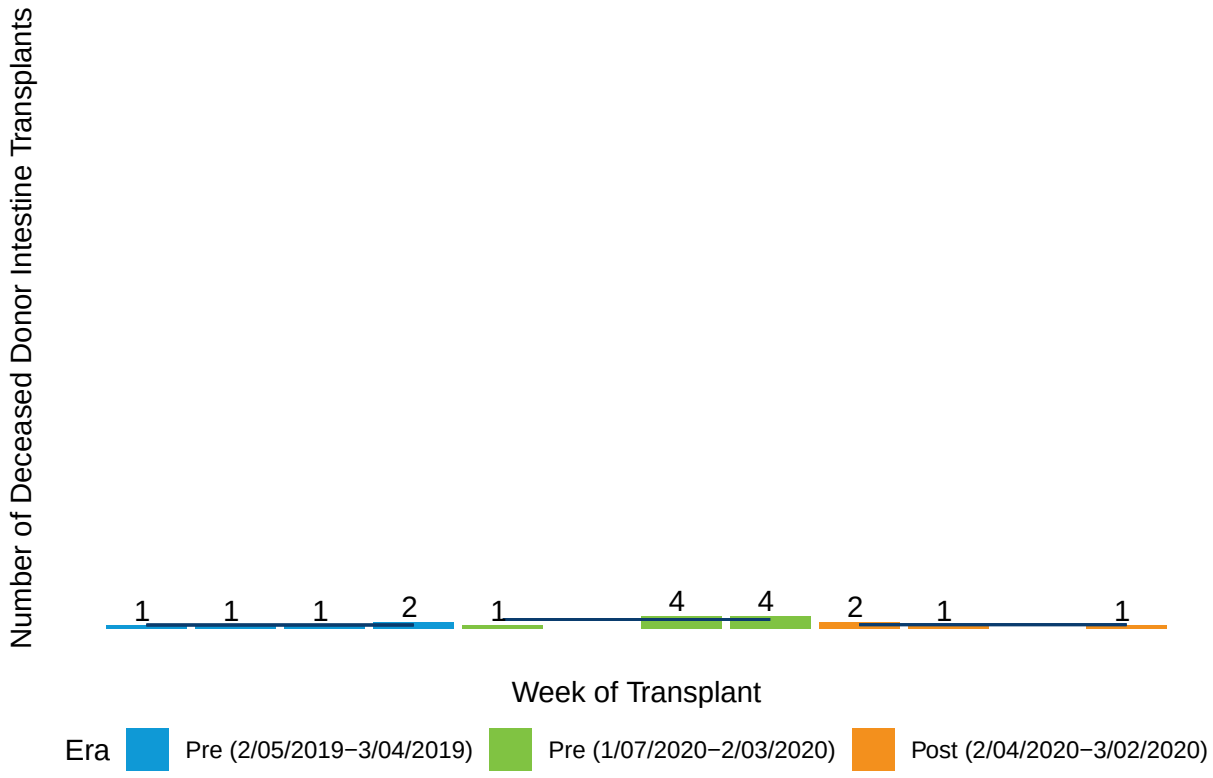
Figure 20. Number of Intestine Donors Recovered by Week



* 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 (2/05/2019-3/04/2019) era, 3 in the Pre (1/07/2020-2/03/2020) era, and 1 in the Post (2/04/2020-3/02/2020) era.

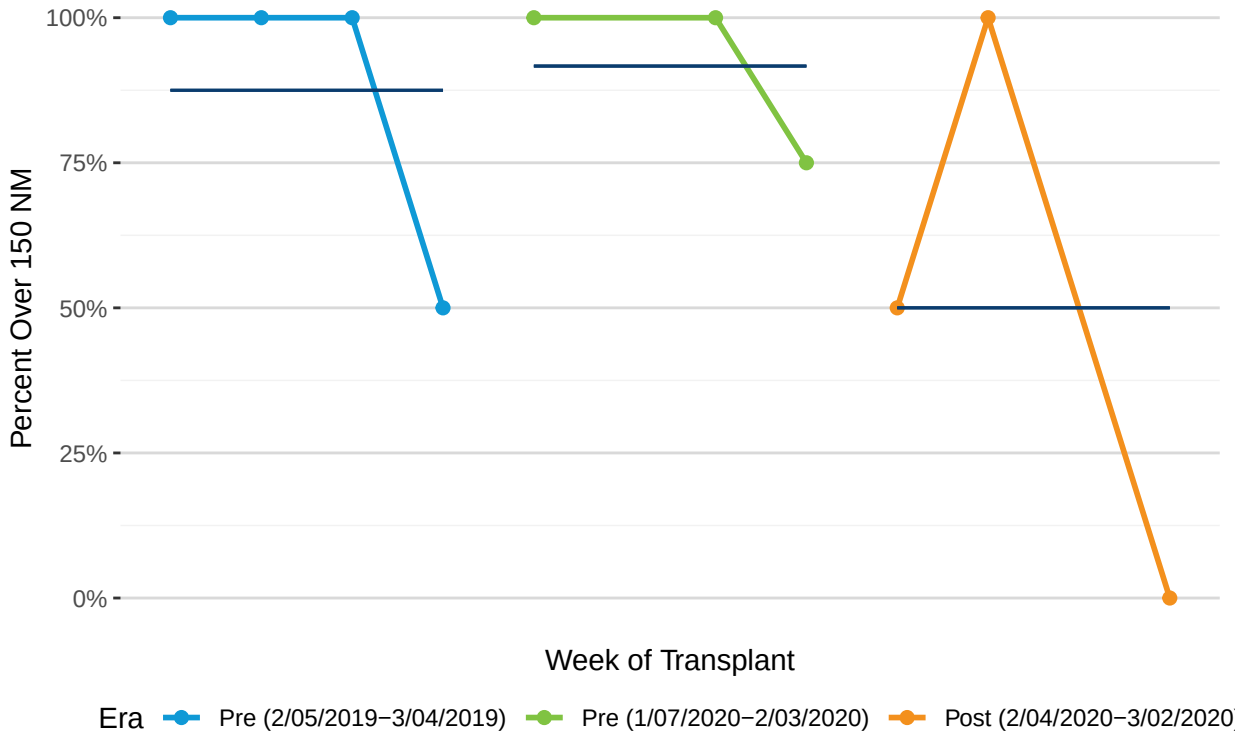
Figure 21. Number of Deceased Donor Intestine Transplants by Week



* 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 deceased donor intestine transplants per week was 1 in the Pre (2/05/2019-3/04/2019) era, 3 in the Pre (1/07/2020-2/03/2020) era, and 1 in the Post (2/04/2020-3/02/2020) era. There were 5 total deceased donor intestine transplants in the Pre (2/05/2019-3/04/2019) era, 9 in the Pre (1/07/2020-2/03/2020) era, and 4 in the Post (2/04/2020-3/02/2020) era.

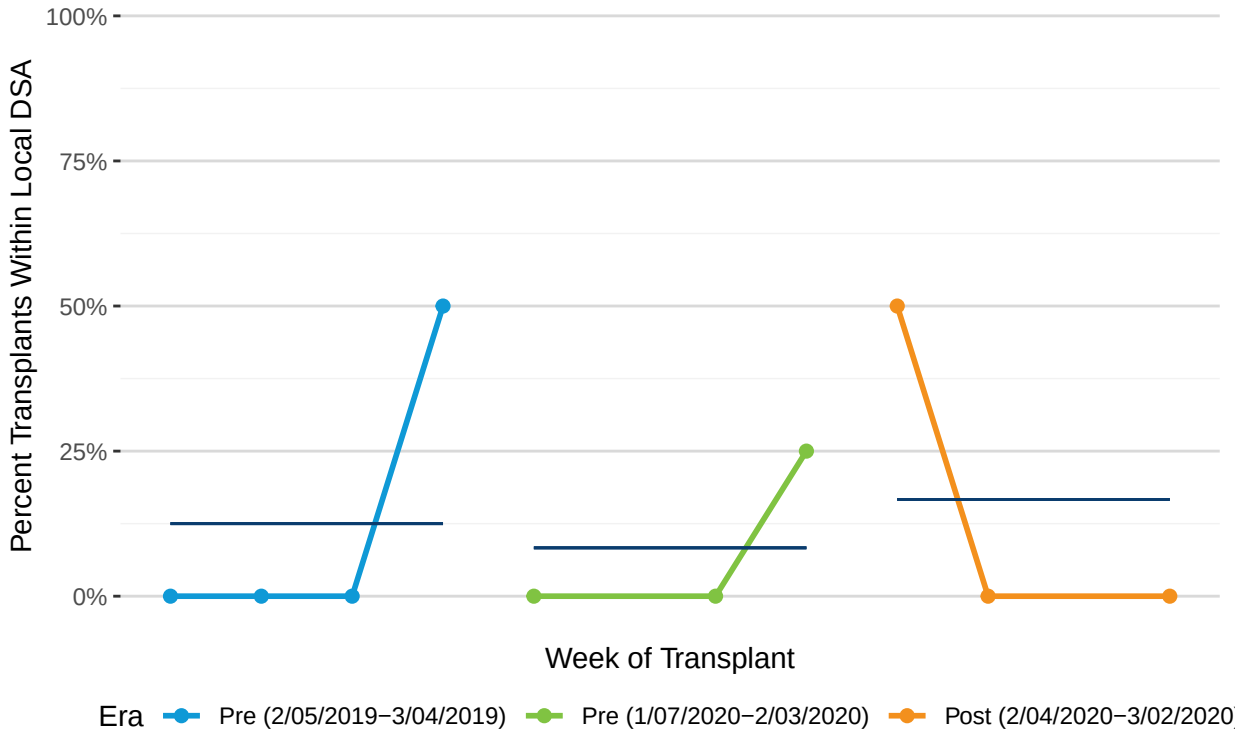
Figure 22. Percent of Deceased Donor Intestine Transplants that Traveled Further than 150 NM by Week



* 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 87.5% for the Pre (2/05/2019-3/04/2019) era, 91.7% in the Pre (1/07/2020-2/03/2020) era, and 50% in the Post (2/04/2020-3/02/2020) era.

Figure 23. Percent of Deceased Donor Intestine Transplants that Occurred Within Same DSA as Donor Hospital by Week

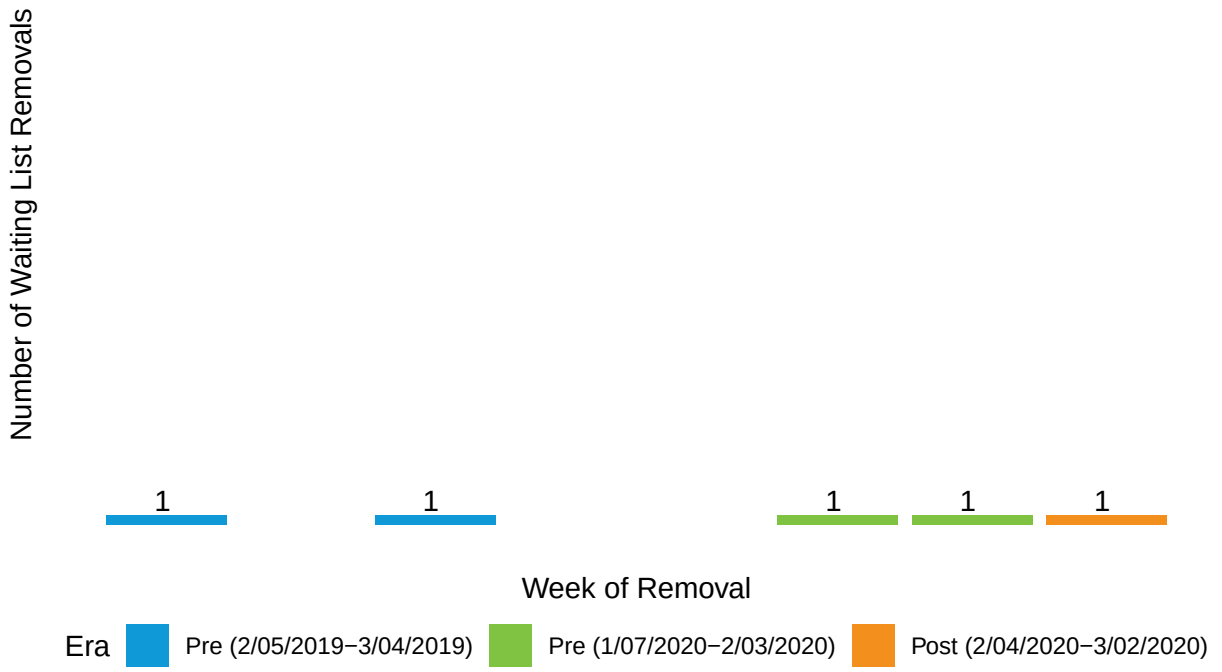


* Navy solid lines are computed by calculating the percent within each week, and then averaging across all weeks in the era.

Approximately 25% of deceased donor intestine transplants in the Post (2/04/2020-3/02/2020) era were at a transplant hospital within the DSA of the recovery hospital. In the Pre (2/05/2019-3/04/2019) era, approximately 20% and Pre (1/07/2020-2/03/2020) era approximately 11.1% 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 in Figure 16.

Figure 24. Number of Intestine Candidates Removed Due To Death or Too Sick to Transplant by Week



* 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 constrained to data points that are reliably available while allowing for the data submission lags allowed in OPTN policy. These early metrics suggest no apparent changes compared to the pre-periods with respect to data trends. 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. Additionally, as data accumulate, data will be shown more in aggregate versus on a weekly basis. Future analyses will also consider comparisons to expected trends and directions from SRTR modeling results.