Final Report

OPTN Membership and Professional Standards

Descriptive Data Request

Enhance Transplant Program Performance Monitoring System Two Year Monitoring Report

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Executive Summary

The proposal to enhance transplant program performance metrics was approved by the OPTN Board of Directors on December 06, 2021 (intervention date) for a phased implementation beginning July 2022. This analysis compares the *actual, observed trends* following policy implementation to predicted (based on historical data) trends of what would have been *expected to occur with no policy change*. This comparison can identify differences that could be further investigated by the Committee.

Overall

 There were no negative impacts or consequences to graft failure rates, waiting list registration additions, or utilization rates at the system-level.

Graft Failure Rates

- The observed trend in one year all-cause graft failure rate after Board Approval was lower (better) than the predicted trends after Board Approval for kidney transplant recipients.
- Observed trends in one year all-cause graft failure rate after Board Approval were similar to predicted trends for all other organs.
- Sensitivity analyses that used the implementation date of the post-transplant graft survival metric (i.e., July 14, 2022) instead of the Board Approval date yielded similar results.

OPTN Waiting List Registration Additions

- The observed trend in waiting list additions after Board Approval was higher (better) than the predicted trends after Board Approval for kidney, liver, and heart waiting list additions.
- Observed trends in waiting list additions after Board Approval were similar to predicted trends for all other organs.
- The COVID-19 pandemic beginning in March 2020 had an impact on registrations added to the OPTN Waiting List for all organs.
- Sensitivity analyses that used the implementation date of the pre-transplant mortality rate ratio metric (i.e., July 25, 2024) instead of the Board Approval date could not be explored in this report due to insufficient follow-up time. However, these sensitivity analyses will be revisited in the future as more data accrue.

Utilization Rates

Utilization rates were defined as the number of organ-specific transplants out of potential organs transplantable. See Methods Section for more details.

- The observed trends in utilization rates after Board Approval were higher (better) than the predicted trends after Board Approval for liver, lung, and heart (to a lesser extent).
- Observed trends in utilization rates after Board Approval were similar to predicted trends for kidney and pancreas.
- Sensitivity analyses that used the implementation date of the offer acceptance rate ratio metric (i.e., July 27, 2023) instead of the Board Approval date yielded similar results, although the magnitude of the difference between observed and predicted trends tended to be smaller.

Note: The interpretation of patterns and trends in utilization rates due to other policy changes or influential events, not the transplant program evaluation changes that are the focus of these analyses, are outside the scope of this report. Overall trends in observed utilization rates over time are not addressed.

Transplant-to-Recovery Rates

Transplant-to-recovery rates were defined as the number of organ-specific transplants out of the number of specific organs recovered. See Methods Section for more details.

- The observed trends in transplant-to-recovery rates after Board Approval were slightly lower (worse) than predicted trends after Board Approval for heart.
- For all other organs, the observed trends in transplant-to-recovery rates after Board Approval were in line with predicted trends after Board Approval.

• When the implementation date of the offer acceptance rate ratio metric (i.e., July 27, 2023) was used instead of the Board Approval date, observed trends in transplant-to-recover rates were similar to predicted trends for all organs.

Note: The interpretation of patterns and trends in transplant-to-recovery rates due to other policy changes or influential events, not the transplant program evaluation changes that are the focus of these analyses, are outside the scope of this report. Overall trends in observed transplant-to-recovery rates over time are not addressed.

Background/Purpose

The Performance Monitoring Enhancements (PME) subcommittee of the OPTN Membership and Professional Standards Committee (MPSC) proposed broadly changing the scope with which transplant programs are evaluated against performance standards, outlined in the OPTN Bylaws. This proposal, passed by the OPTN Board of Directors in December 2021, expanded the family of metrics for which programs are accountable from just two (one-year post-transplant graft survival rate and one-year post-transplant patient survival rate) to four metrics. These four new metrics are intended to survey processes occurring both before (pre-transplant mortality rate and offer acceptance rate) and after (90-day post-transplant graft survival rate, a short-term measurement, and 365-day post-transplant graft survival rate conditional on survival beyond 90 days, a longer-term measurement) transplantation.

Feedback regarding the proposal - though generally positive - expressed concerns surrounding potential consequences of the proposal with regard to innovation, system efficiency, and patient care. With respect to the functions of the transplant system specifically, these concerns referenced the creation of disincentives among programs to list sick patients, accept marginal donor organ offers, and perform transplants with less optimal post-transplant prognoses.

The MPSC treats these as genuine concerns and expressed interest in monitoring these and other key areas of system performance relative to the implementation of this proposed change to OPTN Bylaws. This report outlines the specific populations and outcomes that will be periodically monitored to detect potentially unintended consequences to the system. Subsequent reports will include additional outcomes to evaluate and monitor system performance relative to the implementation of these Bylaws changes.

Strategic Plan Goal or Committee Project Addressed

• Increase the number of transplants:

This request specifically calls for monitoring the number of organs transplanted per deceased donor in order to determine whether changes in the number of transplants can be attributable to the policy while accounting for shifts in the number and makeup of deceased donors over time.

Improve waitlisted patient, living donor, and transplant recipient outcomes:

The introduction of new performance monitoring criteria for the purpose of program evaluation (offer acceptance, waitlist mortality) reflects the commitment of the MPSC to make program evaluations more holistic, encompassing outcomes beyond just post-transplant survival.

• Promote the efficient management of the OPTN:

"Efficiency" can mean many things, but an important goal of the proposal was to shift focus onto other areas of performance, including programs' offer acceptance behavior. It is expected that the introduction of offer acceptance into the family of program evaluation metrics will encourage programs to make effective use of screening criteria and further develop the processes with which they consider deceased-donor organ offers, increasing the efficiency with which the system can find "the right candidate for the right organ".

Data and Methods

Data Sources:

Organ Procurement and Transplantation Network (OPTN) data were used for this analysis. The OPTN data system includes data on all donors, waitlisted candidates, and transplant recipients in the US, submitted by members of the OPTN. Candidate information was submitted through the OPTN Waiting List and Transplant Candidate Registration (TCR) form, recipient and transplant data were submitted via the Transplant Recipient Registration (TRR) form, and donor data were submitted via the OPTN Donor Data and Matching System and the Deceased Donor Registration (DDR) form. Analyses are based on data as of October 25, 2024. Data are subject to change due to future database submission or correction.

Cohort:

Candidates added to the OPTN waiting list from January 01, 2019 through June 30, 2024 were included for evaluation of rates of waitlist additions.

Recipients that received an organ transplant from January 01, 2018 through June 30, 2023 were included to evaluate rates of one-year post-transplant graft failure.

All deceased donors from which at least one organ was recovered for the purposes of transplantation from January 01, 2019 through June 30, 2024 were included to evaluate organ-specific donor yield rates.

The proposal for modifications to the OPTN Bylaws on program evaluation was available for Public Comment from August 3, 2021 through September 30, 2021. It was then passed to the OPTN Board of Directors and was approved on December 6, 2021. It was determined that this proposal would be implemented in three stages post-transplant metrics implemented in July 2022, the pre-transplant offer acceptance metric added in July 2023, and the pre-transplant waitlist mortality metric in July 2024. Because of this tiered approach, the education and awareness within the community of the upcoming changes, the date of intervention was chosen as December 06, 2021 for all outcomes evaluated in monitoring the implementation of this proposal. Sensitivity analyses exploring alternative choices of intervention date are shown in the appendices.

Methods:

Over the course of reporting on this proposal, five main outcomes of interest will be evaluated, across heart (includes heart-lung), kidney, liver, lung, and pancreas (includes kidney-pancreas) and a number of characteristics of interest. Below is a matrix of the intended outcomes (rows) per organ (columns) and characteristic sub-categories (cells) that will be evaluated.

This particular report includes evaluation of the number of waiting list additions, one-year post-transplant graft failure rates, utilization rates, and transplant-to-recovery rates.

Utilization rates and transplant-to-recovery rates were evaluated instead of number of transplants in order to account for trends in the available number of organs as well as differences in the volume of transplants across organ types.

	Kidney	Liver	Heart	Lung	Pancreas
Listing Rates "Have the numbers of new additions to the WL been affected?"	Overall Candidate Age Race/Ethnicity Dialysis Time Primary Payment Urbanicity	Overall Candidate Age Race/Ethnicity MELD/PELD Primary Payment Urbanicity	Overall Candidate Age Race/Ethnicity Allocation Priority Primary Payment Urbanicity	Overall Candidate Age Race/Ethnicity Priority (WLAUC) Primary Payment Urbanicity	Overall Candidate Age Race/Ethnicity Primary Payment Urbanicity
Utilization Rates "Have the numbers of transplants performed been affected?"	Overall Donor Age DCD/DBD Donor KDPI	Overall Donor Age DCD/DBD Macrosteatosis	Overall Donor Age DCD/DBD Donor EF%	Overall Donor Age DCD/DBD Donor pO ₂ /FiO ₂	Overall Donor Age DCD/DBD
Pre-TX Mortality Rates "Have the numbers of candidate deaths on the WL been affected?"	Overall Candidate Age Race/Ethnicity Waiting Time Primary Payment Urbanicity	Overall Candidate Age Race/Ethnicity MELD/PELD Primary Payment Urbanicity	Overall Candidate Age Race/Ethnicity Allocation Priority Primary Payment Urbanicity	Overall Candidate Age Race/Ethnicity Priority (WLAUC) Primary Payment Urbanicity	Overall Candidate Age Race/Ethnicity Primary Payment Urbanicity
Offer Acceptance Rates "Have centers' propensities to accept organ offers been affected?"	Overall Donor KDPI Candidate Race/Ethnicity Primary Payment Urbanicity	Overall Candidate MELD/PELD Candidate Race/Ethnicity Donor Age Primary Payment Urbanicity	Overall Candidate Allocation Priority Candidate Race/Ethnicity Donor Age Primary Payment Urbanicity	Overall Candidate Priority/WLAUC Candidate Race/Ethnicity Donor Age Primary Payment Urbanicity	Overall Candidate Race/Ethnicity Donor Age Primary Payment Urbanicity
First-Year Graft Failure Rates "Have the numbers of graft failures (incl. deaths) during the first year post-TX been affected?"	Overall Recipient Race/Ethnicity Recipient Age Donor Age	Overall Recipient Race/Ethnicity Recipient Age Donor Age	Overall Recipient Race/Ethnicity Recipient Age Donor Age	Overall Recipient Race/Ethnicity Recipient Age Donor Age	Overall Recipient Race/Ethnicity Recipient Age Donor Age

Figure 1: A high-level overview of the outcomes (rows) for each organ type (columns) and characteristics (cells) that will be evaluated to monitor system-level changes due to the implementation of proposed OPTN Bylaw changes regarding transplant program performance metrics.

Data Definitions

The outcomes of interest are defined in the following manner, on a monthly basis:

- Registrations added to the waitlist, as a count
 - Urbanicity of registrations added to the OPTN Waiting List is based on the ZIP code and county entered for the registration at listing. Urbanicity was defined based on the Rural-Urban Commuting Area (RUCA) codes. The U.S. government develops these codes using both the American Community Survey and the Decennial U.S. Census. The codes classify census tracts into ten categories based on both population data from the Decennial U.S. Census and commuting data from the American Community Survey. RUCA codes are based on data from the 2010 Rural Urban Area Commuting Codes (revised 7/3/2019) document available on the U.S. Department of Agriculture (USDA) website. Candidates with RUCA codes 1-3 where classified as "Urban" while candidates with RUCA codes 4-10 were classified as "Rural". Registrations for candidates located outside of the 50 U.S. continental states were excluded from urbanicity evaluation due to RUCA code availability.
- One-year post-transplant all-cause graft failure rate, as a percentage
 - Based on transplant date
 - Event is defined as the graft failed, re-transplant occurred, or patient died within one year of transplant date
 - Failure rate is defined as the number of events out of the number of transplants
- Organ utilization rate, as a percentage
 - For kidney and lung, utilization rates were defined as the number of kidneys or lungs transplanted divided by the total number of kidneys or lungs that could have potentially been transplanted. All organ donors were assumed to have two kidneys or lungs that were able to be transplanted.
 - For liver, pancreas, and heart, all organ donors were assumed to have one organ that was able to be transplanted.
 - Organ donor is defined as a deceased donor with at least one organ recovered for the purposes of transplant.
- Transplant-to-recovery rate, as a percentage
 - Transplant-to-recovery rates were defined as the number of organ-specific transplants divided by the number of specific organs recovered for transplant.

Missing Data

Some a priori specified sub-categories may be presented in a manner deemed more appropriate upon review of the data (i.e, shifted category thresholds or collapsing categories together), or may not be included in this report due to small sample sizes.

Registrations added to the OPTN Waiting List with missing primary source of payment, no available RUCA information, or "Temporarily Inactive" medical urgency status were excluded from characteristic sub-category analyses. Four deceased donors with missing kidney donor profile index (KDPI) were excluded from utilization rate characteristic sub-category analyses.

Modeling

This section provides statistical details as to how analyses were conducted within the report. We used a regression model with auto-regressive integrated moving average (ARIMA) errors to model the trend in each outcome of interest. The ARIMA models are set up in the following manner:

$$ARIMA(p,d,q)(P,D,Q)_m$$

where p is the auto-regressive component (AR), or the series' own lagged values; d is the lagged differences, or the integrated (I) component for the number of times the series must be differenced to achieve stationarity (constant mean and variance); q represents the lagged error terms, or the moving average (MA). The capital versions of these represent the seasonally lagged versions, with the addition of m as the period, or number of observations in a year.

Augmented Dickey-Fuller test, or unit root test, for the null hypothesis that the series is stationary, Ljung-Box test statistic for the null hypothesis that the model residuals are distributed as white noise (i.e., they are uncorrelated).

The best model was fit according to the corrected Akaike information criterion (AICc), AIC, or Bayesian information criterion (BIC) values for each characteristic of interest on data up to the intervention date using the forecast::auto.arima() function in R. This approach is able to take into account potentially confounding effects of other causal mechanisms compared to a more simple pre- and post-intervention aggregate comparison which assumes that the effect of an intervention is well represented as an abrupt, permanent change in the level of the outcome. The ARIMA model based on trends pre-intervention was then used to forecast to the time period post-intervention, or predict what would have happened had the intervention not been in place during the post-intervention period. This provided the average and a 95% confidence interval that can be interpreted as the counterfactual model, or what is to predicted to have happened had the intervention not been in place. Differences between the observed trend in the outcome over time post-intervention are then compared to the counterfactual trend in the outcome over time post-intervention in order to evaluate if the policy has had an effect on the particular outcome of interest.

Note that the ARIMA model was fit to monthly data to ensure more stable parameter estimates. For ease of interpretation, months were defined as calendar months. To minimize potential misclassification of post-intervention follow-up time as pre-intervention follow-up time (or vice versa), the Board Approval date and the implementation dates of each PME metric were rounded before model fitting such that if the intervention date occurred on or before the fifteenth of the month, the forecast started at the beginning of that month, and if the intervention date occurred after the fifteenth of the month, the forecast started at the beginning of the next month. For transparency, however, reference lines in the plots below are placed on the exact day of implementation. Thus, these reference lines may not align exactly with the start of each forecast band.

Abbreviations

ARIMA: Auto-Regressive Integrated Moving Average

CAS: Composite Allocation Score DBD: Donation after Brain Death

DCD: Donation after Cardiac Death KDPI: Kidney Donor Profile Index

LAS: Lung Allocation Score

MELD: Model for End-Stage Liver Disease

OPTN: Organ Procurement and Transplantation Network

PELD: Pediatric End-Stage Liver Disease

WLAUC: Waiting List Area Under the Curve; i.e., the area under the estimated average 1-year waiting list survival curve for each candidate

Results

One Year Post-Transplant All-Cause Graft Failure by Month of Transplant (January 01, 2018 to December 06, 2021 with Predicted Trends from Board Approval (December 06, 2021) to June 30, 2024

Hypothesis: No change in system-level one-year post-transplant graft failure rates attributable to the modification of transplant program performance monitoring metrics

Figure setup: Figures 1 through 5 in this section (and figures in Appendix A) show one-year post-transplant all-cause graft failure rates by month, organized by organ and then by specific sub-categories for each organ.

- The solid black line in each figure represents the actual rate of all-cause graft failure one-year post-transplant for each month following policy implementation.
- Vertical lines indicate the time point of intervention (OPTN Board approval) as well as the implementation of allocation policies such as removing donation service area (DSA) and OPTN Region as units of allocation. The latter were included for reference and understanding of other influential trends that may also be occurring within the data. Reference lines are also included to indicate the implementation dates of the post-transplant graft survival metric and offer acceptance metric; the pre-transplant mortality metric was implemented after the end of the analysis period and will be included in future reports.
- The dotted gray line, which begins at the board-approval date of the policy, indicates the trend (based on historical data) that would have been *expected to occur with no policy change*.*
- The gray shaded area represents, with a 95% confidence interval, the *possible range of the expected trend* with no policy change.*

Comparing observed and predicted trends: By comparing the solid black line (actual rate of all-cause graft failure one-year post-transplant following implementation) with the dotted gray line (predicted trend without implementation) and shaded gray area (range of predicted trend without implementation), we can evaluate the difference, if any, between actual and predicted trends. This comparison can point to any clinically or statistically significant differences caused by the policy implementation that might need to be further investigated.

The observed trend in one year all-cause graft failure rate after Board Approval was lower (better) than the predicted trends after Board Approval for kidney transplant recipients. Observed trends in one year all-cause graft failure rate after Board Approval were similar to predicted trends for all other organs. Sensitivity analyses that used the implementation date of the post-transplant graft survival metric (i.e., July 14, 2022) instead of the Board Approval date yielded similar results (Appendix E).

^{*}Both the expected trend and its range are estimated by the ARIMA model, fit to data occurring prior to implementation of the policy change.

Figure 1. Kidney

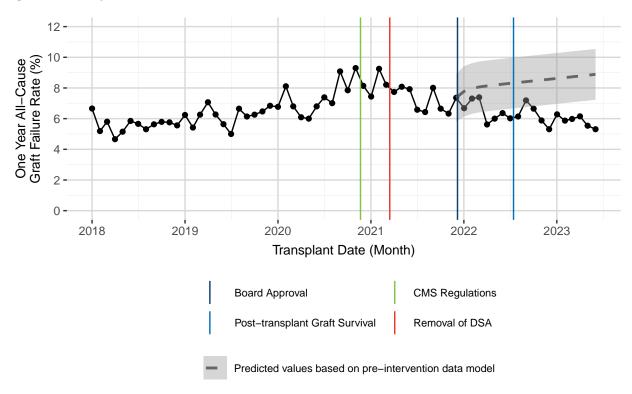


Figure 2. Liver

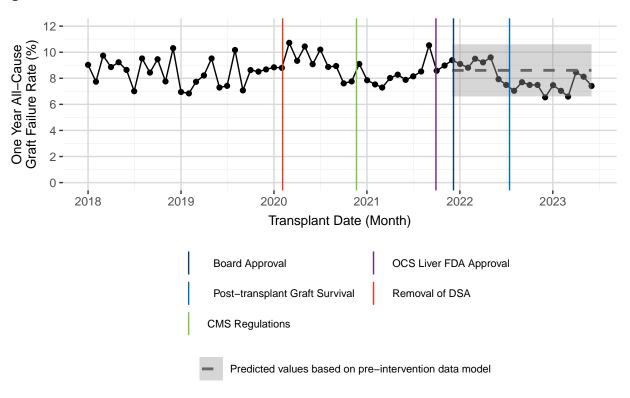


Figure 3. Pancreas/Kidney-Pancreas

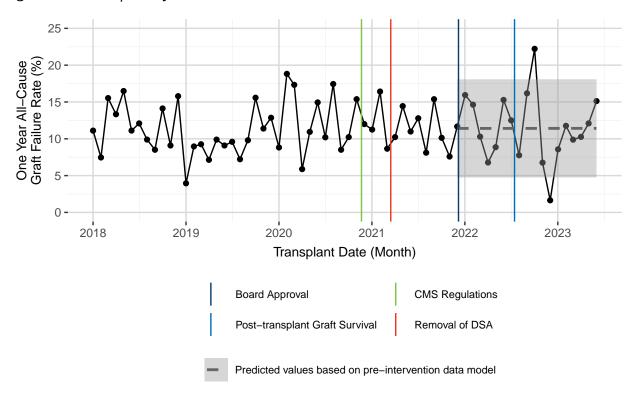


Figure 4. Heart/Heart-Lung

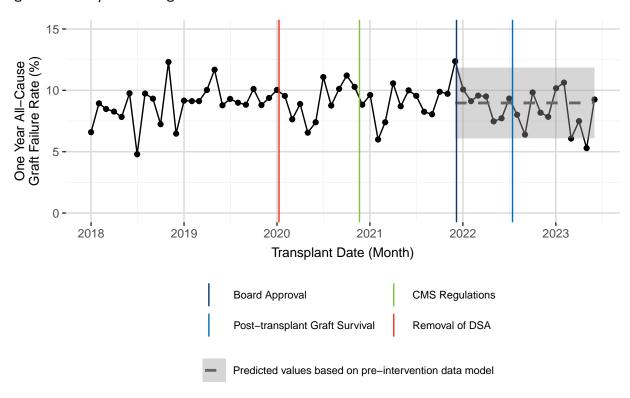
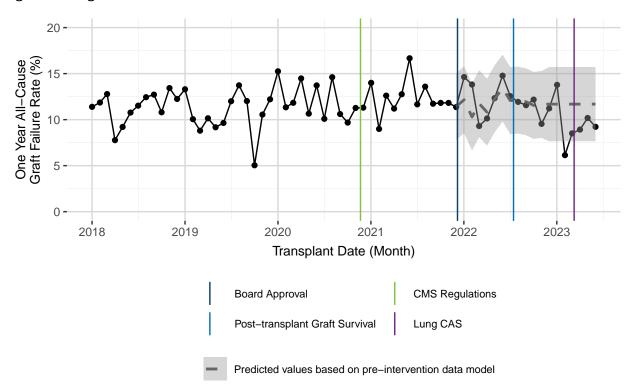


Figure 5. Lung



OPTN Waiting List Registrations Added by Month (January 01, 2019 to December 06, 2021) with Predicted Trends from Board Approval (December 06, 2021) to June 30, 2024

Hypothesis: No changes in volume of new registrations added to the waiting list attributable to the modification of transplant program performance monitoring metrics

Figure setup: Figures 6 through 10 in this section (and figures in Appendix B) show registrations added to the OPTN Waiting list by month, organized by organ and then by specific sub-categories for each organ.

- The solid black line in each figure represents the *actual number of registrations* added for each month following policy implementation.
- Vertical lines indicate the time point of intervention (OPTN Board approval) as well as the implementation of allocation policies such as removing donation service area (DSA) and OPTN Region as units of allocation. The latter were included for reference and understanding of other influential trends that may also be occurring within the data. Reference lines are also included to indicate the implementation dates of the post-transplant graft survival metric and offer acceptance metric; the pre-transplant mortality metric was implemented after the end of the analysis period and will be included in future reports.
- The dotted gray line, which begins at the board-approval date of the policy, indicates the trend (based on historical data) that would have been *expected to occur with no policy change*.*
- The gray shaded area represents, with a 95% confidence interval, the possible range of the expected trend with no policy change.*

Comparing observed and predicted trends: By comparing the solid black line (actual number of registrations following implementation) with the dotted gray line (predicted trend without implementation) and shaded gray area (range of predicted trend without implementation), we can evaluate the difference, if any, between actual and predicted trends. This comparison can point to any clinically or statistically significant differences caused by the policy implementation that might need to be further investigated.

The observed trend in waiting list additions after Board Approval was higher (better) than the predicted trends after Board Approval for kidney, liver, and heart waiting list additions. Observed trends in waiting list additions after Board Approval were similar to predicted trends for all other organs. The COVID-19 pandemic beginning in March 2020 had an impact on registrations added to the OPTN Waiting List for all organs. Sensitivity analyses that used the implementation date of the pre-transplant mortality rate ratio metric (i.e., July 25, 2024) instead of the Board Approval date could not be explored in this report due to insufficient follow-up time. However, these sensitivity analyses will be revisited in the future as more data accrue.

^{*}Both the expected trend and its range are estimated by the ARIMA model, fit to data occurring prior to implementation of the policy change.

Figure 6. Kidney

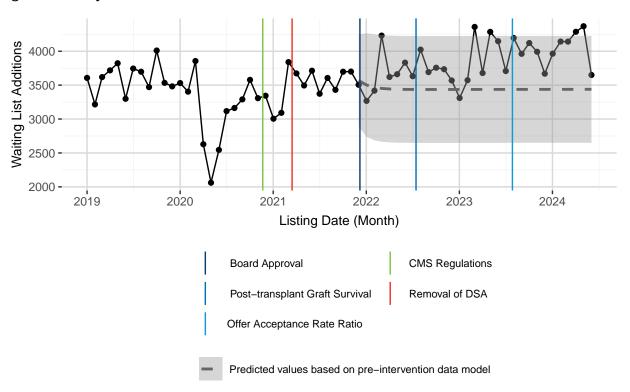


Figure 7. Liver

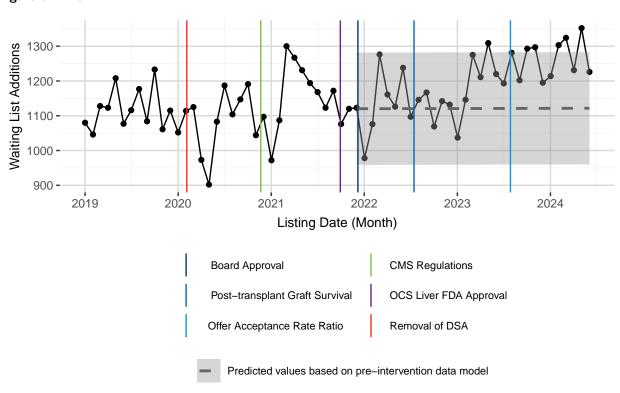


Figure 8. Pancreas/Kidney-Pancreas

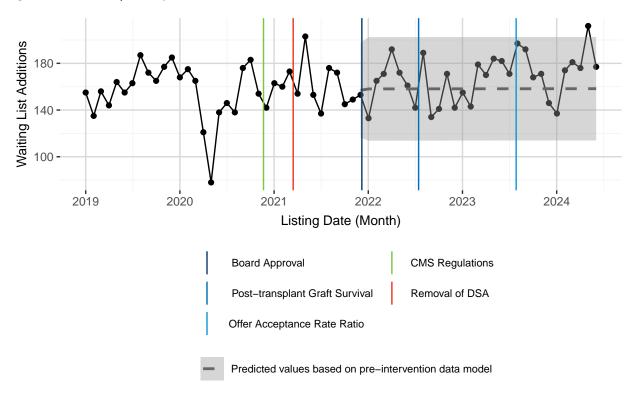


Figure 9. Heart/Heart-Lung

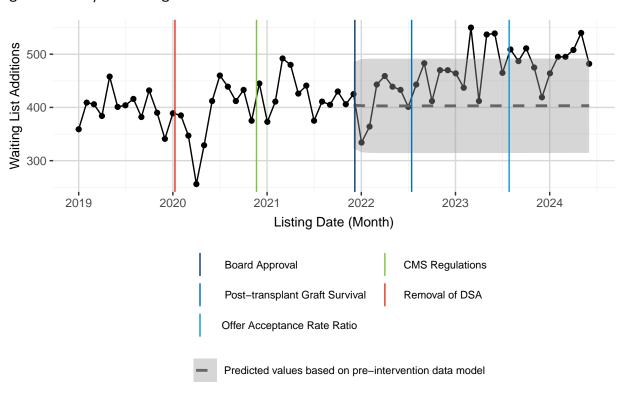
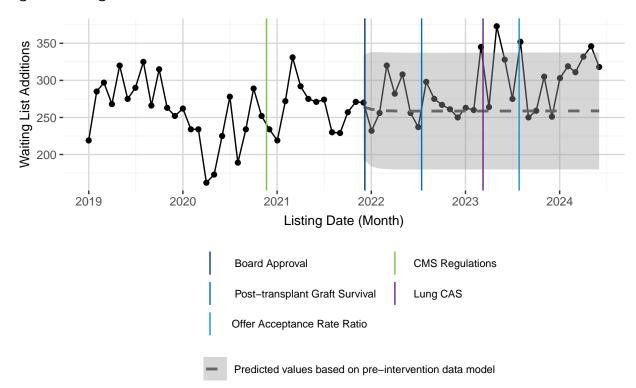


Figure 10. Lung



Utilization Rates by Month (January 01, 2019 to December 06, 2021) with Predicted Trends from Board Approval (December 06, 2021) to June 30, 2024

Hypothesis: Increased transplants attributable to the modification of transplant program performance monitoring metrics

Figure setup: Figures 11 through 15 in this section (and figures in Appendix C) show number of deceased donors, number of deceased donor transplants, and deceased donor utilization rates by month, organized by organ. Figures in Appendix C show deceased donor utilization rates by month, organized by organ and then by specific sub-categories for each organ.

Top left panels show the number of deceased organ donors (deceased donor with at least one organ recovered for the purposes of transplant) and the number of organ-specific deceased donors. The number of deceased organ donors is the denominator for utilization rate. Top right panels show the number of organ-specific transplants that represent the numerator for utilization rate. The bottom panels show the utilization rate.

- The solid black line in each utilization rate figure represents the actual utilization rate for each month following policy implementation.
- Vertical lines indicate the time point of intervention (OPTN Board approval) as well as the implementation of allocation policies such as removing donation service area (DSA) and OPTN Region as units of allocation. The latter were included for reference and understanding of other influential trends that may also be occurring within the data. Reference lines are also included to indicate the implementation dates of the post-transplant graft survival metric and offer acceptance metric; the pre-transplant mortality metric was implemented after the end of the analysis period and will be included in future reports.
- The dotted gray line in each utilization rate figure, which begins at the board-approval date of the policy, indicates the trend (based on historical data) that would have been expected to occur with no policy change.*
- The gray shaded area represents, with a 95% confidence interval, the possible range of the expected trend with no policy change.*

Comparing observed and predicted trends: By comparing the solid black line (actual utilization rate following implementation) with the dotted gray line (predicted trend without implementation) and shaded gray area (range of predicted trend without implementation), we can evaluate the difference, if any, between actual and predicted trends. This comparison can point to any clinically or statistically significant differences caused by the policy implementation that might need to be further investigated.

There have been declining trends in organ utilization rates across most organs in recent years; however, the focus of this report is on *changes to trends after the implementation of this policy*. The observed trends in utilization rates after Board Approval were higher (better) than the predicted trends after Board Approval for liver, lung, and heart (to a lesser extent). Observed trends in utilization rates after Board Approval were similar to predicted trends for kidney and pancreas. The Committee has previously noted that the implementation of perfusion technologies may have influenced observed trends for certain organs in recent years. Sensitivity analyses that used the implementation date of the offer acceptance rate ratio metric (i.e., July 27, 2023) instead of the Board Approval date yielded similar results, although the magnitude of the difference between observed and predicted trends tended to be smaller (Appendix F).

^{*}Both the expected trend and its range are estimated by the ARIMA model, fit to data occurring prior to implementation of the policy change.

Table 1 shows the overall counts for deceased donors, transplantable organs, and organs transplanted between January 01, 2019 and June 30, 2024 for context when evaluating utilization rates by organ-specific characteristics that may not be available for all donors. All organ donors were assumed to have one liver, one pancreas, one heart, two kidneys, and two lungs that could potentially be transplanted. Note that each donor may donate multiple organ types, in which case they would appear in multiple rows of the "Deceased Organ Donors" column of the table below.

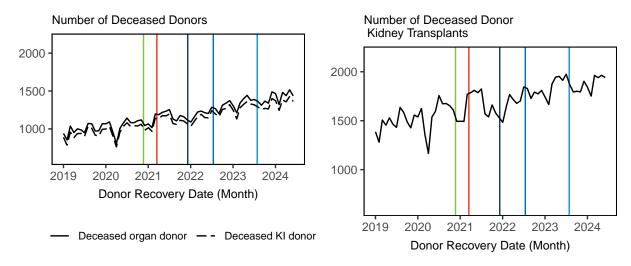
There were 78,221 unique donors between January 01, 2019 and June 30, 2024 (i.e., there were 78,221 donors from whom at least one organ of any type was recovered for the purposes of transplant during this time frame). Consequently, 78,221 livers, 78,221 pancreata, and 78,221 hearts could potentially have been available for transplant; similarly, 78,221 * 2 = 156,442 kidneys and 156,442 lungs could potentially have been available for transplant.

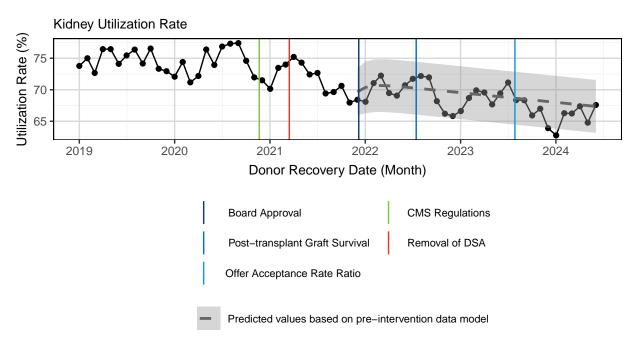
Note that the actual number of organs recovered for each organ type may be equal to or less than the number of organs potentially available for transplant. For information on the actual number of organs recovered for each organ type, please see Table 2 in the "Transplant-to-Recovery Rate" section.

Table 1. Number of Deceased Donors, Organs Available for Transplant, and Organs Transplanted During January 01, 2019 to June 30, 2024

Organ	Deceased Organ Donors	Organs Available for Transplant	Organs Transplanted
Kidney	74,136	156,442	110,663
Liver	54,772	78,221	49,863
Lung	15,924	156,442	28,064
Heart	22,538	78,221	22,262
Pancreas	7,041	78,221	5,282

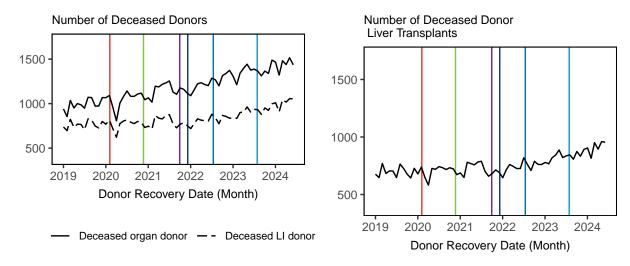
Figure 11. Kidney

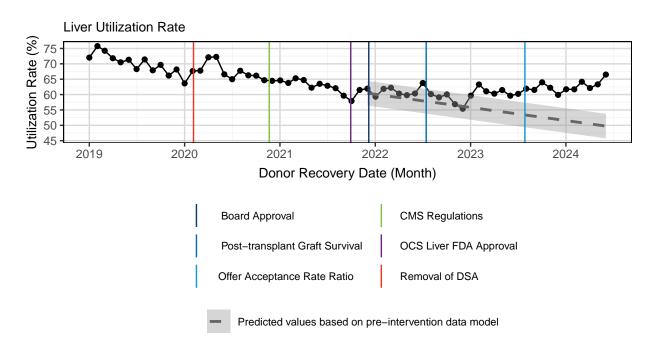




Kidney Utilization Rate (%)= 100 * [# deceased donor KI TX/(2* # deceased organ donors)] Deceased organ donor=Deceased donor w/at least 1 organ recovered for purpose of transplant. Enbloc KI = 2 KIs transplanted.

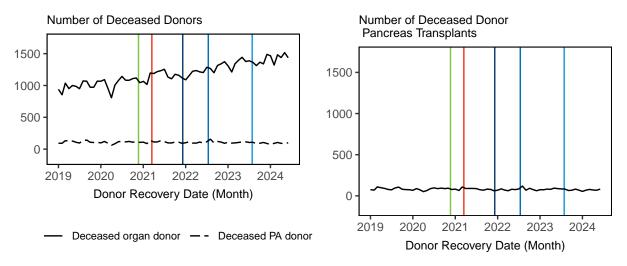
Figure 12. Liver

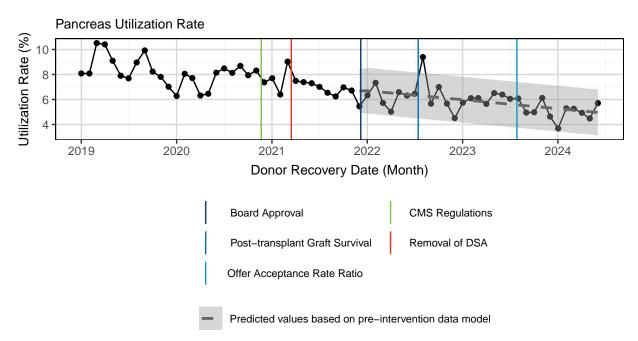




Liver Utilization Rate (%)= 100 * (# deceased donor LI TX/# deceased organ donors)
Deceased organ donor=Deceased donor w/at least 1 organ recovered for purpose of transplant. Split LI = 2 LIs transplanted.

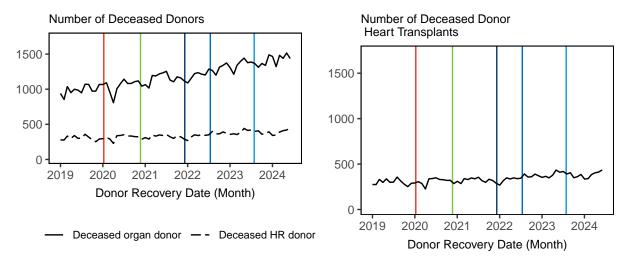
Figure 13. Pancreas

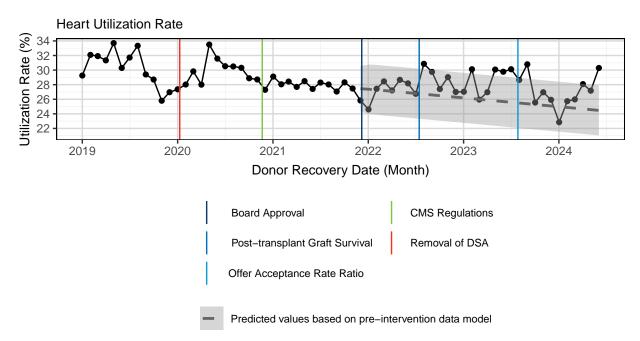




Pancreas Utilization Rate (%)= 100 * (# deceased donor PA TX/# deceased organ donors) Deceased organ donor=Deceased donor w/at least 1 organ recovered for purpose of transplant.

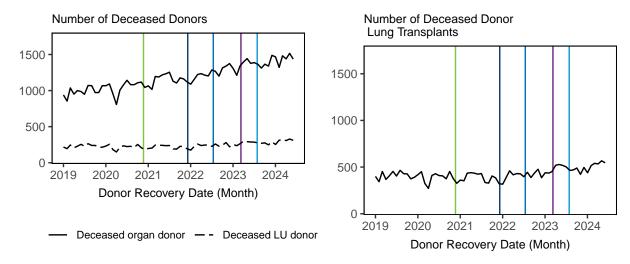
Figure 14. Heart

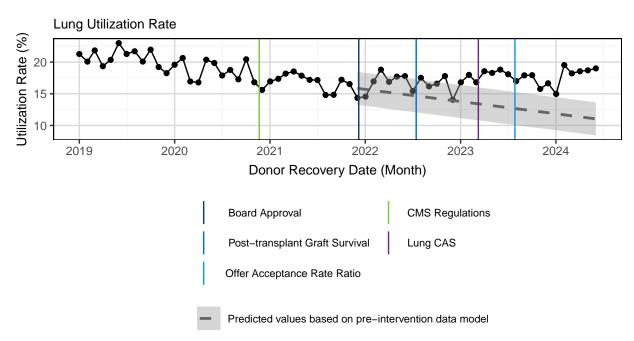




Heart Utilization Rate (%)= 100 * (# deceased donor HR TX/# deceased organ donors) Deceased organ donor=Deceased donor w/at least 1 organ recovered for purpose of transplant.

Figure 15. Lung





Lung Utilization Rate (%)= 100 * [# deceased donor LU TX/(2* # deceased organ donors)] Deceased organ donor=Deceased donor w/at least 1 organ recovered for purpose of transplant. Dual LU = 2 LUs transplanted.

Transplant-to-Recovery Rates by Month (January 01, 2019 to December 06, 2021) with Predicted Trends from Board Approval (December 06, 2021) to June 30, 2024

Hypothesis: Increased transplants attributable to the modification of transplant program performance monitoring metrics

Figure setup: Figures 16 through 20 in this section (and figures in Appendix D) show number of deceased donor organs recovered, number of deceased donor transplants, and deceased donor transplant-to-recovery rates by month, organized by organ. Figures in Appendix D show deceased donor transplant-to-recovery rates by month, organized by organ and then by specific sub-categories for each organ.

Top left panels show the number of organ-specific deceased donor organs recovered; this quantity constitutes the denominator of the transplant-to-recovery rate. Top right panels show the number of organ-specific transplants; this quantity represents the numerator of the transplant-to-recovery rate. The bottom panels depict the transplant-to-recovery rate over time.

- The solid black line in each transplant-to-recovery rate figure represents the actual transplant-to-recovery rate for each month following policy implementation.
- Vertical lines indicate the time point of intervention (OPTN Board approval) as well as the implementation of allocation policies such as removing donation service area (DSA) and OPTN Region as units of allocation. The latter were included for reference and understanding of other influential trends that may also be occurring within the data. Reference lines are also included to indicate the implementation dates of the post-transplant graft survival metric and offer acceptance metric; the pre-transplant mortality metric was implemented after the end of the analysis period and will be included in future reports.
- The dotted gray line in each transplant-to-recovery rate figure, which begins at the board-approval date of the policy, indicates the trend (based on historical data) that would have been expected to occur with no policy change.*
- The gray shaded area represents, with a 95% confidence interval, the *possible range of the expected trend* with no policy change.*

Comparing observed and predicted trends: By comparing the solid black line (actual transplant-to-recovery rate following implementation) with the dotted gray line (predicted trend without implementation) and shaded gray area (range of predicted trend without implementation), we can evaluate the difference, if any, between actual and predicted trends. This comparison can point to any clinically or statistically significant differences caused by the policy implementation that might need to be further investigated.

The organ transplant-to-recovery rate complements the non-use rate and reflects the number of transplants performed among organs recovered for transplant. In recent years, there have been declining trends in transplant-to-recovery rates for most organs; however, the focus of this report is on *changes to trends after the implementation of this policy*. The observed trends in transplant-to-recovery rates after Board Approval were slightly lower (worse) than predicted trends after Board Approval for heart. For all other organs, the observed trends in transplant-to-recovery rates after Board Approval were in line with predicted trends after Board Approval. When the implementation date of the offer acceptance rate ratio metric (i.e., July 27, 2023) was used instead of the Board Approval date, observed trends in transplant-to-recover rates were similar to predicted trends for all organs (Appendix G).

^{*}Both the expected trend and its range are estimated by the ARIMA model, fit to data occurring prior to implementation of the policy change.

Table 2 shows the overall counts for deceased organ-specific donors, organs recovered for transplant, and organs transplanted between January 01, 2019 and June 30, 2024. For liver, pancreas, and heart donors, at most one organ of each type can be recovered. For kidney and liver donors, at most two organs of each type can be recovered. Thus, the upper bound for the "Deceased Donor Organs Recovered" column is one times the number shown in the "Deceased Organ Donors" column for liver, heart, and pancreas; the upper bound is two times the number shown in the "Deceased Organ Donors" column for kidney and liver. For example, at most 54,772 * 1 = 54,772 livers, 22,538 * 1 = 22,538 hearts, and 7,041 * 1 = 7,041 pancreata can be recovered from these donors; similarly, at most 74,136 * 2 = 148,272 kidneys and 15,924 * 2 = 31,848 lungs can be recovered from these donors.

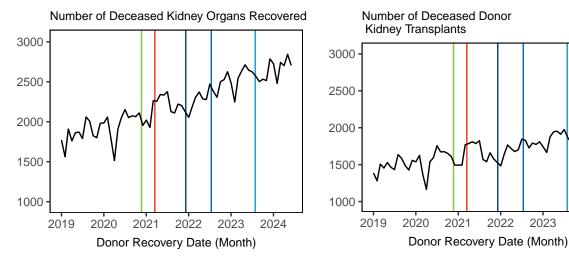
The numbers that appear in the "Deceased Donor Organs Recovered" column reflect the actual number of organs recovered for each organ type, and thus may be equal to or less than these upper bounds. These quantities can help contextualize the transplant-to-recovery rate figures shown here and in Appendix D.

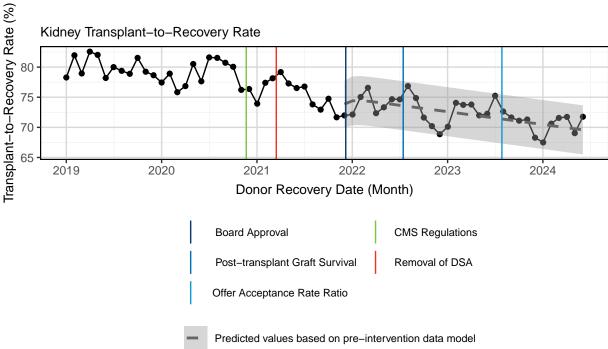
Table 2. Number of Deceased Organ-Specific Donors, Organs Recovered for Transplant, and Organs Transplanted During January 01, 2019 to June 30, 2024

Organ	Deceased Organ Donors	Deceased Donor Organs Recovered	Organs Transplanted
Kidney	74,136	147,570	110,663
Liver	54,772	54,772	49,863
Lung	15,924	30,547	28,064
Heart	22,538	22,538	22,262
Pancreas	7,041	7,041	5,282

2024

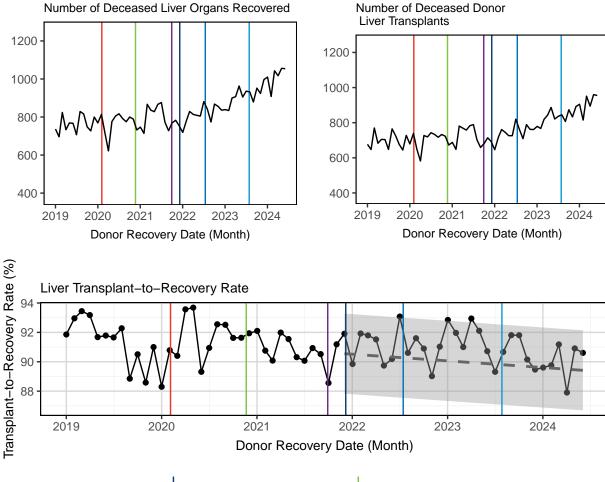
Figure 16. Kidney





Kidney Transplant-to-Recovery Rate (%)= 100 * [# deceased donor KI TX/(# deceased donor kidneys recovered)].

Figure 17. Liver



Board Approval CMS Regulations

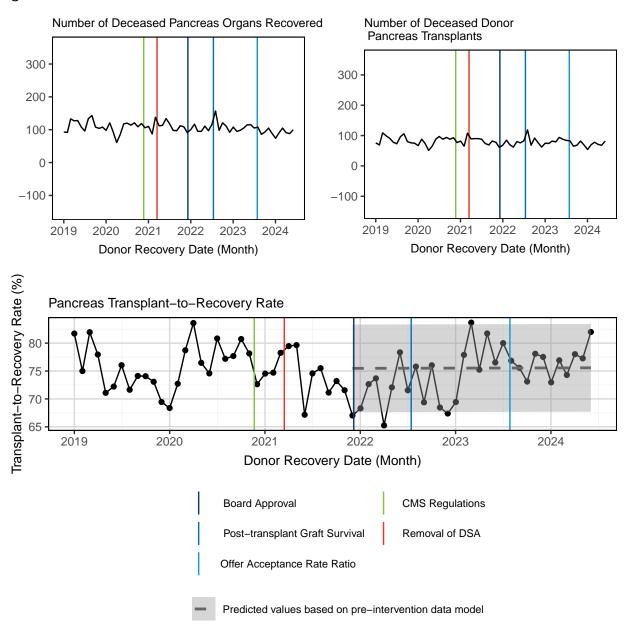
Post-transplant Graft Survival OCS Liver FDA Approval

Offer Acceptance Rate Ratio Removal of DSA

Predicted values based on pre-intervention data model

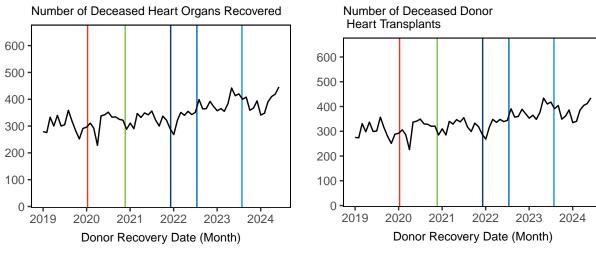
Liver Transplant-to-Recovery Rate (%)= 100 * (# deceased donor LI TX/# deceased donor livers recovered).

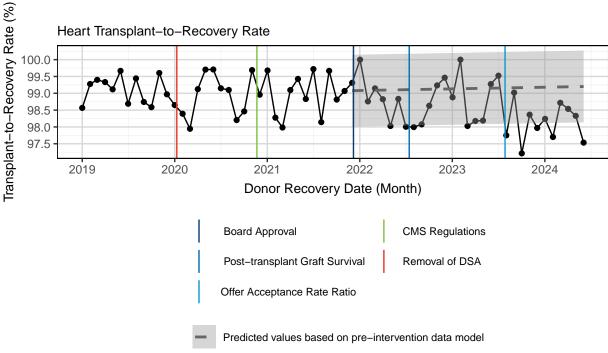
Figure 18. Pancreas



Pancreas Transplant-to-Recovery Rate Rate (%)= 100 * (# deceased donor PA TX/# deceased donor pancreata recovered).

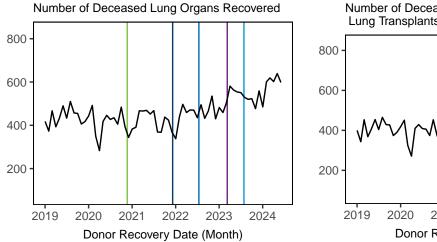
Figure 19. Heart

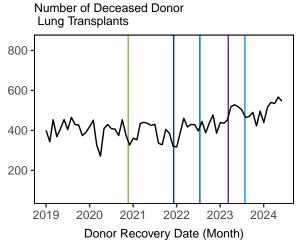


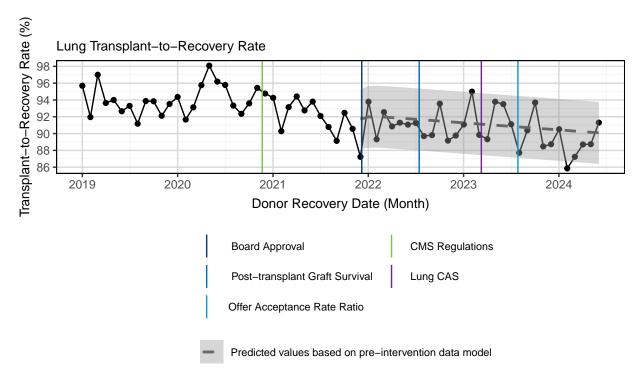


Heart Transplant-to-Recovery Rate (%)= 100 * (# deceased donor HR TX/# deceased donor hearts recovered).

Figure 20. Lung







Lung Transplant-to-Recovery Rate Rate (%)= 100 * [# deceased donor LU TX/(# deceased donor lungs recovered)].

Appendices

The following noteworthy trends were seen in subcategory analyses:

One Year Post-Transplant All-Cause Graft Failure

The following sub-categories had observed trends in the one year post-transplant all-cause graft failure rate that were lower (better) than what was predicted post-Board Approval:

- Kidney
 - Black, non-hispanic race/ethnicity
 - Recipient Age 50-64 and 65+ years
 - Donor KDPI 35-85% and 85-100%

For all other organs and sub-categories, the observed trends in the one year post-transplant all-cause graft failure rate were consistent with predicted trends post-Board Approval.

OPTN Waiting List Registration Additions

The following sub-categories had observed trends in the number of waiting list registration additions that indicate sustained increases compared to what was predicted post-Board Approval:

- Heart
 - Adult (18+ years at listing)
 - Urban urbanicity
 - Heart statuses 1/2
- Lung
 - White, non-Hispanic and Black, non-Hispanic race/ethnicity
 - Public insurance
 - WLAUC at listing between 320-365 days

For all other organs and sub-categories, the observed trends in the number of waiting list registration additions were consistent with predicted trends post-Board Approval.

Utilization Rates

The following sub-categories had observed trends in utilization rates that indicate sustained increases compared to what was predicted post-Board Approval:

- Liver
 - Donors 18-34 years, 35-49 years, and 50+ years
 - DCD donor type
 - Donors with percent macrosteatosis 50-100% and donors with percent macrosteatosis missing/not biopsied
- Heart
 - Donors <18 years, 18-34 years, and 35-49 years
 - Donors with LV Ejection Fraction 65-100%
- Lung
 - Donors 18-34 years, 35-49 years, and 50+ years
 - DBD and DCD donor types
 - pO2/FiO2 ratio between 3.5-<4.0

For all other organs and sub-categories, the observed trends in utilization were fairly consistent with predicted trends post-Board Approval.

Transplant-to-Recovery Rates

The following sub-categories had observed trends in transplant-to-recovery rates that indicate sustained increases compared to what was predicted post-Board Approval:

- Pancreas
 - Donors <18 years

For all other organs and sub-categories, the observed trends in transplant-to-recovery rates were fairly consistent with predicted trends post-Board Approval.

Appendix A: One Year Post-Transplant All-Cause Graft Failure Characteristic Stratifications

Kidney

Figure 21. Recipient Race/Ethnicity

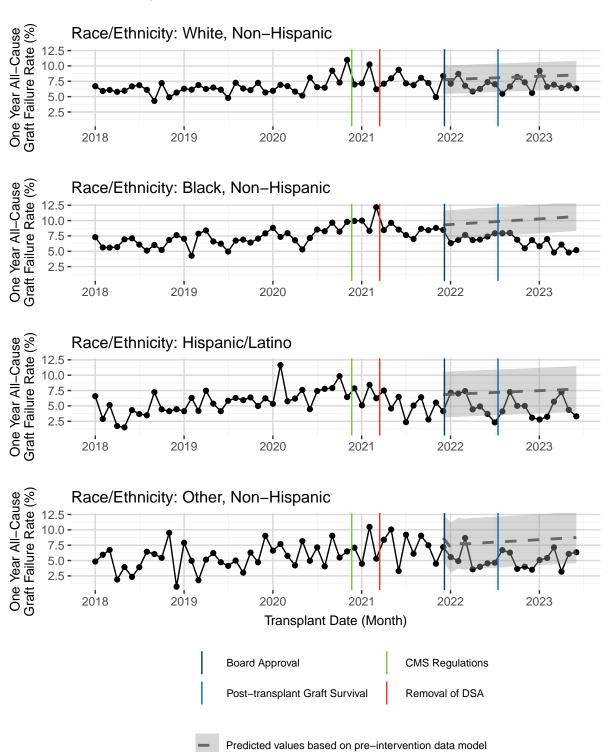
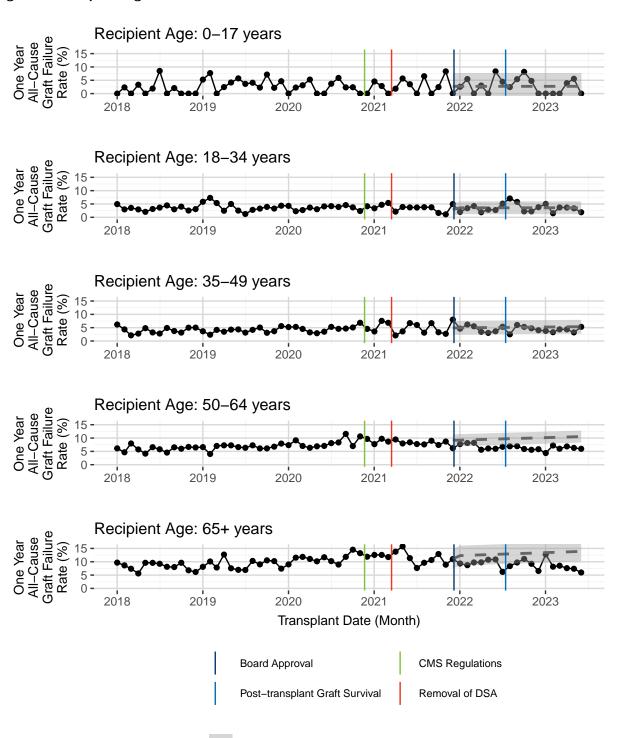
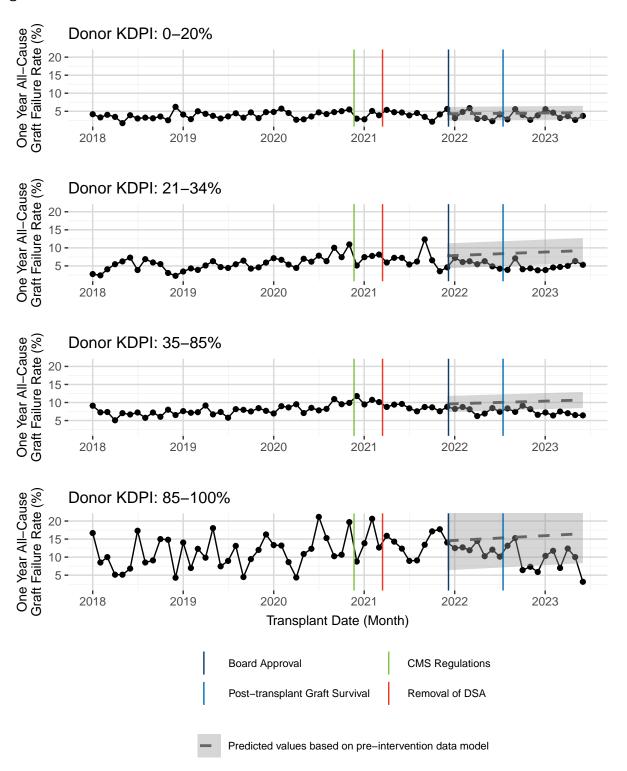


Figure 22. Recipient Age



Predicted values based on pre-intervention data model

Figure 23. Donor KDPI



Liver

Figure 24. Recipient Race/Ethnicity

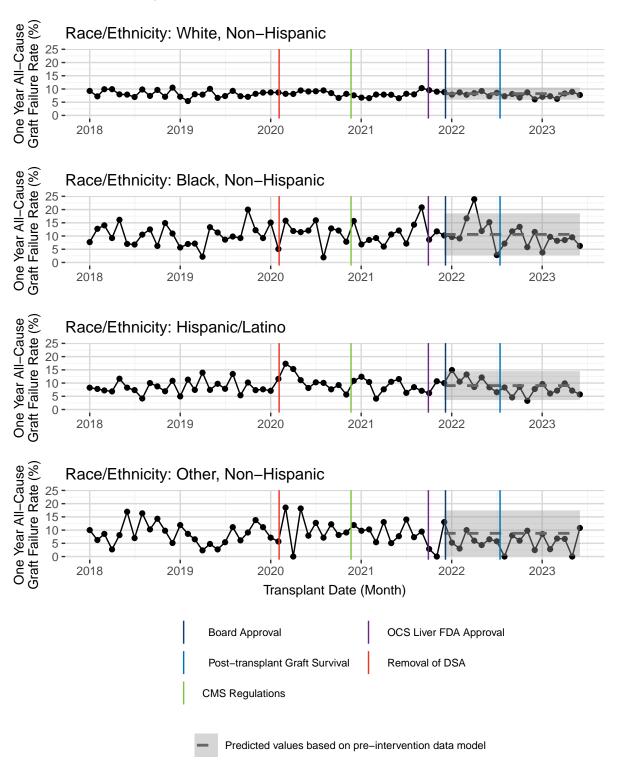


Figure 25. Recipient Age

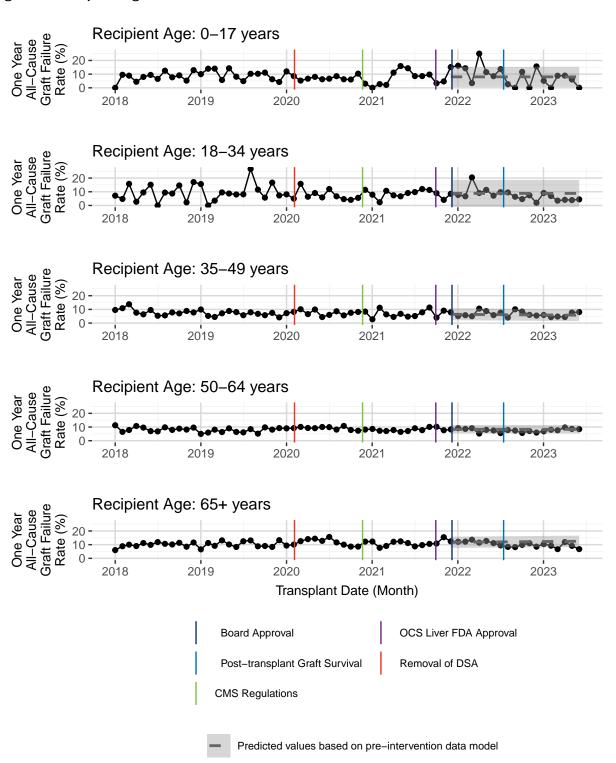
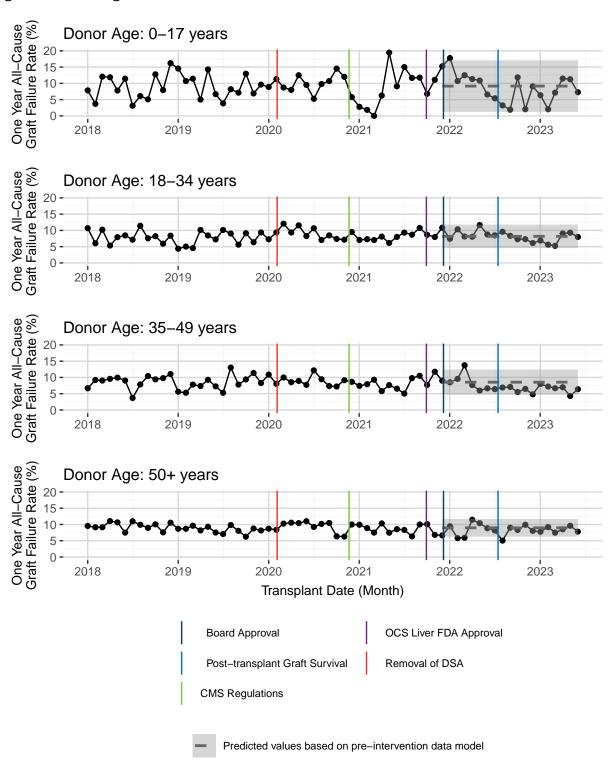


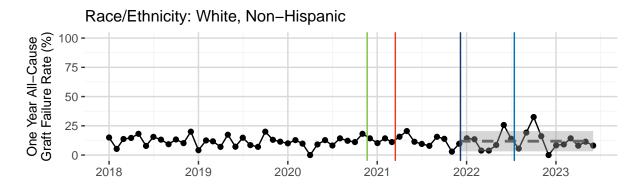
Figure 26. Donor Age

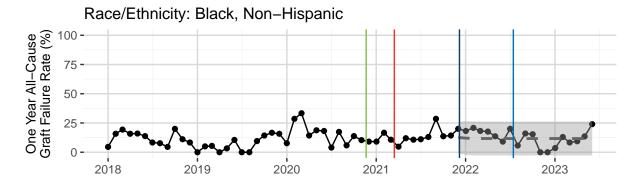


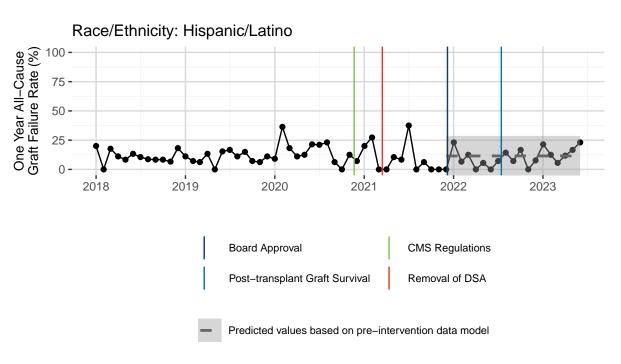
Pancreas/Kidney-Pancreas

Due to small numbers the Other, Non-Hispanic group is not shown below. There were 287 Other, Non-Hispanic pancreas/kidney-pancreas transplants over the time period. The average graft failure rate per month for the Other, Non-Hispanic transplant group was 8.9% compared to 17.1% overall.

Figure 27. Recipient Race/Ethnicity

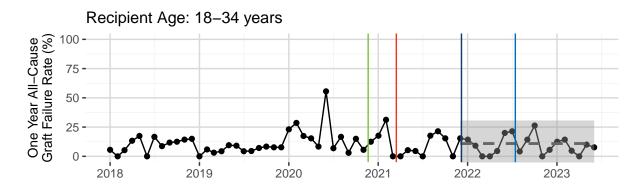


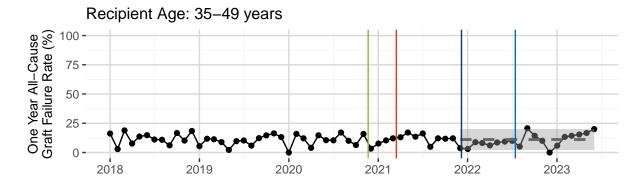




Due to small numbers the pediatric (age < 18 at transplant) group is not shown below. There were 120 pediatric pancreas/kidney-pancreas transplants over the total time period. The average graft failure rate per month for the pediatric group was 17.9% compared to 33.3% overall.

Figure 28. Recipient Age





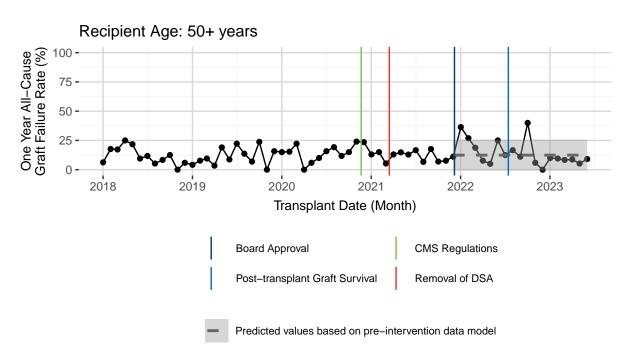
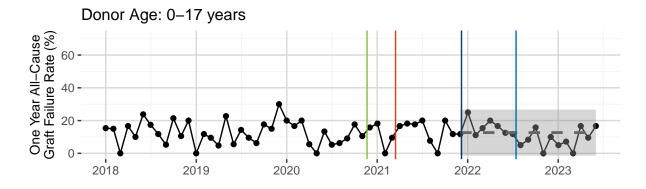
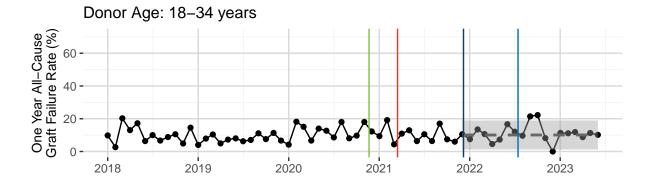
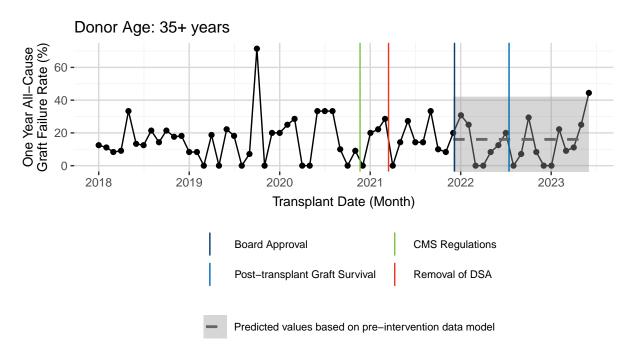


Figure 29. Donor Age







Heart/Heart-Lung

Figure 30. Recipient Race/Ethnicity

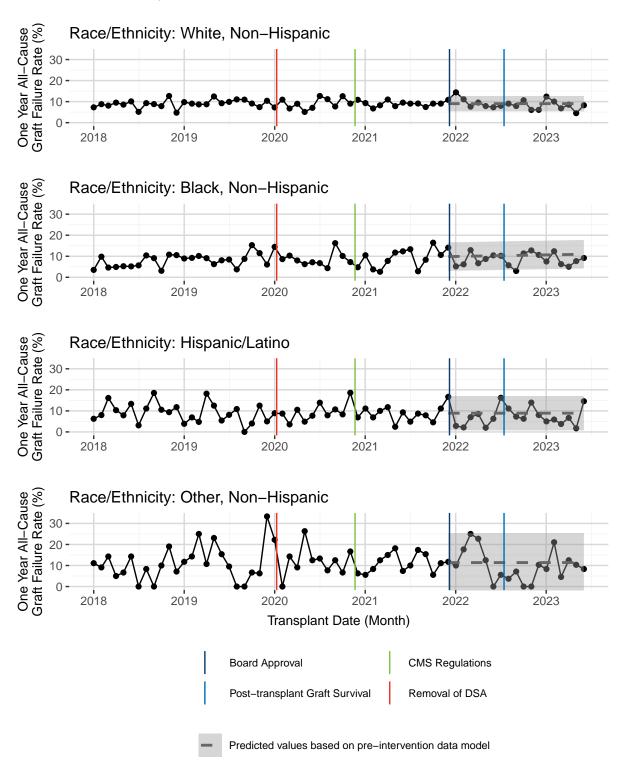
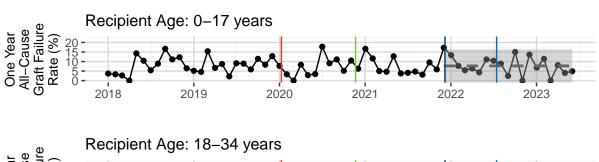
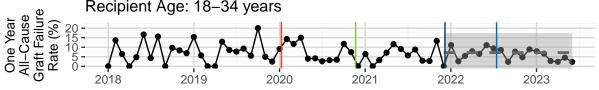
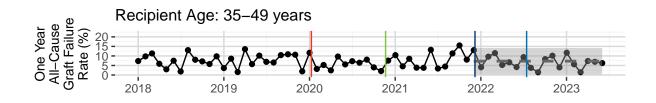
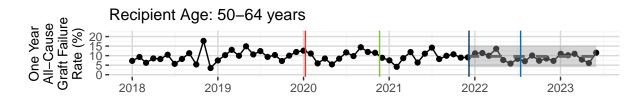


Figure 31. Recipient Age









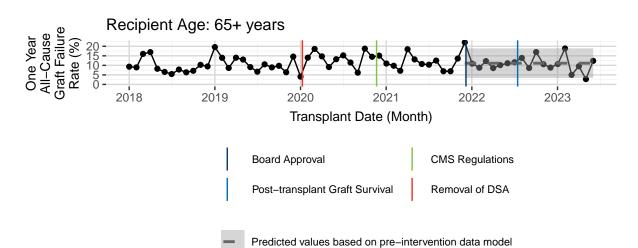
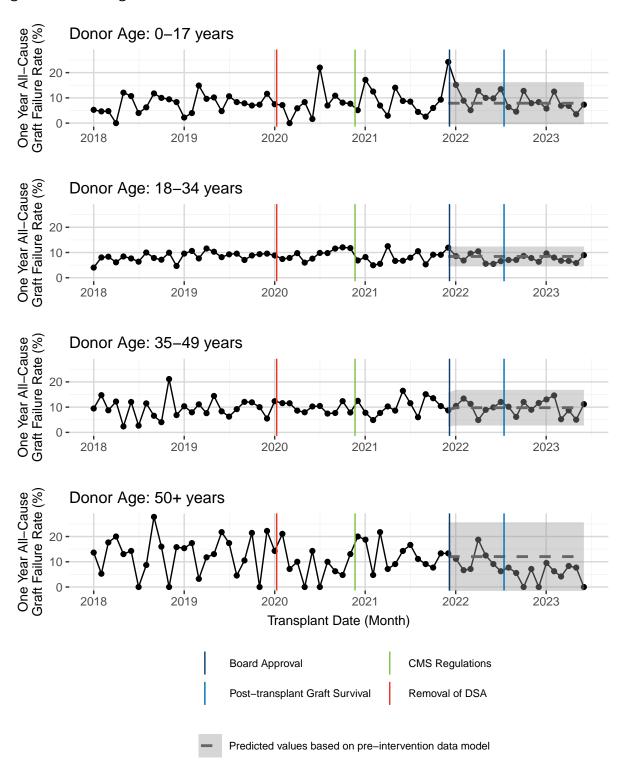


Figure 32. Donor Age

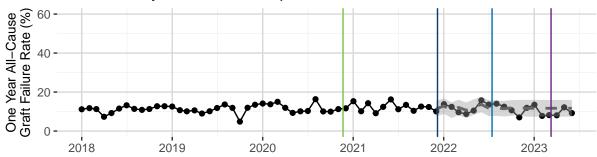


Lung

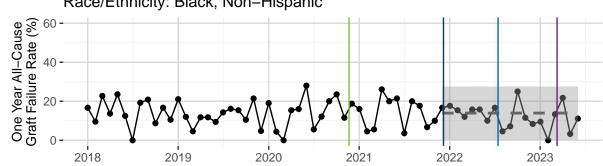
Due to small numbers the Other, Non-Hispanic group is not shown below. There were 588 Other, Non-Hispanic lung transplants over the time period. The average graft failure rate per month for Other, Non-Hispanic lung transplants was 11.4% compared to 26.9% overall.

Figure 33. Race/Ethnicity

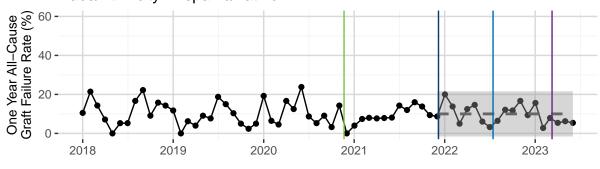




Race/Ethnicity: Black, Non-Hispanic



Race/Ethnicity: Hispanic/Latino



Board Approval CMS Regulations Post-transplant Graft Survival Lung CAS

Predicted values based on pre-intervention data model

Due to small numbers the pediatric (age < 18 at transplant) group is not shown below. There were 176 pediatric lung transplants over the total time period. The average graft failure rate per month for the pediatric transplant group was 13% compared to 40.9% overall.

Figure 34. Recipient Age

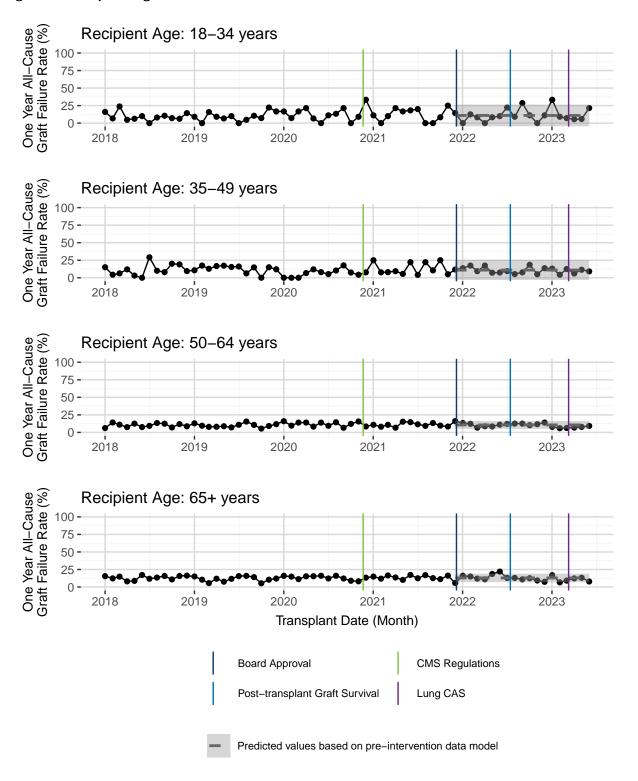
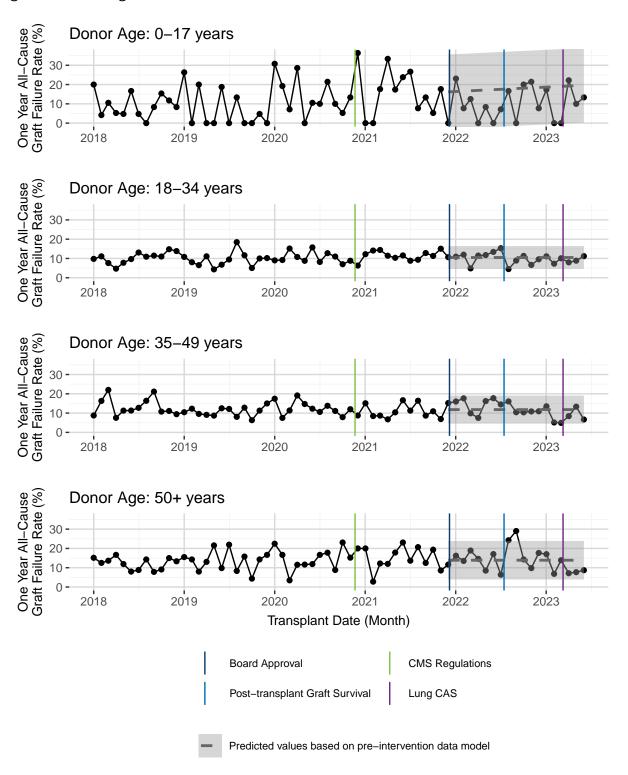


Figure 35. Donor Age



Appendix B: OPTN Waiting List Registrations Added by Characteristic Stratifications

Kidney

Figure 36. Candidate Race/Ethnicity

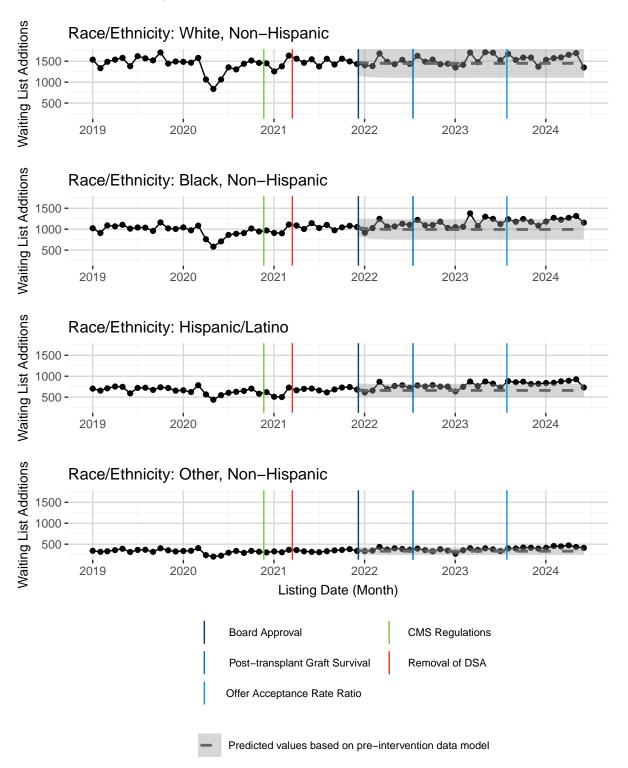
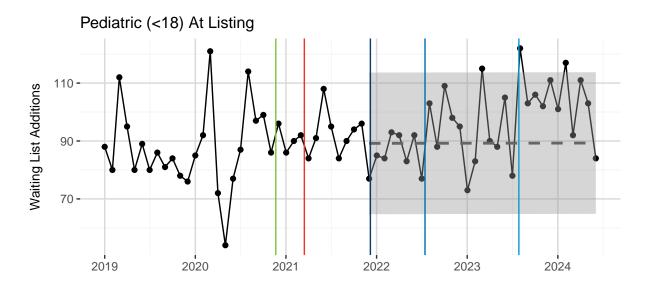


Figure 37. Candidate Age at Listing



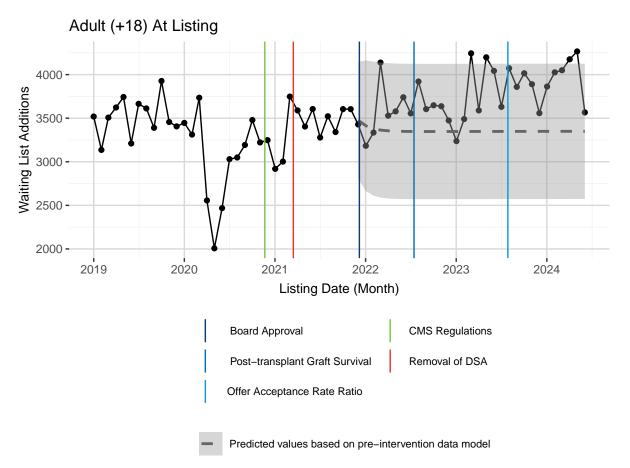
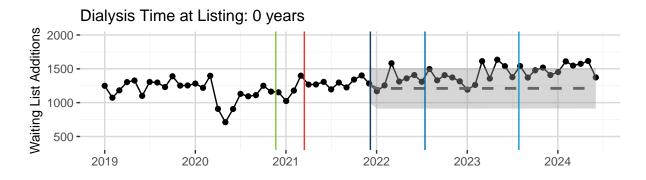
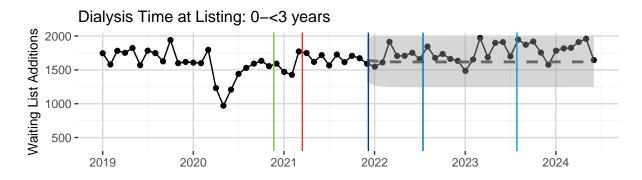
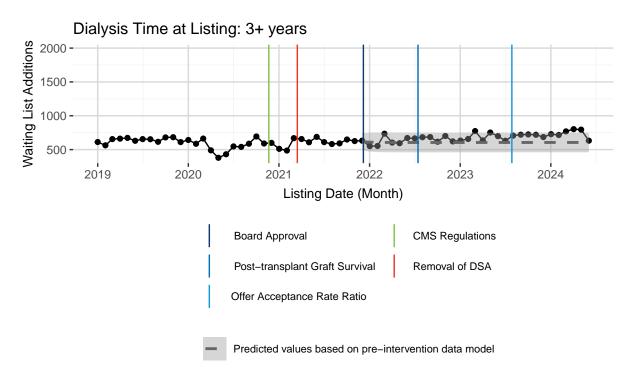


Figure 38. Candidate Time on Dialysis at Listing

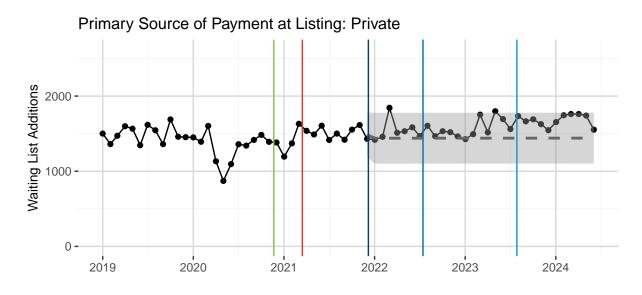


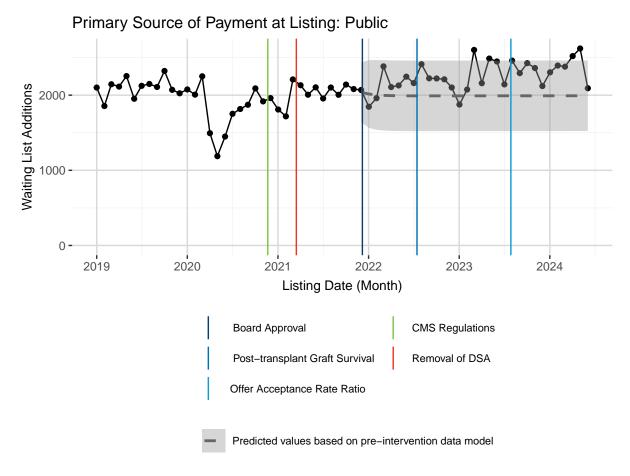




Primary payment information was missing for 216 kidney registrations between January 01, 2019 to June 30, 2024, with the largest proportion missing from January 2023 (N=8).

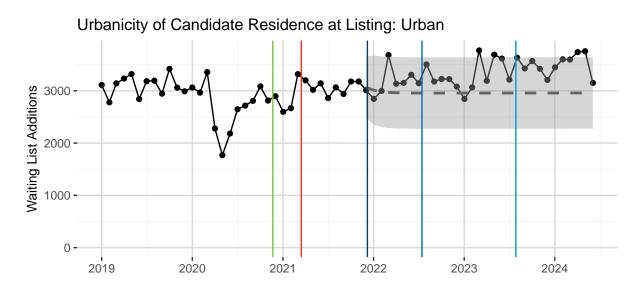
Figure 39. Candidate Primary Source of Payment at Listing

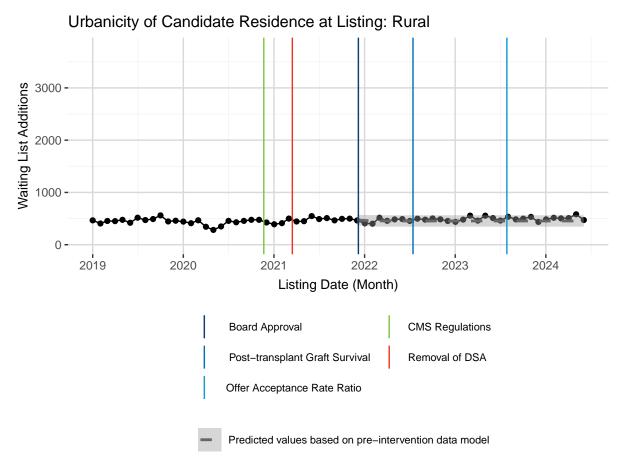




RUCA information was not available for 1813 kidney registrations between January 01, 2019 to June 30, 2024, or an average of 27.5 registrations per month.

Figure 40. Urbanicity of Candidate Residence at Listing





Liver

Figure 41. Candidate Race/Ethnicity

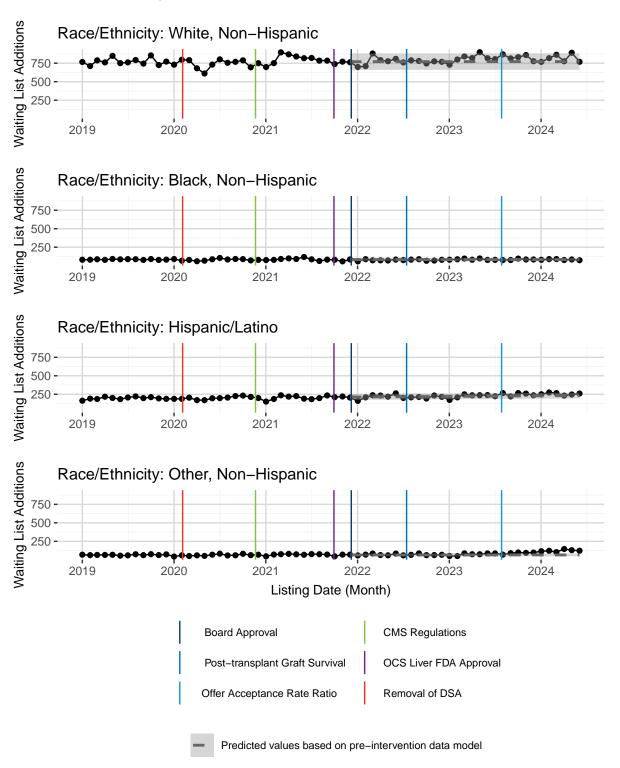
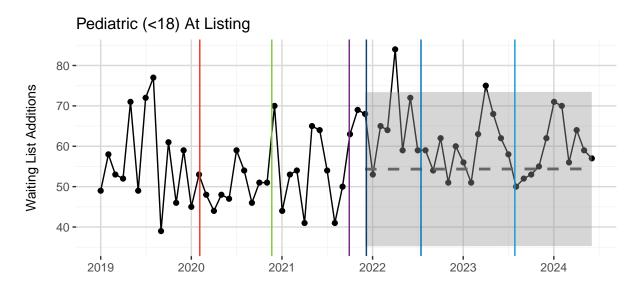
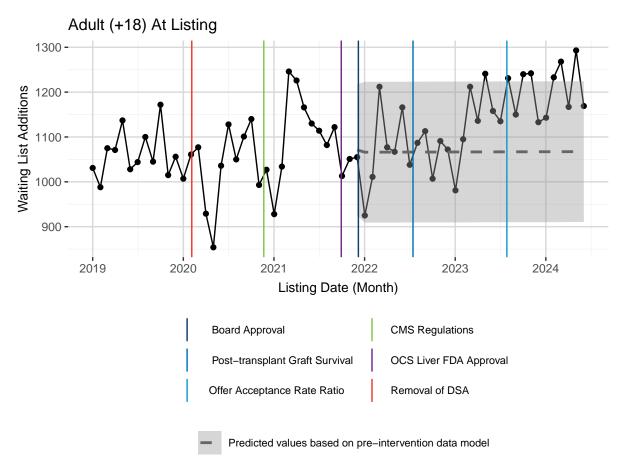


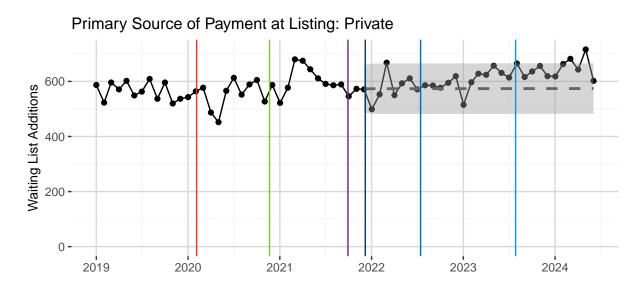
Figure 42. Candidate Age at Listing

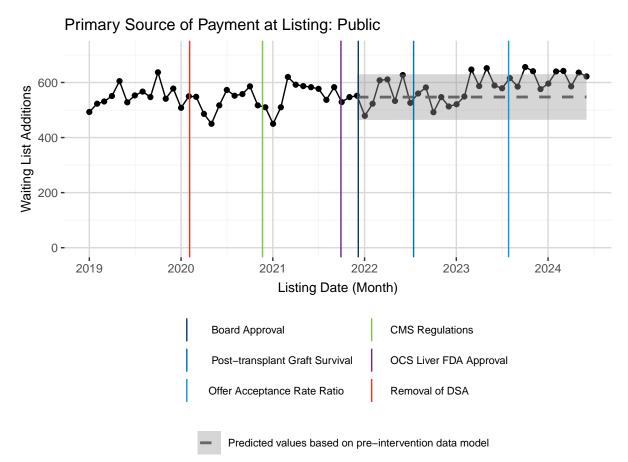




Primary payment information was missing for 14 liver registrations between January 01, 2019 to June 30, 2024.

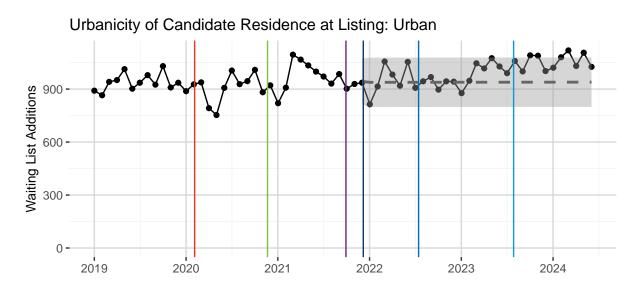
Figure 43. Candidate Primary Source of Payment at Listing

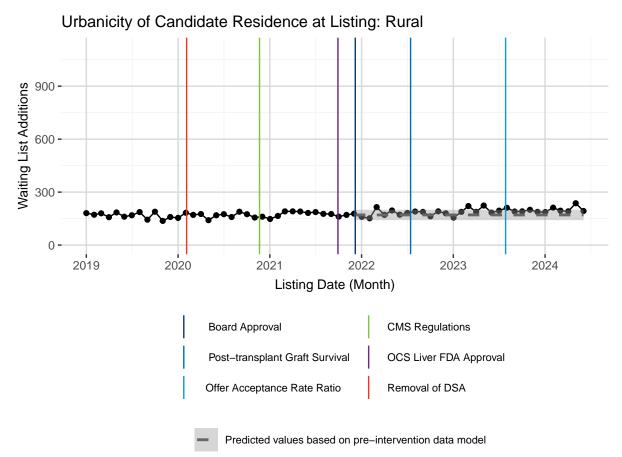




RUCA information was not available for 662 liver registrations between January 01, 2019 to June 30, 2024, or an average of 10 registrations per month.

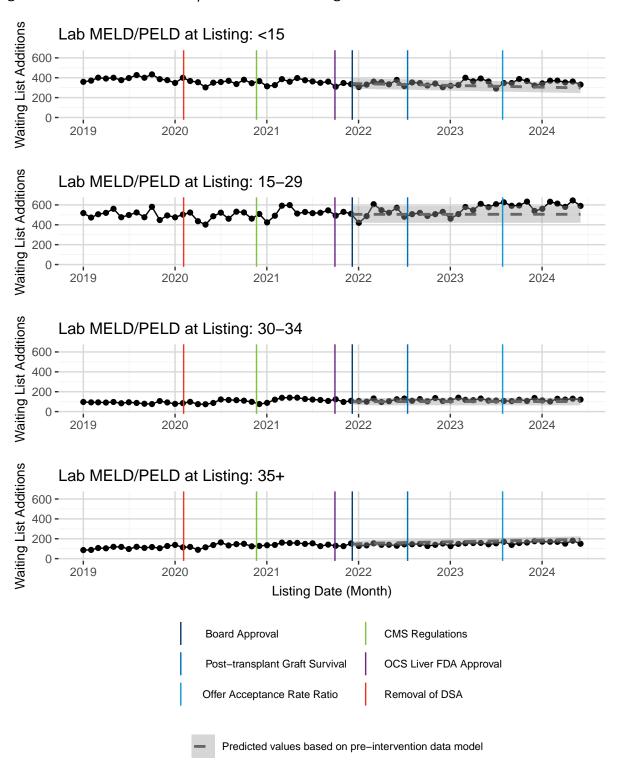
Figure 44. Urbanicity of Candidate Residence at Listing





Liver registrations added to the waiting list at Status 1A or 1B were not separated out in the figure below and were categorized by their lab MELD or PELD score at listing rather than status. There were 1493 liver registrations with a medical urgency status of "Temporarily Inactive" at listing between January 01, 2019 to June 30, 2024, an average of 22.6 registrations per month.

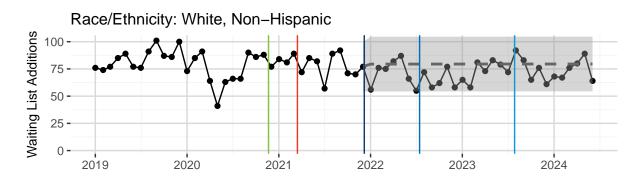
Figure 45. Candidate Lab MELD/PELD Score at Listing

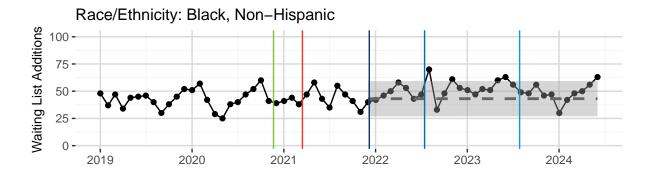


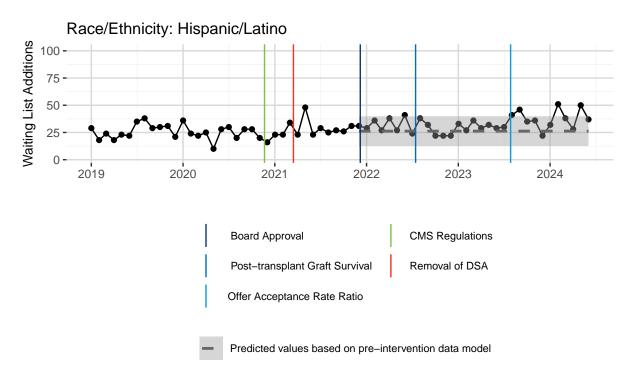
Pancreas/Kidney-Pancreas

Due to small numbers for pediatric (age < 18 at listing) pancreas/kidney-pancreas waiting list additions, stratification by age at listing is not shown. On average there were 2.9 pediatric pancreas/kidney-pancreas registrations added per month and a total of 191 over the time period. Due to small numbers the Other, Non-Hispanic group for pancreas/kidney-pancreas is not shown below. On average there were 10.5 Other, Non-Hispanic pancreas/kidney-pancreas registrations added per month and a total of 690 over the time period.

Figure 46. Candidate Race/Ethnicity

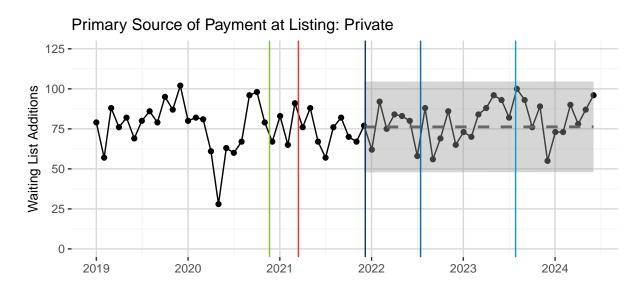


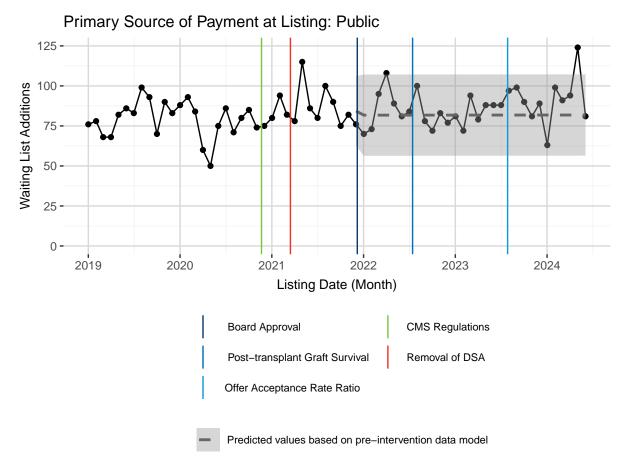




Primary payment information was missing for 30 pancreas/kidney-pancreas registrations between January 01, 2019 to June 30, 2024, with the largest proportion missing from April 2024 (N=4).

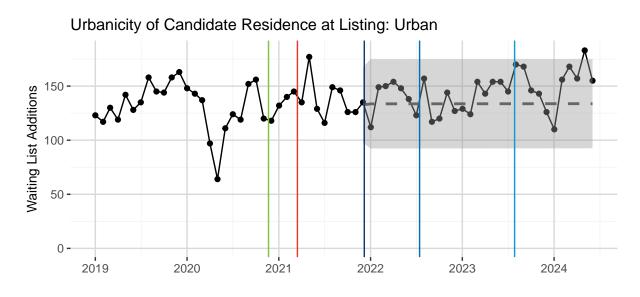
Figure 47. Candidate Primary Source of Payment at Listing

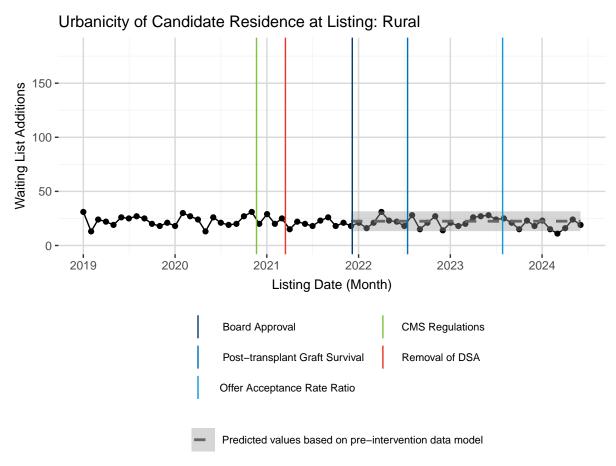




RUCA information was not available for 144 pancreas/kidney-pancreas registrations between January 01, 2019 to June 30, 2024, or an average of 2.2 registrations per month.

Figure 48. Urbanicity of Candidate Residence at Listing





Heart/Heart-Lung

Figure 49. Candidate Race/Ethnicity

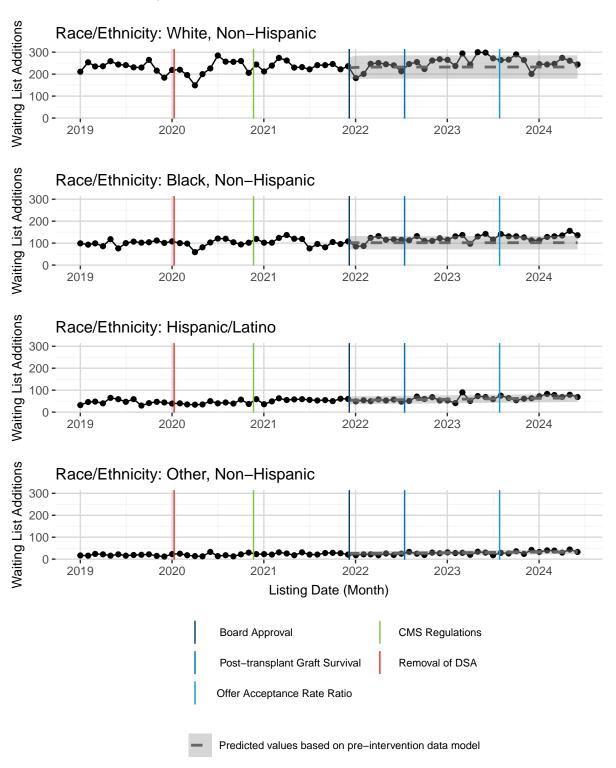
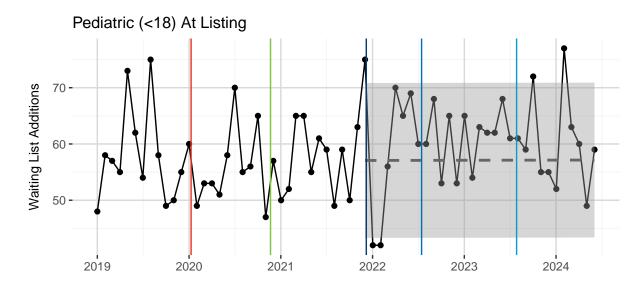
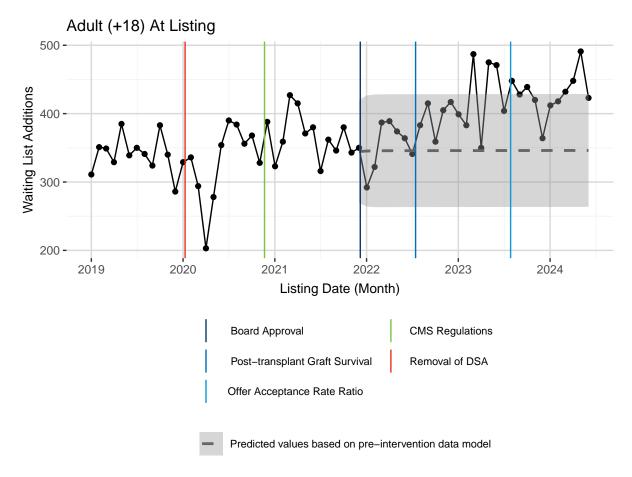


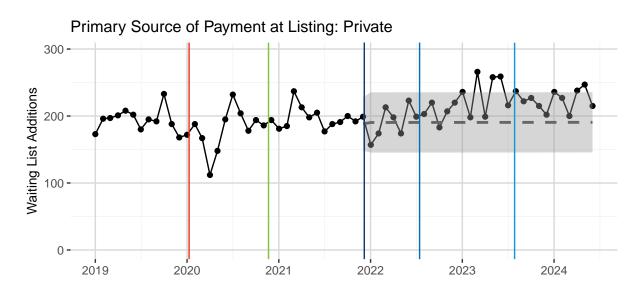
Figure 50. Candidate Age at Listing

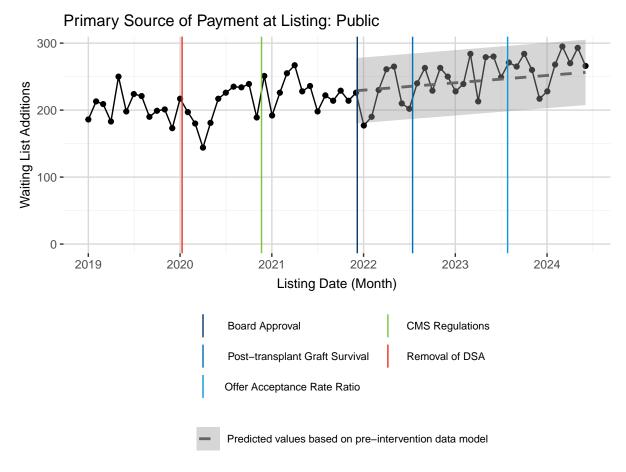




Primary payment information was missing for 8 heart/heart-lung registrations between January 01, 2019 to June 30, 2024.

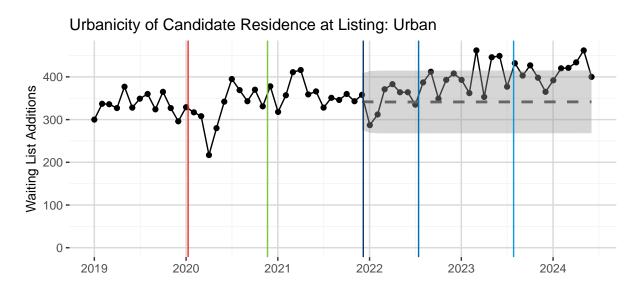
Figure 51. Candidate Primary Source of Payment at Listing

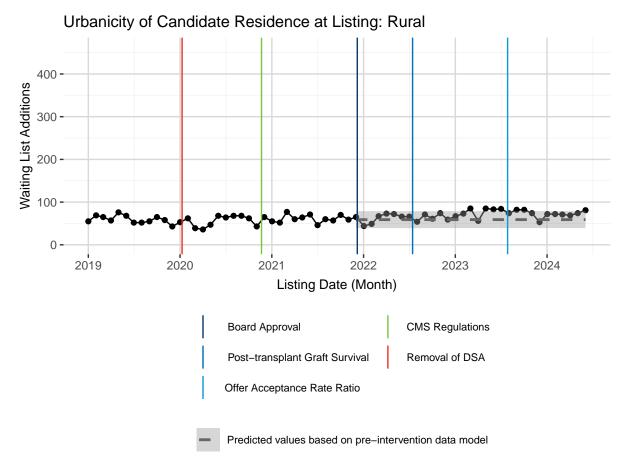




RUCA information was not available for 181 heart/heart-lung registrations between January 01, 2019 to June 30, 2024, or an average of 2.7 registrations per month.

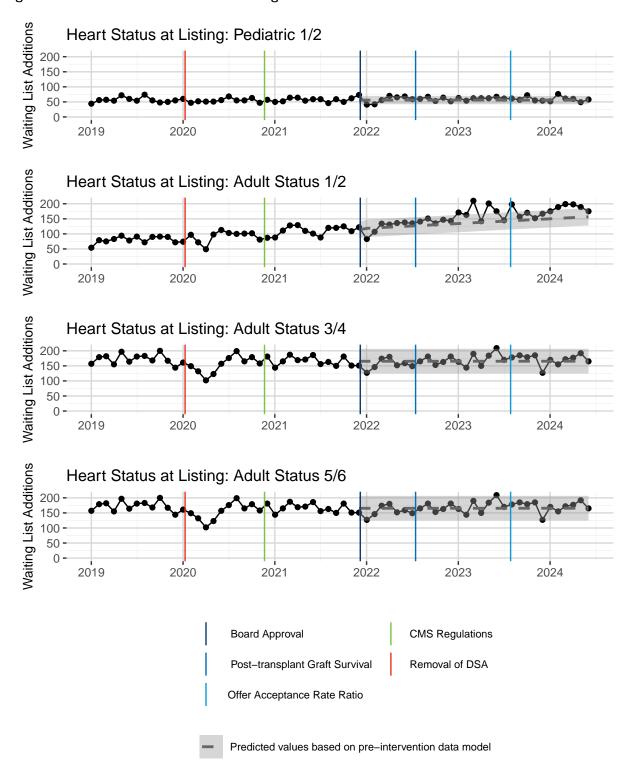
Figure 52. Urbanicity of Candidate Residence at Listing





There were 263 heart/heart-lung registrations with a medical urgency status of "Temporarily Inactive" at listing between January 01, 2019 to June 30, 2024, an average of 4 registrations per month.

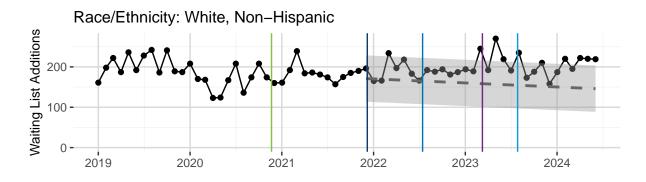
Figure 53. Candidate Heart Status at Listing

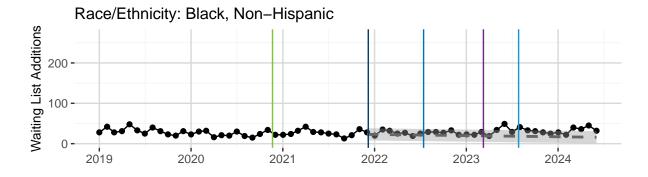


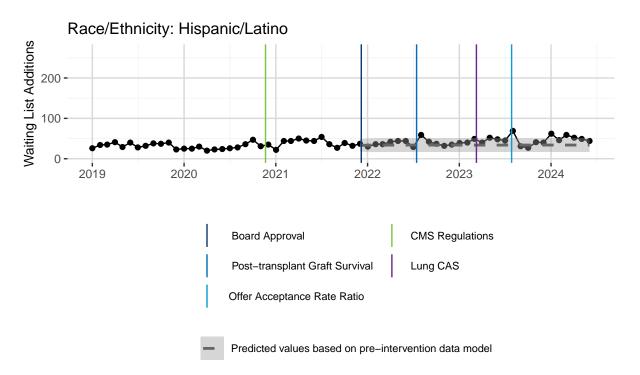
Lung

Due to small numbers for pediatric (age < 18 at listing) lung waiting list additions, stratification by age at listing is not shown. On average there were 4 pediatric lung registrations added per month and a total of 262 over the time period. Due to small numbers the Other, Non-Hispanic group for lung is not shown below. On average there were 13.9 Other, Non-Hispanic lung registrations added per month and a total of 917 over the time period.

Figure 54. Candidate Race/Ethnicity

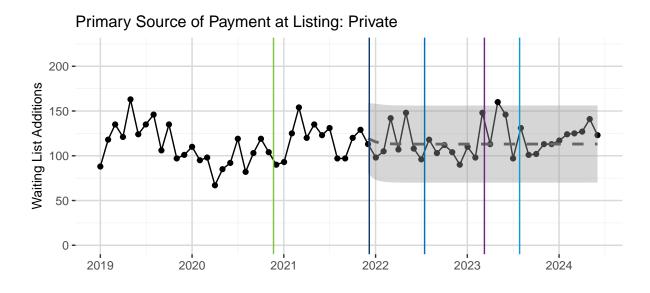


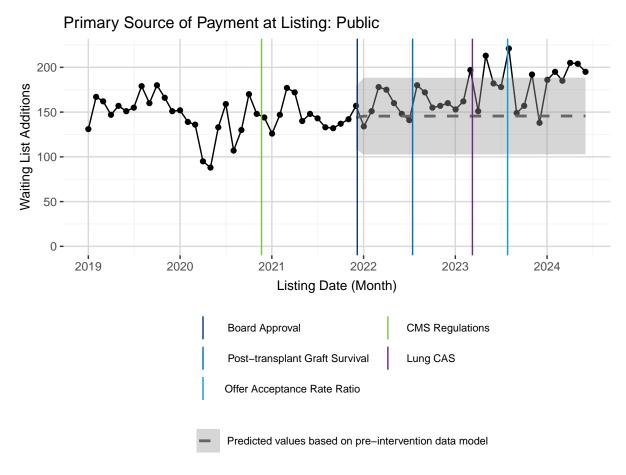




Primary payment information was missing for 3 lung registrations between January 01, 2019 to June 30, 2024.

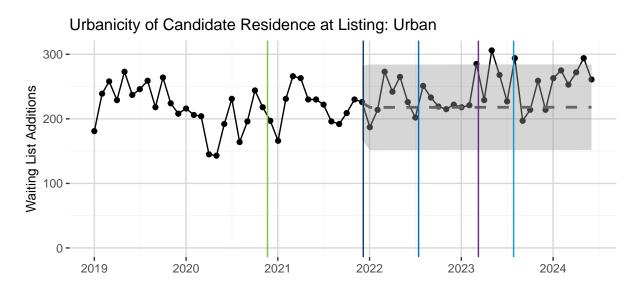
Figure 55. Candidate Primary Source of Payment at Listing

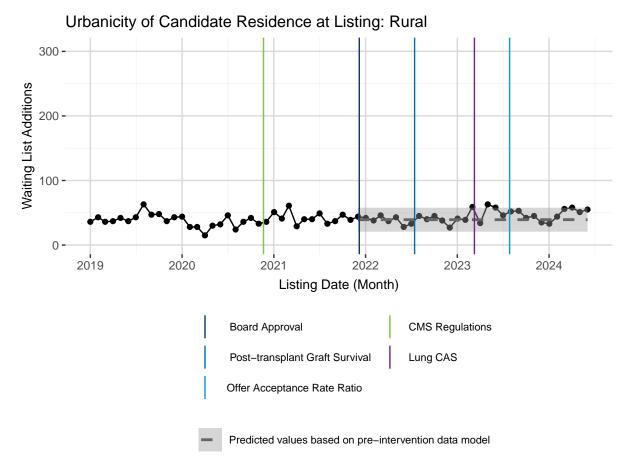




RUCA information was not available for 133 lung registrations between January 01, 2019 to June 30, 2024, or an average of 2 registrations per month.

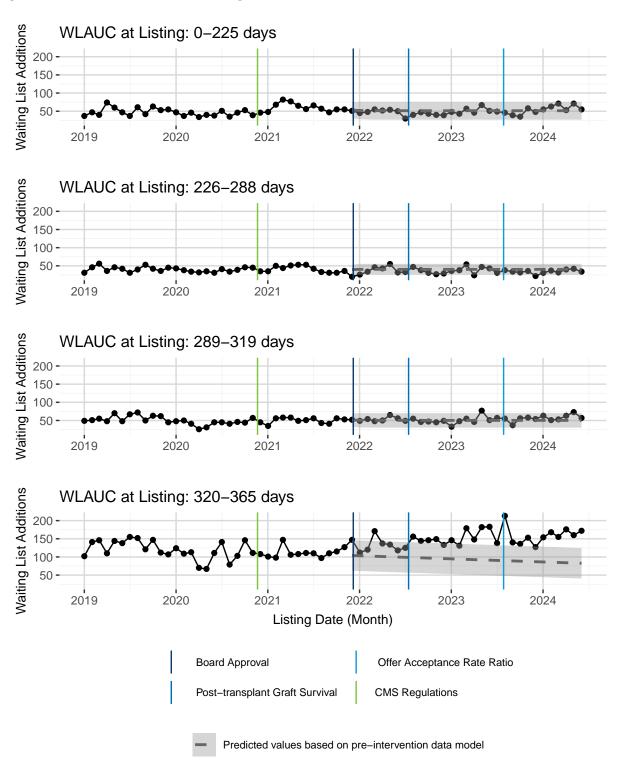
Figure 56. Urbanicity of Candidate Residence at Listing





The Lung Continuous Distribution policy that was implemented on March 09, 2023 affected how medical urgency was calculated. More specifically, this policy separated out the waiting list and post-transplant survival components of the previous Lung Allocation Score (LAS) by creating separate waiting list and post-transplant survival attributes. These attributes were then combined with other attributes such as blood type, CPRA, height, pediatric, prior living donor, travel efficiency, and proximity efficiency, to create an overall Composite Allocation Score (CAS). Because the CAS contains additional attributes beyond medical urgency, it cannot be directly compared to the LAS pre-policy. However, the underlying calculation for waiting list survival remained the same pre- and post-Lung Continuous Distribution: namely, waiting list survival is estimated as the number of days in the next year a registration is predicted to survive without transplant. Mathematically, this quantity is computed as the area under the estimated average 1-year waiting list survival curve for each candidate (WLAUC). For more details on the computation of WLAUC, please see the OPTN Guide to Calculating the Lung Composite Allocation Score. The analyses below group registrations into the following categories based on WLAUC to be consistent with OPTN Lung Continuous Distribution Policy Monitoring Reports: WLAUC 0-225 days, WLAUC 226-288 days, WLAUC 289-319 days, and WLAUC 320-365 days.

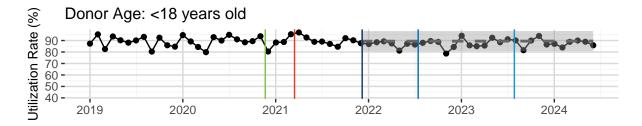
Figure 57. Candidate WLAUC at Listing

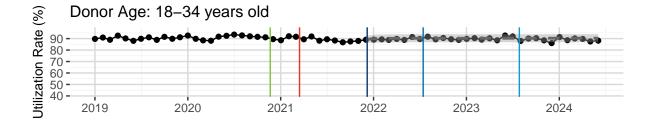


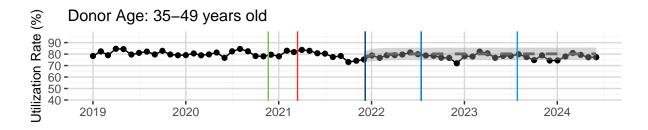
Appendix C: Utilization Rates by Characteristic Stratifications

Kidney

Figure 58. Donor Age







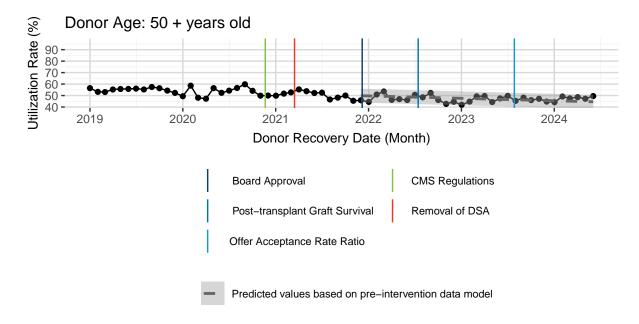
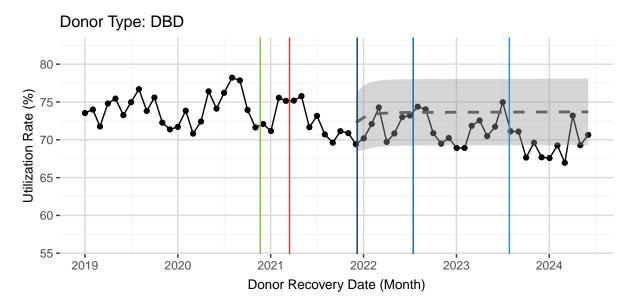


Figure 59. Donor Type



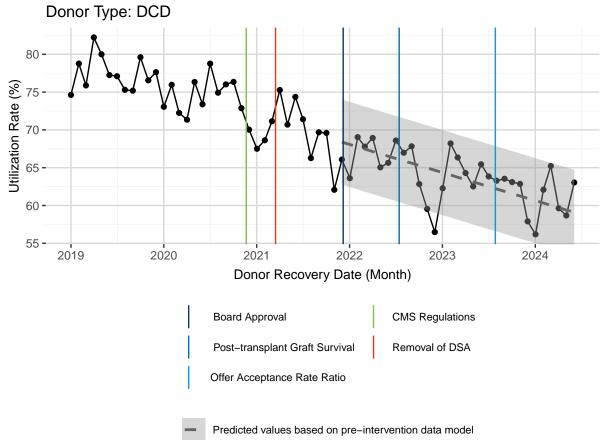
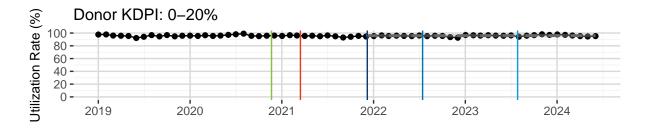
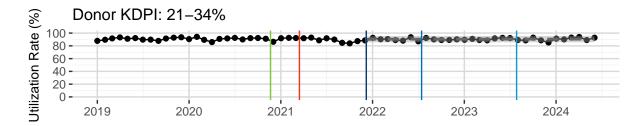
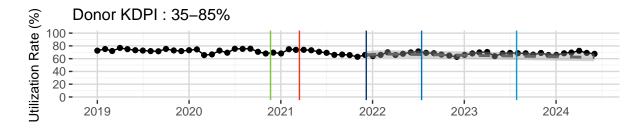
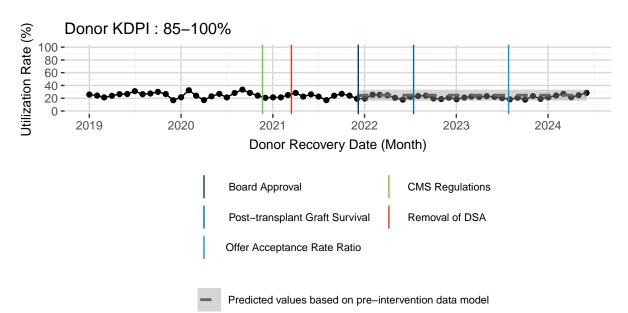


Figure 60. Donor KDPI



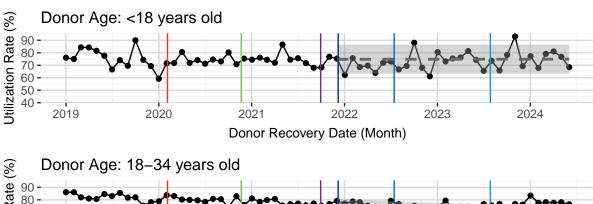


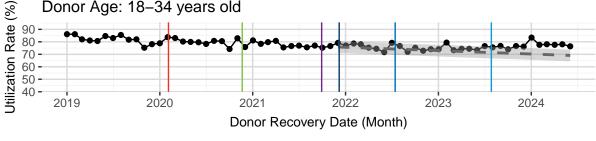


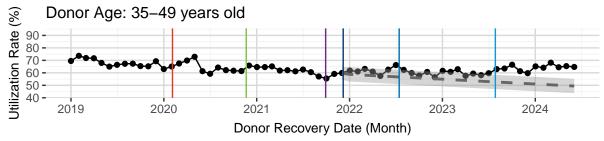


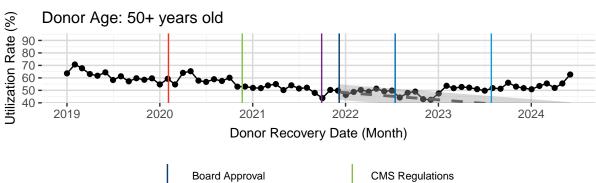
Liver

Figure 61. Donor Age





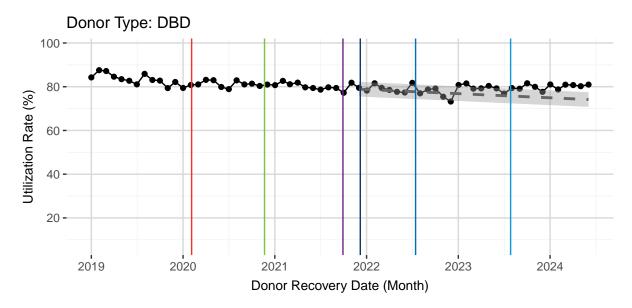


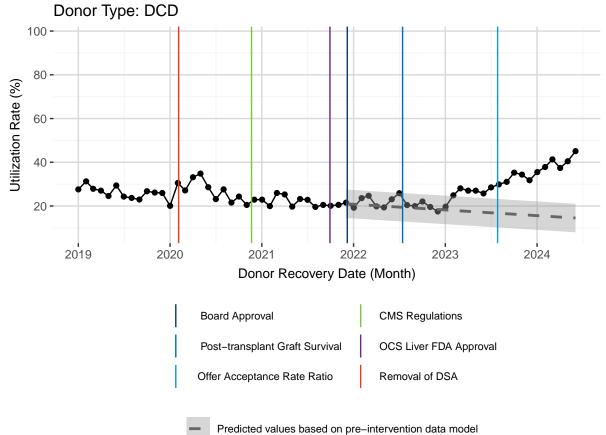




Predicted values based on pre-intervention data model

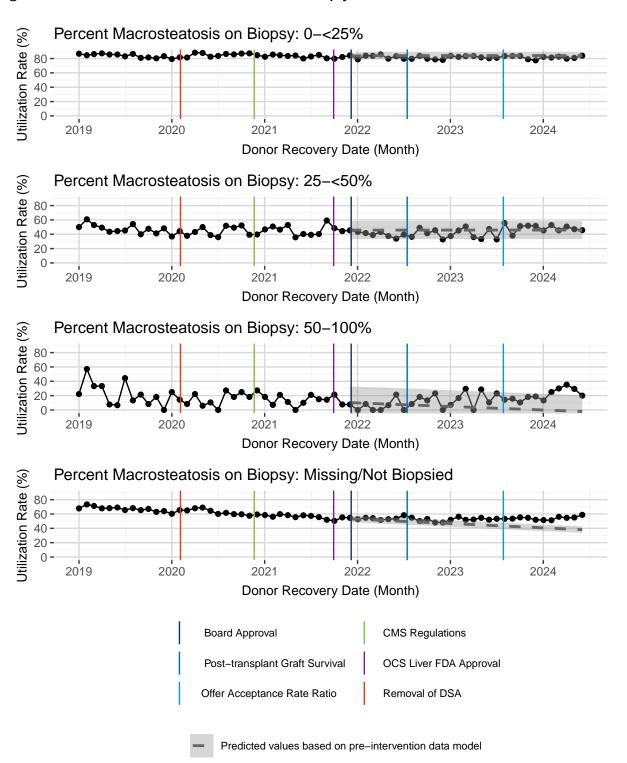
Figure 62. Donor Type





Donor macrosteatosis (%) on a biopsy is a measure of particular interest for liver donors; however, a liver biopsy is not required to be performed for each donor. The majority of organ donors did not have a liver biopsy completed, and therefore did not have a measure of macrosteatosis (N=50,339,64.4%). A larger proportion of organ donors with no liver recovered were missing this measure (85.2%) than organ donors with a liver recovered (55.4%). For contextual numbers regarding donors and organs donated please see Table 2.

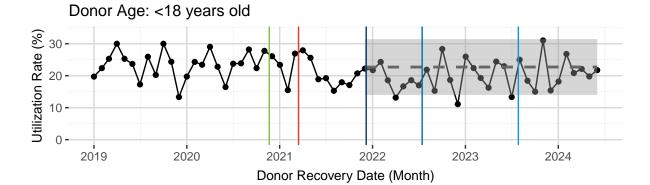
Figure 63. Percent Macrosteatosis on Donor Liver Biopsy

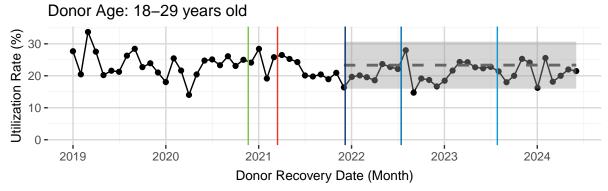


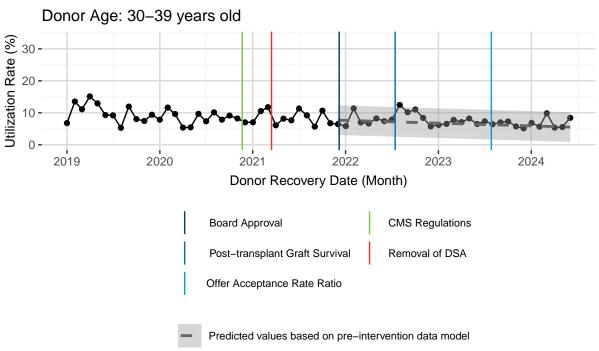
Pancreas

Due to small numbers, stratification by donor type is not shown for pancreas. On average there were 5.3 DCD pancreata recovered and 2.6 DCD pancreata transplanted per month, with an average utilization rate of 0.8% per month. Due to small numbers the pancreas utilization rate for donors age 40 or older is not shown below. On average there were 7.2 donors age 40 or older with pancreata recovered and 4 pancreata from donors age 40 or older transplanted per month, with an average utilization rate of 0.6% per month.

Figure 64. Donor Age







Heart

Figure 66. Donor Age

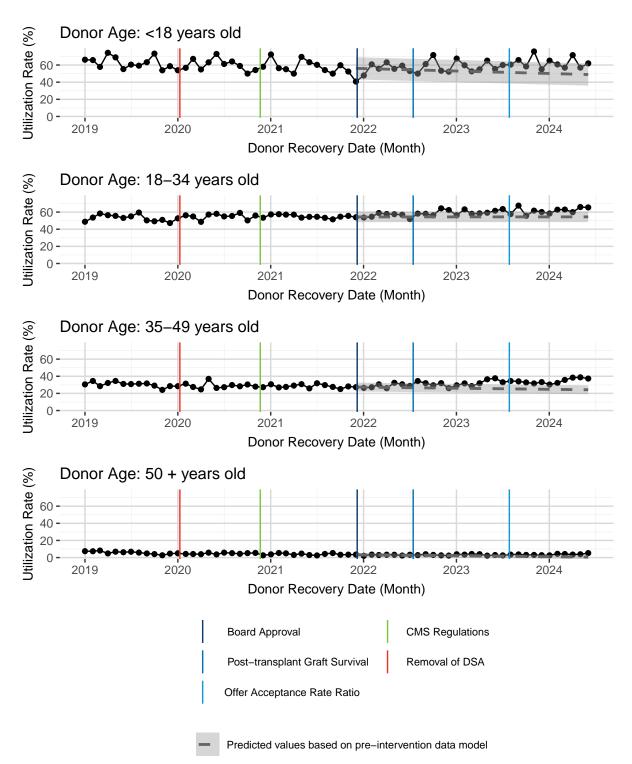
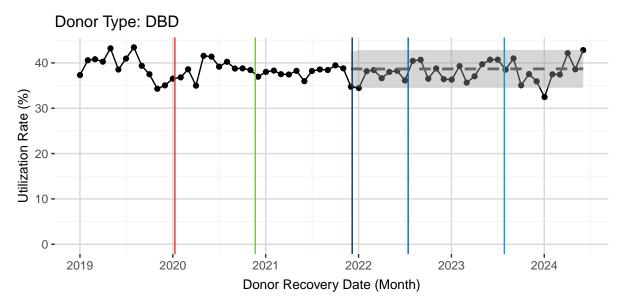
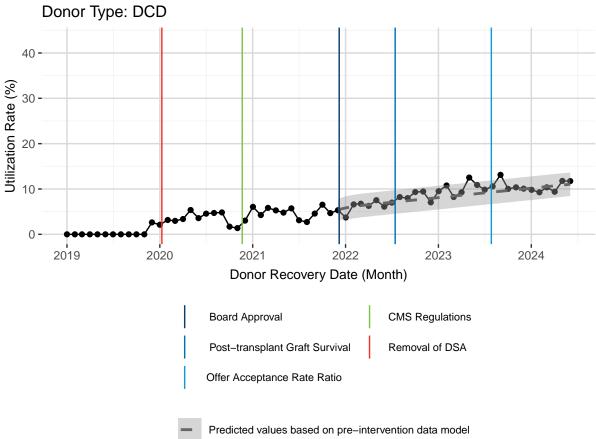


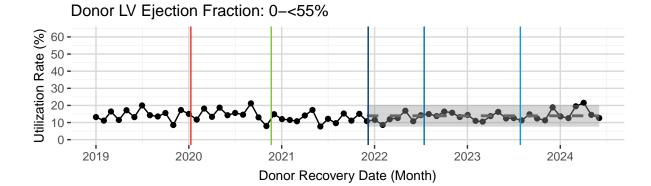
Figure 67. Donor Type

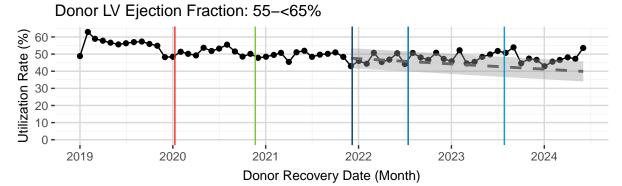


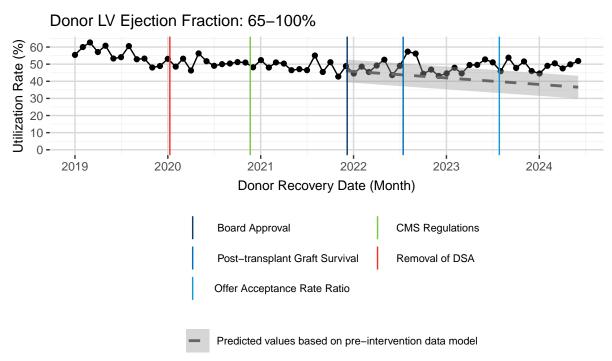


Donor left ventricle (LV) ejection fraction is a measure of interest for heart donors, but is not required to be reported. The majority of organ donors were not missing a measure of LV ejection fraction (N=52,564,67.2%). A larger proportion of organ donors with no heart recovered were missing this measure (45.9%) than organ donors with a heart recovered (0.4%). For contextual numbers regarding donors and organs donated please see table 2.

Figure 68. Donor LV Ejection Fraction







Lung

Figure 69. Donor Age

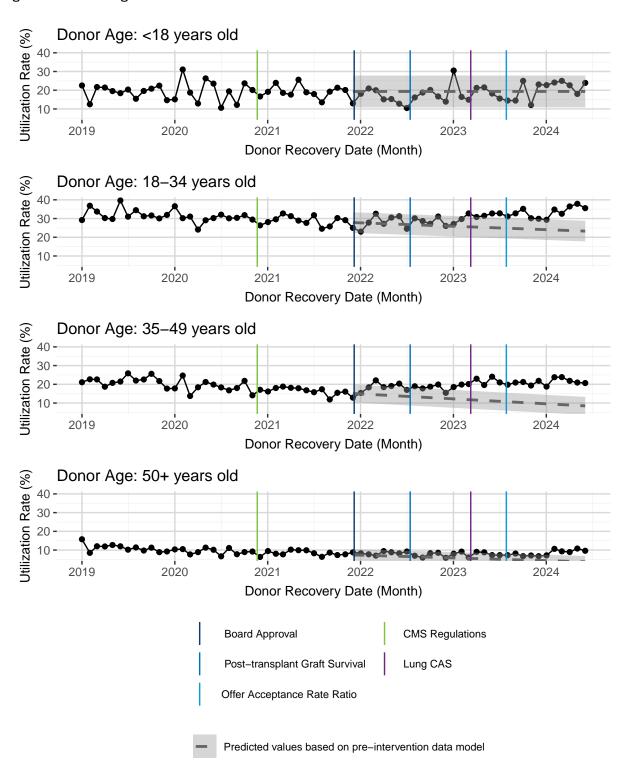
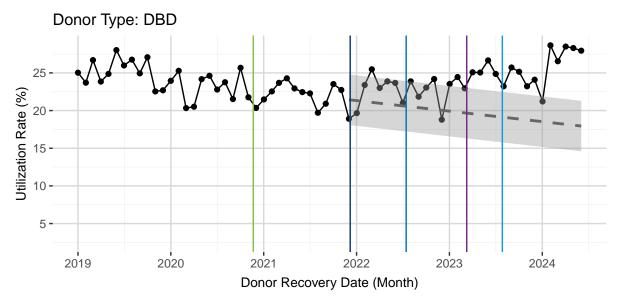
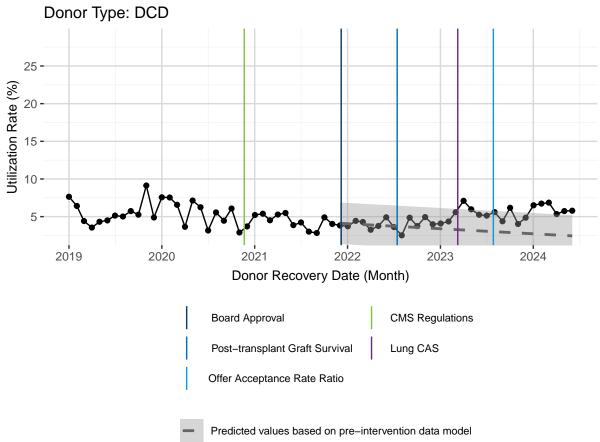


Figure 70. Donor Type

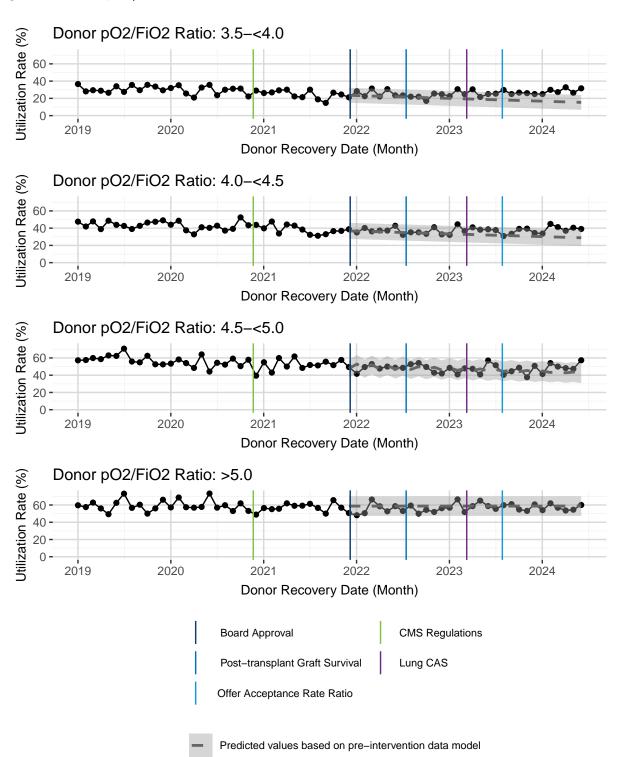




The donor pO2/FiO2 ratio was missing for 0.8% (N=588) organ donors. A larger proportion of organ donors with no lungs recovered were missing this measure (0.8%) than organ donors with lung(s) recovered (0.5%). Due to small numbers the lung utilization rate for organ donors with pO2/FiO2 ratio < 3.5 is not shown below. On average there were 73.8 lungs from donors with pO2/FiO2 ratio < 3.5 recovered and 61.3 lungs from donors with pO2/FiO2 ratio < 3.5 transplanted per month, with an average utilization rate of 4.1% per month.

For contextual numbers regarding donors and organs donated please see table 2.

Figure 71. Donor pO2/FiO2 Ratio



Appendix D: Transplant-to-Recovery Rates by Characteristic Stratifications

Kidney

Figure 72. Donor Age

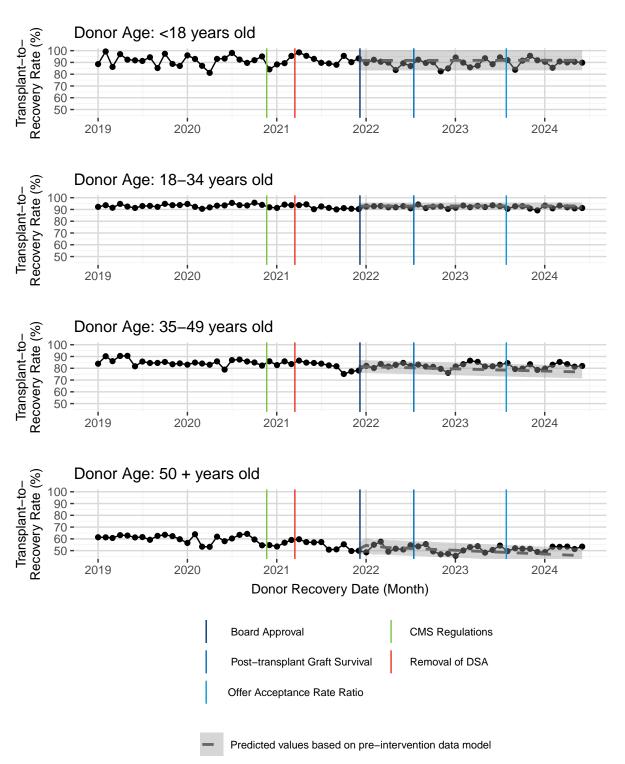
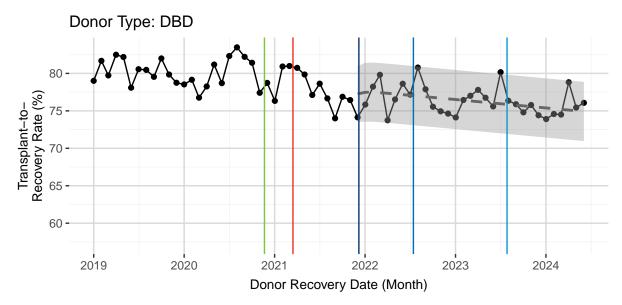


Figure 73. Donor Type



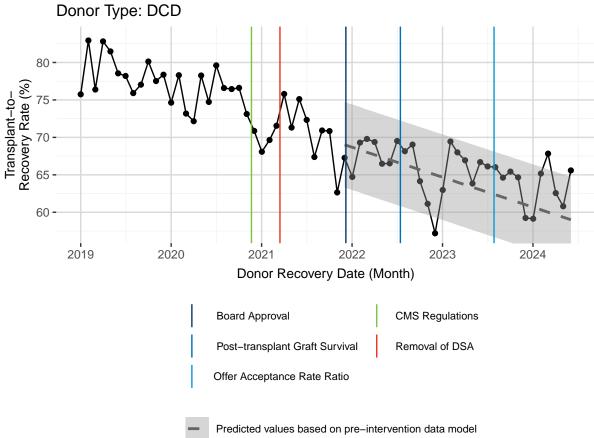
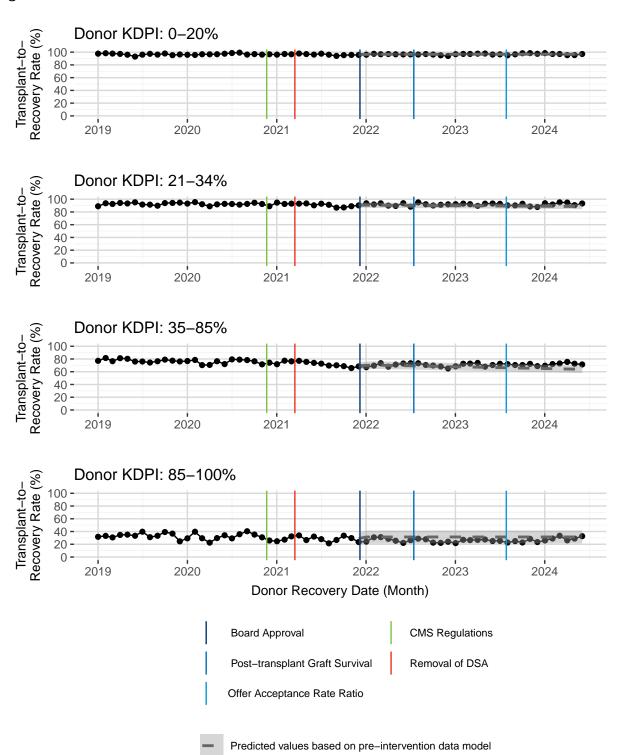


Figure 74. Donor KDPI



Liver

Figure 75. Donor Age

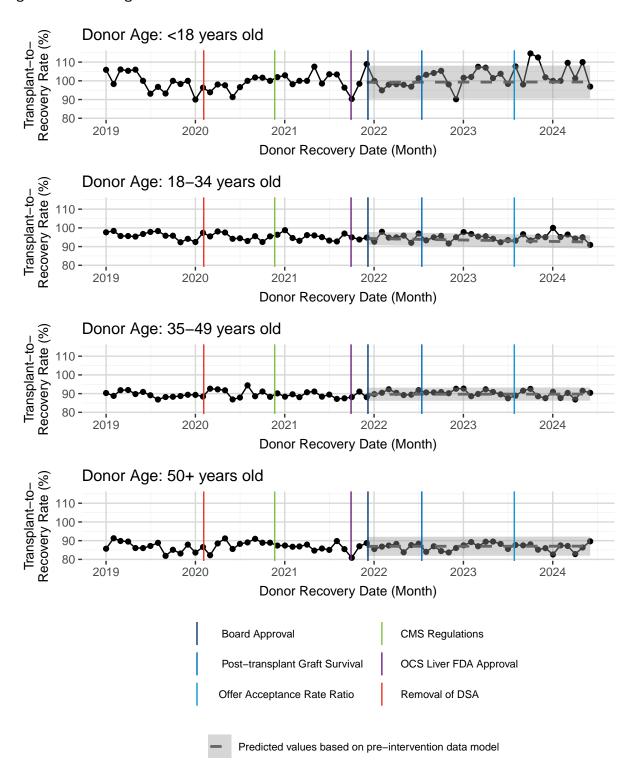
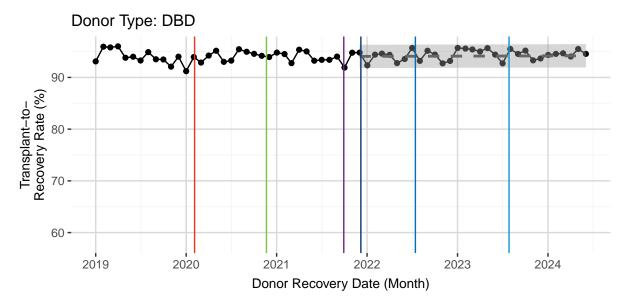
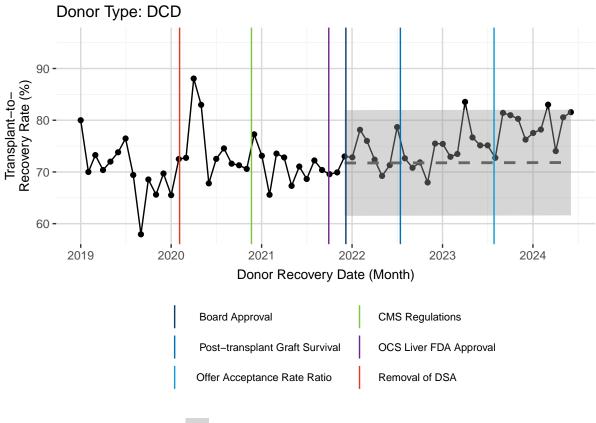


Figure 76. Donor Type

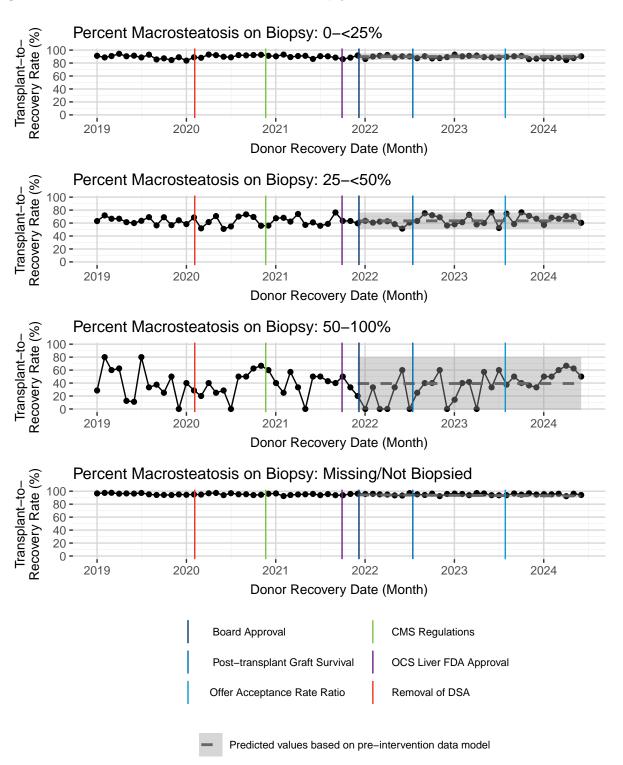




Predicted values based on pre-intervention data model

Donor macrosteatosis (%) on a biopsy is a measure of particular interest for liver donors; however, a liver biopsy is not required to be performed for each donor. The majority of organ donors did not have a liver biopsy completed, and therefore did not have a measure of macrosteatosis (N=50,339,64.4%). A larger proportion of organ donors with no liver recovered were missing this measure (85.2%) than organ donors with a liver recovered (55.4%). For contextual numbers regarding donors and organs recovered please see Table 2.

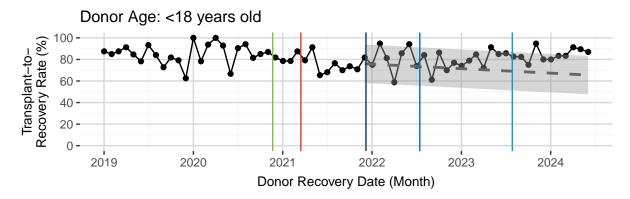
Figure 77. Percent Macrosteatosis on Donor Liver Biopsy

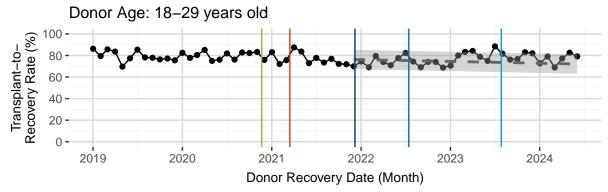


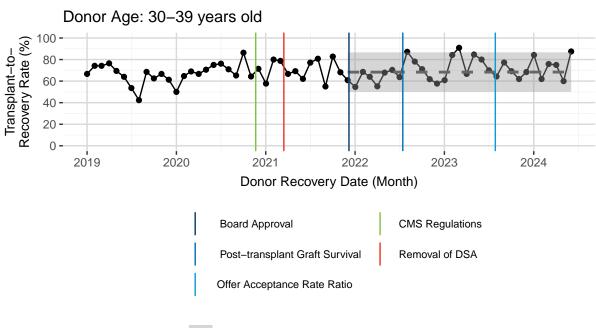
Pancreas

Due to small numbers, stratification by donor type is not shown for pancreas. On average there were $5.3\ DCD$ pancreata recovered and $2.6\ DCD$ pancreata transplanted per month, with an average transplant-to-recovery rate of 48.1% per month. Due to small numbers the pancreas transplant-to-recovery rate for donors age 40 or older is not shown below. On average there were 7.2 donors age 40 or older with pancreata recovered and 4 pancreata from donors age 40 or older transplanted per month, with an average transplant-to-recovery rate of 55.4% per month.

Figure 78. Donor Age







Predicted values based on pre-intervention data model

Heart

Figure 80. Donor Age

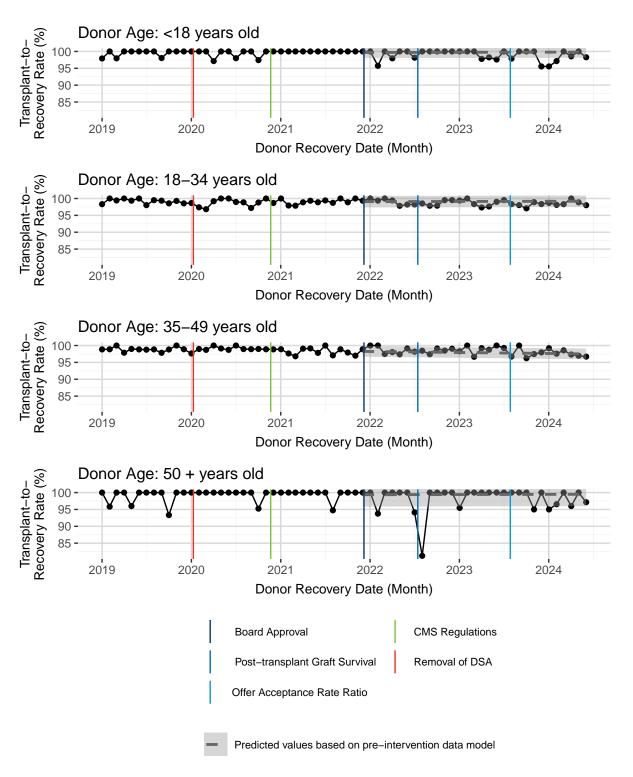
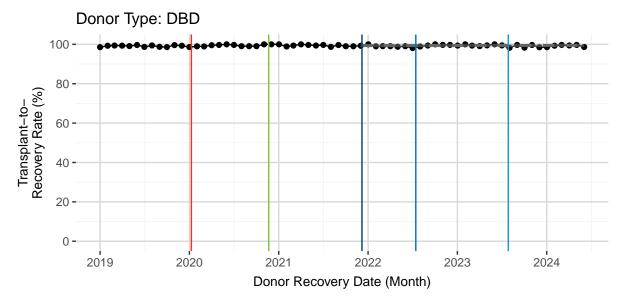
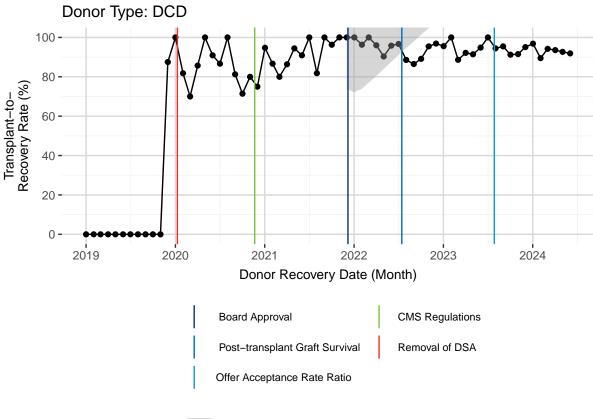


Figure 81. Donor Type

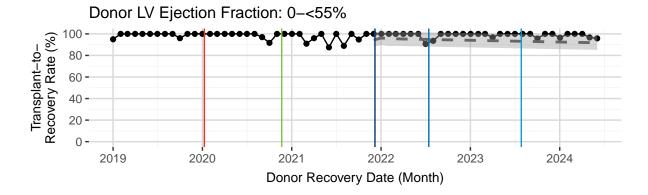


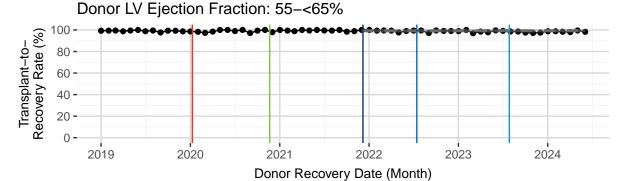


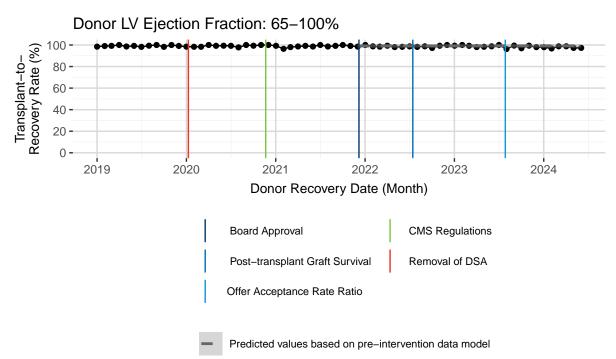
Predicted values based on pre-intervention data model

Donor left ventricle (LV) ejection fraction is a measure of interest for heart donors, but is not required to be reported. The majority of organ donors were not missing a measure of LV ejection fraction (N=52,564,67.2%). A larger proportion of organ donors with no heart recovered were missing this measure (45.9%) than organ donors with a heart recovered (0.4%). For contextual numbers regarding donors and organs recovered please see table 2.

Figure 82. Donor LV Ejection Fraction







Lung

Figure 83. Donor Age

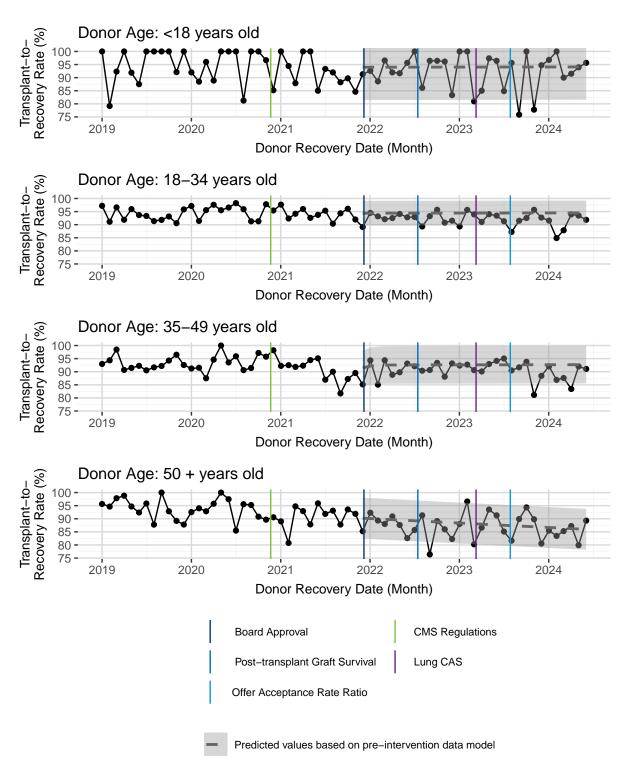
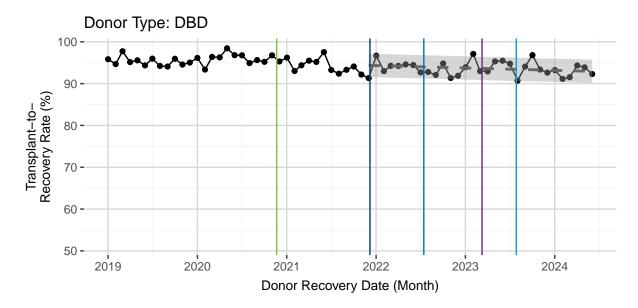
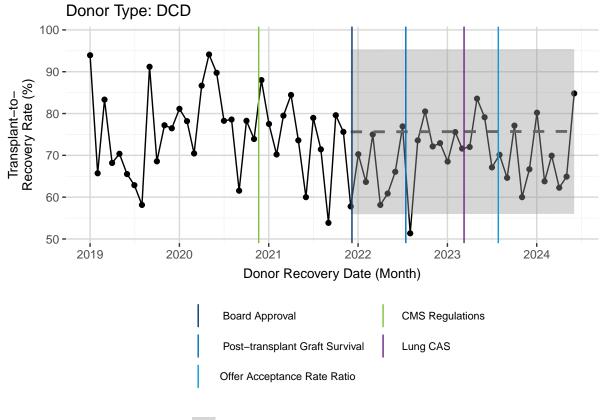


Figure 84. Donor Type



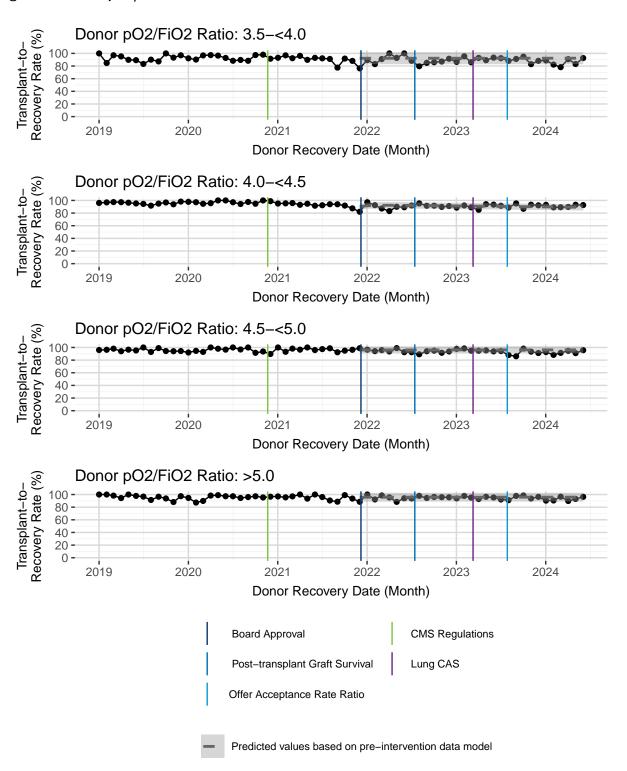


Predicted values based on pre-intervention data model

The donor pO2/FiO2 ratio was missing for 0.8% (N=588) organ donors. A larger proportion of organ donors with no lungs recovered were missing this measure (0.8%) than organ donors with lung(s) recovered (0.5%). Due to small numbers the lung transplant-to-recovery rate for organ donors with pO2/FiO2 ratio <3.5 is not shown below. On average there were 73.8 lungs from donors with pO2/FiO2 ratio <3.5 recovered and 61.3 lungs from donors with pO2/FiO2 ratio <3.5 transplanted per month, with an average transplant-to-recovery rate of 83.5% per month.

For contextual numbers regarding donors and organs recovered please see Table 2.

Figure 85. Donor pO2/FiO2 Ratio



Appendix E: Sensitivity Analyses: One Year Post-Transplant All-Cause Graft Failure by Month of Transplant (January 01, 2018 to July 14, 2022 with Predicted Trends from the Implementation Date of the Post-Transplant Graft Survival Metrics (July 14, 2022) to June 30, 2024

Hypothesis: No change in system-level one-year post-transplant graft failure rates attributable to the implementation of the 90-day and one-year conditional post-transplant graft survival metrics

Figure setup: Figures in this section show one-year post-transplant all-cause graft failure rates by month, organized by organ and then by specific sub-categories for each organ.

- The solid black line in each figure represents the actual rate of all-cause graft failure one-year post-transplant for each month following implementation of the 90-day and one-year conditional graft survival metrics.
- Vertical lines indicate the time point of intervention (implementation of the post-transplant graft survival metric) as well as the implementation of allocation policies such as removing donation service area (DSA) and OPTN Region as units of allocation. The latter were included for reference and understanding of other influential trends that may also be occurring within the data. Reference lines are also included to indicate the OPTN Board Approval date and the implementation date of the offer acceptance metric; the pre-transplant mortality metric was implemented after the end of the analysis period and will be included in future reports.
- The dotted gray line, which begins at the implementation date of the 90-day and one-year conditional graft survival metrics, indicates the trend (based on historical data) that would have been expected to occur with no implementation of these metrics.*
- The gray shaded area represents, with a 95% confidence interval, the possible range of the expected trend with no implementation of these metrics.*

Comparing observed and predicted trends: By comparing the solid black line (actual rate of all-cause graft failure one-year post-transplant following implementation of the 90-day and one-year conditional graft survival metrics) with the dotted gray line (predicted trend without implementation of these metrics) and shaded gray area (range of predicted trend without implementation of these metrics), we can evaluate the difference, if any, between actual and predicted trends. This comparison can point to any clinically or statistically significant differences caused by the implementation of the 90-day and one-year conditional graft survival metrics that might need to be further investigated.

^{*}Both the expected trend and its range are estimated by the ARIMA model, fit to data occurring prior to implementation of the post-transplant graft survival metrics.

Figure 86. Kidney

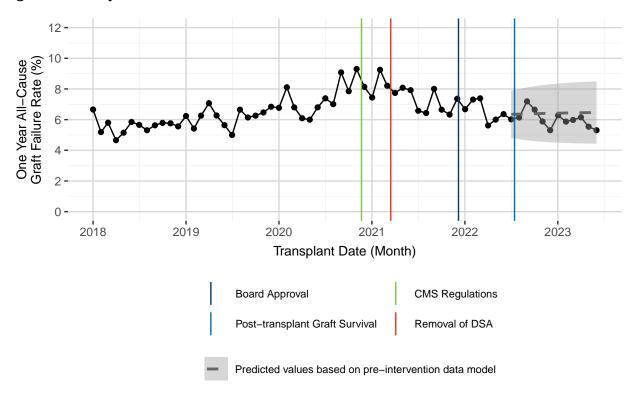


Figure 87. Liver

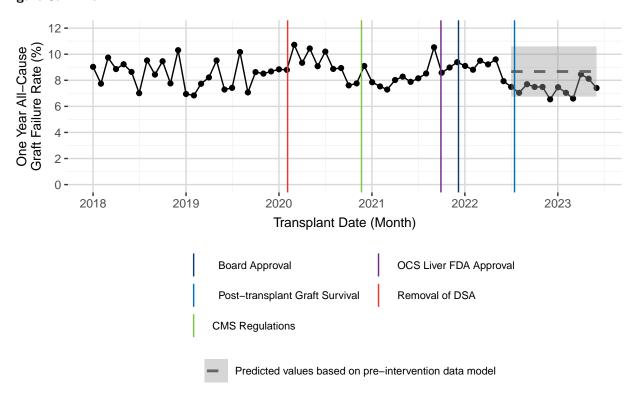


Figure 88. Pancreas/Kidney-Pancreas

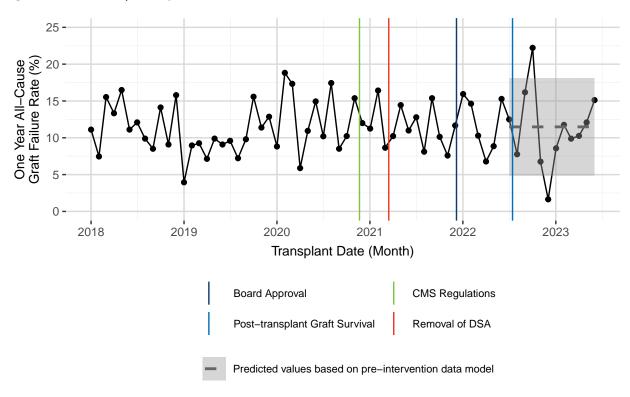


Figure 89. Heart/Heart-Lung

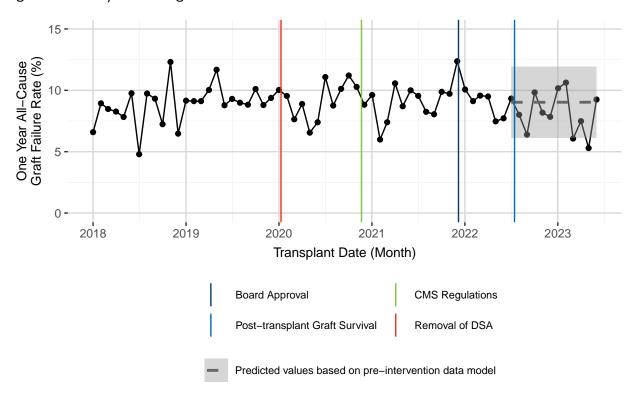
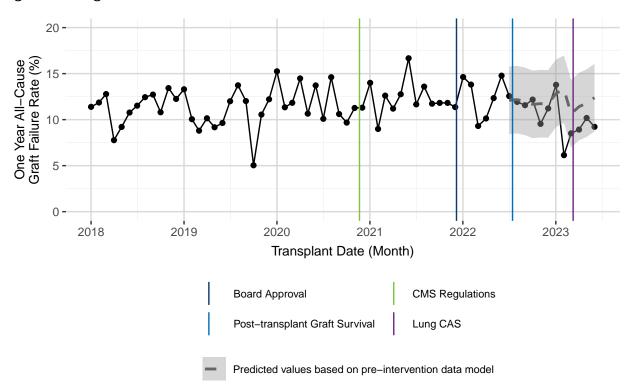


Figure 90. Lung



Appendix F: Sensitivity Analyses: Utilization Rates by Month (January 01, 2019 to July 27, 2023) with Predicted Trends from the Implementation Date of the Offer Acceptance Rate Ratio Metric (July 27, 2023) to June 30, 2024

Hypothesis: Increased transplants attributable to the implementation of the offer acceptance rate ratio metric

Figure setup: Figures in this section show the number of deceased donors, number of deceased donor transplants, and deceased donor utilization rates by month, organized by organ.

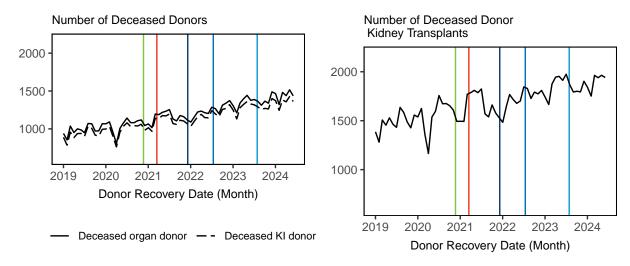
Top left panels show the number of deceased organ donors (deceased donor with at least one organ recovered for the purposes of transplant) and the number of organ-specific deceased donors. The number of deceased organ donors is the denominator for utilization rate. Top right panels show the number of organ-specific transplants that represent the numerator for utilization rate. The bottom panels show the utilization rate.

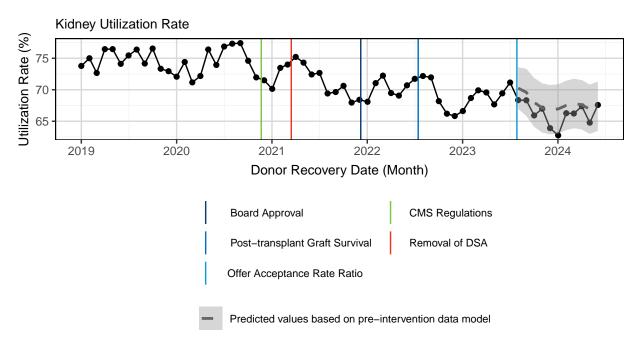
- The solid black line in each utilization rate figure represents the actual utilization rate for each month following implementation of the offer acceptance rate ratio metric.
- Vertical lines indicate the time point of intervention (implementation of the offer acceptance rate ratio metric) as well as the implementation of allocation policies such as removing donation service area (DSA) and OPTN Region as units of allocation. The latter were included for reference and understanding of other influential trends that may also be occurring within the data. Reference lines are also included to indicate the OPTN Board Approval date and the implementation date of the post-transplant graft survival metric; the pre-transplant mortality metric was implemented after the end of the analysis period and will be included in future reports.
- The dotted gray line in each utilization rate figure, which begins at the implementation date of the offer acceptance rate ratio metric, indicates the trend (based on historical data) that would have been expected to occur with no implementation of this metric.*
- The gray shaded area represents, with a 95% confidence interval, the possible range of the expected trend with no implementation of this metric.*

Comparing observed and predicted trends: By comparing the solid black line (actual utilization rate following implementation of the offer acceptance rate ratio metric) with the dotted gray line (predicted trend without implementation of this metric) and shaded gray area (range of predicted trend without implementation of this metric), we can evaluate the difference, if any, between actual and predicted trends. This comparison can point to any clinically or statistically significant differences caused by the implementation of the offer acceptance rate ratio metric that might need to be further investigated.

^{*}Both the expected trend and its range are estimated by the ARIMA model, fit to data occurring prior to implementation of the offer acceptance rate ratio metric.

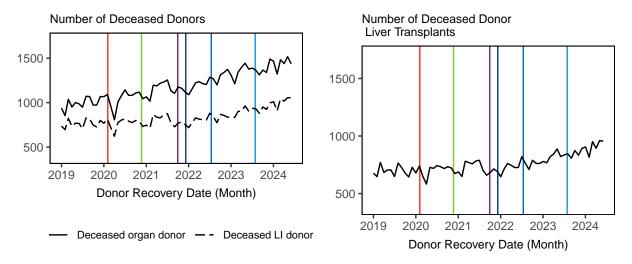
Figure 91. Kidney

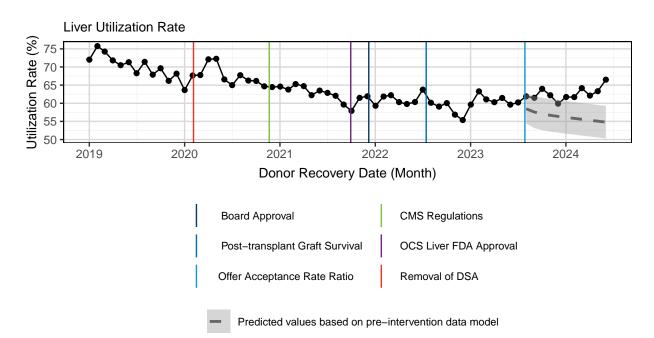




Kidney Utilization Rate (%)= 100 * [# deceased donor KI TX/(2* # deceased organ donors)] Deceased organ donor=Deceased donor w/at least 1 organ recovered for purpose of transplant. Enbloc KI = 2 KIs transplanted.

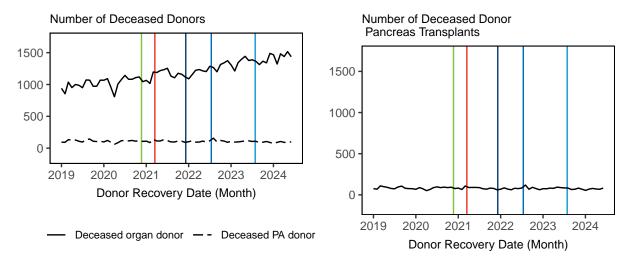
Figure 92. Liver

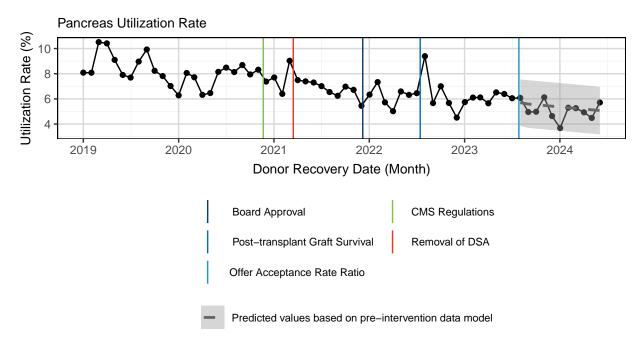




Liver Utilization Rate (%)= 100 * (# deceased donor LI TX/# deceased organ donors) Deceased organ donor=Deceased donor w/at least 1 organ recovered for purpose of transplant. Split LI = 2 LIs transplanted.

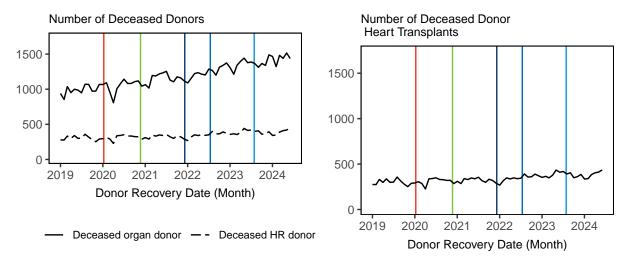
Figure 93. Pancreas

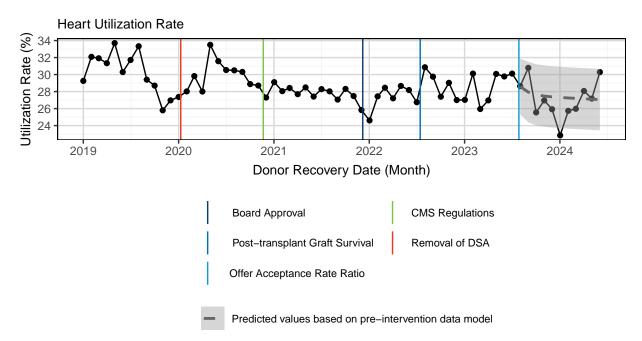




Pancreas Utilization Rate (%)= 100 * (# deceased donor PA TX/# deceased organ donors) Deceased organ donor=Deceased donor w/at least 1 organ recovered for purpose of transplant.

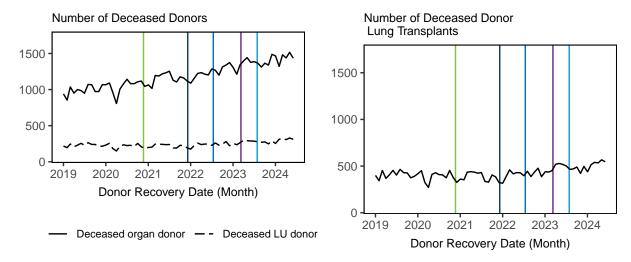
Figure 94. Heart

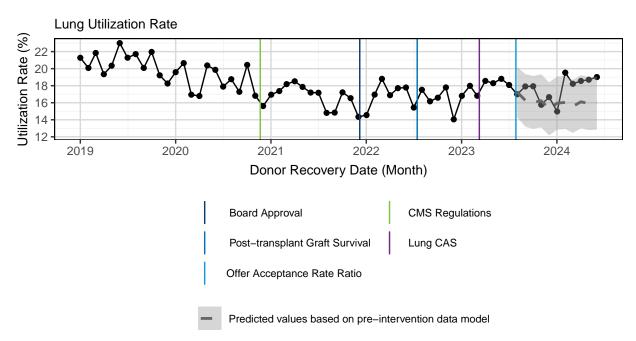




Heart Utilization Rate (%)= 100 * (# deceased donor HR TX/# deceased organ donors) Deceased organ donor=Deceased donor w/at least 1 organ recovered for purpose of transplant.

Figure 95. Lung





Lung Utilization Rate (%)= 100 * [# deceased donor LU TX/(2* # deceased organ donors)] Deceased organ donor=Deceased donor w/at least 1 organ recovered for purpose of transplant. Dual LU = 2 LUs transplanted.

Appendix G: Sensitivity Analyses: Transplant-to-Recovery Rates by Month (January 01, 2019 to July 27, 2023) with Predicted Trends from the Implementation Date of the Offer Acceptance Rate Ratio Metric (July 27, 2023) to June 30, 2024

Hypothesis: Increased transplants attributable to the implementation of the offer acceptance rate ratio metric

Figure setup: Figures in this section show number of deceased donor organs recovered, number of deceased donor transplants, and deceased donor transplant-to-recovery rates by month, organized by organ.

Top left panels show the number of organ-specific deceased donor organs recovered; this quantity constitutes the denominator of the transplant-to-recovery rate. Top right panels show the number of organ-specific transplants; this quantity represents the numerator of the transplant-to-recovery rate. The bottom panels depict the transplant-to-recovery rate over time.

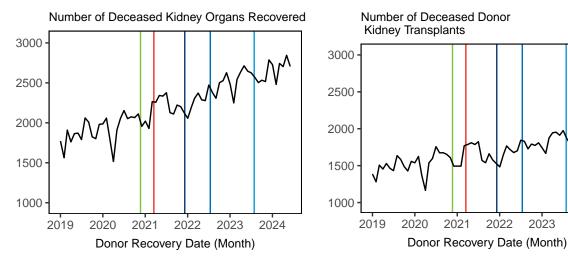
- The solid black line in each transplant-to-recovery rate figure represents the actual transplant-to-recovery rate for each month following implementation of the offer acceptance rate ratio metric.
- Vertical lines indicate the time point of intervention (implementation of the offer acceptance rate ratio metric) as well as the implementation of allocation policies such as removing donation service area (DSA) and OPTN Region as units of allocation. The latter were included for reference and understanding of other influential trends that may also be occurring within the data. Reference lines are also included to indicate the OPTN Board Approval date and the implementation date of the post-transplant graft survival metric; the pre-transplant mortality metric was implemented after the end of the analysis period and will be included in future reports.
- The dotted gray line in each transplant-to-recovery rate figure, which begins at the implementation date of the offer acceptance rate ratio metric, indicates the trend (based on historical data) that would have been expected to occur with no implementation of this metric.*
- The gray shaded area represents, with a 95% confidence interval, the possible range of the expected trend with no implementation of this metric.*

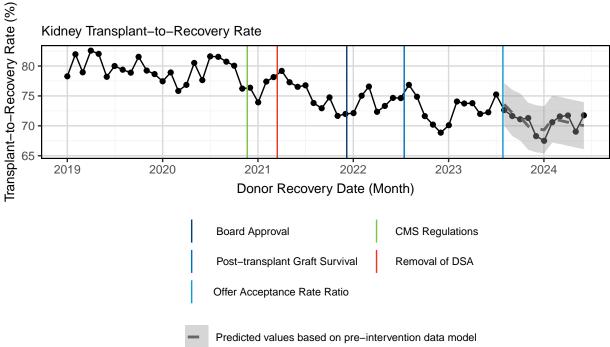
Comparing observed and predicted trends: By comparing the solid black line (actual transplant-to-recovery rate following implementation of the offer acceptance rate ratio metric) with the dotted gray line (predicted trend without implementation of this metric) and shaded gray area (range of predicted trend without implementation of this metric), we can evaluate the difference, if any, between actual and predicted trends. This comparison can point to any clinically or statistically significant differences caused by the implementation of the offer acceptance rate ratio metric that might need to be further investigated.

^{*}Both the expected trend and its range are estimated by the ARIMA model, fit to data occurring prior to implementation of the offer acceptance rate ratio metric.

2024

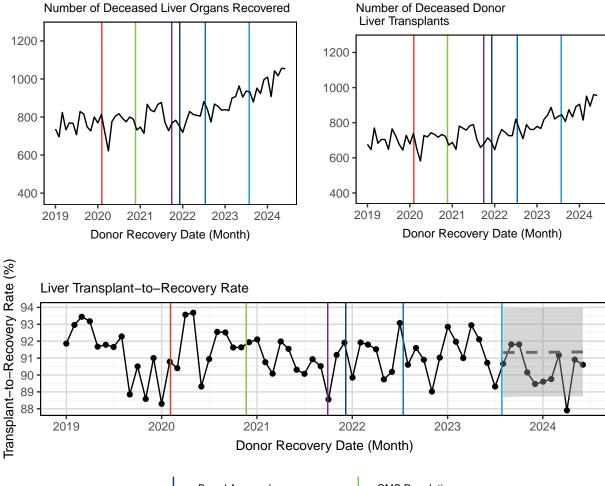
Figure 96. Kidney





Kidney Transplant-to-Recovery Rate (%)= 100 * [# deceased donor KI TX/(# deceased donor kidneys recovered)].

Figure 97. Liver



Board Approval CMS Regulations

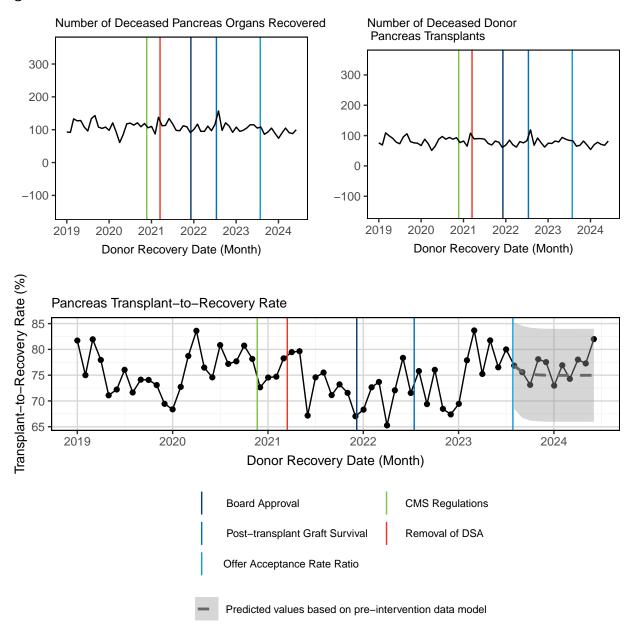
Post-transplant Graft Survival OCS Liver FDA Approval

Offer Acceptance Rate Ratio Removal of DSA

Predicted values based on pre-intervention data model

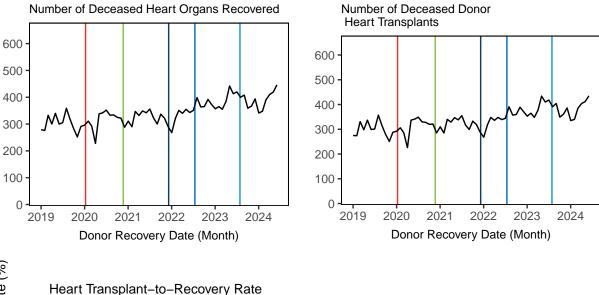
Liver Transplant-to-Recovery Rate (%)= 100 * (# deceased donor LI TX/# deceased donor livers recovered).

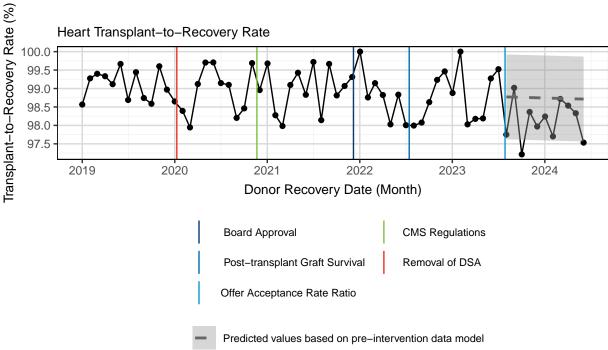
Figure 98. Pancreas



Pancreas Transplant-to-Recovery Rate Rate (%)= 100 * (# deceased donor PA TX/# deceased donor pancreata recovered).

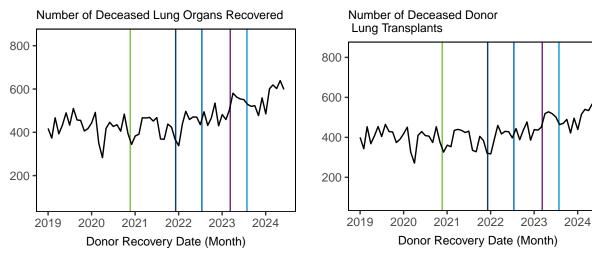
Figure 99. Heart

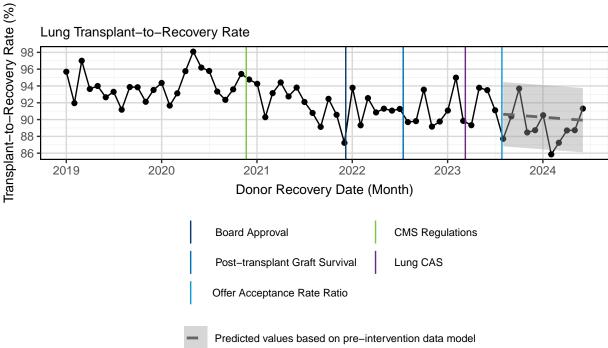




Heart Transplant-to-Recovery Rate (%)= 100 * (# deceased donor HR TX/# deceased donor hearts recovered).

Figure 100. Lung





Lung Transplant-to-Recovery Rate Rate (%)= 100 * [# deceased donor LU TX/(# deceased donor lungs recovered)].