Analysis Report

Data request from the OPTN Liver and Intestinal Organ Transplantation Committee: Additional Modeling Data to Support "Redistricting" Project

February 11, 2016

Meeting: November 20, 2015 (teleconference)

This report was provided to HRSA by SRTR in support of ongoing policy consideration by the OPTN Liver and Intestinal Organ Transplantation Committee. The analysis described herein was conducted at the specific request of the OPTN Committee and does not represent a full or final analysis related to the policy issue under consideration.

Prepared By: David Schladt, MS; Joshua Pyke, PhD; Charlotte Bolch, MS; Ajay K. Israni, MD; Bertram L. Kasiske, MD; John R. Lake, MD; Susan N. Leppke, MPH; Jessica Zeglin, MPH

Data Request ID#: LI2015_03 (Data Request 2)

Timeline

Request made	December 7, 2015
Analysis plan submitted	December 21, 2015
Final analysis to be submitted	February 15, 2016
Next committee meeting	February 25, 2016

Table of Contents

Table of Figures

Table of Tables

914 SOUTH 8TH STREET SUITE S4.100 MINNEAPOLIS, MN 55404 1.877.970.SRTR WWW.SRTR.ORG

OPTN Data Request

Background: Data Request 2: Additional Modeling Data to Support "Redistricting" Project

Several Committee members and members of the transplant community have expressed concerns about the possibility that, under broader sharing, livers will move from areas with higher waitlist mortality to areas with lower waitlist mortality. During the November 20, 2015 teleconference, The Committee requested additional data to be derived from existing LSAM outputs (from earlier data request, LI2015_01) that would help address these questions.

Strategic Goal or Committee Project Addressed

Goal #2, Provide equity in access to transplants.

Request: Additional LSAM Output Data

Under the following scenarios, do livers flow from areas with higher waitlist mortality to areas with lower waitlist mortality?

1. Current Policy
2. Full Regional sharing (11 Regions)
3. Full Regional sharing (11 Regions) with 3 point proximity circles ("out-district")
4. 4 districts with 150-mile 3 point proximity circles (in-district only)
5. 8 districts with 150-mile 3 point proximity (in-district only)

Wait list mortality should be stratified by those with MELD/PELD scores at removal of >15, >25 and > 35.

Executive Summary

This analysis examined whether livers flow from areas with higher waitlist mortality to areas with lower waitlist mortality under the simulated scenarios of current policy, 11 regions with full regional sharing, 11 regions with 3-point proximity circles (out district), 8 districts with 3-point proximity circles (in district), and 4 districts with 3-point proximity circles (in district). The main findings were that there was no significant association between waitlist mortality rate and liver flow or net import in any of the 5 simulated scenarios. There was no significant association between waitlist mortality rate in the current scenario and change in liver flow in any of the 4 simulated scenarios.

Study Population

This analysis reexamines data from previously requested modeled redistricting scenarios (request LI2015_01). Data used for modeling of these scenarios included real patient data for liver transplant candidates on the waiting lists as of December 31, 2006, and candidates added to those waiting lists and organs donated between January 1, 2007, and December 31, 2011.

914 SOUTH 8TH STREET SUITE S4.100 MINNEAPOLIS, MN 55404 1.877.970.SRTR WWW.SRTR.ORG

Analytic Approach

The Committee has requested several reports to date to model various potential redistricting proposals and examine data on various possible effects of those proposals. During 2015, the Committee requested that SRTR model redistricted systems including 4- and 8-district systems with different types of proximity point circles (Data Request LI2015_01). Following that analysis, the Committee requested further analysis of redistricting simulation results looking at effects for patients with different exception statuses (no exceptions, HCC exceptions, or non-HCC exceptions, presented in Data Request LI2015_02 Data Request 1). The previous request (LI2015_01) included modeling of 28 unique scenarios. For the analysis described herein, LI2015_03 Data Request 2, the Committee requested further evaluation of the simulation results for 5 of the scenarios. Table 1 shows the full list of 28 previously assessed scenarios. The scenarios that will be further evaluated under this data request are marked with a "Yes," to be analyzed further in LI2015_03 (runs 1, 5, 12, 20, and 28).

Table 1. LI2015_01 Simulation Scenarios

Run #	# of Districts	# of Points	Radius	Candidate Designation	To be analyzed further in LI2015_03?
1	Current 11	None	None	None	Yes
2	4	None	None	None	No
3	8	None	None	None	No
4	Current 11	3	150	In district	No
5	Current 11	3	150	Out of district	Yes
6	Current 11	3	250	In district	No
7	Current 11	3	250	Out of district	No
8	Current 11	5	150	In district	No
9	Current 11	5	150	Out of district	No
10	Current 11	5	250	In district	No
11	Current 11	5	250	Out of district	No
12	4	3	150	In district	Yes
13	4	3	150	Out of district	No
14	4	3	250	In district	No
15	4	3	250	Out of district	No
16	4	5	150	In district	No
17	4	5	150	Out of district	No
18	4	5	250	In district	No
19	4	5	250	Out of district	No
20	8	3	150	In district	Yes
21	8	3	150	Out of district	No
22	8	3	250	In district	No
23	8	3	250	Out of district	No
24	8	5	150	In district	No
25	8	5	150	Out of district	No
26	8	5	250	In district	No
27	8	5	250	Out of district	No
28	Current system	None	None	None	Yes

SRTR further analyzed simulation results to assess each scenario's effect on liver flow within DSA (differences in imports and exports) compared with waitlist mortality within DSA. Waitlist mortality was stratified by allocation MELD/PELD scores of > 15, > 25, and > 35 at removal.

In the previous request (LI2015_01), we simulated 28 unique allocation scenarios with LSAM and compared the results. Each simulation was repeated 10 times to provide an estimate of variability with independent sets of organ and waitlist arrivals and distinct random number seeds used for each scenario. Each scenario simulated 5 years of transplants. The 28 simulated scenarios included a range of configuration parameters for proximity points, optimized geographic distribution districts, and broader sharing. The results of the 28 scenarios are available in the reports for requests LI2015_01 and LI2015_02 Data Request 1.

For the current request, the Liver and Intestine Committee identified 5 scenarios (**Table 1**) to examine, to assess whether livers would flow from areas with higher waitlist mortality to areas with lower waitlist mortality in a system using "redistricted" optimized geographic areas. To assess each scenario's effect within DSA, we calculated number of livers imported and exported for each DSA annually. We further define the metrics shown in this report below.

Metric Definitions

- **Liver Flow** is defined as the number of livers imported into the DSA, minus the number of livers exported from the DSA (import - export), annually within the 5 years of the simulation. A positive liver flow number indicates that the DSA imports more livers than it exports, and a negative number indicates that the DSA exports more livers than it imports.
- **Net Import** provides a rate of liver flow, standardized by the number of livers recovered within the DSA. Net import is defined as liver flow (number of imported livers minus number of exported livers) divided by the number of livers recovered within the DSA ((import-export)/recovered). A positive net import number indicates more imports than exports in the DSA, and a negative number indicates more exports than imports. Net import is scaled by the number of local organ recoveries to simplify comparisons between DSAs of different sizes.
- **Change in Liver Flow** is defined as the difference in liver flow between the new scenario and the current scenario (liver flow for new scenario - liver flow for current scenario). Using change in liver flow allows us to determine the difference in liver flow between each of the new scenarios and the current policy.
- **Waitlist Mortality Rate** is defined as the number of deaths on the waiting list divided by the length of time candidates were listed. For the measures including all candidates, all time on the waiting list was counted. For subgroups such as candidates with MELD/PELD > 35, time on the waiting list was counted as the time with a MELD/PELD of > 35. Waitlist mortality rates shown in the graphs below are deaths per person-year on the waiting list.

To generate the data used in the analyses, we ran a full simulation of the national allocation system using the allocation and distribution rules for a given scenario for a full 5 years of simulated time. In addition, for each of the scenarios we ran these simulations 10 times to allow for variability that may occur in real life. For each of the metrics shown, we used the mean value across the 10 simulation iterations for each scenario in the analysis results reported below. For each of the 5 scenarios, liver flow and net import by DSA were plotted against the waitlist mortality rate per year for that DSA (**Figure 1**-**Figure 8**). The change in liver flow metric calculated for the 4 new scenarios by DSA was plotted against the waitlist mortality rate per year for the current scenario for that DSA (**Figure 9**-**Figure 12**). Waitlist mortality was also stratified by allocation MELD/PELD scores of > 15, > 25, and > 35 at removal.

Interpretation of Graphs

The data for each scenario are the means (e.g., mean liver flow) of the 10 iterations. The vertical y-axis shows liver flow, net import, or change in liver flow (as defined above) per year among DSAs, and the horizontal x-axis shows the waitlist mortality rate per person-year among DSAs. Each point on the graph indicates the estimate of the y-axis and the x-axis data within an individual DSA. Each individual graph includes a simple linear regression line that shows the trend of the data among all DSAs. The grey region around each linear regression line is the confidence band, which is calculated using the 95% confidence intervals for each individual point. The R^2 for each graph is a statistical measure of how close the data are to the linear regression line. The *P* values provided in each graph test whether or not the slope of the regression line is equal to 0. When the *P* value is greater than 0.05, the R^2 value is not significantly different from 0%, indicating no association between the x- and y-axis variables.

Results and Discussion

Liver Flow Graphs

Figure 1 through **Figure 4** show liver flow by waitlist mortality rate for all candidates and each MELD subgroup.

Figure 1. Liver Flow vs. Waitlist Mortality Rate by DSA: All Candidates

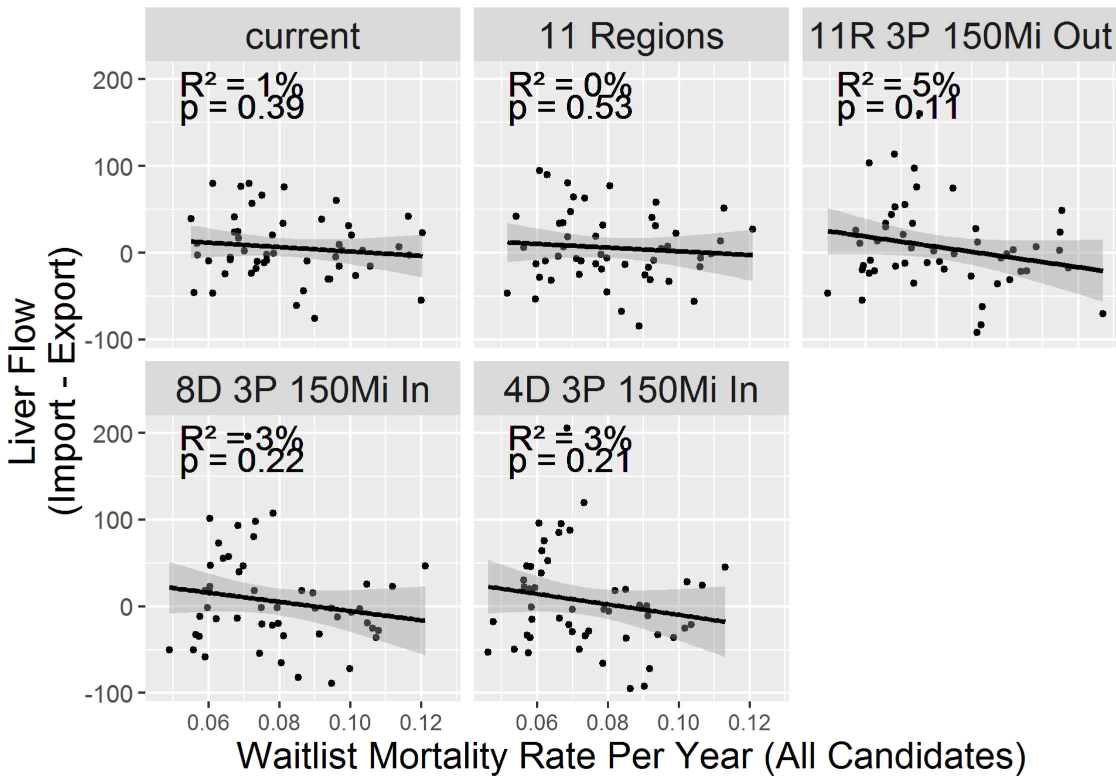

Figure 1 shows liver flow compared with annual waitlist mortality rate for all candidates for each of the examined scenarios. DSAs with lower waitlist mortality are represented by dots on the left side of each graph, and DSAs with higher waitlist mortality by dots on the right side. DSAs that import more livers than they export are represented by dots above the 0 line, and DSAs that export more livers than they import by dots below the 0 line.

Figure 1 shows an R^2 value very close to zero for all scenarios, and the *P* value is always greater than 0.05, indicating that none of the relationships are statistically significant. The simulated scenarios for the current system, 11 regions with full regional sharing, 11 regions with 3-point proximity circles (out district), 8 districts with 3-point proximity circles (in district), and 4 districts with 3-point proximity circles (in district) all show similar trends among DSAs of a relatively constant liver flow by waitlist mortality rate per year. There was no significant association between waitlist mortality rate and liver flow in any of the 5 simulated scenarios.

Figure 2. Liver Flow vs. Waitlist Mortality Rate by DSA: MELD/PELD > 15

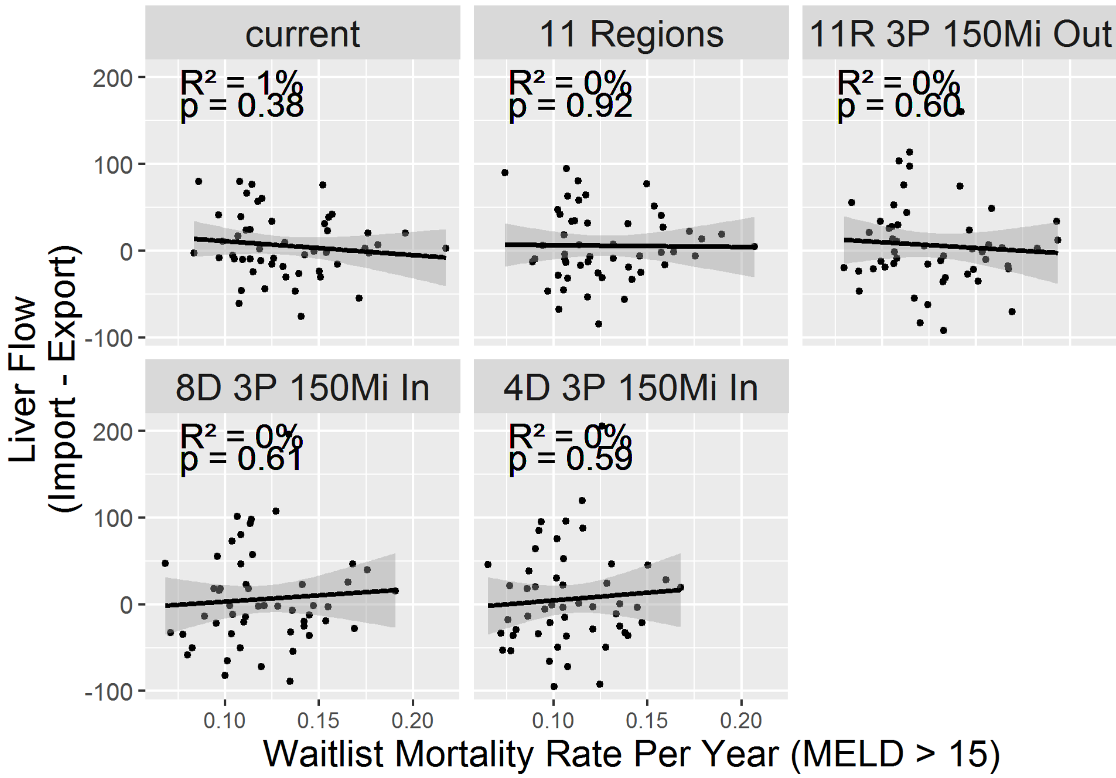

Figure 2 shows liver flow vs. waitlist mortality rate by DSA for allocation MELD/PELD scores greater than 15 at removal. The simulated scenarios all show similar trends among DSAs of a constant liver flow by waitlist mortality rate per year. There was no significant association between waitlist mortality rate and liver flow in any of the 5 simulated scenarios for the MELD/PELD > 15 subgroup.

Figure 3. Liver Flow vs. Waitlist Mortality Rate by DSA: MELD/PELD > 25

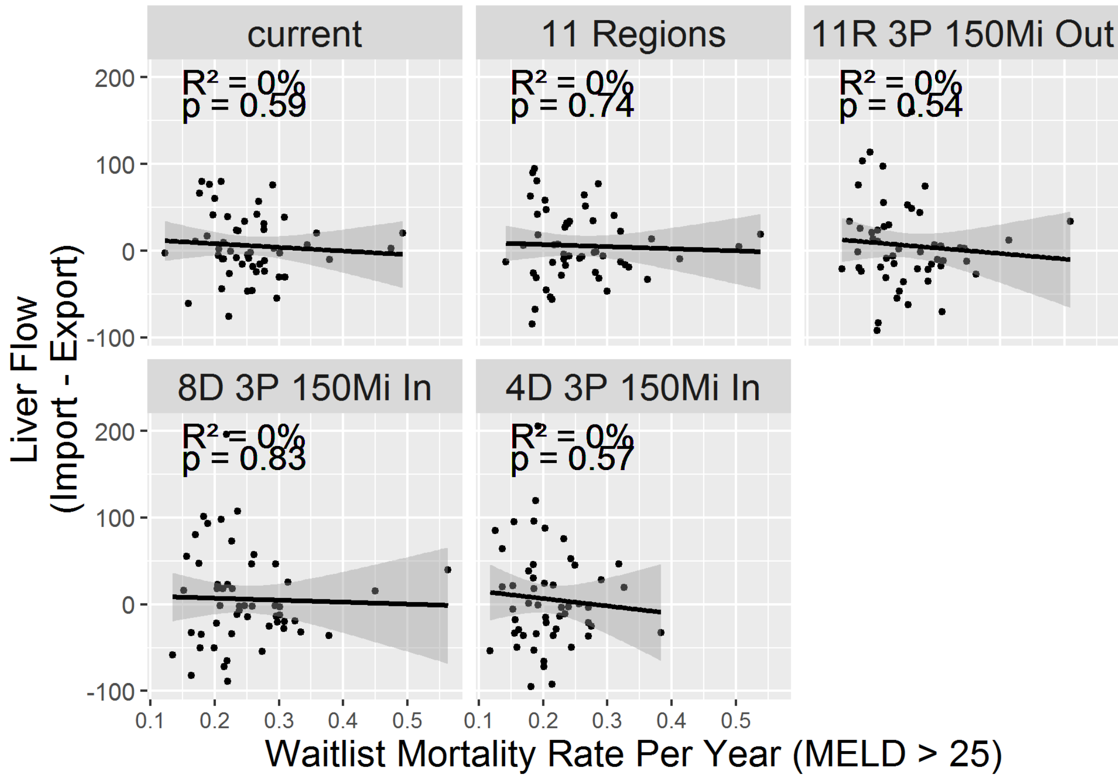

Figure 3 shows liver flow vs. waitlist mortality rate by DSA for allocation MELD/PELD scores greater than 25 at removal. The simulated scenarios all show similar trends among DSAs of a relatively constant liver flow by waitlist mortality rate per year. There was no significant association between waitlist mortality rate and liver flow in any of the 5 simulated scenarios for the MELD/PELD > 25 subgroup.

Figure 4. Liver Flow vs. Waitlist Mortality Rate by DSA: MELD/PELD > 35

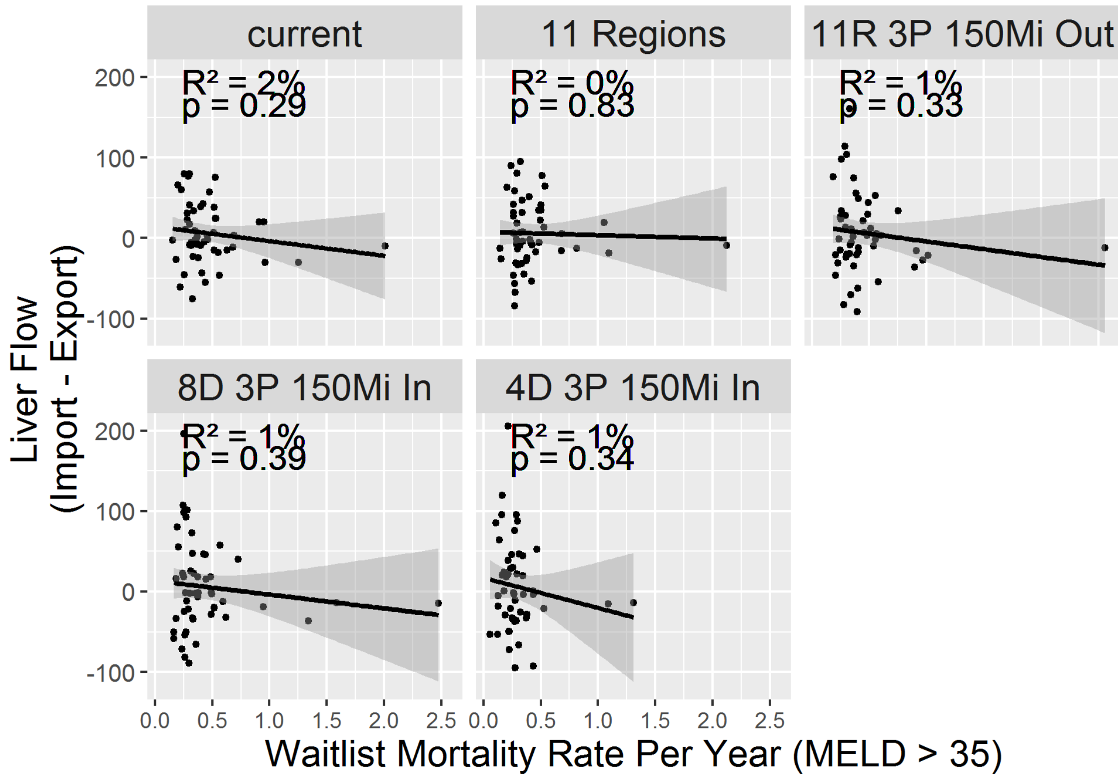

Figure 4 shows liver flow vs. waitlist mortality rate by DSA for allocation MELD/PELD scores greater than 35 at removal. The simulated scenarios all show similar trends among DSAs of a constant or relatively constant liver flow by waitlist mortality rate per year. There was no significant association between waitlist mortality rate and liver flow in any of the 5 simulated scenarios for the MELD/PELD > 35 subgroup. The high-mortality outlier values in this metric are due to small numbers of patients in the MELD > 35 subgroup in some DSAs.

Net Import Graphs

Figure 5 through **Figure 8** show net import by waitlist mortality rate for all candidates and by each MELD subgroup.

Figure 5. Net Import vs. Waitlist Mortality Rate by DSA: All Candidates

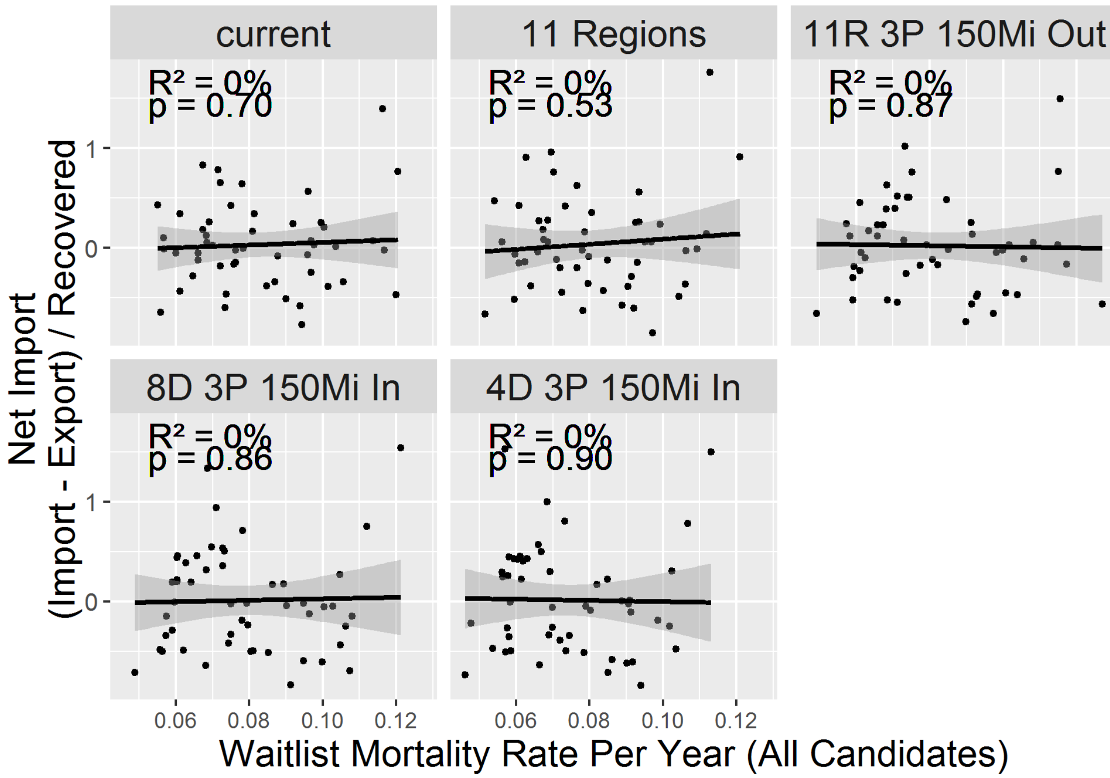

Figure 5 shows net import vs. waitlist mortality rate by DSA for all candidates. Net import is the number of livers imported minus the number of livers exported divided by the number of livers recovered for transplant by the DSA. The simulated scenarios for the current policy, 11 regions with full regional sharing, 11 regions with 3-point proximity circles (out district), 8 districts with 3-point proximity circles (in district), and 4 districts with 3-point proximity circles (in district) all show similar trends among DSAs of a constant net import around zero. There was no significant association between waitlist mortality rate and net import in any of the 5 simulated scenarios.

Figure 6. Net Import vs. Waitlist Mortality Rate by DSA: MELD/PELD > 15

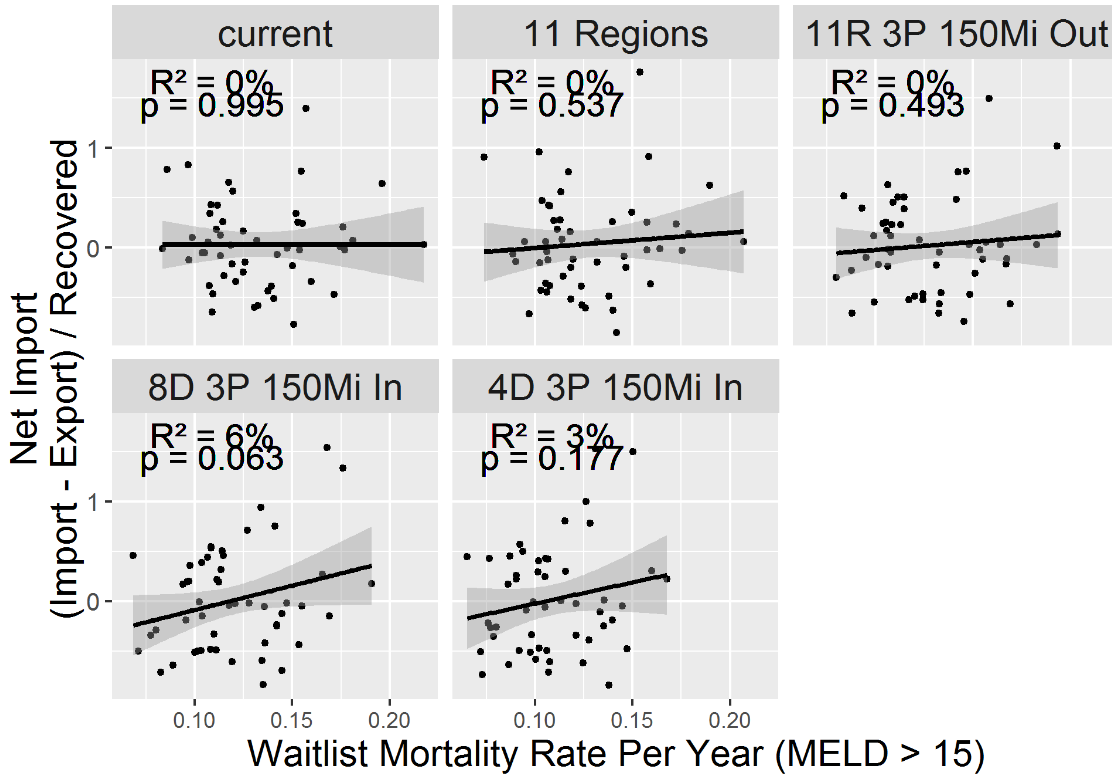

Figure 6 shows net import vs. waitlist mortality rate by DSA for allocation MELD/PELD scores greater than 15 at removal. The simulated scenarios all show similar trends among DSAs of a constant net import around zero. There was no significant association between waitlist mortality rate and net import in any of the 5 simulated scenarios for the MELD/PELD subgroup > 15.

Figure 7. Net Import vs. Waitlist Mortality Rate by DSA: MELD/PELD > 25

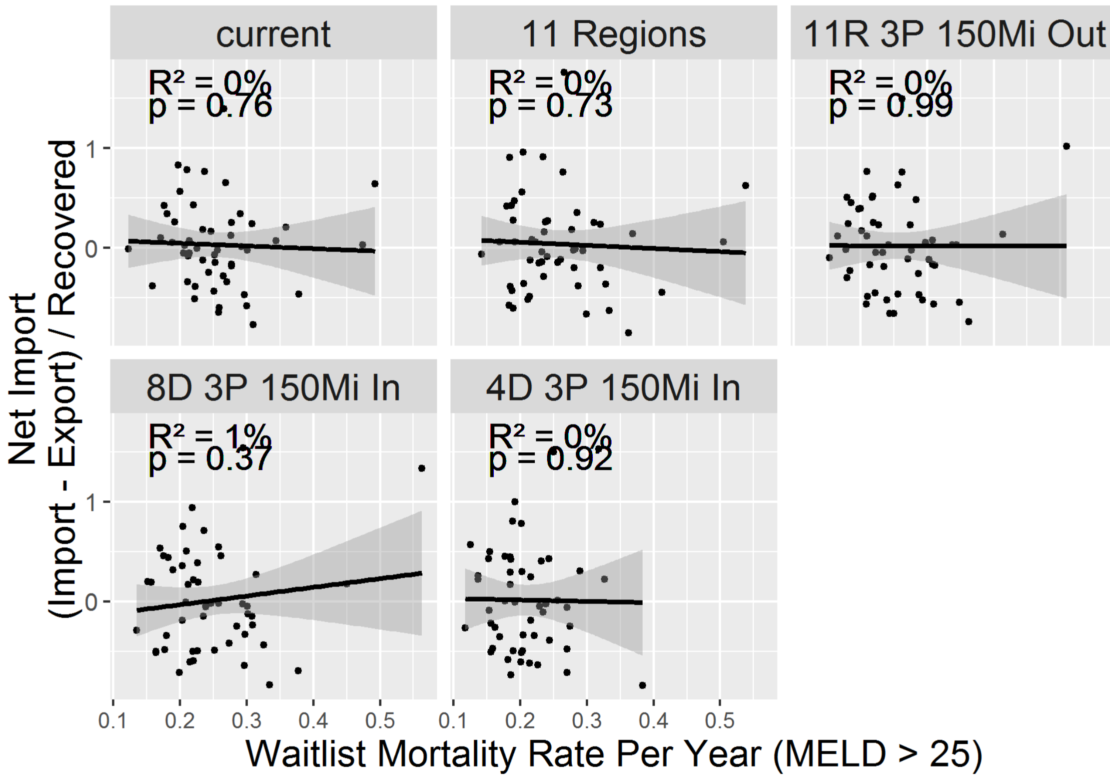

Figure 7 shows net import vs. waitlist mortality rate by DSA for allocation MELD/PELD scores greater than 25 at removal. The simulated scenarios all show similar trends among DSAs of a constant net import around zero. There was no significant association between waitlist mortality rate and net import in any of the 5 simulated scenarios for the MELD/PELD subgroup > 25.

Figure 8. Net Import vs. Waitlist Mortality Rate by DSA: MELD/PELD > 35

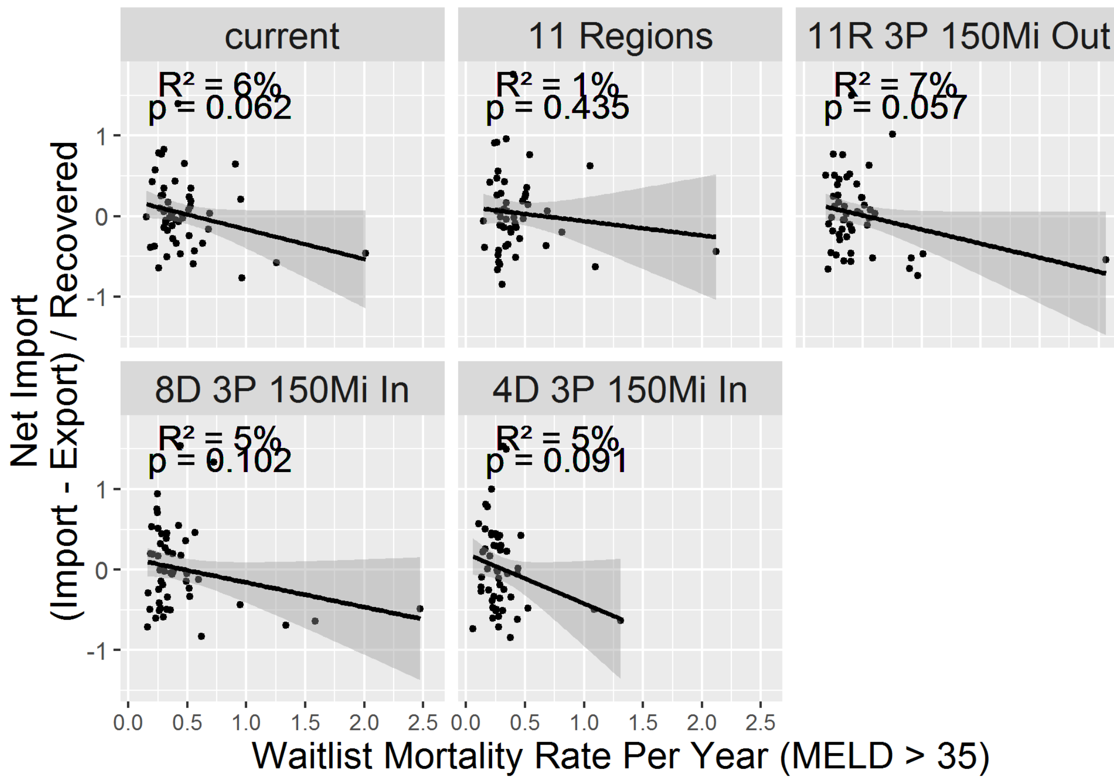

Figure 8 shows net import vs. waitlist mortality rate by DSA for allocation MELD/PELD scores greater than 35 at removal. The simulated scenarios all show similar trends among DSAs of a constant net import around zero. There was no significant association between waitlist mortality rate and net import in any of the 5 simulated scenarios for the MELD/PELD subgroup > 35. The high-mortality outlier values in this metric are due to small numbers of patients in the MELD > 35 subgroup in some DSAs.

Change in Liver Flow Graphs

Figure 9 through **Figure 12** show change in liver flow by waitlist mortality rate in the current scenario for all candidates and each MELD subgroup.

Figure 9. Change in Liver Flow vs. Waitlist Mortality Rate by DSA: All Candidates

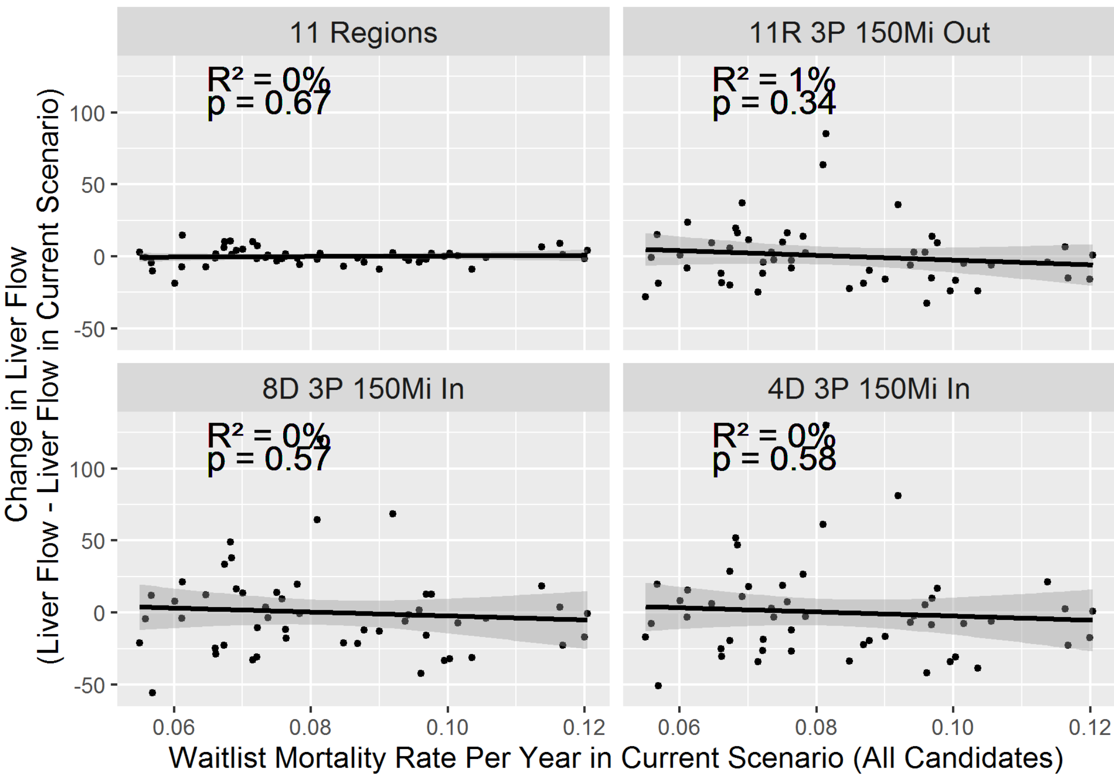

Figure 9 shows change in liver flow vs. waitlist mortality rate by DSA for all candidates. Change in liver flow is defined as liver flow for the new simulated scenario minus liver flow for the current scenario. This metric is intended to indicate whether liver flow would change in the new scenarios compared with the current scenario. The simulated scenarios for 11 regions with full regional sharing, 11 regions with 3-point proximity circles (out district), 8 districts with 3-point proximity circles (in district), and 4 districts with 3-point proximity circles (in district) all show similar trends among DSAs of a change in liver flow around zero. There was no significant association between waitlist mortality rate and change in liver flow in any of the 4 simulated scenarios.

Figure 10. Change in Liver Flow vs. Waitlist Mortality Rate by DSA: MELD/PELD > 15

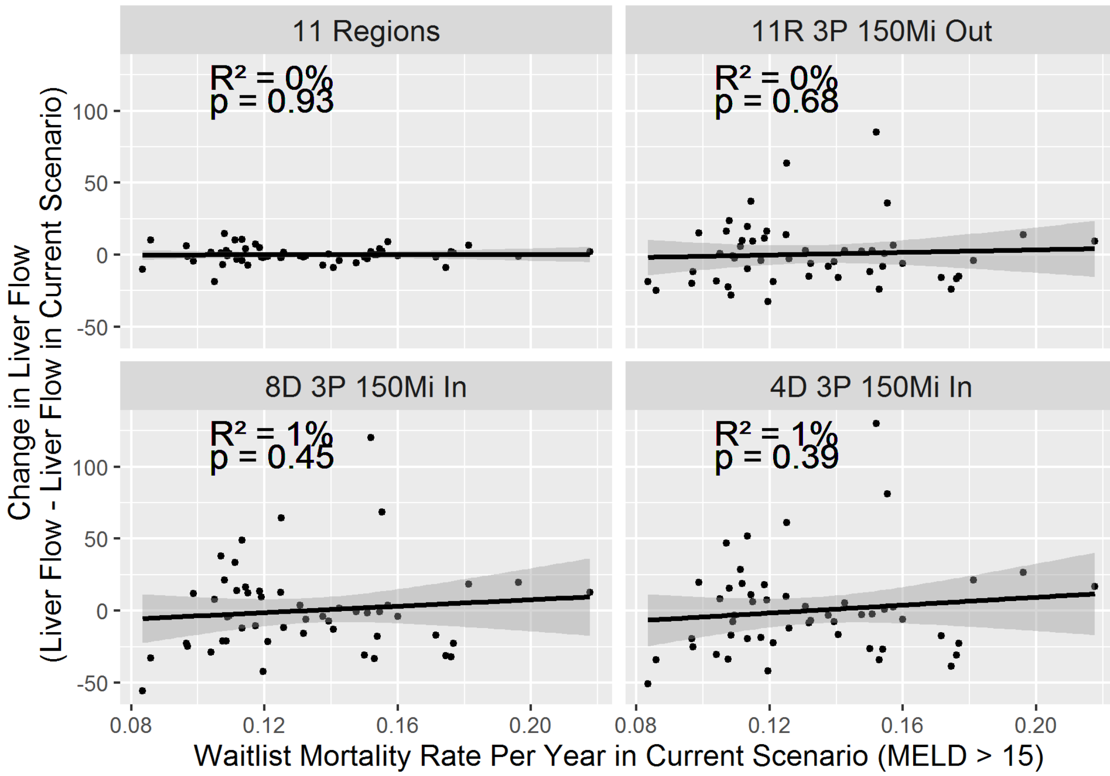

Figure 10 shows change in liver flow vs. waitlist mortality rate by DSA for allocation MELD/PELD scores greater than 15 at removal. The simulated scenarios all show similar trends among DSAs of a change in liver flow around zero. There was no significant association between waitlist mortality rate and change in liver flow in any of the 4 simulated scenarios for the MELD/PELD subgroup > 15.

Figure 11. Change in Liver Flow vs. Waitlist Mortality Rate by DSA: MELD/PELD > 25

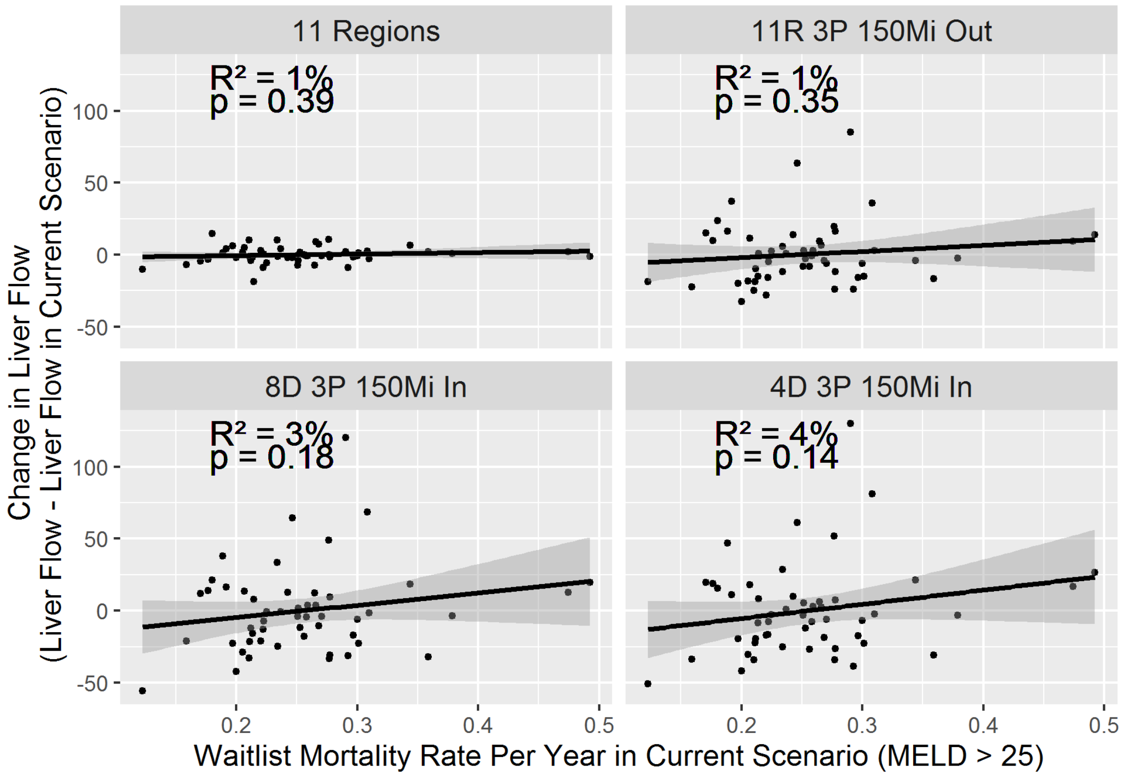

Figure 11 shows change in liver flow vs. waitlist mortality rate by DSA for allocation MELD/PELD scores greater than 25 at removal. The simulated scenarios all show similar trends among DSAs of a change in liver flow around zero. There was no significant association between waitlist mortality rate and change in liver flow in any of the 4 simulated scenarios for the MELD/PELD subgroup > 25.

Figure 12. Change in Liver Flow vs. Waitlist Mortality Rate by DSA: MELD > 35

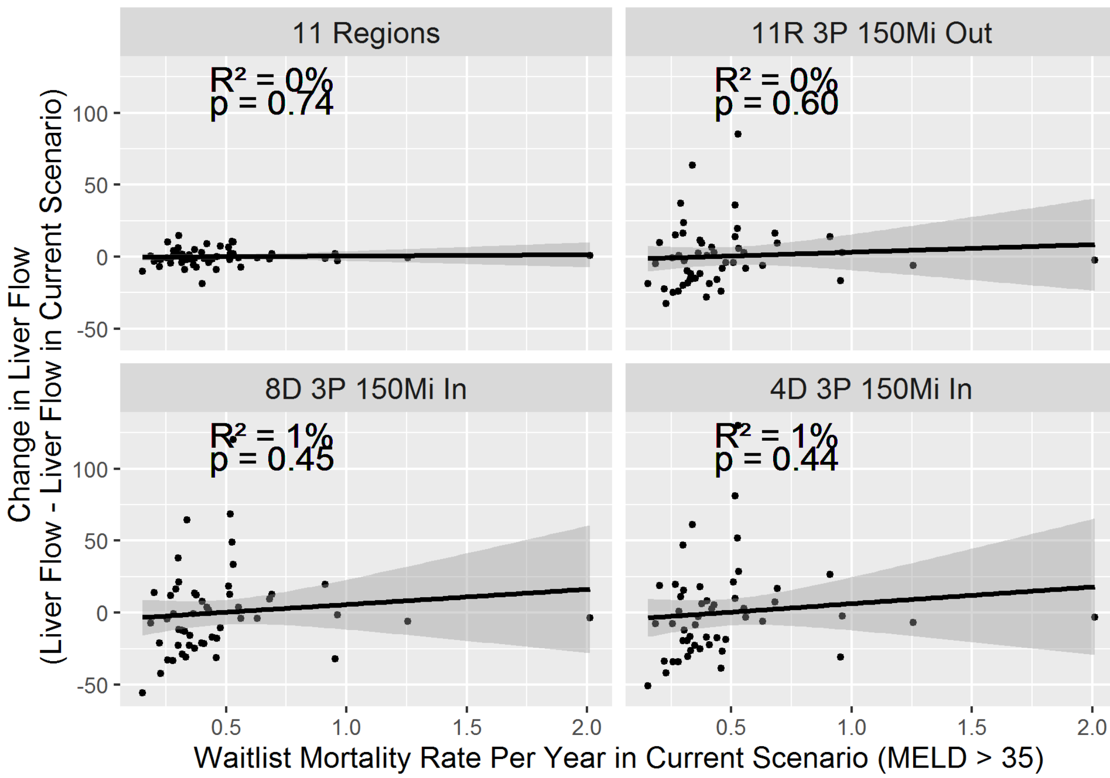

Figure 12 shows change in liver flow vs. waitlist mortality rate by DSA for allocation MELD/PELD scores greater than 35 at removal. The simulated scenarios all show similar trends among DSAs of a change in liver flow around zero. There was no significant association between waitlist mortality rate and change in liver flow in any of the 4 simulated scenarios for the MELD/PELD subgroup > 35. The high-mortality outlier values in this metric are due to small numbers of patients in the MELD > 35 subgroup in some DSAs.

Discussion

This analysis follows earlier study of the effect of potential redistricting scenarios presented in LI2015_01. This study further examined whether livers will move from areas with higher waitlist mortality to areas with lower waitlist mortality. The key findings include:

The liver flow and net import graphs (**Figure 1** through **Figure 8**):

- There was no significant association between waitlist mortality rate and liver flow or net import in any of the 5 simulated scenarios.

The change in liver flow graphs (**Figure 9** through **Figure 12**):

- There was no significant association between waitlist mortality rate in the current scenario and change in liver flow in any of the 4 simulated scenarios.

Overall, there is no evidence that broader sharing within the current 11 regions, broader sharing within the current 11 regions with the addition of proximity points, or redistricting with 4- or 8-district scenarios with proximity points would increase liver flow from DSAs with higher waitlist mortality to DSAs with lower waitlist mortality.