
**Final Analysis for Data Requests from the OPTN Thoracic Organ
Transplantation Committee Meeting of February 2, 2007**

Prepared by Jeff Moore, M.S., Tempie Shearon, M.S., Susan Murray Sc.D., Robert Merion, M.D., Robert Wolfe, Ph.D. and Staff, of the Scientific Registry of Transplant Recipients (Arbor Research/University of Michigan)

Data Request Routing Information and Analysis Timeline:

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Analysis Plan submitted: 03/02/07

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Final Analysis submitted to HRSA and OPTN Committee: 04/16/07

Next Committee Date: 05/03/07

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Request 1: Impact of Serially Obtained Bilirubin on the Waiting List Mortality Component of the LAS

Background

The Thoracic Committee continues to refine the LAS utilizing existing data; their current focus is the impact of creatinine and bilirubin on waiting list mortality. (These fields were collected in the retrospective data project so are available on a large cohort of patients that were used in the development of the LAS.) Results from these analyses were presented at the 2/2/2007 meeting and demonstrated the statistically significant impact of both creatinine and bilirubin on waiting list mortality. Some of the bilirubin results were somewhat counterintuitive; the Committee felt that this might be a reflection of the differential distribution and impact of bilirubin across diagnosis groups. Therefore the Committee expressed interest in refining these analyses to assess the differential impact of bilirubin by diagnosis group. Additionally there was interest in examining whether peak bilirubin was a predictor of mortality.

Request

Refine lung waiting list mortality multivariate analysis to examine the differential impact of serially collected bilirubin on waiting list mortality by diagnosis group. Additionally, assess whether peak bilirubin rather than current bilirubin is a significant predictor of waiting list mortality.

HRSA Program Goal Addressed

Increase life years gained (net benefit).

Summary

Peak bilirubin within a 6-month, post-listing period is significantly associated with increased mortality risk on the waitlist. Specifically, an increase of at least 50% from listing to peak bilirubin is an indication of increased risk. Additionally, there appears to be a differential effect of change in bilirubin within the LAS diagnoses groups where an increase of 50% for a diagnosis group B patient indicates a statistically significant increase in mortality risk. Groups A, C, and D did not show statistically significant trends towards increased or decreased risk.

Methods

Cox proportional hazard regression models were used to model mortality on the lung waiting list. Models included effects for bilirubin and creatinine as detailed below, as well as all established LAS factors.

Study Population

Patients aged 12+ in the retrospective lung audit data who were first listed for a lung transplant between January 01, 1998 and December 31, 2003.

Analytical Approach

The models predict mortality based on measures of serial bilirubin and creatinine adjusted for the current LAS factors.

Censoring takes place at the earliest of transplant, removal from the waiting list, or March 01, 2004.

Missing data at listing was supplemented with OPTN data where possible.

The model consisted of creatinine and bilirubin effects defined as below. In addition, effects to examine interactions between change in bilirubin and diagnosis group were assessed:

- Peak bilirubin: the maximum value of bilirubin observed in the 6-month (183 days), post-listing period.
- Follow-up creatinine: the value of creatinine closest to 6-months (183 days) post-listing.
- Categorical change in bilirubin: An increase of at least 50% from listing to the peak value of bilirubin in the 6-month, post-listing period where the listing value is the latest value available within 180 days of listing, inclusive.
- Categorical change in creatinine: 6-month percent increase in creatinine of at least 30%. Change in creatinine is extrapolated to 6-months based on the change observed from listing to follow-up creatinine where the listing value is the latest value available within 180 days of listing, inclusive.

Results

There are 1171 patients available for analysis. A serial increase in bilirubin of at least 50% from listing to the peak bilirubin value within 6-months of listing is significantly associated with increased risk of mortality.

A test for interaction of a 50% increase in bilirubin and diagnosis group was statistically significant ($p=0.0060$). The specific changes in bilirubin within diagnosis group interactions are detailed in table 1 below. The only significant effect is found within the Group B (PPH) diagnosis:

Table 1: Increase in Bilirubin \geq 50% within LAS Diagnosis Group

Parameter	Percent *	Hazard Ratio	P-value
Change in Bilirubin \geq 50% within Group A	2.6%	1.11	0.8462
Change in Bilirubin \geq 50% within Group B	4.0%	2.49	0.0015
Change in Bilirubin \geq 50% within Group C	3.9%	0.82	0.5606
Change in Bilirubin \geq 50% within Group D	2.1%	1.81	0.1368

* Percent of total patients both within the given diagnosis group and with a change in bilirubin of at least 50%.

Table 2 below provides estimates for a model incorporating peak bilirubin, an indicator for change \geq 50% from listing to peak bilirubin within Diagnosis Group B, follow-up creatinine, an indicator of creatinine \geq 30% from listing to follow-up, and established LAS factors.

Table 2: Lung Waitlist Survival Modeled for LAS Factors, Serial Creatinine, and Serial Bilirubin

Parameter	Mean or Percent	Hazard Ratio	P-Value
Peak Bilirubin	0.82	1.08	0.3283
Increase \geq 50% in Bilirubin for Group B	6.3%	2.48	0.0016
Increase \geq 50% in Bilirubin for A, C, and D	9.2%	1.09	0.7433
Follow-up (6-month) Creatinine	0.85	1.41	0.0002
Increase \geq 30% in Creatinine (vs. other)	11.6%	2.32	<.0001
Diagnosis Group			
Diagnosis: Group A (COPD + others)	30.1%	1.00	Ref

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Parameter	Mean or Percent	Hazard Ratio	P-Value
Diagnosis: Group B (PPH + others)	26.6%	5.16	<.0001
Diagnosis: Group C (CF)	25.9%	2.02	0.0275
Diagnosis: Group D (IPF + others)	17.4%	1.63	0.3403
Diagnosis			
Diagnosis: obliterativebronchiolitis / bronchiectasis	1.8%	0.87	0.8179
Diagnosis: Eisenmenger	2.9%	0.55	0.1169
Diagnosis: lymphangioliomyomatosis	0.7%	1.32	0.7840
Diagnosis: obliterativebronchiolitis (non-retransplanted)	0.8%	0.30	0.2104
Diagnosis: Pulmonary Fibrosis other	2.3%	0.87	0.7025
Diagnosis: Sarcoidosis and PA mean > 30 mm/Hg	1.3%	0.21	0.0321
Diagnosis: Sarcoidosis and PA mean <= 30 mm/Hg	0.9%	1.01	0.9931
Physiologic Reserve at Listing			
Age at listing for Dgn Groups A,B,C (yrs)	40.5	1.01	0.4075
Age at listing for Dgn Group D (yrs)	48.3	1.02	0.0221
BMI (kg/m ²)	24.5	0.96	0.0029
Diabetes: Yes vs. No	15.8%	1.44	0.0350
Functional Status: I	42.7%	1.00	REF
Functional Status: II	47.2%	1.09	0.5230
Functional Status: III	2.0%	1.48	0.2962
Six-min walk distance: < 150 feet	4.7%	1.66	0.0564
Six-min walk distance: 150+ feet	89.2%	1.00	REF
Severity at Listing			
PA systolic (mm/Hg) for Dgn Groups A, C, D	23.9	1.01	0.0769
PaCO2 Worse (vs. Other) *	1.9%	1.65	0.2286
Follow-up PaCO2	49.4	1.02	0.0185
FVC at Listing	56.6	0.99	0.0087
O2 requirement at rest Dgn Groups A, D (L/min)	2.2	1.28	<.0001
O2 requirement at rest Dgn Group B (L/min)	1.6	0.99	0.8956
O2 requirement at rest Dgn Group C (L/min)	1.3	1.26	0.0066
On ventilator at listing	0.4%	0.73	0.7382

* Patients were missing a PaCO2 change score 80% of the time. This is due to requiring patients to have either a non-missing bilirubin or creatinine change score to be included in the analysis. Many patients with one or both of these parameters were missing PaCO2. While the effect for

PaCO₂ Worse in terms of the hazard ratio is even greater than what has been seen previously, the excessive amount of missing data interferes with the model's ability to detect this signal.

**Draft Analysis for Data Requests from the OPTN Thoracic Organ
Transplantation Committee Meeting of May 3, 2007**

**Prepared by Jeff Moore, M.S., Tempie Shearon, M.S., Susan Murray Sc.D., Brad
Dyke, M.D., Robert Wolfe, Ph.D. and Staff, of the Scientific Registry of Transplant
Recipients (Arbor Research/University of Michigan)**

Data Request Routing Information and Analysis Timeline:

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Final Analysis submitted to be submitted to Committee: 09/18/07

Next Committee Date: 10/02/07

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Request 3: Impact of Serial Creatinine and Bilirubin on Lung Allocation Score and Its Components

Background

The Thoracic Committee continues to refine the LAS utilizing existing data; their current focus is the impact of creatinine and bilirubin on waiting list mortality. Results from these analyses were presented at the 5/3/2007 meeting and demonstrated the statistically significant impact of serial creatinine and serial bilirubin on waiting list mortality, incorporating an interaction between diagnosis group and bilirubin. The Committee was also interested in determining whether these risk factors were significant for post-transplant survival.

Request

Assess the impact of serial creatinine and serial bilirubin in the multivariable post-transplant survival model. Interactions between these factors and diagnosis group should also be considered. Based on the results of these analyses, examine the impact of creatinine and bilirubin on the LAS calculation.

HRSA Program Goal Addressed

Increase expected life-years gained post-transplant.

Study Populations

Post-Transplant Analyses

Patients aged 12+ in the audit data who first received a lung transplant between January 01, 1998 and December 31, 2003.

LAS Impact

Scores and rankings are provided for all patients in the retrospective data with complete LAS factor information on the lung transplantation waitlist on June 30, 2004.

Analytical Approach

Post-Transplant Model:

A Cox regression model was fit to predict survival from time of transplant until death based on follow-up and serial change values of creatinine and bilirubin, along with established post-transplant LAS factors.

LAS Scores and Rankings:

The LAS scores are examined using descriptive statistics and scatter plots. LAS scores are generated for all patients in the retrospective data on the lung transplantation waitlist on June 30, 2004.

Scores are generated based on:

- The current LAS algorithm (including PCO₂),
- The current algorithm along with the addition of serial creatinine and bilirubin factors.

Results

Post-Transplant Model:

Neither bilirubin nor creatinine was a significant predictor of post-transplant mortality and thus neither is considered on the post-transplant side of the LAS calculation.

LAS Scoring:

As a reminder, the creatinine and bilirubin parameters on the waitlist are defined as follows:

Peak bilirubin: the maximum value of bilirubin observed in the 6-month (183 days), post-listing period.

Follow-up creatinine: the value of creatinine closest to 6-months (183 days) post-listing.

Categorical change in bilirubin: An increase of at least 50% from listing to the peak value of bilirubin in the 6-month, post-listing period where the listing value is the latest value available within 180 days of listing, inclusive.

Categorical change in creatinine: 6-month percent increase in creatinine of at least 30%. Change in creatinine is extrapolated to 6-months based on the change observed from listing to follow-up creatinine where the listing value is the latest value available within 180 days of listing, inclusive.

The waitlist model results adjusting for established LAS factors are as follows (Index-of-concordance=0.72):

Table 1: Model Results (N=1171)

Parameter	Number with Parameter Available	Mean or Percent	Potential Hazard Ratio *	P-Value
Peak Bilirubin	722	0.82	1.00	0.3283
Increase \geq 50% in Bilirubin for Group B #	200	24.5%	1.55	0.0016
Increase \geq 50% in Bilirubin for A, C, or D #	522	13.6%	1.00	0.7433
Follow-up (6-month) Creatinine	1141	0.88	1.76	0.0002
Increase \geq 30% in Creatinine (vs. other) #	1141	12.3%	1.08	<.0001

* Non-significant ($p > 0.10$) factors have a hazard ratio of 1.00 (no effect) in the LAS calculation.

Significant bilirubin and creatinine factors ($p \leq 0.10$) have a potential LAS hazard ratio based on the lower bound of the 90% confidence interval of the true hazard ratio in this cohort. This is to provide a conservative, but non-trivial, effect to the LAS for bilirubin and creatinine consistent to how the PCO_2 effect was applied.

Percentage based on the number reaching the “worsening” threshold out of the number of patients with a calculable change score (at least 2 observations) available for the parameter.

LAS Results

There were 43 patients with non-missing LAS factors, as well as both non-missing change in creatinine and bilirubin.

The mean LAS score for all 43 patients based on the current, approved, algorithm is 42.1 (median=37.9). After modifying the LAS with creatinine and bilirubin results from the lung audit data the mean is 56.2 (median=52.5).

Table 2 provides LAS scores for both algorithms by diagnosis group:

Table 2: LAS Scores by Scoring Algorithm and Diagnosis Group					
Diagnosis Group	Scoring Algorithm	N	Mean	Median	(Min, Max)
Group A	Current	17	36.1	36.3	(30.2, 42.7)
	Modified	17	46.4	45.5	(32.5, 62.6)
Group B	Current	4	35.3	35.9	(32.7, 36.9)
	Modified	4	56.2	57.5	(40.8, 69.0)
Group C	Current	5	45.5	37.7	(35.8, 60.0)

Diagnosis Group	Scoring Algorithm	N	Mean	Median	(Min, Max)
	Modified	5	59.1	49.4	(47.4, 75.2)
Group D	Current	17	48.7	41.8	(36.0, 86.2)
	Modified	17	65.3	60.5	(46.2, 88.1)

Table 3 gives some information on the comparability of the LAS components for the cohort of 43 patients shown in Table 2 and Figure 1 compared to the overall population of patients listed between January 1999, and December 2003. The subset of available patients for group B used in displaying LAS scores is older and therefore may not be representative of the general population of group B candidates. Note that age was adjusted for in calculating hazard ratios in model development.

Table 3: Descriptive Statistics		Overall Means (All Patients Listed between January 1999, and December 2003)		Means for Patients with Serial Bilirubin and Creatinine Information	
LAS Diagnosis Group	Parameter	N	Mean (%)	N	Mean (%)
A	FVC	3621	54.2	17	53.0
	PCO2 Current	79	51.5	17	49.3
	PCO2 Worse *	79	16.5%	17	5.9%
	Oxygen At Rest	3621	2.0	17	2.4
	Age	3621	54.3	17	57.9
	BMI	3621	24.2	17	26.0
B	FVC	734	79.8	4	76.8
	PCO2 Current	31	34.3	4	36.0
	PCO2 Worse *	31	6.5%	4	0.0%
	Oxygen At Rest	734	1.6	4	0.0
	Age	734	39.1	4	57.9
	BMI	734	25.7	4	26.0
C	FVC	1275	45.8	5	40.6
	PCO2 Current	65	59.5	5	59.1
	PCO2 Worse *	65	21.5%	5	0.0%
	Oxygen At Rest	1275	1.5	5	1.2
	Age	1275	27.5	5	28.5
	BMI	1275	19.0	5	17.8

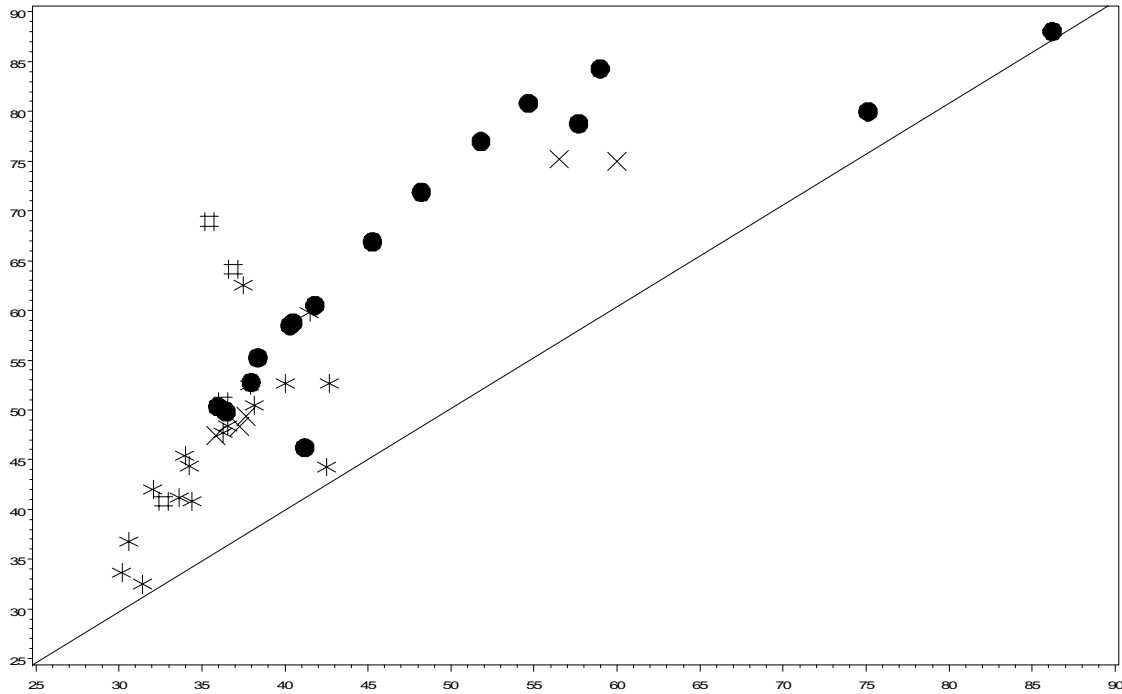
D	FVC	2541	49.9	17	45.6
	PCO2 Current	62	49.8	17	45.2
	PCO2 Worse *	62	19.4%	17	17.6%
	Oxygen At Rest	2541	2.5	17	2.4
	Age	2541	51.7	17	49.2
	BMI	2541	27.8	17	27.4

* Percent of PCO2 worse is the percent of patients with follow-up PCO2 available that reached the worsening threshold.

The following plot provides the shift in scores within each diagnosis group based on the LAS results above (N=43):

Lung Allocation Scores
Original Scores vs. Modified Scores

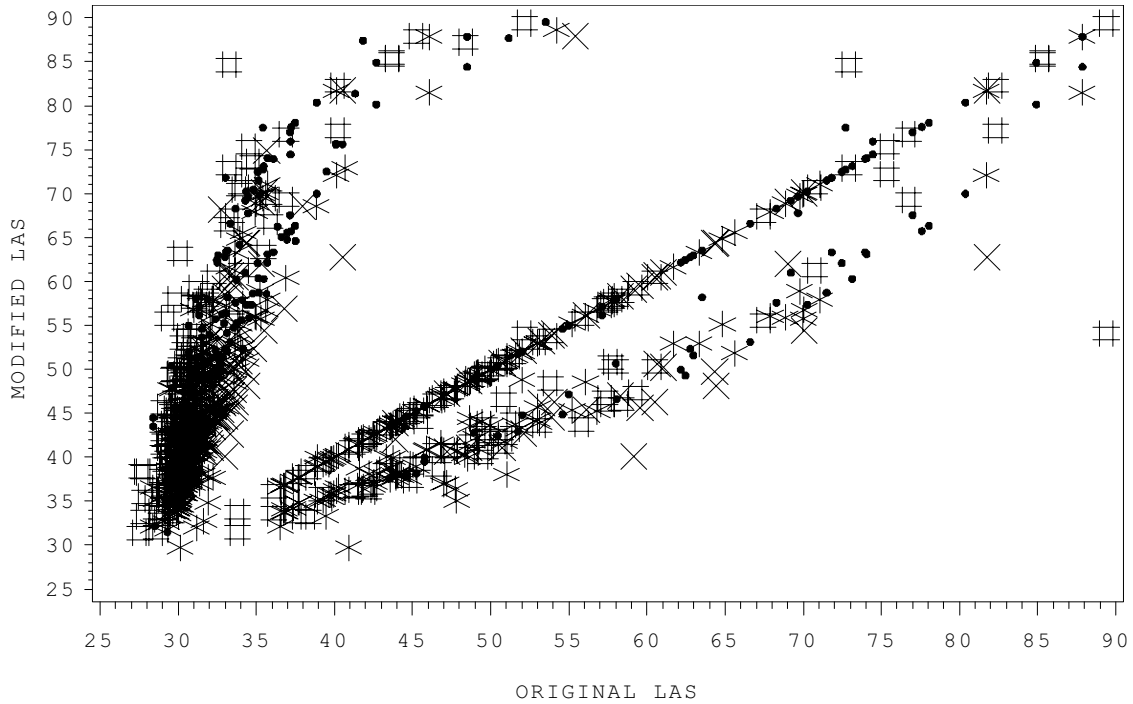
Modified
LAS



Original LAS

* = LAS Group A # = LAS Group B X= LAS Group C •=LAS Group D

The following graph compares the LAS scores for the current, approved policy to scores additionally adjusted for bilirubin and creatinine effects after imputing values of 40, 0.0, and 0.7 for missing PCO₂, bilirubin, and creatinine values, respectively. For patients with missing values a “no change” was imputed for the respective worsening parameters. After the imputations, there were 606 patients available for analysis. Patients for which an LAS parameter other than PCO₂, bilirubin, or creatinine is missing do not have a calculable LAS in this analysis and therefore do not appear on the graph below.



LAS Diagnosis Group A, B, C, or D * * * A # # # B x x x C ● ● ● D

Final Data Report for Data Request #1 from the OPTN Thoracic Conference Call of 02/05/08

Prepared by Jeff Moore M.S., Tempie Shearon, M.S., Susan Murray Sc.D., Brad Dyke, M.D., Robert Merion, M.D., Robert Wolfe, Ph.D. and Staff of the Scientific Registry of Transplant Recipients

This analysis plan is submitted by the Scientific Registry of Transplant Recipients (SRTR) in response to the data request from the OPTN Thoracic Organ Allocation Committee Conference Call of 02/05/08.

Data Request Routing Information and Analysis Timeline

OPTN Thoracic Organ Allocation Committee Conference Call date: 02/05/08
OPTN Thoracic Organ Allocation Committee data request made: 02/07/08
Request Received by SRTR: 02/07/08
Analysis plan submitted: 02/18/08
Final Analysis submitted to HRSA and OPTN Committee: 2/22/08 for Request #1
Next Committee Date: 3/10/08

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Request 1: SUMMARY OF BILIRUBIN DATA USED FOR LAS MODIFICATION ANALYSES

Background

The Lung Subcommittee reviewed results the SRTR provided examining the impact of bilirubin and change in bilirubin on the waiting list mortality model underlying the LAS calculation. A change in bilirubin of 50% or greater in a 6-month window following a lung candidate's addition to the lung waiting list, based on the lung retrospective data project, had a significantly increased hazard of mortality for candidates in diagnosis grouping B.

In order to develop a fully specified policy proposal, the Subcommittee requested further details regarding the underlying bilirubin data that were used in the analyses that have been presented. For example, depending on the underlying data, the proposal may include a minimum level for bilirubin below which a 50% change threshold will not have an impact on the LAS.

Program Goal Addressed: Life-years gained

Request

Provide a summary of the bilirubin data used in the analyses previously presented for the 200 diagnosis group B candidates. This summary should include the lowest value, the highest (peak) value, the percentage change, and an indication of whether the candidate died while waiting. It was suggested that a scatterplot may be useful in summarizing this information.

NOTE: These results were requested to be provided for the Lung Subcommittee meeting to be held on March 9 or March 10.

Study Population

Patients aged 12+ in the retrospective lung audit data who were first listed for a lung transplant between January 01, 1998 and December 31, 2003.

Analytical Approach

A summary of the diagnosis B patients used in the previously presented analysis is provided. The summary includes information about the distribution of bilirubin values for these patients at listing and at peak, along with data on the percentage change in bilirubin. Deaths of the waiting list are also summarized for these patients.

Results

The following table provides statistics describing the distribution of bilirubin values at listing and at peak for the 200 Diagnosis B patients with change in bilirubin available.

Table 1: Bilirubin Values for PPH Patients with Measurable Change							
Bilirubin Value	N	Mean	Minimum	25th %	50th %	75th %	Maximum
Peak	200	1.30	0.20	0.70	1.00	1.70	12.90
Listing	200	1.09	0.10	0.60	0.90	1.40	5.20
% Change	200	31.2	-66.7	-20.00	6.74	44.51	700.00

Table 2 provides the information for the subset of Diagnosis B patients that reached the 50% change in bilirubin threshold.

Table 2: Bilirubin Values for PPH Patients with Change in Bilirubin ≥ 50%							
Bilirubin Value	N	Mean	Minimum	25th %	50th %	75th %	Maximum
Peak	49	2.02	0.50	1.10	1.60	2.30	12.90
Listing	49	0.87	0.10	0.50	0.70	1.10	2.80
% Change	49	149.22	50.00	76.19	118.75	166.67	700.00

Table 3 provides the waitlist experience for all diagnosis groups broken down by reaching, or not reaching, the 50% change in bilirubin threshold. The only significant factor in the model is reaching the threshold for PPH patients. Reaching the threshold for the other diagnosis groups is not significant, nor is a continuous bilirubin factor at any time point.

The following two tables provide the information above by waitlist experience.

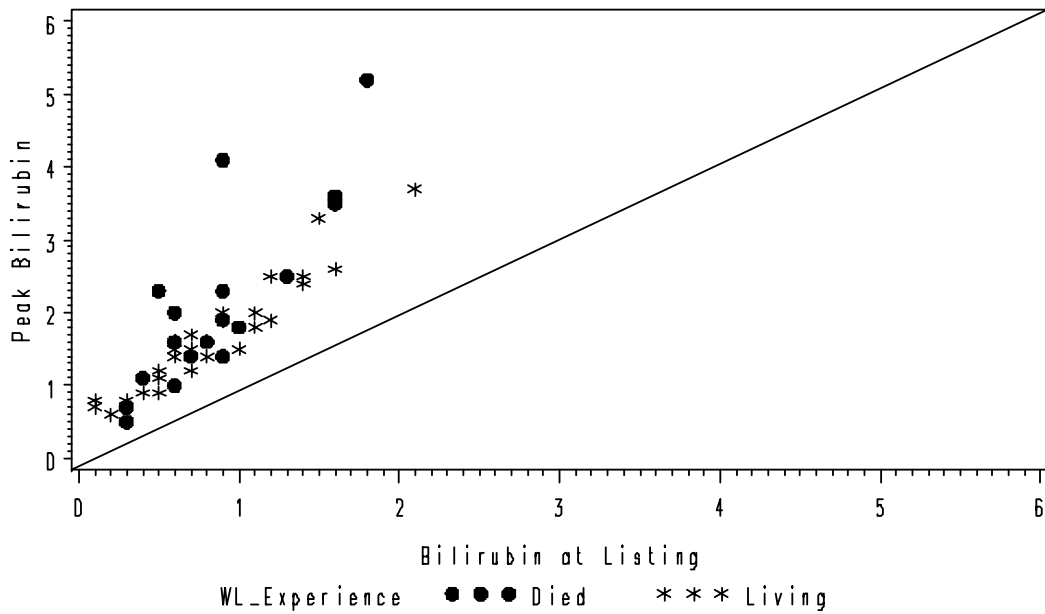
Table 3: Bilirubin Values for PPH Patients with Measurable Change by Waitlist Status								
WL Outcome	Bilirubin Value	N	Mean	Minimum	25th %	50th %	75th %	Maximum
Alive	Peak	148	1.15	0.20	0.70	0.90	1.50	6.60
	Listing	148	1.09	0.10	0.60	0.90	1.35	5.20
	% Change	148	21.55	-66.67	-22.73	0	32.05	700.00
Died	Peak	52	1.73	0.20	0.80	1.20	2.05	12.90
	Listing	52	1.10	0.20	0.65	0.90	1.50	2.80
	% Change	52	58.50	-50.00	-9.35	20.00	100.00	360.71

Table 4: Bilirubin Values for PPH Patients with Change in Bilirubin \geq 50% by Waitlist Status								
WL Outcome	Bilirubin Value	N	Mean	Minimum	25th %	50th %	75th %	Maximum
Alive	Peak	30	1.60	0.50	1.00	1.50	2.00	3.70
	Listing	30	0.80	0.10	0.50	0.70	1.10	2.10
	% Change	30	142.22	50.00	71.43	111.31	142.86	700.00
Died	Peak	19	2.71	0.50	1.40	1.90	3.50	12.90
	Listing	19	0.97	0.30	0.60	0.90	1.30	2.80
	% Change	19	160.27	55.56	92.31	125.00	188.89	360.71

Table 5: Waitlist Experience By Change in Bilirubin Category			
Diagnosis Group	Bilirubin Change	N	% Died on Waitlist
Group A (COPD)	< 50%	191	11.0%
	\geq 50%	31	12.9%
Group B (PPH)	< 50%	151	21.9%
	\geq 50%	49	38.8%
Group C (CF)	< 50%	130	20.8%
	\geq 50%	46	26.1%
Group D (IPF)	< 50%	99	30.3%
	\geq 50%	25	36.0%

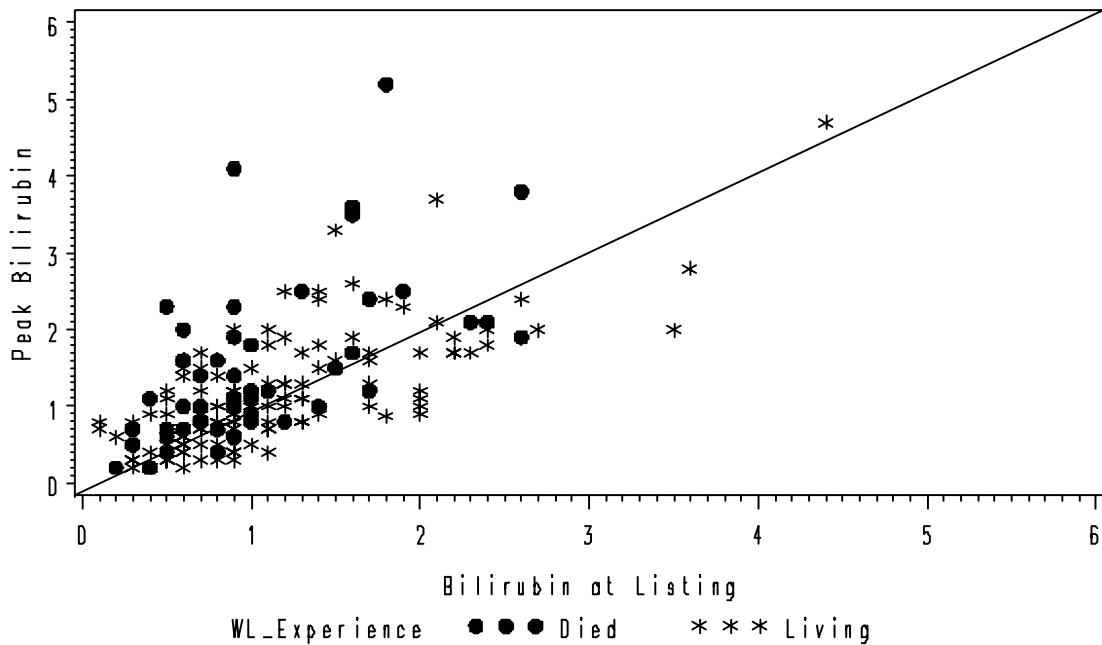
The following graph provides the waitlist experience for Diagnosis B patients reaching the 50% threshold. One patient not displayed here had a listing bilirubin of 2.8 and a peak bilirubin of 12.9. This patient died on the waitlist.

Patients in Group B With At Least 50% increase in Bilirubin



The following graph provides the waitlist experience for all Diagnosis B patients with calculable change scores. The patient mentioned above is not displayed here.

All Patients With Available Change in Group B



Additional Waitlist Mortality Model

Given the data above, an additional model was evaluated adjusting for peak bilirubin only when the peak was above 1.0, and an effect describing the risk of experiencing at least a 50% change from listing to peak for PPH patients with peaks greater than 1.0. The index of concordance for this model (and this population of patients) is 0.64, compared to 0.62 when the current LAS model is used to predict outcomes for the same population of patients.

Table 6: Waitlist Mortality Model Results				
Parameter	Number with Parameter Available	Mean or Percent	Potential Hazard Ratio *	P-Value
Peak Bilirubin (Continuous) when Peak Bilirubin > 1.0	143	1.89	1.02	0.0676
Increase \geq 50% in Bilirubin for Group B Patients With Peaks > 1.0	200	19% (n=38)	1.45	0.0043

* Based on the lower bound of the 90% confidence interval.