Proposal to Revise the Lung Allocation Score (LAS) System

Sponsored by the Thoracic Organ Transplantation Committee

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Current LAS System

- Calculates score for lung transplant candidates 12 years of age and older
- Candidates receive offers based on LAS, geography and blood type
- Categorizes candidates into four diagnosis groups: A, B, C, and D

Problem

- LAS was intended to be a “dynamic” policy but not significantly revised since implementation in 2005
- Disease severity not adequately captured for all diagnosis groups

Goals

- Address the disease severity of candidates by modifying the covariates, and updating their coefficients, in the LAS system's statistical models
- Update the baseline survival rates to reflect the current waiting list and transplant population
- Make LAS system more transparent

Supporting Evidence/Modeling

- LAS system considers two survival models:
  - Waiting List Urgency Model
  - Post-transplant Survival Model
- SRTR began to assess the contemporary validity of the statistical models in 2009
- SRTR reviewed, refined, updated and validated the revised LAS system

Factors in Waiting List Urgency Model

Added	Deleted	Modified	Unchanged
Cardiac Index	Percent Predicted FVC for Diagnosis Groups A,B,C	FVC (Group D only)	Diabetes
Central Venous Pressure (for Group B)		BMI	Diagnosis Groups
Creatinine – serum		Age	Detailed diagnoses
		Functional Status	PCO_2 and Increase PCO_2
		O_2 at rest	Bilirubin and Increase in Bilirubin*
		PA systolic pressure	
		6-minute walk distance	

*Adopted by Board of Directors in 2009, but not yet implemented

Factors in Post-Transplant Survival Model

Added	Deleted	Modified	Unchanged
Increase in creatinine of at least 150%**	Percent Predicted FVC for Diagnosis Groups B and D	Age	Continuous mechanical ventilation
Cardiac Index**	Pulmonary capillary wedge mean pressure for Group D	Creatinine	Diagnosis Groups
Oxygen needed at rest		Functional Status	Detailed diagnoses
6-minute walk distance if less than 1200 feet			

**With conditions defined in policy

Components Added to Policy for Transparency

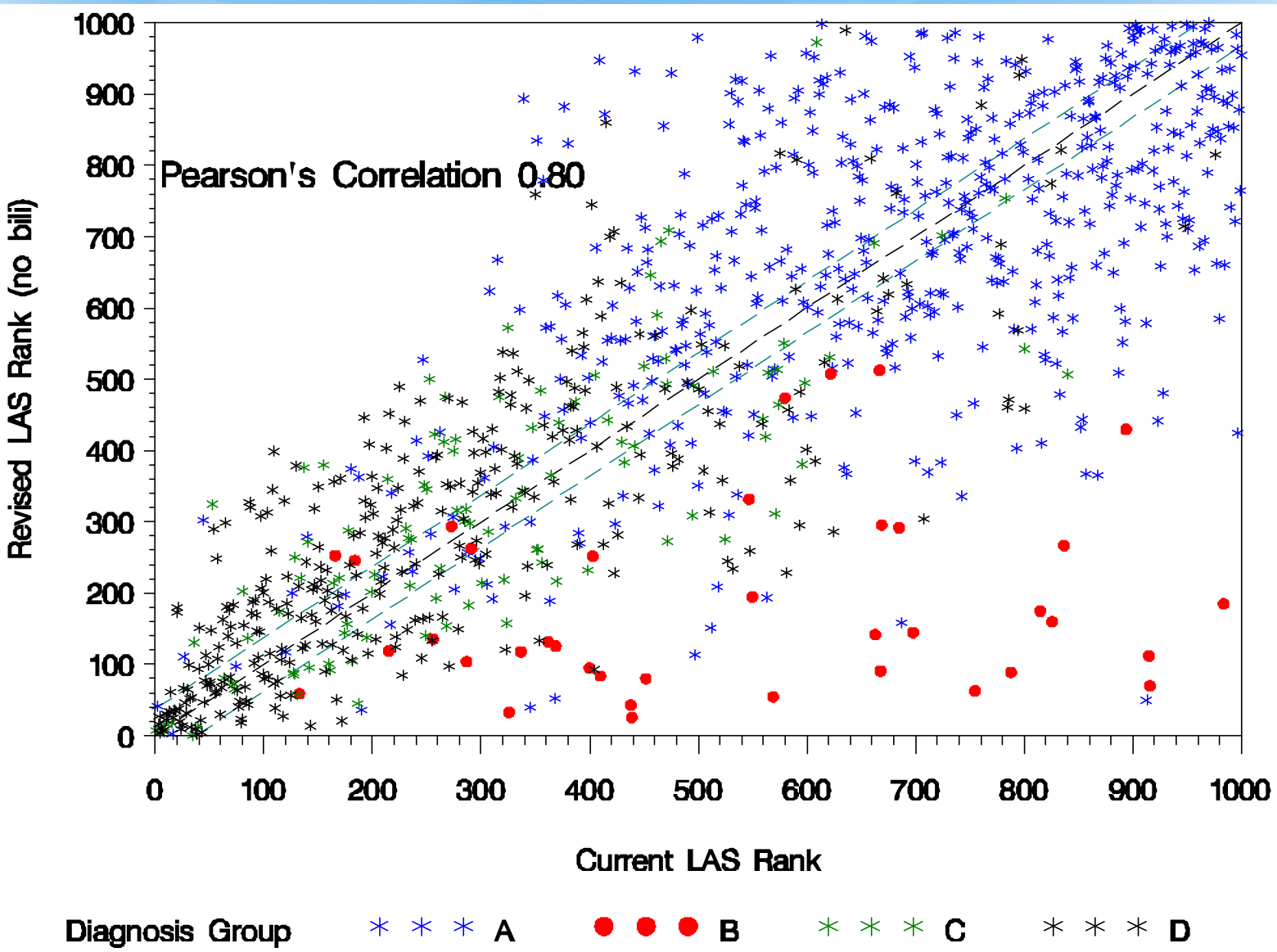
- Equation to calculate the LAS
- Baseline survival rates
- Coefficient for each covariate in the model
- Complete listing of diseases in each diagnosis group
- Identification of values that will be substituted for covariate data that are missing or expired

Other Significant Modifications

- Missing or expired data for the functional status or assisted ventilation covariates no longer results in LAS of zero
- Entry of bilirubin data for LAS calculation purposes

Anticipated Impact of Revision

- Implementation of bilirubin likely to result in higher LASs for candidates in Group B
- Candidates with poor functional status, low cardiac index values, high creatinine, high CVP, or need for continuous mechanical ventilation likely to experience higher LASs
- Candidates in all age groups will be affected similarly



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Public Comment Response At-A-Glance

Type of Response	Response Total	In Favor	Opposed	No Vote/No Comment/ Did Not Consider
Individual	297	267 (89.9%)	1 (0.34%)	29
Regional	11	11 (100%)	0 (0%)	0
Committee	19	2 (100%)	0 (0%)	17

- Individual comments overwhelmingly supportive, particularly from the pulmonary arterial hypertension community
- AST, ASTS and NATCO all supportive

Specific Concerns and Responses

Concern	Response
FVC removed from waiting list survival model for Groups A, B and C	Modeling revealed that FVC is not a statistically significant marker for distinguishing candidates in those groups
Standardize O_2 use during 6 minute walk test, and include O_2 requirements on exertion	Committee included clarifying language in data reporting requirements in Tables 1 and 2
Effect of BiPAP and how this may affect a candidate's CO_2 in the LAS, for concern that there is a disincentive to put candidates on BiPAP at night	BiPAP and CPAP are not considered "continuous mechanical ventilation" for the purposes of the LAS. If a candidate is being treated with BiPAP or CPAP for impending respiratory failure, the transplant program should apply to the LRB for an exception
ECMO not included in post-transplant survival model	The Thoracic Committee is currently determining how to capture ECMO data use for future revisions of the LAS, but did not have ample data to include it in this iteration

Post-Public Comment Revisions

- Transparency edits: tables included in final proposal contain values rounded to 16th, rather than 2nd, decimal place
- Intent edits: Committee incorporated clarifications regarding how to report certain data
  - O_2 reporting for 6 minute walk distance
  - Cardiac index and PA systolic pressure should be taken “at rest, prior to any exercise”
  - Ventilation status only if candidate is “hospitalized”
  - 6 month anniversary date definition clarification
- Plain language edits and section number changes

Resolution

** RESOLVED, that Policies 3.7.6 (Lung Allocation) through 3.7.6.1.5 (Creatinine in the Lung Allocation Score), 3.7.6.3 (Candidate Variables in UNet℠), 3.7.6.3.1 (Updating Candidate Variables), and 3.7.9.2 (Waiting Time Accrual for Lung Candidates Age 12 and Older Following Implementation of Lung Allocation Scores Described in Policy 3.7.6) shall be modified as set forth in Resolution 17, effective pending programming and notice to the OPTN membership.