

Thoracic Simulated Allocation Model



Version 2015



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1 Getting Started

1.1 Purpose of the Program

The purpose of the Thoracic Simulated Allocation Model (TSAM) is to simulate the allocation of hearts and/or lungs to candidates waiting for thoracic organ transplants and their outcomes. Input files are provided based upon the OPTN thoracic waiting list and organs for the time period May 1, 2003 – April 30, 2005. TSAM is a computer simulation program developed by the Scientific Registry of Transplant Recipients (SRTR).

The program has been designed to support studies of alternative organ allocation policies. It can use a variety of allocation rules to determine how a series of thoracic organs would be allocated to a list of potential recipients under each of the rules considered. The allocation process involves some random components reflecting the uncertainty in acceptance decisions when an organ is offered to a potential recipient and reflecting the unpredictable life expectancy that can result from receiving a transplant or not. In order to account for such random variation, the program can make organ allocations several times with the same set of allocation rules, candidate lists, and organs in order to determine what happens on average.

This guide describes the means by which the user can simulate the organ allocation process by creating or editing an Allocation Run package, which consists of a named collection of input files and specifications. Default files that reflect actual experience are provided for this purpose. Alternatively, input files could be created by the user with candidate characteristics, candidate histories, and organ characteristics.

1.2 Installing the Software

You must be running Microsoft Windows XP, Windows Vista or Windows 7 to install the Kidney-Pancreas Simulated Allocation Model. You may need administrator rights to install TSAM. The software for the current version of the TSAM program is available on CD from the SRTR.

- 1. Insert the software CD into your CD drive.
- 2. Using Windows Explorer, select your CD drive and double-click on setup.exe. The Setup Wizard will then start.
- 3. The Setup Wizard will prompt you to select Next to continue installation.
- 4. After reading the Information screen, please select Next.
- 5. You may type in your name and company, then select Next.
- 6. The setup program will show the recommended default folder for installing the program, which can be changed. Select Next.
- 7. The setup program will ask you if you want to create a start menu folder and desktop shortcut
- 8. The Setup Wizard gives you a summary of your installation settings. Select Install to continue.
- 9. Software program files will be copied to the appropriate folders. A folder called \SRTR\ TSAM will be created on your hard disk, and sample data files will be put into \SRTR\ TSAM \Input\.
- 10. Select Finish to exit the Setup Wizard Completed screen. The process should take less than two minutes. Remove the CD from your drive and store in CD case.

1.3 Deleting the software

If you choose to remove the program from your computer, do not start by deleting the files in the TSAM folder. On the taskbar at the bottom left of your screen, click the Start button to bring up the Start menu. Choose Settings, then Control Panel. Double-click on the icon Add/Remove Programs. Then highlight Liver Simulated Allocation Model, click Add/Remove, and follow the on-screen instructions.

You may also select the uninstall option from the start menu folder if you chose to create one during installation.

1.4 Moving the software

If you want to move the software, first delete it as described above, then reinstall the software to a new location.

1.5 Starting the Program

The Setup Wizard has created two shortcuts that you can use to start the TSAM program:

- 1) On the taskbar at the bottom-left of your screen, click the Start button; the Start menu appears. Choose Programs, SRTR, and then TSAM.
- 2) Alternatively, you can click on the TSAM icon that the Setup Wizard put on your Desktop.
- 3) You may also open the folder the program was installed in and click on the TSAM icon.

1.6 Setting Input Parameters

The information that TSAM uses must be prepared according to very detailed specifications. This information is extensive, and computer files must be prepared with this information. Descriptions of these files are available in Chapters 5 and 6 of this document. After you have prepared these files, you can use them with TSAM. The TSAM user interface prompts users to identify the files that contain the input data (organ and candidate characteristics and other information related to organ allocation, acceptance, and posttransplant survival) that define a single Allocation Run of the program. The interface also supports the direct input of selected aspects of the allocation rules in dialogue boxes in the program.

The next few pages will take you through the steps needed to create an Allocation Run Package. Below is the first screen of the program. To get started, click on the Package button on the right of the screen.

| JINS Generation | |
|---|-------|
| Current Rules, Cohort May 1, 2003 through April 30, 2005 OlderModel 2004 quick run testrules | |
| | |
| | E. |
| | |
| | Queue |
| | |
| Summary | Exit |

If any Allocation Run packages have been defined previously, the program will list them on this screen. In that case, you also may proceed by selecting one of the existing Allocation Run packages and then selecting the Open Box button (immediately below the Package button). This will take you to the Allocation Run Specification screen, where you may run that package or edit its definition.

The remaining buttons allow you to duplicate an Allocation Run package, delete an Allocation Run package, run a Queue or create a Summary file.

Run Specification

The Run Specification screen contains two tabs, which are used to select the files from which the program will read its input data for this Allocation Run Specification.

Identification

On the Identification tab of the Run Specification screen, you will need to set:

Model Name – listed on the main screen and used to identify the Model Allocation Run. Use abbreviations that describe the model parameters, i.e., "CY01RegShare" instead of "Model02."

Model Short Name – used to assign output file names by appending the short name of the Allocation Run before the output file names. For example, the file "CY01RegShareMatch.out" contains the match run results for an allocation run with Model Short Name "CY01RegShare."

Model Start Date - the beginning date of this Model Allocation Run.

Model End Date – the ending date of this Model Allocation Run.

| 🕻 Run Specification | | |
|--------------------------------------|----------------------|----------------|
| Identification Specification | | |
| Model Control | | |
| Model Name | | |
| Current Rules, Cohort May 1, 2003 th | rough April 30, 2005 | |
| Model Short Name | Model Start Date | Model End Date |
| Cur20032005 | 05/01/2003 | 04/30/2005 |
| , Model Description | , | |
| | | |
| Run the Model | ок | Cancel |
| | | |

Select the Specification tab to continue.

Run Specification

Specification

Model Specifications – the next few pages will take you through setting these parameters.

| T Run Specification | | | 23 |
|--|----|------|----|
| Identification Specification | | | |
| Model Specification | | | |
| Specify Input Streams | | | |
| Specify Allocation Rules | | | |
| Specify Model Parameters | | | |
| Specify Output Destination C:\SRTR\TSAM\TSAMv4.0\Output\ | | | |
| | | | |
| Run the Model OK | Ca | ncel | |
| | | | |

Select the Specify Input Streams button to continue.

Input Selection

The Input Selection screen contains two tabs, which are used to select the files from which the program will read its input data for this Allocation Run.

Model Structure

The first tab allows you to specify where the Base and Additional Data Definition, Score Boost, Allocation, Acceptance and Survival files are located. See Chapter 6, Input File Specifications, of this document for more detailed information about each input file.

To change a data source from its default value, select the filing cabinet button on the right. This will bring up a standard Windows file selection dialog.

The double green arrows on the right will reload information from these files. You might use this, for instance, if you've made changes to the post-graft survival calculations (discussed later in this manual), and then decide to start over with the default survival calculations.

| T Input Selection | |
|---|------------|
| Model Structure Input Streams Input Streams (cont) | |
| Base Data Definition C:\SRTR\TSAM\TSAMv4.0\Input\DefDataDef.txt | 5 |
| Additional Data Definition C:\SRTR\TSAM\TSAMv4.0\Input\OptDataDef.txt | 9 |
| Default Score Boosts C:\SRTR\TSAM\TSAMv4.0\Input\DefBoostDef.txt | 5 M |
| Default Allocation C:\SRTR\TSAM\TSAMv4.0\Input\DefMethods.txt | B |
| DefaultAcceptance C:\SRTR\TSAM\TSAMv4.0\Input\DefAccept.txt | B |
| Default Survival C:\SRTR\TSAM\TSAMv4.0\Input\DefSurvival.txt | § M |
| | |
| | |
| ок | Cancel |
| | |
| | |

Next, select the Input Streams tab.

Input Selection

Input Streams

The second tab allows you to specify where the ABO Compatibility matrix, Location Mapping, Initial Waiting List, Organ Arrivals, New Patient Arrivals and Patient Status Update files are located. To change the location, click on the filing cabinet icon to the right of the file name. See Chapter 6, Input File Specifications, of this document for more detailed information about each input file.

| T Input Selection | | |
|--------------------------|--|----------|
| Model Structure Input St | reams Input Streams (cont) | |
| ABO Compatibility | C:\SRTR\TSAM\TSAMv4.0\Input\ABOChart.txt | a |
| Location Mapping | C:\SRTR\TSAM\TSAMv4.0\Input\LocMap20032005.txt | 5 |
| Initial Waiting List | C:\SRTR\TSAM\TSAMv4.0\Input\waitlist20032005.txt | 9 |
| Organ Arrivals | C:\SRTR\TSAM\TSAMv4.0\Input\organs20032005.txt | 9 |
| New Patient Arrivals | C:\SRTR\TSAM\TSAMv4.0\Input\patients20032005.txt | 9 |
| Patient Status Updates | C:\SRTR\TSAM\TSAMv4.0\Input\status20032005.txt | 9 |
| | | |
| | | |
| | ок | Cancel |
| | | |

The Input Streams (cont) tab is currently empty in TSAM.

Multiple sample organ arrivals files have been provided with this installation. The same organs become available in each of the files, but their arrivals dates and times have been shuffled in each of the files in order to more closely simulate the randomness with which donor organs become available. The user may choose to specify that TSAM use a different ordering of organ arrivals per iteration by choosing the organ file with the phrase "AltOrd1" in its name as the organ arrivals file on this screen. TSAM will then use AltOrd1 for its first iteration, AltOrd2 for its second iteration, etc.

Run Specification

Next, let's look at Specify Allocation Rules:

| T Run Specifi | cation | | | | 23 |
|----------------|----------------------------|------------------------|---------|--------|----|
| Identification | Specification | | | | |
| Model Speci | fication | | | | |
| 9 | Specify Input Streams | | | | |
| - <u>10</u> | Specify Allocation Rules | | | | |
| <u>P</u> XX | Specify Model Parameters | | | | |
| <u>a</u> | Specify Output Destination | C:\SRTR\TSAM\TSAMv4.0\ | Output\ | | I |
| | | | | | |
| • | Run the Model | | ок | Cancel | |
| | | | | | |

Please select the Specify Allocation Rules button.

Allocation Rules Definition

The Allocation Rules dialog contains two tabs. Use the Allocation Rules and Score Boosts tabs to design the rules for the allocation of hearts and lungs.

Allocation Rules

The first tab allows you to specify the rules to use. See Sections 3.1 and 3.2 of this document for more detailed information about each rule.

| T Allocation Rul | es Definition | |
|------------------|---|--------|
| Allocation Rules | | |
| | Current Adult Donor Heart (with or without lungs) Current Adolescent Donor Heart (with or without lungs) Current Child Donor Heart (with or without lungs) Current Adult Lung (without Heart) Current Adolescent Lung (without Heart) Current Child Lung (without Heart) | |
| | ОК | Cancel |
| | | |

The buttons on this screen are defined as follows:



Create new Edit Copy Delete

Highlight one of the Allocation Rules, such as "Current Adult Donor Heart (with or without lungs)", and select the edit button (blue pencil) to continue.

Allocation Rule Specification

The Allocation Rule Specification screen contains three tabs which are used to define the rules for organ allocation.

Rule Name

Use the Rule Name tab to specify the name of this allocation rule. The name should describe the set of donors to whom this rule applies.

| C Allocation Rule Specification | _ 0 | 23 |
|--|--------|----|
| Rule Name Rule Group Rule Components Rule Definition Name Name Current Adult Donor Heart (with or without lungs) | | |
| | | |
| | | |
| ок | Cancel | |

Next, select the Rule Group tab.

Allocation Rule Specification

Rule Group

Use the Rule Group screen to define the group of donors to whom this allocation rule applies.

The source must be the organ record, which you will see is the only choice. Choose a variable from the drop-down list. This list contains all fields whose usage has been defined as "category" in the default or optional data definitions files. Choose a level for this variable from the level drop-down list. These, too, have been defined in the default or optional data definitions files. See Chapter 6, Input File Specifications, of this document for more detailed information about the data definitions files.

You may combine any number of rules together using the plus sign button at the right to narrow the donor list to whom this rule applies. An organ donor must meet all of the group definitions in order for this allocation rule to apply.

| Allocation Rule Specification | |
|--|--------|
| Rule Name Rule Group Rule Components Group Component Source Variable NotUsed Image: Component state Image: Component state | • |
| Group Definition Organ:HasHeart=True Organ:DonAgeGrp=Adult | |
| ОК | Cancel |
| | |

Next, select the Rule Components tab.

Allocation Rule Specification

Rule Components

The Rule Components tab displays the ordered list of patient categories for the selected allocation rule. To change the ordering, select a category and use the up- and down-arrow keys on the left to promote or demote the category. To create a new category, select the create button (light bulb) on the right side. To edit a category, select the category and then select the edit button (blue pencil) on the right side. To delete a category, select it and then select the erase button (pencil eraser). See Chapter 3 of this document for more detailed information about the allocation methods.

| Image: Construct of the second sec | sification- | No. 11 Action | 07 | 0 | 1.5 | |
|---|-------------|---------------|----|---|-----|-----|
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| | | 1 | | | | |

Highlight one of the rule components, and then select the edit button to continue.

Allocation Group Definition

Group Definition

The Group Definition tab allows the user to define the patient categories. The drop-down list of variables contains all patient variables whose usage has been defined as "category" in the default or optional data definition files. Choose a variable from the list, and then choose a level for this variable from the level drop-down list. These, too, have been defined in the default or optional data definitions files. Rearranging the group definitions list using the up- and down-arrows to the left will merely change the order in which the criteria are checked for each organ. Therefore, putting the more-restrictive criteria closer to the top of the list may speed processing. See Chapter 6, Input File Specifications, of this document for more detailed information about the data definitions files.

Within each patient sub-group, you may want to order the patients by other criteria. Use the Sort Order Within Group section of the screen for that sub-group ordering. To add a patient characteristic to the list, highlight that characteristic in the available list, then select the right arrow button. To remove a characteristic, highlight it in the selected list, then select the left arrow button. To promote or demote a characteristic, highlight it in the selected list, then select the up- or down-arrow key.

You will see in the next section how to boost the value(s) of any of the sub-group fields for patient and organ combinations that have certain characteristics.

| Allocation Group Definition | |
|--|----------|
| Group Definition | |
| Group Component | |
| Variable Level | <u> </u> |
| Group Definition | |
| Image: NeedHeart=True GeogZone=ZONEA CurHeartStat=1A ABOCompat=I | |
| Sort Order Within Group Available: Selected: | |
| ABOEnum ArrivalTime BothLuEnum CAN_AT_REST_02_wmm_AD CAN_AT_REST_02_wmm_b_pph CAN_AT_REST_02_wmm_c_cf CAN_FVC_wmm CAN_PULM_ART_SYST_wmm_ACD | |
| ок | Cancel |
| | |

From the Allocation Group Definition screen, select the OK or Cancel button to return to the Allocation Rule Specification screen. Select the OK or Cancel button from there to return to the Allocation Rules Definition screen.

Next, select the Score Boosts tab from the Allocation Rules Definition screen.

Allocation Rules Definition

Score Boosts

You may use the Score Boosts tab to increase the value of certain patients' fields. Those fields, then, may be used for sub-group sorting in the allocation process. Please refer to the previous section, Allocation Group Definition, for information on how to use those fields in the allocation process.

Here you will define the patient and organ characteristics which must be present, and the calculation for the points those patients will gain.

| L Allocation Rules Definition | | | 23 |
|---------------------------------|-----------|--------|----|
| Allocation Rules Score Boosts | | | |
| Boost Definitions Available: | Selected: | | |
| | | | |
| | | | |
| | | | |
| | ок | Cancel | |
| | | | |

There are no score boosts defined. Select the 'create new' button.

It is also possible to enter a linear equation as a score boost. The linear equation score boosts cannot be entered, viewed, or modified using the TSAM input panels. They must be entered using the Def-BoostDef.txt input file, instead. Please refer to the Allocation Score Boost Definition section of the Input File Specification chapter for more information.

The Boost Name, Organ Specification and Patient Specification tabs on the next screen are similar to the Rule Name and Rule Group tabs in the Allocation Rule Specification. Please refer to the Allocation Rule Specification, earlier in this chapter, for more information on those two tabs.

Please select the Boost Specification tab to continue.

Allocation Score Boost Definition

Boost Specification

The Boost Specification tab is used to specify which patient characteristic(s) will be increased, and by how much. You may multiply the field by a factor and/or add an amount to the field. In addition, you can specify that you want that field increased at a given interval if they remain on the waitlist. You may also put upper limits on the number of intervals or the score itself, and you may truncate a calculated score.

| oost Name Organ Specification Patie | ent Specification Boost Specification |
|--|---|
| Score Boost Component Score Variable Interval (Days) 365.25 | Initial Multiply By Factor Initial Add To Amount 0.0 Periodic Multiply By Factor Periodic Add To Amount 1.0 0.0 |
| Maximum Intervals | Maximum Score |
| | |
| | |
|] | |

We have completed our allocation rules definitions. Next, we will explore the model parameters you may specify for random number generation, acceptance probability, and post-graft survival.

Please select the OK or Cancel buttons twice to return to the Run Specification panel, and then choose the Specify Model Parameters button to continue.

Model Parameter Specification

Random Number Generator

This list of choices allows you to choose how the program will generate random numbers for allocation. Random numbers are used in several places in this simulation; for example, once the probability of organ acceptance for a certain organ/recipient pair is calculated as a percentage, the program will use random numbers from this generator to decide whether or not that recipient accepts that particular organ. For most purposes, it will not matter which generator is picked.

The default generator, MT19937, is preferred, although the stream of random numbers produced by each of these generators should be good enough.

If you wish to duplicate the results of a run exactly, you must provide the same seed and the same generator.

You can accept the existing seed, enter a new seed in the window, or select the clock button for the program to select a new seed. See Section 2.1 of this document for information on how the random number generator is used by the model.

| Model Parameter Specification | _ 0 | 23 |
|--|----------|----|
| Random Number Generator Acceptance Post-Graft Survival | | |
| Seed 10179376 | | |
| Generator | | |
| MT19937 - Mersenne Twister 19937-bit Twisted Feedback Shift Register Generator | • | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| ок | Cancel | |
| | | |

Next, select the Acceptance tab.

Model Parameter Specification

Acceptance

Acceptance probability is determined by model input. The mechanism is described in detail in the following pages.

| Acceptance Definitions Image: Acceptance Lung Acceptance Image: Acceptance Heart-Lung Acceptance Image: Acceptance Heart-Lung Acceptance Image: Acceptance Ima | andom Number Generator | Acceptance Post-Graft | Survival | | |
|---|------------------------|-----------------------|----------|---|---|
| Image: Comparison of the second se | Acceptance Definitions | | | | |
| | Lung Ac Heart-Lu | ceptance | | | |
| OK Cancel | | ount 200 숮 | | 1 | 1 |

Highlight one of the Acceptance models provided and select the edit button.

The Calculation Name and Patient Group tabs on the next screen are similar to the Rule Name and Rule Group tabs in the Allocation Rule Specification. Please refer to the Allocation Rule Specification, earlier in this chapter, for more information on those two tabs.

Please select the Covariates tab to continue.

Calculation Definition (Acceptance)

Covariates

Here you may define an equation to represent organ acceptance probability. Values that may be used in this equation are scalar variables (coefficients), characteristics of the organ or donor, characteristics of the potential organ recipient, and/or values that are calculated from characteristics of the specific organ and patient combination under consideration. For each organ offered, this equation will be solved by the model, and the resulting value, βX , transformed using an inverse logit transformation (exp(βX) / 1+exp(βX)). That value will then be compared to a random number between 0 and 1. If it is greater than the random number, then the organ is accepted, otherwise it is rejected.

| Calculation Name | Patient Group Covariates | | |
|-------------------|--------------------------|-------|------------|
| -Term Compone | nt | | |
| Coefficient | Source | | Variable |
| 0.0 | NotUsed | • | · · · |
| | NotUsed | - | |
| -Term Definition- | | | |
| -0.014100 | * 1.0 | * 1.0 | + * |
| -0.959000 | * Patient:wgt_ratio_m | * 1.0 | |
| -1.504100 | * Patient:wgt_ratio_q1 | * 1.0 | + <u>-</u> |
| 0.246400 | * Patient:wgt_ratio_q2 | * 1.0 | + |
| -0.286000 | * Patient:wgt_ratio_q3 | * 1.0 | + |
| -0.112400 | * Patient:abo_compat | * 1.0 | + |
| 0.316900 | * Patient:can_stat_1a | * 1.0 | + |
| -0.607900 | * Patient:can_stat_1b | * 1.0 | + |
| -0.122300 | * Patient:can_age_lt_10 | * 1.0 | + |
| -0.214300 | * Patient:can_age_10_20 | * 1.0 | + |
| -0.270400 | * Patient:can_age_20_30 | * 1.0 | + |
| -0.160000 | * Patient:can_age_30_40 | * 1.0 | + |
| -0.224600 | * Patient:can_age_40_50 | * 1.0 | + • |
| | | | |
| | | | OK Cancel |

Please select the OK or Cancel button once to return to the Model Parameter Specification panel, and then choose the Post-Graft Survival tab to continue.

Model Parameter Specification

Post-Graft Survival

Post-graft survival time and intermediate patient status changes are determined by model input. The mechanism for specifying these post-graft survival parameters is described in detail in the following pages.

| andom Number | Generator Acceptance | Post-Graft Survival | | |
|------------------|--|---------------------|----|--------|
| Survival Definit | | | | |
| | Heart Recipients Heart/Lung Recipients Lung Recipients | | | |
| | | | ок | Cancel |

Highlight one of the sample Survival models and select the edit button.

The Calculation Name and Patient Group tabs on the next screen are similar to the Rule Name and Rule Group tabs in the Allocation Rule Specification. Please refer to the Allocation Rule Specification, earlier in this chapter, for more information on those two tabs.

Please choose the Covariates tab to continue the post-graft survival definitions.

Covariates

The post-graft survival equations are also specified by the user. The user defines an equation for each patient group they've defined. This equation represents either the placement into a step table from a Cox model, or the calculation of a Weibull function.

The equation, similar to the acceptance equations, may be made up of scalar variables, organ characteristics, patient characteristics, and/or calculations that depend on information from both the organ and the patient. Each time a transplant is performed in the allocation run, this equation is solved, and the resulting value is combined with a random number, with the result then being used to determine the organ failure date.

| Calculation Name | Patient Group Covariates Survival | Functio | on Outcomes | | |
|------------------|--------------------------------------|---------|-------------|-----|--------|
| -Term Compone | nt | | | | |
| Coefficient | Source | | Variable | | |
| 0.0 | NotUsed | - | | - | |
| , | | _ | | | |
| | NotUsed | • | | - | |
| | , | | | | |
| Term Definition | | | | | |
| -0.160942 | ,,,,,, | 1.0 | | + 🔺 | 11 |
| 0.390476 | | 1.0 | | + | |
| -0.343414 | _ | 1.0 | | + | |
| -0.064821 | _ | 1.0 | | + | |
| 0.232317 | | 1.0 | | + | |
| 0.296168 | | 1.0 | | + = | |
| 0.179779 | | 1.0 | | + | |
| 0.548747 | * Patient:can_drug_treat_hyperten_r* | | | + | |
| 0.262109 | * Patient:can_drug_treat_hyperten_)* | 1.0 | | + | |
| 0.230338 | * Patient:yr3volume_lt_10 * | 1.0 | | + | |
| 0.560149 | * Patient:can_has_vad * | 1.0 | | + | |
| -0.123701 | * Organ:don_age_lt_18 * | 1.0 | | + | |
| 0.198112 | * Organ:don_age_40_50 * | 1.0 | | + * | |
| | | | | | |
| | | | | | 1 |
| | | | OK | | Cancel |
| | | | | | |

Please select the Survival Function tab to continue.

Survival Function – Cox Model Step Function

On this screen, you may choose between a Cox model step function and a Weibull distribution for determining the graft failure date. If the Cox model is chosen, then steps must be entered indicating the postgraft survival steps and associated failure times. Please refer to Chapter 5, Modeling Post-graft Survival, Graft Failures and Relistings for more information about post-graft survival input.

| Calculation Name Pa | tient Group Covariates | Survival Function | Outcomes | | |
|---------------------|------------------------|-------------------|-----------------|----|--------|
| Survival Function | | | | | |
| Function | | | | | |
| StepFunc | • | | | | |
| | | | | | |
| Step Function | | | | | |
| 1.000000 | 0.00 Days | | | | |
| 0.995270 | 0.00 Days | | | | |
| 0.989808 | 1.00 Days | | | | |
| 0.987294 | 2.00 Days | | | | |
| 0.985920 | 3.00 Days | | | | |
| 0.983397 | 4.00 Days | | | | |
| 0.981556 | 5.00 Days | | | | |
| 0.979483 | 6.00 Days | | | | |
| 0.977868 | 7.00 Days | | | | |
| 0.976251 | 8.00 Days | | | Ψ. | |
| Maha | | | Time Units Dave | | |
| Value | Time | | Time Units Days | - | • |
| | | | | | |
| | | | | 1 | 1 |
| | | | OK | | Cancel |
| | | | | | |

Survival Function – Weibull Function

If a Weibull function is chosen, you must enter the type of formulation you'd like to use for the Weibull equation. Each type of formulation requires that you enter two parameters – either shape and intercept, or shape and scale. Please refer to Chapter 4, Modeling Post-graft Survival, Graft Failures and Relistings for more information about post-graft survival input.

| Calculation Definition | |
|--|--------|
| Calculation Name Patient Group Covariates Survival Function Outcomes | |
| Survival Function | |
| Function | |
| Weibull | |
| Weibull Parameters | |
| Shape | |
| | |
| Scale Weibull Model Formulation | |
| PH: exp[-scale * t^shape] | |
| | |
| | |
| | |
| | |
| | |
| | |
| OK | Cancel |
| ОК | Cancer |
| | |
| 8 | |

Please choose the Outcomes tab to continue.

Outcomes

Each row in the Time to Graft Failure section represents one step in a step table, and an associated organ failure date (which is equivalent to death date). Here, we will associate a set of outcomes with each step. Each outcome has a probability, also defined by the user. In order to see the Outcome Distribution for a particular step, you must highlight the step, and then select the edit button to the right of the Time to Graft Failure.

Each outcome has a probability, and the number of days prior to failure at which this outcome will occur. In addition, if the type of outcome is relist, there may be one or more status updates between relisting and organ failure. These are also defined by the user, and are shown on the next page.

As an example, suppose a patient gets transplanted and arrives at this outcome step table with a failure time of 246 days after transplant. Another random number is drawn, and the patient is assigned an outcome from the list at the bottom of the screen. Let's suppose this patient ended up in Relist Group 2. Therefore, at 220 days prior to organ failure, this patient will relist. The patient may also have status updates, which we will see on the next page.

| 👌 Calculatio | on Definition | | | | |
|---------------|----------------------------|----------------------|------------------|-----------------|--------|
| Calculation N | lame Patient Group Co | ovariates Survival | Function Outcome | es | |
| Time to Gra | ift Failure | | | | |
| 243.00 | | | | - | |
| 244.00 | • | | | | |
| 248.00 | | | | Ē | |
| Cutcome Ti | ime Step | | | | |
| | | ne Units Days | - | | • |
| Outcome D | istribution for Time Step- | | | | |
| Туре | Outcome | Probability | Nominal Weight | Days to Failure | |
| Death | Death | 0.97 | 0.97 | 0.0 | |
| Relist | Relist Group 1 | 0.01 | 0.01 | 240 | |
| Relist | Relist Group 2 | 0.01 | 0.01 | 220 | |
| Relist | Relist Group 3 | 0.01 | 0.01 | 200 | |
| | | | | | |
| | | | | | |
| | | | | ок | Cancel |
| | | | | | |
| | | | | | |
| | | | | | |

Status Updates

Updates

All status updates that you would like for this patient to receive subsequent to transplant should be defined on this screen. Each update is relative to the date on which the patient is scheduled to relist, which is relative to the organ failure date. Possible status updates are changes to Urgency Status, a change to the list of organs for which the patient is waiting, or changes in patient characteristics.

In our example, above, the patient will relist 220 days before organ failure. On that date, their heart status will be set to 1B. At 130 days before organ failure (90 days after relist), the patient's status will change again. At 246 days after transplant, the patient's graft will fail (from the time to graft failure on the previous page) unless the patient gets a second transplant prior to that date.

| tatus Updates lates | | | | | | | | _ [| |
|------------------------|------------|------------|-------------|--------------|-------------|-------------|--------------|------|--|
| utcome | | | | | | | | | |
| Relist | 220 Days | | | | | | | | |
| í Itatus Updates | | | | | | | | | |
| Days After Relist | Need Heart | Need Lungs | Need Left L | Need Right I | Need Either | Need Both I | Heart Statu: | Lung | |
| 0 | | | | | | | 18 | | |
| 90 | | | | | | | 1A | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| • | | | | | | | | F | |
| | | | | | | | | | |
| | | | | | | 1 | | | |
| | | | | | | ЭК | Can | cel | |
| | | | | | | | | | |

Run Specification

Specification

The final step is to specify the destination of outputs. The current output destination can be viewed next to the Specify Output Destination button of the Specification tab.

| [Run Specif | ication | | | | X |
|----------------|----------------------------|------------------------|---------|--------|---|
| Identification | Specification | | | | |
| Model Speci | fication | | | | |
| 67 | Specify Input Streams | | | | |
| 1. 1. | Specify Allocation Rules | | | | |
| P X | Specify Model Parameters | | | | |
| 5 | Specify Output Destination | C:\SRTR\TSAM\TSAMv4.0\ | Output\ | | I |
| | | | | | |
| 40 | Run the Model | | ок | Cancel | |
| | | | | | |

Choose the Specify Outcome Destination button, and the Specify Output Directory dialog appears.

Run Specification

Specify Output Directory

The simulation creates output files for each Allocation Run in the selected directory. The file names are those used in the source code. The model assigns each output file a different name by prefixing the model short name of the Allocation Run. See Chapter 7 for more details.

This screen operates with the usual conventions of a Windows save dialog. The process for selection or creation of an output folder should be familiar to Windows users.

| Computer | ► Local Disk (C:) ► SRTR ► TSAM ► TSAM | 4.0 Vutput | | ✓ ✓ Search Outpu | t |
|------------------------|--|-------------------|----------|------------------|---|
| Organize 🔻 New folder | | | | | • |
| 🔆 Favorites | Name | Date modified | Туре | Size | |
| | Cur20032005Death.out | 5/10/2011 9:29 AM | OUT File | 10,173 KB | |
| 潯 Libraries | Cur20032005Graft.out | 5/10/2011 9:29 AM | OUT File | 5,661 KB | |
| Documents | Cur20032005Grpat.out | 5/10/2011 9:29 AM | OUT File | 21,923 KB | |
| 👌 Music | Cur20032005Relist.out | 5/10/2011 9:29 AM | OUT File | 3 KB | |
| Pictures | Cur20032005Remove.out | 5/10/2011 9:29 AM | OUT File | 4,982 KB | |
| 📑 Videos | Cur20032005Summary.out | 5/10/2011 9:29 AM | OUT File | 32 KB | |
| | Cur20032005Wait.out | 5/10/2011 9:29 AM | OUT File | 47,262 KB | |
| 💺 Computer | | | | | |
| 📭 Network | | | | | |
| File name: Output. | | | | | |
| Save as type: Output F | files (".out) | | | | |

The example lists the output files from an Allocation Run named Cur2006. You also may find it useful to create new folders to hold the inputs and outputs of different sets of Allocation Runs.

Select Save to return to the Allocation Run Specification screen.

Running the Model

We have visited the screens that specify the input data for the model and have returned to the Run Specification screen.

Run Specification

Now all the Allocation Run parameters are set, and we can run the model.

| T Run Specification | | | 23 |
|--|----|-------|----|
| Identification Specification | | | |
| Model Specification | | | |
| Specify Input Streams | | | |
| Specify Allocation Rules | | | |
| Specify Model Parameters | | | |
| Specify Output Destination C:\SRTR\TSAM\TSAMv4.0\Output\ | | | |
| | | | |
| Run the Model OK | Са | incel | |
| | | | |

Select the Run the Model button. The Run Progress screen appears.

Run Progress

At this screen, you can select the number of replications to run and, optionally, you can choose to Log Events and/or Log Updates. You can also choose to log the organ offers that are made by marking the box next to Log Match. Please note that the match offers log file can get quite large, so if you are running multiple replications, you may want to avoid logging the match offers. See Chapter 7 for more details about these options.

Then choose Start. You will see the summary statistics and progress bars updated periodically as the Allocation Run progresses. While the model is processing, the Start button changes to a Stop button. This permits you to interrupt the Allocation Run process if considered necessary. The Start and Stop button changes to a faded Done message and the total running time is displayed in the Current Event box when the Model Allocation Run is complete.

The random number seed stream is initialized before the first replication. Subsequent iterations just continue drawing from that stream where the previous iteration left off.

| Run Progress | |
|---|---------------------|
| Progress | |
| Run Start Model End Time Log Match Log Events Replications 05/01/2003 00:00:00 05/01/2004 00:00:00 Log Updates 1 | Start |
| Current Replication Summary Statistics | |
| Transplants Discards Initial Waitlist New Listings Removals Waitlist Description Isolated Heart Image: Comparison of the second sec | aths Final Waitlist |
| Isolated Lungs | |
| Heart-Lung | |
| Progress | |
| Current Event | |
| Current Replication | |
| Current Status | |
| | |
| Summary | Close |
| | |

At the completion of the Allocation Run, you may view the summary statistics by selecting the Summary button. (Summary statistics also are recorded in an output file.) From the Summary screen, the Close button returns you to the Run Progress screen.

When finished with the Allocation Run, select the Close button. You will be taken to the Allocation Run Specification screen. Closing out of that screen takes you back to the Thoracic Simulated Allocation Model main screen.

Main Screen

Upon returning to the main screen, you have several options. If you have no more Allocation Runs to perform, select the Exit button, and the program will terminate.

| Thoracic Simulated Allocation Model Version 4.1.5 | |
|--|--------|
| Runs Generation | |
| Current Rules, Cohort May 1, 2003 through April 30, 2005 | |
| |) M |
| | |
| | Ē |
| | |
| | Queue |
| | |
| Summary | Exit |
| | |

If you have just defined a new Allocation Run package, its name will be listed on the main screen, along with the names of any previously defined packages. You may start another Allocation Run by selecting one of the listed Allocation Run packages and then selecting the Open Box button. This will take you to the Run Specification screen, where you may run that package or edit its definition. Other button options are to create another new Allocation Run package, duplicate an Allocation Run package, delete an Allocation Run package from the list, run a Queue or create a Summary file

Four options are allowed on run packages:

- Create a new Allocation Run package (wrapped package)
- Open the selected Allocation Run package (open box)
- Copy the selected Allocation Run package (two wrapped packages)
- Delete the selected Allocation Run package (lightning bolt destroying package)

1.7 Queue

The Queue feature allows the user to select multiple models to run one after another without any more user input. The user specifies the models, their order and their settings and then the program does all the runs and returns to the Queue screen.

| To | open | it, se | lect tl | he Ç | Jueue | button | at the | TSAM | main s | screen. | |
|----|------|--------|---------|------|-------|--------|--------|------|--------|---------|--|
| | | | | | | | | | | | |

| T Queue | | | 23 |
|---|-----------|------|----|
| Queue | | | |
| Current Rules, Cohort May 1, 2003 throu | | | |
| V # of Iterations 1 Constraints Log Match | | | |
| Log Events | | | |
| Reset Log Updates Ap | ply to Al | | |
| Specify Queue Summary Output C:\SRTR\TSAM\TSAMv4.0\QueueSummary.csv | | | |
| Run Queue | E | Exit | |

All the models are listed when the Queue is opened. The user can use the buttons in the middle to change their order (runs go from top to bottom), remove runs or reset the queue. They can select options for each model on the right side, and apply the settings to all models in the queue.

After the run is completed, the Queue creates a QueueSummary.csv file which has all the model summary files in an Excel-friendly format.

To run the queue, select the Run Queue button on the bottom left. After the queue is completed, the program will return to the queue screen, informing the user of the run time and if any errors occurred.

1.8 Summary

The Summary feature allows the user to create an output file from any available model summaries.

To open it, select the Summary button on the bottom left of the main screen of the TSAM.

| T Create Summary | _ 0 | 22 |
|--|------|----|
| Summary Output | | |
| Current Rules, Cohort May 1, 2003 through April 30, | | |
| V | | |
| remove | | |
| Reset | | |
| Specify Output Destination C:\SRTR\TSAM\TSAMv4.0\OutputSummary.csv | | |
| Create Summary | Exit | |

The program scans the models and checks if an output summary exists in the model's specified location (for example, if you create a model called and specify to place output in My Documents\ TSAM Output, the program will look for the output summary in that folder). The user will see the models for which the output summary exists.

The user can select the order, remove models or reset the list. They can also select the OutputSummary destination.

Select the Create Summary button on the bottom left to create the summary file. The file is in .csv format.

1.8 Viewing Output Files

The simulation creates output files for each Allocation Run, and it assigns file names by appending the short title of the Allocation Run before a specific identifier. For example, the file xxxGraft.out contains the list of transplants (grafts) that were performed when an Allocation Run titled "xxx" was run.

To view the output files, you can use Excel or another spreadsheet application and open the file with the vertical bar "]" as the **delimiter.**

2 Overview

This chapter provides an overview of both the modeling methods and the way computation is organized in the prototype of the organ allocation model. The discussion includes the basic modeling approach (including which processes are random in the model), the top-level organization of the model, the main data structures referenced by the model, and the event handler routines.

2.1 Basic Approach and Random Processes

The model simulates the organ allocation system with an event-sequenced Monte Carlo technique. That is, some of the modeled processes are random in nature, and the model samples pseudo-random numbers to simulate a realization of processes over the specified time period. Each such realization of the organ allocation system constitutes a single replication. The model generates a user-specified number of replications, saves the detailed histories of these replications in user-specified files, and describes the set of replications in terms of the means, medians, and standard deviations of selected variables.

Some important assumptions:

- 1. Arrivals of candidates are input to the model with a data file.
- 2. The initial wait list is input to the model with a data file.
- 3. An entire history of wait-list status changes (to the end of the Allocation Run, death, or removal from the wait-list) must be input to the model for each patient (medical urgency status changes, time of removal, and time of death). This is the history that will be used for the patient up until the time (if any) that the patient is allocated a transplant during the simulation. Note that this history does NOT specify the time of a transplant. This history can be based on actual experience, although a hypothetical history must be prepared for transplanted patients to tell what would have happened to them had they not received a transplant. Alternatively, the histories can be based on data generated from hypothesized models.
- 4. Once a candidate receives an organ, that patient's input stream of status changes no longer applies. If the patient relists, the model assigns a status change history to the patient by randomly selecting a set of status changes from a pool of user-defined histories specifically provided for this purpose.
- 5. The values of several other parameters are specified in the program or tables and remain constant during a run. These include the parameters of the graft failure time distribution and the geographic membership relationships among institutions, local units (OPOs), and zones. For example, it is assumed that patients do not move among institutions, and institutions do not change affiliation with OPOs. Because these parameters and relationships are controlled by input data, they can vary from case to case.

As items 1-4 state, the model represents several important processes – candidate and organ arrivals and changes of medical urgency status – through user input. Sample histories of these processes must be created outside the model (e.g., historical data) and formatted into time-ordered streams of records for input to the model.

Other processes are represented internally to the model. The following processes are simulated within the model using Monte Carlo techniques, i.e., a pseudo-random number generator:

- 1. Organ acceptance: The user defines a calculation used to compute the organ acceptance probability. Values that may be used in this calculation are scalar variables, characteristics of the organ or donor, characteristics of the potential organ recipient, and/or values that are calculated from characteristics of the specific organ and patient combination under consideration. For each patient to whom the organ is offered, this calculation is performed, and the resulting value, $X\beta$, is transformed using an inverse logit transformation ($\exp(X\beta)/1+\exp(X\beta)$). That value is then compared to a random number between 0 and 1. If the random number is less than this value, then the organ is accepted, otherwise it is refused. An organ is said to have been discarded after it is either offered to all potential recipients (up to the maximum organ offer count specified on the Acceptance Definitions panel) and each of those offers has been refused.
- 2. Post-graft survival: Post-graft survival is also specified by the user in the model. The user defines a calculation which is then used to determine the patient's death date after a transplant. The calculation, once again, may be made up of scalar variables, organ characteristics, patient characteristics, and/or calculations that depend on information from both the organ and the patient. Each time a transplant is performed in the model, this calculation is performed and the resulting value is combined with a random number, the result of which is used to determine the death date, using the method chosen by the user either a Cox proportional hazard model or a Weibull distribution. A set of possible outcomes and their relative probabilities is associated with each death date. The possible outcomes are relisting at differing times prior to the death date and with differing medical characteristics, or not relisting.

Here, a relisted graft recipient is one who received a graft during the time span of the simulation, not necessarily one who enters the model with a prior graft. The latter set of individuals will enter the model on the arrival stream or in the initial wait list, and valid records will presumably exist for these individuals in the status change input stream (until such time as the simulation awards new grafts to these individuals).

The model draws all random numbers from a single random number stream.

2.2 Top Level Overview

Event Queues

The simulation maintains time-ordered queues of several kinds of events, from which it can pick the next event in order for processing:

- 1) organ arrivals (input-driven)
- 2) status changes for wait list candidates who have not yet received grafts (input-driven)
- 3) patient arrivals (input-driven)
- 4) status changes for relisted graft recipients (sampled from a pool of possible outcomes)
- 5) relisting events of recipients whose grafts fail (sampled by the model)
- 6) deaths of graft recipients not on the wait list (sampled by the model)

Note that status change events include changes that indicate the patient has been removed from the waitlist or has died while on the waitlist.

2.3 Event Handlers

Organ Arrival Event

This event handler selects a candidate to receive the organ that has become available. It applies the allocation rules that have been defined in the model. It performs the match run by reordering the wait list according to the rules and offering the organ to candidates in order. It simulates the organ acceptance process by sampling from a uniformly distributed random variable and comparing this to the probability of acceptance, which is calculated using acceptance inputs to the model. If no candidate accepts the organ, the organ is discarded. If the organ is accepted, the event handler removes the recipient from the wait list. Whatever the outcome, the event handler writes a record with the results of the match run.

Heart-lung candidates are on both the heart waiting list and the lung waiting list. The allocation rules for a combined heart-lung package allocate to either the heart list or the lung list, depending upon the heart-lung allocation rules which are input to TSAM. If the patient who accepts the organ package needs both the heart and lungs, they get both. If they need only a heart, for example, they take the heart and the remaining organ(s) become the next organ allocation. If the organ package being offered includes only a heart, it is offered to the heart list excluding heart-lung candidates. If the organ package includes only a lung (or double lungs), it is offered to the lung list excluding heart-lung candidates.

The event handler places the recipient on a list of graft recipients and schedules a death event for the recipient. It uses the model (as described in Chapter 4) to determine a possible outcome prior to death and the time that will elapse until this outcome. It then schedules the outcome events, which could include a relisting and possibly some post-graft status change events. Please note that these status change events are defined differently in the model from those that take place prior to transplant. The latter are described next.

Status Change Event

The status change file contains records that describe the medical status history of every wait list candidate from the time of the candidate's arrival to the model (either the initial wait list snapshot or arrival to the wait list) until the candidate's death. This history is valid until such time as the candidate may receive a graft. If a transplant recipient relists, the recipient's status history is provided by a different source. Whichever source of status changes applies, the model invokes the status change event handler when a status change event occurs.

If the candidate's medical status has changed, the model updates variables that keep track of the time that the candidate has been in the previous medical status. The event handler updates the candidate's medical status to the new value and updates other variables that keep track of status occupancy time.

If the new status is 9 (removal), the event handler removes that candidate from the wait list and places the candidate on a list of removed patients. If the new status is 8 (death), the event handler removes the candidate from the wait list and writes an outcome record for the patient. If the patient dies after removal from the wait list, the model removes the patient from the list of living removed patients.

Candidate Arrival Event

This event occurs when a patient joins the wait list. When this happens, the event handler places the patient on the wait list and initializes all descriptions of the candidate, e.g., demographic descriptors, medical status, previous transplantation status, and institution where listed. The specifications of the candidate arrival record appear in Chapter 6 of this guide.

Post-Transplantation Events

When a patient receives a graft (i.e., at the time of an organ arrival event), the simulation samples the future time of graft failure and determines whether the patient will relist or not. The simulation accordingly schedules the patient's death and, potentially, the relist event. The event handler for post-transplantation events processes these events.

In the case of a death event, the event handler removes the patient from the list of living graft recipients and writes an outcome record. In the case of a relisting event, the simulation removes the patient from the list of non-wait-listed graft recipients and adds the patient to the wait list. A status change history was already selected for the patient at the time of the organ arrival event, and the event handler initializes the patient's medical status to the initial set of values provided in this history.

2.4 Limitations

As discussed at the beginning of this chapter, TSAM relies on the inputs selected at runtime to simulate liver allocation. Any bias or omissions in the input data may affect simulation results. In addition to this general caveat, several specific limitations are worth noting when using TSAM and interpreting its results.

2.4.1 Reliance on Historical Data

TSAM uses statistical models to simulate multiple parts of the organ allocation process. These models were trained on historical data from OPTN and SRTR transplant archives; thus, they may not respond to changes in allocation policy in the same way the real system would. This is particularly true of the organ acceptance model, which simulates the decision-making behavior of patients and clinicians based on historical acceptance data. LSAM also does not identify trends over time in the training data, so gradual changes in the characteristics of donors and candidates will not be reflected in TSAM results.

2.4.2 Standardized Behavior

The OPTN allocation guidelines are extensive, but they do not eliminate all ambiguity. In practice, there is some amount of variation in policy and behavior between different OPOs and transplant centers. However, TSAM assumes that all centers and OPOs implement allocation policies in the same way and exhibit the same organ acceptance behavior. TSAM also does not model any directed or expedited allocation of donated organs.

2.4.3 Status Matching and HCC

Patients who underwent transplant in real life have no status updates in their patient records past the transplant date, so status updates from other patients were appended to fill out their TSAM patient histories in the SRTR-provided status input file. These patients are matched on expected mortality but not on specific diagnosis, so TSAM's ability to predict outcomes in diagnosis subgroups (such as HCC patients) is limited.

2.4.4 Single Listings, Single Organs

TSAM does not model patients who list at multiple transplant centers or who are listed for multiple organs. TSAM also does not model multi-organ transplants or split livers.

2.4.5 Discards

Organs are discarded after a fixed number of declined offers, regardless of organ and donor characteristics.

3 Allocation Rules

The model is sufficiently flexible to allow the user to specify a wide range of allocation policies through the input files that are provided specifically for that purpose.

3.1 Zones

A patient and potential donor are considered 'local' if they are within the same OPO. If they are not local, but are within 500 miles of each other, then they are defined to be within Zone A. They are in Zone B if they are within 1000 miles of each other but greater than 500 miles from each other, and Zone C if they are further than 1000 miles apart.

- Local Same OPO
- Zone A within 500 miles
- Zone B within 1000 miles
- Zone C within 1500 miles
- Zone D within 2500 miles
- Zone E further than 2500 miles

3.2 Heart (with or without lungs) Allocation Order

Adult Donors

The rule offers a heart and possibly one or both lungs from an adult donor to candidates in the following order of classification, and it allocates the organs to the highest priority candidate who accepts them. Note that heart-lung patients will also be offered the organ package if it contains lungs in addition to the heart.

- 1. Local, status 1A, ABO-identical patients in descending wait time order.
- 2. Local, status 1A, ABO-compatible patients in descending wait time order.
- 3. Local, status 1B, ABO-identical patients in descending wait time order.
- 4. Local, status 1B, ABO-compatible patients in descending wait time order.
- 5. Local, status 2, ABO-identical patients in descending wait time order.
- 6. Local, status 2, ABO-compatible patients in descending wait time order.
- 7. Zone A, status 1A, ABO-identical patients in descending wait time order.
- 8. Zone A, status 1A, ABO-compatible patients in descending wait time order.
- 9. Zone A, status 1B, ABO-identical patients in descending wait time order.
- 10. Zone A, status 1B, ABO-compatible patients in descending wait time order.
- 11. Zone B, status 1A, ABO-identical patients in descending wait time order.
- 12. Zone B, status 1A, ABO-compatible patients in descending wait time order.
- 13. Zone B, status 1B, ABO-identical patients in descending wait time order.
- 14. Zone B, status 1B, ABO-compatible patients in descending wait time order.
- 15. Zone A, status 2, ABO-identical patients in descending wait time order.
- 16. Zone A, status 2, ABO-compatible patients in descending wait time order.
- 17. Zone B, status 2, ABO-identical patients in descending wait time order.
- 18. Zone B, status 2, ABO-compatible patients in descending wait time order.
- 19. Zone C, status 1A, ABO-identical patients in descending wait time order.
- 20. Zone C, status 1A, ABO-compatible patients in descending wait time order.
- 21. Zone C, status 1B, ABO-identical patients in descending wait time order.
- 22. Zone C, status 1B, ABO-compatible patients in descending wait time order.

- 23. Zone C, status 2, ABO-identical patients in descending wait time order.
- 24. Zone C, status 2, ABO-compatible patients in descending wait time order.
- 25. Zone D, status 1A, ABO-identical patients in descending wait time order.
- 26. Zone D, status 1A, ABO-compatible patients in descending wait time order.
- 27. Zone D, status 1B, ABO-identical patients in descending wait time order.
- 28. Zone D, status 1B, ABO-compatible patients in descending wait time order.
- 29. Zone D, status 2, ABO-identical patients in descending wait time order.
- 30. Zone D, status 2, ABO-compatible patients in descending wait time order.
- 31. Zone E, status 1A, ABO-identical patients in descending wait time order.
- 32. Zone E, status 1A, ABO-compatible patients in descending wait time order.
- 33. Zone E, status 1B, ABO-identical patients in descending wait time order.
- 34. Zone E, status 1B, ABO-compatible patients in descending wait time order.
- 35. Zone E, status 2, ABO-identical patients in descending wait time order.
- 36. Zone E, status 2, ABO-compatible patients in descending wait time order.

Within each classification, the rule offers the organs to candidates according to length of waiting time. For an adult donor, each classification is drawn from both adult and pediatric candidates.

Pediatric Donors (Child or Adolescent)

The rule offers a heart and, possibly, one or both lungs from a pediatric donor to candidates in the following order of classification, and it allocates the organ(s) to the highest priority candidate who accepts them. Note that heart-lung patients will also be offered the organ package if it contains lungs in addition to the heart. The policy, as implemented in the input files supplied with this version of the model, splits each priority level into pediatric followed by adult:

- 1. Local, status 1A, ABO-identical pediatric patients in descending wait time order.
- 2. Local, status 1A, ABO-identical adult patients in descending wait time order.
- 3. Local, status 1A, ABO-compatible pediatric patients in descending wait time order.
- 4. Local, status 1A, ABO-compatible adult patients in descending wait time order.
- 5. Local, status 1B, ABO-identical pediatric patients in descending wait time order.
- 6. Local, status 1B, ABO-identical adult patients in descending wait time order.
- 7. Local, status 1B, ABO-compatible pediatric patients in descending wait time order.
- 8. Local, status 1B, ABO-compatible adult patients in descending wait time order.
- 9. Local, status 2, ABO-identical pediatric patients in descending wait time order.
- 10. Local, status 2, ABO-identical adult patients in descending wait time order.
- 11. Local, status 2, ABO-compatible pediatric patients in descending wait time order.
- 12. Local, status 2, ABO-compatible adult patients in descending wait time order.
- 13. Zone A, status 1A, ABO-identical pediatric patients in descending wait time order.
- 14. Zone A, status 1A, ABO-identical adult patients in descending wait time order.
- 15. Zone A, status 1A, ABO-compatible pediatric patients in descending wait time order.
- 16. Zone A, status 1A, ABO-compatible adult patients in descending wait time order.
- 17. Zone A, status 1B, ABO-identical pediatric patients in descending wait time order.
- 18. Zone A, status 1B, ABO-identical adult patients in descending wait time order.
- 19. Zone A, status 1B, ABO-compatible pediatric patients in descending wait time order.
- 20. Zone A, status 1B, ABO-compatible adult patients in descending wait time order.
- 21. Zone B, status 1A, ABO-identical pediatric patients in descending wait time order.
- 22. Zone B, status 1A, ABO-identical adult patients in descending wait time order.
- 23. Zone B, status 1A, ABO-compatible pediatric patients in descending wait time order.
- 24. Zone B, status 1A, ABO-compatible adult patients in descending wait time order.
- 25. Zone B, status 1B, ABO-identical pediatric patients in descending wait time order.

26. Zone B, status 1B, ABO-identical adult patients in descending wait time order. 27. Zone B, status 1B, ABO-compatible pediatric patients in descending wait time order. 28. Zone B, status 1B, ABO-compatible adult patients in descending wait time order. 29. Zone A, status 2, ABO-identical pediatric patients in descending wait time order. 30. Zone A, status 2, ABO-identical adult patients in descending wait time order. 31. Zone A, status 2, ABO-compatible pediatric patients in descending wait time order. 32. Zone A, status 2, ABO-compatible adult patients in descending wait time order. 33. Zone B, status 2, ABO-identical pediatric patients in descending wait time order. 34. Zone B, status 2, ABO-identical adult patients in descending wait time order. 35. Zone B, status 2, ABO-compatible pediatric patients in descending wait time order. 36. Zone B, status 2, ABO-compatible adult patients in descending wait time order. 37. Zone C, status 1A, ABO-identical pediatric patients in descending wait time order. 38. Zone C, status 1A, ABO-identical adult patients in descending wait time order. 39. Zone C, status 1A, ABO-compatible pediatric patients in descending wait time order. 40. Zone C, status 1A, ABO-compatible adult patients in descending wait time order. 41. Zone C, status 1B, ABO-identical pediatric patients in descending wait time order. 42. Zone C, status 1B, ABO-identical adult patients in descending wait time order. 43. Zone C, status 1B, ABO-compatible pediatric patients in descending wait time order. 44. Zone C, status 1B, ABO-compatible adult patients in descending wait time order. 45. Zone C, status 2, ABO-identical pediatric patients in descending wait time order. 46. Zone C, status 2, ABO-identical adult patients in descending wait time order. 47. Zone C, status 2, ABO-compatible pediatric patients in descending wait time order. 48. Zone C, status 2, ABO-compatible adult patients in descending wait time order. 49. Zone D, status 1A, ABO-identical pediatric patients in descending wait time order. 50. Zone D, status 1A, ABO-identical adult patients in descending wait time order. 51. Zone D, status 1A, ABO-compatible pediatric patients in descending wait time order. 52. Zone D, status 1A, ABO-compatible adult patients in descending wait time order. 53. Zone D, status 1B, ABO-identical pediatric patients in descending wait time order. 54. Zone D, status 1B, ABO-identical adult patients in descending wait time order. 55. Zone D, status 1B, ABO-compatible pediatric patients in descending wait time order. 56. Zone D, status 1B, ABO-compatible adult patients in descending wait time order. 57. Zone D, status 2, ABO-identical pediatric patients in descending wait time order. 58. Zone D, status 2, ABO-identical adult patients in descending wait time order. 59. Zone D, status 2, ABO-compatible pediatric patients in descending wait time order. 60. Zone D, status 2, ABO-compatible adult patients in descending wait time order. 61. Zone E, status 1A, ABO-identical pediatric patients in descending wait time order. 62. Zone E, status 1A, ABO-identical adult patients in descending wait time order. 63. Zone E, status 1A, ABO-compatible pediatric patients in descending wait time order. 64. Zone E, status 1A, ABO-compatible adult patients in descending wait time order. 65. Zone E, status 1B, ABO-identical pediatric patients in descending wait time order. 66. Zone E, status 1B, ABO-identical adult patients in descending wait time order. 67. Zone E, status 1B, ABO-compatible pediatric patients in descending wait time order. 68. Zone E, status 1B, ABO-compatible adult patients in descending wait time order. 69. Zone E, status 2, ABO-identical pediatric patients in descending wait time order. 70. Zone E, status 2, ABO-identical adult patients in descending wait time order. 71. Zone E, status 2, ABO-compatible pediatric patients in descending wait time order. 72. Zone E, status 2, ABO-compatible adult patients in descending wait time order.

3.3 Lung Allocation Order

The DefMethods.txt file shows lung allocation by LAS (Lung Allocation Score).

LAS: All Donor Organs Allocated to Candidates By Lung Allocation Score

The rule offers a lung or lungs, and the heart if it is also available, from an adult donor to lung and heartlung candidates in the following order of classification, and it allocates the organ(s) to the highest priority candidate who accepts them:

- 1. Local, ABO-identical adult and adolescent patients in descending LAS order.
- 2. Local, ABO-identical child patients in descending wait time order.
- 3. Local, ABO-compatible adults and adolescent patients in descending LAS order.
- 4. Local, ABO-compatible child patients in descending wait time order.
- 5. Zone A, ABO-identical adult and adolescent patients in descending LAS order.
- 6. Zone A, ABO-identical child patients in descending wait time order.
- 7. Zone A, ABO-compatible adult and adolescent patients in descending LAS order.
- 8. Zone A, ABO-compatible child patients in descending wait time order.
- 9. Zone B, ABO-identical adult and adolescent patients in descending LAS order.
- 10. Zone B, ABO-identical child patients in descending wait time order.
- 11. Zone B, ABO-compatible adult and adolescent patients in descending LAS order.
- 12. Zone B, ABO-compatible child patients in descending wait time order.
- 13. Zone C, ABO-identical adult and adolescent patients in descending LAS order.
- 14. Zone C, ABO-identical child patients in descending wait time order.
- 15. Zone C, ABO-compatible adult and adolescent patients in descending LAS order.
- 16. Zone C, ABO-compatible child patients in descending wait time order.
- 17. Zone D, ABO-identical adult and adolescent patients in descending LAS order.
- 18. Zone D, ABO-identical child patients in descending wait time order.
- 19. Zone D, ABO-compatible adult and adolescent patients in descending LAS order.
- 20. Zone D, ABO-compatible child patients in descending wait time order.
- 21. Zone E, ABO-identical adult and adolescent patients in descending LAS order.
- 22. Zone E, ABO-identical child patients in descending wait time order.
- 23. Zone E, ABO-compatible adult and adolescent patients in descending LAS order.
- 24. Zone E, ABO-compatible child patients in descending wait time order.

Within each classification, the rule offers the organs(s) to adult and adolescent candidates according to LAS and to child candidates according to wait time.

There are similar allocation rules coded for adolescent donors and child donors. Organs from child donors are offered first to child candidates and then to adult or adolescent candidates within each classification. Organs from adolescent donors are offered first to adolescent candidates, then to child candidates and, finally, to adult candidates within each classification.

3.4 Screening Criteria

The rules screen out candidates from consideration for any one of the following reasons:

- 1) **ABO:** donor and candidate types incompatible.
- 2) Weight: donor weight not in candidate's acceptable weight range

- 3) Height: donor height not in candidate's acceptable height range
- 4) **HCV status:** donor's hepatitis C core antibody status is positive and candidate will not accept HCV positive donor
- 5) **Program status:** the heart-lung program at the candidate's transplant center is temporarily inactive
- 6) Candidate status: candidate's status is temporarily inactive

3.5 Heart Medical Status

The following table summarizes the medical statuses for adult patients. For the model, medical status incorporates both the medical urgency status and the removal codes from the SRTR data into one field.

| Status | Definition |
|--------|--|
| 1 | Pre-1999 Medical Urgency Status code for critically ill patients. Pa- tients who were listed as Status 1 at the time the new system was im- plemented became either Status 1A or 1B. |
| 1A | Includes critically ill patients who require continuous high-dose ino- tropic drug therapy or mechanical assistance, if that mechanical assis- tance is less than 30 days in place, has a device-related complication, is a total artificial heart, or is mechanical ventilation Patients with an urgency and potential for benefit similar to the patients defined above (e.g. life expectancy < 7 days without transplant) can also be includ- ed. |
| 1B | Includes medically stable patients who require continuous inotropic drug therapy or mechanical assistance. |
| 2 | Includes patients with chronic heart failure who do not meet the high- er urgency criteria for Status 1A or 1B listing. |
| 7 | Patient is temporarily inactive. Waiting time will not be accrued by patients registered as inactive. |
| 8 | Patient has died while waiting for a transplant. |
| 9 | Patient has been removed from the waiting list and is no longer con- sidered a part of the system. |

The definitions apply to adult candidates. There are different status definitions for pediatric patients. More complete definitions appear on the OPTN Web site ("www.optn.org, Policies/Bylaws, Policies, Section 3.0 Organ Distribution, 3.7 Allocation of Thoracic Organs".)

3.6 Lung Medical Status

The following table summarizes the medical statuses for adult lung patients. The model medical status incorporates both the medical urgency status and the removal codes from the SRTR data into one field.

| Status | Definition |
|--------|---|
| 1 | All patients awaiting isolated lung transplantation are considered to be the same urgency status. |
| 7 | Patient is temporarily inactive. Waiting time will not be accrued by patients registered as inactive. |
| 8 | Patient has died while waiting for a transplant. |
| 9 | Patient has been removed from the waiting list and is no longer con- sidered a part of the system. |

The definitions apply to adult candidates. There are different status definitions for pediatric patients. More complete definitions appear on the OPTN Web site ("http://optn.transplant.hrsa.gov/, Policy Management, Policies, Section 3.7 Organ Distribution: Allocation of Thoracic Organs".)

3.7 ABO Typing for Heart Allocation

Within each heart status category, hearts will be allocated to patients according the following blood type compatibilities:

| | Candidate's Blood Type | | | |
|-------|------------------------|---|---|----|
| Donor | 0 | Α | В | AB |
| 0 | Ι | С | Ι | С |
| Α | Х | Ι | Х | Ι |
| В | Х | Х | Ι | Ι |
| AB | Х | Х | Х | Ι |

- I: Treated as Identical for purposes of allocation
- C: Compatible
- X: Incompatible

3.8 ABO Typing for Lung Allocation

Candidates who have the identical blood type as the donor and are awaiting an isolated lung transplant will be allocated the thoracic organs before candidates who have a compatible blood type and are awaiting an isolated lung transplant.

4 Modeling Post-Graft Survival, Graft Failures and Relistings

For organ allocation, post-transplant survival is an important factor to consider. This section discusses how the simulator, based on model inputs, estimates how long a patient would live should that patient be given a particular organ at a particular time. This can be used to calculate, after a series of model runs, whether a given policy would result in greater organ utility as measured by overall post-transplant survival.

4.1 Time to Graft Failure Determined with a Cox Proportional Hazards Model

This section describes the process for entering the parameters which are required in order for TSAM to determine the time to graft failure using a Cox proportional hazards model.

When a patient receives a graft, the model samples the time, T, remaining before death.

The user specifies the survival model by specifying the model variables and the coefficients of the following survival function:

$$Prob [survival time > T] = S_{j}(T) \xrightarrow{exp(\Sigma b_{..}x_{..}y_{..})}{ij \ ij \ ij}$$

Where:

Sj(T) is a step function specified by the model user,

- j is an indicator for patient group as specified by fields in the patient and organ records. The user may select a different set of variables and coefficient values for each group, e.g. diagnosis-specific survival models,
- b_{ij} is the ith coefficient within group j, i.e. $\Sigma b_{ij}x_{ij}y_{ij}$ = the sum of the product bxy over all covariates (i) within group j,
- xij is either the ith covariate within group j, or the first part of an interaction term within group j, y_{ij} , if specified, is the second part of an interaction term within group

Covariates and Parameters. Each element x_{ij} and y_{ij} is either the value of a model variable or unity. (A model variable here means the value of a variable describing either the recipient or the organ involved in the graft event.) The user selects the variables x_{ij} and y_{ij} , and provides the corresponding coefficients b_{ij} . This is done separately for each patient group.

 $\begin{array}{l} x_{ij}=1 \mbox{ and } y_{ij}=1 \mbox{ implies that this is the intercept term} \\ x_{ij}=\mbox{ variable and } y_{ij}=1 \mbox{ implies that this is an ordinary term within the model} \\ x_{ij}=\mbox{ variable1 and } y_{ij}=\mbox{ variable2 implies that this is an interaction term between variable1 and} \\ \mbox{ variable2} \end{array}$

Survival Time. At each transplantation event, the model determines the remaining survival time, T, by sampling a value u from a U(0,1) distribution and inverting the complementary cumulative probability distribution of the survival time for this patient:

$$\begin{split} \text{Prob} \; [\text{survival time} > T] \; &= S_j(T) \overset{exp(\Sigma b_{ij} x_{ij} y_{ij})}{Ij} \; = \; u \\ T &= S_j^{-1}(exp(\ln(u)/exp(\Sigma b_{ij} x_{ij} y_{ij}))) \end{split}$$

Step Function. The model reads data for $S_j(t_{kj}) = v_{kj}$ in tabular form (separately for each group j). These are specified by the user either in the Default Survival input file, described in Chapter 7, or on the Step Function screen, described in Chapter 1. Specifically, the table includes values of t increasing from t=0 (time of transplant) to t=maxtime and corresponding values of v declining from v=1 (i.e. all patients are alive at time zero) at t=0 to v=0 for the largest t (eventually all the patients will die).

The model reads the N_j time values for group j as input: $0=t_{0j} < t_{1j} < \ldots < t_{N j}$ and the values as $1=v_{0j} > v_{1j} > \ldots > 0=v_{Nj}$.

Note that in any given dataset, it will be rare that all patients are followed until they die. Some patients live a long time and some drop out of contact. The user will have to decide how the survival curve should be extrapolated to $S(t_{Nj}) = 0$ when they create the input file for this step function.

At each graft event, the model samples a value u from a U(0,1) distribution and solves the equation S(T) = u for the survival time T. Solving for the survival time requires putting the sample value, u, into the inverted survival function:

$$T = S^{-1}(u) = S_{j}^{-1}(exp(ln(u)/exp(\Sigma b_{ij}x_{ij}y_{ij})))$$

To perform this inversion, the model first computes the value of the transformed probability v:

$$v = \exp(\ln(u)/\exp(\Sigma b_{ij}x_{ij}y_{ij}))$$

We are guaranteed that $0 \le v \le 1$. The model then uses the step function to determine the corresponding survival time. That is, if the value of v lies between v_{nj} and $v_{n-1,j}$, the survival time is $T = t_{nj}$. This condition will be true for some value of n for n = 1 to N.

The step function for the proportional hazards survival function is the baseline survival curve $s_0(t)$. The step function is a flexible way to approximate survival curves of any shape. It is important to remember to enter the baseline survival function¹ rather than the survival function for the average patient on this screen. In SAS, the baseline survival function can be created as follows:

First, create a separate dataset where all the covariates in the post-transplant survival model are set to zero, e.g.

data covzeros; age = 0; male = 0; weight = 0; height = 0; run;

Then run the post-transplant survival model using this dataset to supply the covariates for the survival curve to be output, e.g.

proc phreg data=analysis_data; model patient_days*died(0) = age male weight height; baseline out = ph_step_function covariates = covzeros survival = survival /nomeans; run;

¹ In the baseline survival function, all covariates in the model are set to zero. This includes covariates that normally cannot equal zero, such as patient weight.

The proportional hazards baseline step function data are now saved in the output dataset ("ph_step_function" in the example above). These data can either be entered into the SAM manually or through an input file ("Default Survival" under "Model Structure").

4.2 Time to Graft Failure Determined with a Weibull Survival Model

This section describes the process for entering the parameters which are required in order for TSAM to determine the time to graft failure using a Weibull survival model.

The Weibull model is one of the exponential families of survival models. A strictly exponential survival model assumes that the same proportion of patients die over the same amount of time, a situation known as having a constant hazard rate. For example, if 10% of the patients die in the first year, then 10% of the remaining 90% will die in the second year, leaving 81% of the original population alive. The parameters entered into the model alter this overall percentage for certain groups of patients, but they do not alter the shape of the curve. For example, older patients may die at a rate of 15% per year while younger patients die at a rate of 5% per year, but in the strictly exponential model both groups are assumed to have this constant mortality rate at all times. Weibull models are more flexible than the strictly exponential models in that their hazard rates can be monotone increasing, decreasing, or constant. This helps model situations like post-transplant mortality, where the hazard is expected to be high at first (due to the operative stresses), then to decrease over time. Aside from the covariates in the model, there are two parameters that define the overall shape of the survival curve, defining this change in the hazard. These two parameters can differ depending on the model formulation.

There are three Weibull model formulations, each corresponding to a commonly-used parameterization of the two Weibull parameters needed. The parameterization to be used depends on the software used to generate the model. For example, SAS output from the lifereg procedure includes the intercept, scale, and shape parameters. In SAS, the scale and the shape parameter are the inverse of each other, so only the shape and the intercept parameters are used in the SAM. If the results of a lifereg procedure in SAS are to be used to describe post-transplant mortality, the formulation used should be the Accelerated Failure Time formulation: "AFT: exp[-exp(shape*(ln(t)-intercept))]". The "shape" and "intercept" should be supplied in the spaces provided. To use another formulation, such as the proportional hazards "PH: exp[-(t/scale)^shape]", use the shape parameter as before and put exp(intercept) in the space provided for the scale. The answers received via each formulation will be identical if the scale and the shape parameters are correctly entered.

4.3 Outcomes

Associated with each survival time in the step function is a table of probabilities for various possible outcomes (death or various relisting events). The model samples a value u from a U(0,1) distribution and compares it with the table of probabilities to determine the outcome.

4.4 Relisting

Associated with each relisting outcome is a time before failure at which relisting occurs, and a sequence of status updates for the relisted patient. The model schedules a relisting event at the specified time before failure, and schedules the status update events. The model also schedules a death event for the patient at the calculated failure time if a retransplant has not occurred.

5 Creating Input Data Files

Please note that the creation of suitable input files is not a trivial task. A number of problems can arise when data from real-world data sets are fed into the model. For example, if a status update file is created from real data, then patients who actually received transplants will not receive any status updates after the date of their transplant. Thus, no patient who actually received a transplant will ever die or get removed from the list in the model, even if this means these patients survive for months or years as status 1A without getting a transplant. In order to obtain realistic results, one should devise a method to generate simulated death or removal dates and status changes for patients who received transplants.

5.1 Validating Input Data

The thoracic model program does not catch inconsistencies in the input data. For instance, if a patient starts with status 1A time longer than total time on the wait list, the program doesn't check to make sure those are consistent.

5.2 Sharing Input Files Among Users

If input files are to be shared among users on different computers, it is important to remember that the Allocation Run Specification file refers to each data file with its full path. Some editing of the file may be needed if the directory organization or location of the application on the target machine is different than on the source machine.

5.3 General Principles for All Input Files

Selecting Time Frame for Data

The model will simulate new arrivals, status changes, deaths, and transplants beginning with the snapshot date on the waitlist input data. Statistics will be reported only for the time period designated by the start and end dates selected when the model is run. Any changes that occur prior to the start date are not reported in the summary statistics. They are, however, applied to the waitlist to make it current at the start date.

Formatting DateTime Fields

Format: (mm/dd/yyyy hh:mm:ss). As the time information is not on the SRTR data, the time portion is randomly generated during the creation of the input files.

Format of Input Files

All input files are ASCII text files, one line per record, vertical bar "|" delimiter separated fields.

5.4 Running Multiple Iterations with Randomized Organ Arrivals

In order to more closely simulate the randomness with which donor organs become available, the user may specify that for each iteration of TSAM, the donor organs will arrive in a different order. The user specifies the organ file that contains "AltOrd1" in its filename as the organ arrivals file. TSAM will then use AltOrd1 for the first iteration, AltOrd2 for the second, and so on. Please refer to section 1.6 for more information

6 Input File Specifications

This section gives the specifications of the input files. Each specification lists fields in the order they occur in a record, followed by an example. The specification of each field gives the name of the field, its data type, and a short definition. (The field names are those used in the source code.)

6.1 Organ Arrivals

Organs.txt contains arrivals of donor organs that become available from the model start date through and including the model end date. Each record contains information about one donor. Each donor can have any combination of heart, left lung, and right lung. Records selected for inclusion: we suggest using dispositions 5 (recovered for transplant but not transplanted) and 6 (transplanted).

Sort order: EventTime ascending.

| Field Name | Data Type | Short Definition |
|---------------------------------|-------------------|---|
| EventTime | DateTime | organ arrival date-time (mm/dd/yyyy hh:mm:ss) |
| ItemID | string | item identifier (donor ID) |
| InstitID | string | institution where donated |
| DonorAge | double | age of donor (same units as in patient record) |
| ABOType | string | ABO blood type of donor (codes defined in blood compatibility file) |
| HasHeart | boolean | Arrival includes a heart (True False) |
| HasLeftLung | boolean | Arrival includes a left lung (True False) |
| HasRightLung | boolean | Arrival include a right lung (True False) |
| WeederFld(1) | double | first referenced weeder field |
| WeederFld(n) WeedFlag(1) | double boolean | nth referenced weeder field first referenced weed flag field |
| WeedFlag(n) | boolean | nth referenced weed flag field |
| OptOrganFld(1) | specified | first specified optional organ data field |
| OptOrganFld(n) | specified | nth specified optional organ data field |

```
Example:
```

 $10/01/2000\ 2:39:28 |OJA010|741|64.6 |A| True |False|False|72.999854|162.3 |False|72.999854|162.3 |False|72.3 |False|72.99984|162.3 |False|72.9998|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|72.9000|$

Note:

The number of weeder fields expected is determined by what is found in the Optional Data Definition file. The order in which they appear here must be the same as the order in which they appear in the Optional Data Definition file. The number and order of weed flag fields are also determined by what is found in the Optional Data Definition file. The number of optional fields expected, and their order, is also determined by what is found in the Optional Data Definition file. Please refer to the section in this chapter which describes that input file for more information.

6.2 Patient Waiting List and Patient Arrivals Files

The Waiting List (waitlist.txt) and Patient Arrivals (patients.txt) files are of the same format. They are both described in this section.

Waitlist.txt contains all candidates on the waiting list (active and inactive) as of the day prior to the model start.

Patients.txt contains new patients added to the wait list with listing dates from the model start date through and including the model end date.

The time portion of the EventTime (hh:mm:ss) had to be randomly set since that information is not in the SRTR data. Sometimes a status change occurs on the same day as a new patient record. As we want all status changes to occur after the new patient listing, we intentionally set all the new patients listings to take place in the AM and the status changes take place in the PM. This insures that all status changes submitted on the same day as a new patient listing will occur after the new listing. Sort order: EventTime ascending.

In order to avoid over-counting, new patients who are relisted after receiving a transplant during the model run time period should be excluded from the input data. Relistings after transplant are simulated in the model.

| Field Name | Data Type | Short Definition |
|------------------|-----------|--|
| SnapDate | DateTime | as-of date for current status of patient (mm/dd/yyyy hh:mm:ss) |
| EventTime | DateTime | patient arrival date-time (mm/dd/yyyy hh:mm:ss) |
| ItemID | string | item identifier (patient ID) |
| CenterID | string | transplantation center identifier |
| PatientAge | double | patient age as of snapdate for initial waitlist file {years} |
| C | | patient age at time of listing for patient arrivals file {years} |
| ABOType | string | ABO blood type (codes defined in blood compatibility file) |
| NeedHeart | boolean | This patient is a candidate for a heart |
| NeedLungs | boolean | This patient is a candidate for a lung or lungs |
| NeedLeftLung | boolean | This patient is a candidate for a left lung |
| NeedRightLung | boolean | This patient is a candidate for a right lung |
| NeedEitherLung | boolean | This patient is a candidate for a either lung |
| NeedBothLungs | boolean | This patient is a candidate for a both lungs |
| OrgHeartStat | string | Original heart medical urgency status {1A 1B 2 7 0} |
| CurHeartStat | string | Current heart medical urgency status {1A 1B 2 7 0} |
| OrgLungStat | string | Original lung medical urgency status {1 7 0} |
| CurLungStat | string | Current lung medical urgency status {1 7 0} |
| HasIPFDiag | boolean | Lung candidate diagnosed with Idiopathic Pulmonary Fibrosis |
| ElapsedTime | double | Elapsed time (days) in active status on wait list |
| ElapsedStat(1A) | double | Elapsed time (days) in heart Status 1A |
| ElapsedStat(1B) | double | Elapsed time (days) in heart Status 1B |
| ElapsedStat(2) | double | Elapsed time (days) in heart Status 2 |
| ElapsedStat(7) | double | Elapsed time (days) in heart status 7 (inactive) |
| WeederFld(1) Min | double | first referenced weeder field minimum value |
| WeederFld(1) Max | double | first referenced weeder field maximum value |
| | | |
| WeederFld(n) Min | double | nth referenced weeder field minimum value |
| WeederFld(n) Max | double | nth referenced weeder field maximum value |
| WeedFlag(1) | boolean | first referenced weed flag field |
| | | |
| WeedFlag(n) | boolean | nth referenced weed flag field |
| OptPatientFld(1) | specified | first specified optional patient data field |
| | | |

OptPatientFld(n) specified nth specified optional patient data field

Example: (long line has been wrapped)

 $01/03/2000\ 2:21:54|01/03/2000\ 2:21:54|111056|446|68|O|True|False|False|False|False|False|False|2|2|0|0|\\False|0|0|0|0|0|0.0|84.0|136.0|300.0|False|M|White|Heart: Cardiomyopathy$

Note:

Create the waitlist input file to be fixed as the existing waitlist on the day before the Model Allocation Run start date; i.e., if Model Allocation Run is to start on 1/1/1999, create waitlist ending 12/31/1998. Cumulative times are calculated up to and including the last status change date (SnapDate). For candidates without status changes, cumulative times will all be 0 (see exception below) and SnapDate will be the listing date/time. Waitlist input file sort order: none. Patient Arrivals input file sort order: EventTime ascending.

The number of weeder fields expected is determined by what is found in the Optional Data Definition file. The order in which they appear here must be the same as the order in which they appear in the Optional Data Definition file. The number and order of weed flag fields are also determined by what is found in the Optional Data Definition file. The number of optional fields expected, and their order, is also determined by what is found in the Optional Data Definition file. Please refer to the section in this chapter which describes that input file for more information.

6.3 Status Updates

The simulation uses actual waitlist arrivals, status changes, and removal information for candidates on the waiting list during the model run timeframe. Status.txt contains records that describe the medical status updates for candidates who have a change in status from the time of the candidate's arrival to the model (either the initial wait list snapshot or arrival to the wait list) until the candidate's removal or death.

We had to randomly set the EventTime (hh:mm:ss) since that information is not in the SRTR data. Sometimes a status change occurs on the same day as a new patient record. As we want status changes to occur after the new patient listing, we intentionally set all the new patients listings to take place in the AM and the status changes to take place in the PM during the creation of the input files. That way if a status change comes through on the same day as a listing, we know it will happen afterward. If more that one status change occurs on the same date, we have not added logic to evaluate their order.

Input data should include all status changes, from the model start date through and including the model end date. Use current Status codes. Status changes should *not* include those removed due to transplant (status 4). Candidates removed due to death will have Status 8. All other status changes that removed the candidate from the waitlist should be set = 9, e.g.., due to improvement in or deterioration of the candidate's condition.

Patients who in real life actually received transplants will not receive any status updates after the date of their transplant unless their status histories are completed in some manner, such as the predictive mean matching described in the input files manual. Thus, no patient who actually received a transplant will ever die or get removed from the list in the model, even if this means these patients survive for months or years as status 1A without getting a transplant. In order to obtain realistic results, generate artificial status changes and death or removal dates for patients who received transplants.

Sort order: EventTime ascending. Note: MedUrgStat 7=inactive; 8=death; 9=removed

| Field Name | Data | Short Definition |
|-----------------|-----------|--|
| | Туре | |
| EventTime | DateTime | event date-time (mm/dd/yyyy hh:mm:ss) |
| ItemID | string | item ID (Patient ID) |
| NeedHeart | boolean | Patient is a candidate for a heart transplant |
| NeedLungs | boolean | Patient is a candidate for a lung transplant |
| NeedLeftLung | boolean | Patient is a candidate for a left lung |
| NeedRightLung | boolean | Patient is a candidate for a right lung |
| NeedEitherLung | boolean | Patient is a candidate for either lung |
| NeedBothLung | boolean | Patient is a candidate for both lungs |
| CurHeartStat | string | Current heart medical urgency status $\{1A 1B 2 7 8 9 0\}$ |
| CurLungStat | string | Current lung medical urgency status {1 7 8 9 0} |
| OptStatusFld(1) | specified | first specified optional status data field |
| | | |
| OptStatusFld(n) | specified | nth specified optional status data field |

Example:

01/01/2000 12:56:33|8993|True|False|False|False|False|False|8|8

Note:

The number of optional fields expected, and their order, is determined by what is found in the Optional Data Definition file. Please refer to the section in this chapter which describes that input file for more information.

6.4 Location Mapping

LocMap.txt first lists the definition of geographic zones, followed by the locations of all of the transplant centers and donation institutions. Each location is mapped to a local unit with the coordinates allowing distance calculations to place transplant centers in zones. This is an ASCII text file, one line per location, using the vertical bar "]" as the field delimiter. Sort order: CenterID unique, ascending.

First, the zones must be defined. The zones are enclosed in <ZONEDEF> ... </ZONEDEF> tags.

| Field Name | Short Definition |
|---------------|--|
| Local | same OPO, cut points are ignored |
| ZoneA | Potential recipient is 0 to 500 nautical miles from donor location |
| ZoneB | Potential recipient is 500 to 1000 nautical miles from donor location |
| ZoneC | Potential recipient is 1000 to 1500 nautical miles from donor location |
| ZoneD | Potential recipient is 1500 to 2500 nautical miles from donor location |
| ZoneE | Potential recipient is over 2500 nautical miles from donor location |

Example: <ZONEDEF> LOCAL|0.0|0.0 ZONEA|0.0|500.0 ZONEB|500.0|1000.0 ZONEC|1000.0|1500.0 ZONED|1500.0|2500.0

ZONEE|2500.0|10800.0 </ZONEDEF>

| Field | Data | Short Definition |
|-----------|--------|---|
| Name | Туре | |
| CenterID | string | location identifier (donation institution or transplant center) |
| LocalID | string | local unit (OPO) |
| Latitude | string | latitude at which center/institution is located |
| Longitude | string | longitude at which center/institution is located |
| | | |

Example: 4|ALOB|33.508|86.8032

Distance is calculated as shown below:

PiValue = 3.1415926535897932385;// approximate value of piDegreeToRadian = PiValue / 180.0;// radians per degreeRadianToNautMi = 180.0 * 60.0 / PiValue;// nautical mile is one minuteCircumNaut = 360.0 * 60.0;// circumference of earth

rlata := LatA * DegreeToRadian; rlatb := LatB * DegreeToRadian; hlondif := Abs(LonA - LonB) * DegreeToRadian / 2.0; hlatdif := Abs(LatA - LatB) * DegreeToRadian / 2.0;

```
a := Sqr(Sin(hlatdif)) + Cos(rlata) * Cos(rlatb) * Sqr(Sin(hlondif));

if a >= 1.0 then // points are antipodal

RadDist := PiValue

else

RadDist := 2.0 * ArcTan (Sqrt(a) / Sqrt(1.0 - a) );
```

DistNautMi := RadDist * RadianToNautMi;

6.5 Blood Compatibility

ABOChart.txt is a listing of all possible donor and candidate blood type combinations. It consists of an ASCII text file, one line per blood type, "|" delimiter separated fields. It includes both Heart Compatibility and Lung Compatibility.

| Field Name | Data Type | Short Definition |
|------------|------------------|--|
| OrgABOType | string | Organ ABO blood type {O A B AB} |
| PatABOType | string | Patient ABO blood type {O A B AB} |
| CompatCode | string | {I = Identical (or first priority); C = Compatible; X = Incompatible } |
| Fxample | | |

Example: O|B|I|C O is Organ ABO Type B is Patient ABO Type I is Heart Compatibility C is Lung Compatibility

6.6 Default Data Definition

DefDataDef.txt contains the definition of the default fields that are available for forming allocation rules, score boost specifications, acceptance calculations, and post-graft survival calculations. The program must contain code to support each field that is referenced in this file.

DefDataDef.txt is an ASCII text file that contains blocks, which are surrounded by defined block begin and block end tags.

Field List: <FIELDLIST>...</FIELDLIST>

The field list tag is the outer-most tag. All other blocks are contained inside the field list start and end tags.

Field Definition: <FIELDDEF>...</FIELDDEF>

The field definition block defines one field. The format for this block is:

<FIELDDEF> fldname|fldsource|fldstate|fldtype|fldusage|fldbasis </FIELDDEF>

fldname provides the name of the field. This must be a recognized field name.

fldsource identifies the source {Patient; Organ} of the field.

fldstate must be one of the following {Default; DefCalc; DefComp; DefCut} which defines how the program determines the value of the field.

Default: a field on the default patient or organ input record

DefCalc: a field calculated by default by the program

DefComp: a field whose value is determined by the program by comparing the patient and organ records

DefCut: a field calculated by the program using cutpoints on a known field.

fldtype must be one of the following: {String; Double; DateTime} which defines how the program stores the value of the field.

fldusage must be one of the following: {Category; Score} which defines how the field is used by the program.

fldbasis identifies the numeric field to which the cutpoints are applied if the field state is a cutpoint field. Otherwise, this item is omitted.

Level Definition: <LEVELDEF>...</LEVELDEF>

The level definition block defines the acceptable values for the field. The format for this block is:

<LEVELDEF> label|lowcut|highcut </LEVELDEF>

label identifies, for category fields, which string values can be used for allocation, boost, etc. **lowcut** defines the lower cutpoint for this level. Used only for cutpoint (fldstate = DefCut) fields. Otherwise, this item is omitted

highcut defines the upper cutpoint for this level. Used only for cutpoint (fldstate = DefCut) fields. Otherwise, this item is omitted.

Example: <FIELDLIST>

<FIELDDEF> ABOCompat|Patient|DefComp|String|Category <LEVELDEF> I C </LEVELDEF> </FIELDDEF> </FIELDDEF>

6.7 Optional Data Definition

OptDataDef.txt consists of three sections: weeder definitions, flag definitions, and optional data definitions.

OptDataDef.txt is an ASCII text file that contains blocks, which are surrounded by defined block-begin and block-end tags.

Weeder Definition: <WEEDDEF>...</WEEDDEF>

Each weeder definition specifies a value field in the organ record and a pair of range fields (minimum and maximum) in the patient (and initial wait list) record. Patients for whom the organ value does not fall within the specified range are weeded from the allocation for that organ. The weeder definition block may define multiple weeder fields. The format for this block is:

<WEEDDEF> fieldname|organidx </WEEDDEF>

fieldname provides the name of the field. The name has to be unique within the data source. **organidx** identifies the organ to which this weeder field applies. For the Thoracic Model, 1 indicates hearts, 2 indicates lungs, and 3 indicates both.

Flag Field Definition: <FLAGDEF>...</FLAGDEF>

Each flag field definition specifies a boolean value in the organ record that indicates whether a condition is present and a boolean value in the patient record that indicates whether presence of that condition in an offered organ is acceptable to the patient. Thus, if the organ value is true and the patient value is false, the patient will be weeded from the allocation for that organ. In all other cases, the patient will not be weeded. The flag field definition block may define multiple flag fields. The format for this block is:

<FLAGDEF> fieldname|organidx </FLAGDEF>

fieldname provides the name of the field. The name has to be unique within the data source. **organidx** identifies the organ to which this weeder field applies. For the Thoracic Model, this should be set to 1 for hearts, 2 for lungs, and 3 for both.

Optional Data Field Definitions Group: <DATADEF>...</DATADEF>

The Optional Data Field Definitions Group block contains definitions for the optional data fields, each of which is contained in its own <FIELDDEF> block. The format for the optional data definitions group block is:

<DATADEF> <FIELDDEF> ... </FIELDDEF> ... </DATADEF>

There are three types of data field definitions which may be defined in the Optional Data Field Definitions Group. They are the Optional Data Field, the Optional Cutpoint Field, and the Optional Calculation Field. Each of the three types is described below. The following definitions apply to all three optional field definitions.

fldname provides the name of the field. The name has to be unique within the data source. **fldsource** identifies the source {Patient; Organ; Status} of the field. Patient fields apply, also, to waitlist records, which have the same format as patient records.

fldtype must be one of the following: {String|Double|DateTime} which defines how the program stores the value of the field.

Optional Data Field Definition: <FIELDDEF>...</FIELDDEF>

The optional field definition block defines one optional field. The value Optional indicates to the program that the field will be supplied on the appropriate input file. The field source parameter specifies which file(s) will include the field – organ, patient and waitlist, or status update. The level definition block within the field definition block contains a list of possible values of Category fields. The format for the optional data field definition is:

<FIELDDEF> fldname|fldsource|*Optional*|fldtype|fldusage <LEVELDEF> { when fldusage=Category } value-1 ... value-n </LEVELDEF> </FIELDDEF>

fldusage must be one of the following: {Category|Score|PassThru} which defines how the field is used by the program.

Category identifies a category field. This must be a string.

Score identifies a numeric field. This must be Double or DateTime.

PassThru identifies a field which is read from the input stream and written to the output without being used by the program.

Optional Cutpoint Field Definition: <FIELDDEF>...</FIELDDEF>

When the field state is *OptCut*, a category field will be created by the program using the specified cut points on the specified basis field, **fldbasis**. The level definition block contains a list of possible values for this field. The **label** gives a name to values of the basis field which fall between the lower and upper cutpoints (**lowcut**, **highcut**) defined for this level.

<FIELDDEF>

fldname|fldsource|OptCut|fldtype|Category|fldbasis

<LEVELDEF> label-1|lowcut|highcut

label-n|lowcut|highcut </LEVELDEF> </FIELDDEF>

Optional Calculation Field Definition: <FIELDDEF>...</FIELDDEF>

When the field state is *OptCalc*, a score field will be created by the program using the specified calculation operation.

<FIELDDEF> fldname|fldsource|*OptCalc*|fldtype|*Score* <OPTCALC> optfunc|source:variable|source:variable|operator </OPTCALC> </FIELDDEF>

The calculation specification (<OPTCALC> block) for an OptCalc field consists of one of the following functions:

EnumerNum/source:variable which converts the levels of a categorical variable into a number 0,1,... based upon the order in which the levels of that field were specified. *Source* must be {Patient; Organ}.

Sum/source:variable/source:variable which adds the values of the first and second variables. *Source* must be {Patient; Organ, Literal}, where Literal indicates that a numeric value will be specified instead of a field.

Difference/source:variable/source:variable which subtracts the values of the second variable from the value of the first variable. *Source* must be {Patient; Organ, Literal}.

Ratio/source:variable/source:variable which divides the value of the first (score) variable by the value of the second (score) variable. *Source* must be {Patient; Organ, Literal}.

Product/source:variable/source:variable which multiplies the value of the first (score) variable by the value of the second (score) variable. *Source* must be {Patient; Organ, Literal}.

CompareNum/source:variable/source:variable/operator which compares the values of the two specified variables using the specified comparison operator, returning 1=True or 0=False.

In these calculation specifications, *Source* must be {Patient; Organ; Literal}, as above. *Operator* must consist of one of the following comparison operators {GE; GT; LE; LT; EQ; NE}

NaturalLog/source:variable which gives the natural log of the value of the specified variable. *Source* must be {Patient; Organ, Literal}.

Exponential/source:variable which gives the natural log of the value of the specified variable. *Source* must be {Patient; Organ, Literal}.

Power/source:variable/source:variable which gives the value of the first variable to the power of the value of the second variable. *Source* must be {Patient; Organ, Literal}.

BoolOp/source:variable/source:variable/operator which gives a boolean calculation of the value of the two specified variabless. The calculation performed depends on the value of the operator. *Operator* must consist of one of the following Boolean operators {OR, XOR, AND} *Source* must be {Patient; Organ, Literal}.

Equation/equation which gives the result of the specified mathematics formula. The mathematics formula can be constructed using the elements:

+: operand, executes adding operation

-: operand, executes subtraction operation

*: function, executes multiplying operation /: function, executes division operation Sqrt: functions, root of a number. Root can have any degree Div: functions, executes integer division operation Mod: functions, executes remainder operation Int: function, returns the integer part of a number Frac: function, returns the fractional part of a number Random: function, returns random number within the range $0 \le value \le 1$ Trunc: function, truncates a number to an integer Round: function, returns the value rounded to the nearest whole number Sin: function, returns the sine of the angle in radians ArcSin: function, returns the inverse sine of a number Sinh: function, returns the hyperbolic sine of an angle ArcSinh: function, returns the inverse hyperbolic sine of a number Cos: function, returns the cosine of the angle in radians ArcCos: function, returns the inverse cosine of a number Cosh: function, returns the hyperbolic cosine of an angle ArcCosh: function, returns the inverse hyperbolic cosine of a number Tan: function, returns the tangent of the angle ArcTan: function, returns the arctangent of a number Tanh: function, returns the hyperbolic tangent of an angle ArcTanh: function, the inverse hyperbolic tangent of a number CoTan: function, returns the cotangent of the angle ArcCoTan: function, returns the inverse cotangent of a number CoTanh: function, returns the hyperbolic cotangent of an angle ArcCoTanh: function, the inverse hyperbolic cotangent of a number Sec: function, returns the secant of an angle ArcSec: function, returns the inverse secant of a number Sech: function, returns the hyperbolic secant of an angle ArcSech: function, returns the inverse hyperbolic secant of a number Csc: function, returns the cosecant of an angle ArcCsc: function, returns the inverse cosecant of a number Csch: function, returns the hyperbolic cosecant of an angle ArcCsch: function, returns the inverse hyperbolic secant of a number Abs: function, returns an absolute value Ln: function, returns the natural log of an expression Lg: function, returns log base 10 Log: function, returns the log of expression for a specified base Pi: function, returns 3.1415926535897932385 Exp: function, returns the exponential of an expression !: function, returns factorial of an expression ^: function, raises expression to any power ArcTan2 [Y, X: Double] function, calculates ArcTan(Y|X), and returns an angle in the correct quadrant. The values of X and Y must be between -2^{64} and 2^{64} . Inaddition, the value of X can't be 0. The return value will fall in the range from -Pi to Pi radians. Hypot [X, Y: Double] function, returns the length of the hypotenuse of a right triangle. Specify the lengths of the sides adjacent to the right angle in X and Y. Hypot uses the formula $Sqrt(X^{**2} + Y^{**2})$ RadToDeg function, converts radians to degrees RadToGrad function, converts radians to grads RadToCycle function, converts radians to cycles DegToRad function, returns the value of a degree measurement expressed in radians

DegToGrad function, returns the value of a degree measurement expressed in grads DegToCycle function, returns the value of a degree measurement expressed in cycles GradToRad function, converts grad measurements to radians GradToDeg function, converts grad measurements to degrees GradToCycle function, converts grad measurements to cycles CycleToRad function, converts an angle measurement from cycles to radians CycleToDeg function, converts an angle measurement from cycles to degrees CycleToGrad function, converts an angle measurement from cycles to grads. LnXP1 function, returns the natural log of (X+1)Log10 function, calculates log base 10 Log2 function, calculates log base 2 IntPower [Base: Double; Exponent: Integer] function, calculates the integral power of a base value Power [Base: Double; Exponent: Double] function, Raises Base to any power Ldexp [X: Double; P: Double] function, calculates X times (2 to the power of P) Ceil function, rounds variables up toward positive infinity Floor function, rounds variables toward negative infinity Poly [X: Double; Coefficients(1)..Coefficients(N): Double] function, evaluates a uniform polynomial of one variable at the value X Mean [Data(1)..Data(N): Double] function, returns the average of all values in an array Sum [Data(1)..Data(N): Double] function, returns the sum of the elements in an array SumInt [Data(1)..Data(N): Integer] function, returns the sum of the elements in an integer array SumOfSquares [Data(1)..Data(N): Double] function, returns the sum of the squared values from a data array MinValue [Data(1)..Data(N): Double] function, returns smallest signed value in an array MinIntValue [Data(1)..Data(N): Integer] function, returns the smallest signed value in an integer arrav Min [A,B: Double] function, returns the lesser of two numeric values MaxValue [Data(1)..Data(N): Double] function, returns the largest signed value in an array MaxIntValue [Data(1)..Data(N): Integer] function, returns the largest signed value in an integer array Max [A,B: Double] function, returns the greater of two numeric values StdDev [Data(1)..Data(N): Double] function, returns the sample standard deviation for elements in an arrav PopnStdDev [Data(1)..Data(N): Double] function, calculates the population standard deviation Variance [Data(1)..Data(N): Double] function, calculates statistical sample variance from an array of data PopnVariance [Data(1)..Data(N): Double] function, calculates the population variance TotalVariance [Data(1)..Data(N): Double] function, returns the statistical variance from an array of values Norm [Data(1)..Data(N): Double] function, returns the Euclidean 'L-2' norm RandG [Mean, StdDev: Double] function, generates random numbers with Gaussian distribution RandomRange [AFrom, ATo: Integer] function, returns a random integer from a specified range RandomFrom [Value(1)..Value(N): Double] function, returns a randomly selected element from an array EnsureRange [AValue, AMin, AMax: Double] function, returns the closest value to a specified value within a specified range

Example: <WEEDDEF> DonHeight|3 DonWeight|3

</WEEDDEF> # <FLAGDEF> CMVStat|1 HCVDonor|3 </FLAGDEF> # <DATADEF> <FIELDDEF> PatientSex|Patient|Optional|String|Category <LEVELDEF> Μ F </LEVELDEF> </FIELDDEF> <FIELDDEF> PatientRace|Patient|Optional|String|Category <LEVELDEF> Amerind Arabian Asian Black Hawaiian Indian White </LEVELDEF> </FIELDDEF> <FIELDDEF> WtRatio|Patient|OptCalc|Double|Score <OPTCALC> Ratio|Organ:DonorWeight|Patient:PatientWeight </OPTCALC> </FIELDDEF> <FIELDDEF> AdultNum|Patient|OptCalc|Double|Score <OPTCALC> CompareNum|Patient:PatientAge|Literal:18|GE </OPTCALC> </FIELDDEF> <FIELDDEF> PediatNum|Patient|OptCalc|Double|Score <OPTCALC> CompareNum|Patient:PatientAge|Literal:18|LT </OPTCALC> </FIELDDEF> <FIELDDEF> WtRatA|Patient|OptCalc|Double|Score <OPTCALC> CompareNum|Patient:WtRatio|Literal:0.7|GT </OPTCALC> </FIELDDEF> <FIELDDEF> distance|Patient|OptCalc|Double|Score <OPTCALC>

Equation|3443.9*(arccos(cos(Patient:("lat1"))*cos(Patient:("long1"))*cos(Organ:("lat2"))*cos(Organ:("long2")) + cos(Patient:("lat1"))*sin(Patient:("long1"))*cos(Organ:("lat2"))*sin(Organ:("long2")) + sin(Patient:("lat1"))*sin(Organ:("lat2")))) < /OPTCALC> </FIELDDEF> </DATADEF>

6.8 Allocation Method Definition

DefMethods.txt contains a list of allocation method definitions, consisting of a list of default rule definitions. Within a rule definition, the <GROUDEF> block defines the subset of organs for which the rule applies. Fields used in the group definition must be category fields that are defined in either the default data definition file or the optional data definition file. Group components (lines in the groupdef section) are joined using a logical AND. When an organ arrives, the program checks the allocation methods in the order in which they are presented to find the first one that specifies a group to which the organ belongs. If the organ characteristics don't match any of the groups, the organ is discarded and an error message is written to the input stream errors output file.

The lines in the <ORDERDEF> block specify subsets of the patient list. The order in which the order definitions appear determines the order in which subsets of the waiting list are handled. Within a subset, patients are sorted by the sortfields.

Rule List: <RULELIST>...</RULELIST>

The rule list tag is the outer-most tag. All other blocks are contained inside the rule list start and end tags.

Allocation Definition: <ALLOCDEF>...</ALLOCDEF>

The allocation definition block defines the allocation rules for one group of organs. There may be multiple allocation definition blocks within the rulelist block. The format for the allocation definition block is:

<ALLOCDEF> title <GROUPDEF> source:fieldname=level

... </GROUPDEF> <ORDERDEF> patfield=level,...|sortfield,.... patfield=level,...|sortfield,....

these groups | are sorted this way

... </ORDERDEF> </ALLOCDEF>

source:fieldname=level defines the group to which an organ belongs, based on its characteristics. The source is always organ. The field name is any field in the default or optional data definition files that apply to the organ. Level is the value this field must have in order for this organ to be in this group. The organ must characteristics must match all of the definitions in the group.
patfield=level defines a subset of patients to whom this order definition applies.
sortfield defines the sort order of the subset of patients who meet the patient criteria of this order definition statement.

Example: <RULELIST> <ALLOCDEF> Current Adult Donor Heart (with or without lungs) <GROUPDEF> Organ:HasHeart=True Organ:DonAgeGrp=Adult </GROUPDEF> <ORDERDEF> NeedHeart=True.GeogZone=LOCAL,CurHeartStat=1A,ABOCompat=I|Stat1AWaitTime.TotWaitTime NeedHeart=True,GeogZone=LOCAL,CurHeartStat=1A,ABOCompat=C|Stat1AWaitTime,TotWaitTime NeedHeart=True,GeogZone=LOCAL,CurHeartStat=1B,ABOCompat=I|Stat1BWaitTime,TotWaitTime NeedHeart=True,GeogZone=LOCAL,CurHeartStat=1B,ABOCompat=C|Stat1BWaitTime,TotWaitTime NeedHeart=True,GeogZone=LOCAL,CurHeartStat=2,ABOCompat=I|Stat2WaitTime,TotWaitTime NeedHeart=True,GeogZone=LOCAL,CurHeartStat=2,ABOCompat=C|Stat2WaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEA,CurHeartStat=1A,ABOCompat=I|Stat1AWaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEA,CurHeartStat=1A,ABOCompat=C|Stat1AWaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEA,CurHeartStat=1B,ABOCompat=I|Stat1BWaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEA,CurHeartStat=1B,ABOCompat=C|Stat1BWaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEB,CurHeartStat=1A,ABOCompat=I|Stat1AWaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEB,CurHeartStat=1A,ABOCompat=C|Stat1AWaitTime,TotWaitTime NeedHeart=True.GeogZone=ZONEB,CurHeartStat=1B,ABOCompat=I|Stat1BWaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEB,CurHeartStat=1B,ABOCompat=C|Stat1BWaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEA,CurHeartStat=2,ABOCompat=I|Stat2WaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEA,CurHeartStat=2,ABOCompat=C|Stat2WaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEB,CurHeartStat=2,ABOCompat=I|Stat2WaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEB,CurHeartStat=2,ABOCompat=C|Stat2WaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEC,CurHeartStat=1A,ABOCompat=I|Stat1AWaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEC,CurHeartStat=1A,ABOCompat=C|Stat1AWaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEC,CurHeartStat=1B,ABOCompat=I|Stat1BWaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEC,CurHeartStat=1B,ABOCompat=C|Stat1BWaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEC,CurHeartStat=2,ABOCompat=I|Stat2WaitTime,TotWaitTime NeedHeart=True,GeogZone=ZONEC,CurHeartStat=2,ABOCompat=C|Stat2WaitTime,TotWaitTime </ORDERDEF> </ALLOCDEF> </RULELIST>

6.9 Allocation Score Boost Definition

DefBoostDef.txt is used to specify rules that define how scores used to sort patients might be boosted. The idea is that if the offered organ meets specified criteria (listed in the <ORGGRP> block) and the patient meets specified criteria (listed in the <PATGRP> block), then the value of that patient's score will be boosted in the defined manner (defined in the <BOOST> block) for this particular organ being allocated. The boost consists of multiplying the existing score by a value and then adding a second value. Boost definitions may only reference the fields that are described in either the default data definition file or the optional data definition file.

Boost List: <BOOSTLIST>...</BOOSTLIST>

The boost list tag is the outer-most tag. All other blocks are contained inside the boost list start and end tags.

Boost Definition: <BOOSTDEF>...</BOOSTDEF>

The boost definition block contains the definition of one boost rule. There may be multiple boost rules contained within the boost list block.

There are two possible formats for the boost definition block. The format for the standard boost definition block is:

<BOOSTDEF> boostname <ORGGRP> fldname=level ... </ORGGRP> <PATGRP> fldname=level ... </PATGRP> <BOOST>

fldname|boostamnt|boostfact

... </BOOST> </BOOSTDEF>

boostname: gives the name of this boost rule

fldname=level: specifies the criteria the organ and patient must meet in order for the patient to get this boost.

fldname: within the <BOOST> block specifies the field in the patient record which will get the new, booostedscore, where boostedscore = **fldname** * **boostfact** + **boostamnt**

Example: <BOOSTLIST> <BOOSTDEF> ABO Compatible Allocation Points <ORGGRP> </ORGGRP> <PATGRP> ABOCompat=C </PATGRP> <BOOST> AllocPoints|5|1 </BOOST> </BOOSTDEF> </BOOSTLIST>

The alternate boost definition block allows the user to define a linear equation by which to boost the underlying variable. Note that this alternate boost definition can only be entered through input files. There are no input panels in LSAM from which the inputs may be made.

The format for the alternate, linear equation, boost definition block is:

<BOOSTDEF> boostname <ORGGRP> fldname=level

... </ORGGRP> <PATGRP> fldname=level ... </PATGRP> <CALCDEF> fldname <TERMDEF> coeff1|source1a:fieldname1a|source1b:fieldname1b ...

</TERMDEF> </CALCDEF> </BOOSTDEF>

boostname: gives the name of this boost rule

fldname: specifies the field in the patient record which will get the new, boostedscore, where boostedscore = **fldname** *operator* (coeff1*source1a:fieldname1a*source1b:fieldname1b) *operator* ... *operator* (coeff(i)*source(i)a:fieldname(i)a*source(i)b:fieldname(i)b)

operator: the optional operator field is used to indicate the mathematical operation to perform. The default is Sum. Other option is Product. The example below yields this equation:

eNLSB=eNLSB + (21.7258 + (-0.1944 * can_age) + (-0.1852*can_age*can_dgn_kp_dm)) * 0.8*one_minus_DPI_rank

<BOOSTLIST> <BOOSTDEF> Life Years From Transplant (LYFT) Equation <CALCDEF> eNLSB <TERMDEF> 21.7258 -0.1944|Patient:can_age -0.1852|Patient:can_age|Patient:can_dgn_kp_dm Product|0.8|Organ:one_minus_DPI_rank </TERMDEF> </CALCDEF> </BOOSTLIST> </BOOSTLIST> </BOOSTDEF>

6.10 Default Acceptance

DefAccept.txt is the default definition of calculation to perform to determine whether a patient accepts an offered organ.

Acceptance List: <ACCLIST>...</ACCLIST>

The acceptance list tag is the outer-most tag. All other blocks are contained inside the acceptance list start and end tags.

Calculation Definition: <CALCDEF>...</CALCDEF>

Each calculation definition block defines the calculation that will take place, the mathematical function that will be used, and the characteristics of the organ and/or the patient which will be inputs to the mathematical function. The format for the calculation definition block is:

<CALCDEF> accname <GROUPDEF> source:fieldname=level ... </GROUPDEF> <TERMDEF> coeff|source1:fieldname1|source2:fieldname2 ... </TERMDEF> <FUNCTION> funcname

funcname </FUNCTION> </CALCDEF>

accname is the name of this acceptance calculation.

Fields used to define groups must be category fields that are defined in either the default data definition file or the optional data definition file. Group components (lines in the <GROUPDEF> block) are joined using a logical AND.

source:fieldname=level: lists the numeric fields associated with the patient and the organ which will be inputs to the mathematical function. Source: {Patient, Organ}.

Fields used to define terms must be score fields that are defined in either the default data definition file or the optional data definition file. Each term component (line in the <TERMDEF> block) consists of the coefficient (coeff) times the first field (source1:fieldname1) times the second field (source2:fieldname2). Term components (lines in the <TERMDEF> block) are added together. If the second field of a term component is omitted, then the term component consists of the coefficient times the first fields are omitted, then the term component consists of just the coefficient cient.

The function section identified the function to be applied to the result of the linear combination specified in the termdef section. The inverse logit function, $InvLogit(\beta X) = exp(\beta X) / 1 + exp(\beta X)$, where βX = the result of the linear combination specified in the termdef section, is currently the only choice available. Specify INVLOGIT for the **funcname**.

Example: <ACCLIST> <CALCDEF> Sample Acceptance <GROUPDEF> </GROUPDEF> <TERMDEF> 3 0.02|Patient:PatientAge -0.04|Organ:DonorAge </TERMDEF> <FUNCTION> INVLOGIT </FUNCTION> </CALCDEF> </ACCLIST>

6.11 Default Post-Graft Survival Definition

DefSurvival.txt is the default definition of the calculation to perform to determine how long a patient will live after receiving a graft and to assign a series of possible outcomes, such as relisting and status changes, to that patient prior to graft failure.

```
Survival List: <SURVLIST>...</SURVLIST>
```

The survival list tag is the outer-most tag. All other blocks are contained inside the survival list start and end tags.

```
Calculation Definition: <CALCDEF>...</CALCDEF>
```

Each calculation definition block defines the characteristics of the organ and/or the patient to which this survival calculation applies. The format for the calculation definition block is:

<CALCDEF> survname <GROUPDEF> source:fieldname=level ... </GROUPDEF> <TERMDEF> coeff|source1:fieldname1|source2:fieldname2 ... </TERMDEF> <FUNCTION> funcname <STEPFUNC> <STEP> valueltime <OUTCOMES> outtype|outcomename|outprob|outtime <UPDATES> atime|medurgstat||opt(1)|... </UPDATES> ••• </OUTCOMES> </STEP> </STEPFUNC> </FUNCTION> </CALCDEF>

survname is the name of this survival calculation.

Fields used to define groups must be category fields that are defined in either the default data definition file or the optional data definition file. Group components (lines in the <GROUPDEF> block) are joined using a logical AND.

source:fieldname=level: lists the numeric fields associated with the patient and the organ which will be inputs to the mathematical function. Source: {Patient, Organ}.

Fields used to define terms must be score fields that are defined in either the default data definition file or the optional data definition file. Each term component (line in the <TERMDEF> block) consists of the coefficient (coeff) times the first field (source1:fieldname1) times the second field (source2:fieldname2). Term components (lines in the <TERMDEF> block) are added together. If the second field of a term component is omitted, then the term component consists of the coefficient times the first fields are omitted, then the term component consists of just the coefficient cient.

The <FUNCTION> block identifies the type of function to be used to determine survival time. The choices for **funcname** are STEPFUNC or WEIBULL. If **funcname** is StepFunc, then the next block will be <STEPFUNC>. If **funcname** is Weibull, then the next block will be <WEIBULL>

The <STEPFUNC> block identifies the step function to be inverted to determine survival time: $Prob[survival to time > T] = S(T)^{exp(y)}$

where y = the result of the linear combination specified in the termdef section.

The <STEPFUNC> block defines the function as a set of steps connecting the listed points. Associated with each point is a **value** (probability) and a **time** (in days) until failure.

The <WEIBULL> block identifies the values of the parameters and form of a Weibull equation.

parm1|parm2|form name

The parameters required depend on the chosen form. For example, if the chosen form is "Intercept" then the required parameters are shape and intercept. The following table outlines the Weibull equation form choices and their required parameters.

| Weibull Equation form | parm1 | parm2 | form name |
|-------------------------------|-------|-----------|-----------|
| AFT: exp[- | shape | intercept | Intercept |
| exp(shape*(ln(t)- | | | |
| intercept))] | | | |
| PH: $exp[-scale * t^{shape}]$ | shape | scale | Lambda |
| PH: $exp[-(t/scale)^{shape}]$ | shape | scale | Alpha |

Whether the death date is determined by a Cox PH StepFunction or a Weibull Distribution, the patient outcomes prior to death are determined by a series of steps which depend on the days to death.

Each <STEP> block refers to patients with a certain number of days until death. Within each step, there can be one or more outcomes.

Each <OUTCOME> block includes a probability (**outprob**) and a time (**outtime**, in days) before failure that the outcome occurs. For a death outcome, the time is zero. For a relist outcome, the time is the number of days before failure to relist occurs.

Associated with each relist outcome is a set of status updates (<UPDATES> block) for the relisted patient. The relisted patient updates consist of a time (**atime**, in days) after relist that the update occurs. The set of updates does not include an update for death, since that event will already be generated from the failure time for the step. The format of <UPDATES> block is the same as that for the Status Updates input file, which is described earlier in this chapter, except that the patient id is not specified since these post-graft survival status updates may be applied to any patient who receives a transplant.

Example: # <SURVLIST> <CALCDEF> Status 1 patient survival <GROUPDEF> </GROUPDEF> <TERMDEF> Patient:MedUrgStat=1 </TERMDEF> <FUNCTION> StepFunc <STEPFUNC> .9823|0 .9615|1 .9365|3 .9212|6 </STEPFUNC> <STEP> 1.00 <OUTCOMES> Death|Death|0.95 Relist|Relist Group 1|0.05|7.0 <UPDATES> 0.0|1|25 </UPDATES> </OUTCOMES> </STEP> <STEP> 0.90 <OUTCOMES> Death|Death|0.90 Relist|Relist Group 1|0.05|30.0 <UPDATES> 0.0|1|25 </UPDATES> Relist|Relist Group 2|0.05|60.0 <UPDATES> 0.0|2A|20 30.0|1|25 </UPDATES> </OUTCOMES> </STEP> </FUNCTION> </CALCDEF> </SURVLIST>

6.12 Model Allocation Runs

ModelRuns.txt is created by the application, not by the user. The ModelRuns.txt contains the names and file prefixes of all Allocation Runs that have been defined using the application. The model saves the specification when the user hits the OK button or the Run button in the user interface.

Annotated Example: (the annotations in italics do not appear in the input file)

| NAME OPTN Test | name of the Allocation Run |
|--------------------|---|
| FILE OPTN | short name used as file prefix |
| EOF | end of definition |
| NAME OldRules Test | name of another run |
| FILE OldRules | short name used as 2^{nd} file prefix |
| EOF | end of 2^{nd} definition |

6.13 Allocation Run Definition

xxxxModel.inp is generated by the application and is used to save an Allocation Run definition (where xxxx denotes the short name of the Allocation Run). Each file contains the specifications of one of the defined Allocation Runs. The model saves the specification when the user hits the OK button or the Run button in the user interface.

The definitions include paths where the directory can locate the input files for the Allocation Run. If the Allocation Run definition is to be shared among users on different computers, it will be necessary to edit the path definitions to correspond to the locations on the new machine where the application can find the files.

In addition, the allocation run definition file will contain the entire configuration of the allocation run, which will look similar to the contents of the input files previously defined in this chapter.

7 Output File Specifications

This section gives the specifications of output files for the program. The specifications of each output file list fields in the order they occur in a record, followed by an example. The format of each table list gives the name of the field, its data type, and a short definition. The field names are those used in the source code. The program assigns each output file a different name by prefixing the short title of the Allocation Run. *Note: xxxx denotes the Short Name given during the Model Allocation Run in the descriptions below.*

Output Files:

- Waitlist at end of Model Allocation Run
- Patients receiving grafts
- Death list (candidates who died during the Model Allocation Run)
- Removed list (candidates who were removed from the wait list during the Model Allocation Run)
- Relisted (candidates who were relisted following a transplant during the Model Allocation Run)
- Graft list (all of the organs grafted during the Model Allocation Run and the candidate receiving the graft)
- Match list (all candidates to whom each organ was offered)
- Status updates (log of the arriving status update events)
- Event log (log of the arriving events)
- Summary statistics

The following five output files all consist of the same layout. For simplicity, the output layout is only specified one time. All are text files, one line per record, "|" delimiter separated fields.

7.1 Wait List

xxxxWait.out – list of candidate records that represents the status of the waitlist at the end time of the Model Allocation Run.

7.2 Grafted Patients

xxxxGrPat.out – list of patient records that represents all candidates receiving a graft during the Model Allocation Run. Recipients receiving more than one graft will be in this file multiple times.

7.3 Death Listing

xxxxDeath.out – list of candidate records that represents all patients who died during the Model Allocation Run. It includes waitlist deaths, removed candidate deaths, and post-transplant deaths.

7.4 Removed Listing

xxxxRemove.out – list of the patients who were removed from the waitlist during the Model Allocation Run.

7.5 Relistings

xxxxRelist.out – list of the patients who were relisted after transplant during the Model Allocation Run. A patient who has received two transplants during the model run will be listed twice in the relistings file. Each time a patient is relisted, their PatientId is incremented by 0.1, so that relisted patients can be easily identified on the waitlist and in the grafted patients output file.

| Field Name | Data Type | Short Definition |
|------------------|-----------|--|
| Iter | integer | Replication number |
| SnapDate | DateTime | Snapshot for existing wait list date-time (mm/dd/yyyy hh:mm:ss) |
| ArrivalTime | DateTime | Date-time arriving or relisting on wait list (mm/dd/yyyy hh:mm:ss) |
| PatientId | string | Item ID (patient ID) |
| CenterID | string | Transplantation center ID |
| PatientAge | double | Patient age at time of listing |
| ABOType | string | ABO blood type $\{O A A1 A2 B AB A1B A2B\}$ |
| NeedHeart | boolean | Patient is a candidate for a heart transplant |
| NeedLungs | boolean | Patient is a candidate for a lung transplant |
| NeedLeftLung | boolean | Patient is a candidate for a left lung |
| NeedRightLung | boolean | Patient is a candidate for a right lung |
| NeedEitherLung | boolean | Patient is a candidate for either lung |
| NeedBothLung | boolean | Patient is a candidate for both lungs |
| CurHeartStat | string | Current heart medical urgency status {1A 1B 2 7 8 9 0} |
| | | |
| CurLungStat | string | Current lung medical urgency status $\{1 7 8 9 0\}$ |
| HasIpfDiag | boolean | Is the patient's diagnosis idiopathic pulmonary fibrosis? |
| CumTotTime | double | Cumulative waiting time {days} |
| CumStat1ATime | double | Cumulative time in status 1 {days} |
| CumStat1BTime | double | Cumulative time in status 1 or 2a {days} |
| CumStat2Time | double | Cumulative time in status 1, 2a or 2b {days} |
| CumInactTime | double | Cumulative time in inactive status {days} |
| WeederFld(1) Min | double | first referenced weeder field minimum value |
| WeederFld(1) Max | double | first referenced weeder field maximum value |
| | | |
| WeederFld(n) Min | double | nth referenced weeder field minimum value |
| WeederFld(n) Max | double | nth referenced weeder field maximum value |
| WeedFlag(1) | boolean | first referenced weed flag field |
| | | |
| WeedFlag(n) | boolean | nth referenced weed flag field |
| OptPatientFld(1) | specified | first specified optional patient data field |
| | · C' 1 | .1 |
| OptPatientFld(n) | specified | nth specified optional patient data field |
| GraftCount | double | Number of grafts, including this one, that this patient has received |
| DeathDate | DateTime | Date-time the patient died in the model (mm/dd/yyyy hh:mm:ss) |
| RelistDate | DateTime | Date-time of patient relisting (mm/dd/yyyy hh:mm:ss) |
| {GraftID} | string | Organ identifier |
| {ProbAccept} | double | Calculated probability that this patient would accept this organ |
| {GraftDate} | DateTime | Date-time of transplant (mm/dd/yyyy hh:mm:ss) |
| {GotHeart} | boolean | Did this patient receive a heart during the model run? (True False) |
| {GotLeftLung} | boolean | Did this patient receive a left lung during the model run? (True False) |
| {GotRightLung} | boolean | Did this patient receive a right lung during the model run? (True False) |

Example: (long line has been wrapped)

1|01/01/2000 12:36:16|04/21/1999 01:14:35|54813|108|55|O|True|False|False|False|False|False|False|2|1A|0|0| False|1|255.87|32.87|188|35|0|0|84|141|440|False|M|White|Heart: Cardiomyopathy|1| 02/16/2000 12:36:16|.|ML5011|0.53742984534375|01/01/2000 12:36:16|True|False|False

7.6 Grafted Organs

xxxxGraft.out – list of all organs grafted during the Model Allocation Run and the patient receiving the graft.

| Field Name Iter | Data Type | Short Definition |
|----------------------|--------------------|--|
| | integer | Replication number |
| OrganId EventTime | string DateTime | Organ ID Data time of craft (mm/dd/uuru hhummiss) |
| | | Date-time of graft (mm/dd/yyyy hh:mm:ss) |
| HasHeart | boolean | This organ package contained a heart (True False) |
| HasLeftLung | boolean | This organ package contained a left lung (True False) |
| HasRightLung | boolean | This organ package contained a right lung (True False) |
| OrganInstId | string | Donor Institution ID |
| DonorAge | double | Donor age |
| OrganABO | string | ABO blood type $\{O A A1 A2 B AB A1B A2B\}$ |
| PatientId | string | Patient ID |
| ProbAccept | double | Probability of acceptance calculated by the model |
| GotHeart | boolean | This patient received a heart (True False) |
| GotLeftLung | boolean | This patient received a left lung (True False) |
| GotRightLung | boolean | This patient received a right lung (True False) |
| PatCenterID | string | Transplantation center ID |
| PatientAge | double | Patient age at time of listing |
| PatientABO | string | ABO blood type $\{O A A1 A2 B AB A1B A2B\}$ |
| CurHeartStat | string | Heart medical urgency status at time of transplant $\{1A 1B 2 7 0\}$ |
| CurLungStat | string | Lung medical urgency status at time of transplant $\{1 7 0\}$ |
| CumActiveTime | double | Cumulative waiting time {days} |
| CumOneATime | double | Cumulative time in status 1A {days} |
| CumOneBTime | double | Cumulative time in status 1A or 1B {days} |
| CumTwoTime | double | Cumulative time in status 1A, 1B, or 2 {days} |
| CumInactTime | double | Cumulative time in inactive status {days} |
| ArrivalTime | DateTime | Date-time arriving on the wait list (mm/dd/yyyy hh:mm:ss) |
| | | |

Example: (long line has been wrapped)

7.7 Match Offers

xxxxMatch.out – list of all candidates to whom each organ was offered. This file is only produced if requested during the Model Allocation Run by marking the Log Match check box.

| Field Name Data Type Short Definition | |
|---|----------------|
| Iter integer Replication number | |
| OrganId string Organ ID | |
| EventTime DateTime Organ arrival date-time (mm/dd/yyyy hh:mm:ss) | |
| HasHeart boolean This organ package contained a heart (True False) | |
| HasLeftLung boolean This organ package contained a left lung (True False) | |
| HasRightLung boolean This organ package contained a right lung (True False) | |
| OrganInstId string Donor Institution ID | |
| OrganLocUnit string Donor OPO | |
| DonorAge double Donor age | |
| OrganABO string ABO blood type {O A A1 A2 B AB A1B A2B} | |
| PatientId string Patient ID (or Discard if no patient accepted organ) | |
| OfferNumber double How many times this organ has been offered, counting t | this offer |
| Decision boolean Patient accepted the offered organ (Accepted Declined I | Discarded) |
| ProbAccept double Probability of acceptance calculated by the model | |
| GotHeart boolean This patient received a heart (True False) | |
| GotLeftLung boolean This patient received a left lung (True False) | |
| GotRightLung boolean This patient received a right lung (True False) | |
| PatCenterID string Transplantation center ID | |
| PatLocUnit string Patient OPO | |
| GeogZone string The geographic location of the donor relative to the pati | ient being of- |
| fered the organ {local ZoneA ZoneB ZoneC} | |
| PatientAge double Patient age at time of listing | |
| PatientABO string ABO blood type $\{O A A1 A2 B AB A1B A2B\}$ | |
| CurHeartStat string Heart medical urgency status at time of offer {1A 1B 2 | 7 0} |
| CurLungStat string Lung medical urgency status at time of offer $\{1 7 0\}$ | |
| CumTotTime double Cumulative waiting time {days} | |
| CumOneATime double Cumulative time in status 1A {days} | |
| CumOneBTime double Cumulative time in status 1A or 1B {days} | |
| CumTwoTime double Cumulative time in status 1A, 1B, or 2 {days} | |

Example:

 $1|PGD006|01/01/200208:19:23|True|False|False|390111PADV|PADV|52|O|203947|1|Accepted|0.1375392\\86738009|True|False|False|523|PADV|LOCAL|58.841889117|O|1A|0|6.0244444443972|\\6.0244444443972|0|0$

7.8 Status Updates

xxxxStatus.out – log of the arriving status update events. This file is only produced if requested during the Model Allocation Runby marking the Log Updates check box.

| Field Name Iter EventTime PatientId NeedHeart NeedHeart NeedLungs NeedLeftLung NeedRightLung NeedBitherLung NeedBothLung CurHeartStat CurLungStat can_has_vad | Data Type integer DateTime string boolean boolean boolean boolean boolean string string double | Short Definition Replication number Date-time of arrival of the update (mm/dd/yyyy hh:mm:ss) Patient ID Patient is a candidate for a heart transplant Patient is a candidate for a lung transplant Patient is a candidate for a left lung Patient is a candidate for a left lung Patient is a candidate for a right lung Patient is a candidate for either lung Patient is a candidate for both lungs Current heart medical urgency status {1A 1B 2 7 8 9 0 .} Current VAD status {1 0 .} |
|--|---|---|
| can_has_vad crit_e | double double | Current VAD status {1 0 .} Current selection of criteria e {1 0 .} |
| cm_c | uouoie | |

Example:

 $1|01/01/2002\ 13:01:44|50033|True|False|False|False|False|False|False|1B|1|0|0$

7.9 Event Log

EventLog.log – log of the arriving events. This file is only produced if requested during the Model Allocation Run by marking the Log Events check box.

| Field Name | Data Type | Short Definition |
|------------|-----------|--|
| EventTime | DateTime | Date-time of arrival of the update (mm/dd/yyyy hh:mm:ss) |
| EventID | string | Event ID {PatientID OrganID} |
| EventDesc | string | Description of the event |

Example:

01/01/2002 00:54:16 204226 New patient arrives.

7.10 Summary

xxxxSummary.out – summary statistics for each iteration, followed by the mean and standard deviation of each statistic across all the iterations in the Allocation Run.

| Field Name | Data | Short Definition |
|--|---------|--|
| Iterestion - | Туре | hlash of summary statistics for each iteration |
| Iteration x | integer | block of summary statistics for each iteration |
| Heart Initial Waitlist | integer | heart patients on wait list at start time |
| New Heart Patient Listings | integer | new heart patient arrivals between start and end time |
| Removed from Heart Waitlist | double | heart patients who were removed from the waitlist between start and end time |
| Final Heart Waitlist | integer | final heart waitlist at end of run |
| Discarded Isolated Hearts | integer | number of discarded isolated hearts |
| Discarded Hearts Total | integer | total number of discarded hearts (including heart-lungs) |
| Total Heart Transplants | integer | number of heart-only transplants |
| Status 1A Heart Transplants | integer | transplants to status 1A heart patients |
| Status 1B Heart Transplants | integer | transplants to status 1B heart patients |
| Status 2 Heart Transplants | integer | transplants to status 2 heart patients |
| Heart Patient Relistings | integer | number of patients who relisted for hearts after a transplant |
| Heart Retransplants | integer | number of patients who received a heart transplant after an- other transplant |
| Pediatric Heart Transplants | integer | number of pediatric heart transplants |
| Total Heart Waitlist Deaths | integer | deaths of patients while on the heart waitlist |
| Status 1A Heart Waitlist | integer | deaths of status 1A patients while on the heart waitlist |
| Deaths | | |
| Status 1B Heart Waitlist | integer | deaths of status 1B patients while on the heart waitlist |
| Deaths | | |
| Status 2 Heart Waitlist Deaths | integer | deaths of status 2 patients while on the heart waitlist |
| Inactive Heart Waitlist Deaths | integer | deaths of inactive status patients while on the heart waitlist |
| Deaths After Heart Waitlist Removal | integer | deaths of patients after removal from the heart waitlist |
| Deaths After Heart Relisting | integer | deaths of patients after relisting for a heart |
| Total Heart Post-Graft Deaths | integer | deaths of patients after heart transplant |
| Status 1A Heart Post-Graft | integer | deaths of patients after heart transplant, status 1A at transplant |
| Deaths | 0 | |
| Status 1B Heart Post-Graft | integer | deaths of patients after heart transplant, status 1B at transplant |
| Deaths | - | • |
| Status 2 Heart Post-Graft | integer | deaths of patients after heart transplant, status 2 at transplant |
| Deaths | | |

annotated summary statistics example continued...

| Field Name | Data | Short Definition |
|-----------------------------|-------------|--|
| | Туре | |
| Lung Initial Waitlist | integer | lung patients on wait list at start time |
| New Lung Patient Listings | integer | new lung patient arrivals between start and end time |
| Removed from Lung Waitlist | integer | lung patients who were removed from the waitlist between |
| | | start and end time |
| Final Lung Waitlist | integer | final lung waitlist at end of run |
| Discarded Isolated Lungs | integer | number of discarded isolated lungs (not pairs of lungs) |
| Discarded Lungs Total | integer | number of discarded lungs (including heart-lungs) |
| Single Lung Transplants | integer | number of single lung-only transplants |
| Double Lung Transplants | integer | number of double lung-only transplants |
| Lung Patient Relistings | integer | number of patients who relisted for lungs after a transplant |
| Single Lung Retransplants | integer | number of patients who received a single-lung transplant after |
| | | another transplant |
| Double Lung Retransplants | integer | number of patients who received a double-lung transplant after |
| | | another transplant |
| Pediatric Lung Transplants | integer | number of pediatric lung transplants |
| Lung Waitlist Deaths | integer | deaths of patients while on the lung waitlist |
| Deaths After Lung Waitlist | integer | deaths of patients after removal from lung waitlist |
| Removal | | |
| Deaths After Lung Relisting | integer | deaths of patients after relisting for a lung or lungs |
| Lung Post-Graft Deaths | integer | deaths of patients after a lung transplant |
| anno | otated sumn | nary statistics example continued |

| | | mary statistics example continues |
|---|---------------|---|
| Field Name | Data Turno | Short Definition |
| Heart-Lung Initial Waitlist | Type | heart lung nationts on wait list at start time |
| | integer | heart-lung patients on wait list at start time |
| New Heart-Lung Patient List- | integer | new heart-lung patient arrivals between start and end time |
| ings | • | |
| Removed from Heart-Lung | integer | heart-lung patients who were removed from the waitlist be- |
| Waitlist | | tween start and end time |
| Final Heart-Lung Waitlist | integer | final heart-lung waitlist at end of run |
| Discarded Heart-Lungs | integer | number of discarded heart-lung packages |
| Total Heart-Lung Transplants | integer | number of heart-lung transplants |
| Status 1A Heart-Lung Trans- | integer | number of heart-lung transplants of heart status 1A patients |
| plants | | |
| Status 1B Heart-Lung Trans- | integer | number of heart-lung transplants of heart status 1B patients |
| plants | - | |
| Status 2 Heart-Lung Trans- | integer | number of heart-lung transplants of heart status 2 patients |
| plants | e | |
| Heart-Lung Patient Relistings | integer | number of patients who relisted for a heart-lung after a |
| 6 | 8 | transplant |
| Heart-Lung Retransplants | integer | number of patients who received a heart-lung transplant af- |
| ficult Lung Retrumsplants | integer | ter another transplant |
| Pediatric Heart-Lung Trans- | integer | number of pediatric heart-lung transplants |
| plants | integer | number of pediatric near-tung transplants |
| Total Heart-Lung Waitlist | integer | deaths of patients while on the heart-lung waitlist |
| Deaths | Integer | deaths of patients while on the heart-fung waithst |
| | integer | deaths of beart status 1 A patients while on the beart lung |
| Status 1A Heart-Lung Waitlist | integer | deaths of heart status 1A patients while on the heart-lung waitlist |
| Deaths Status 1D Heart Lung Waitligt | interen | |
| Status 1B Heart-Lung Waitlist | integer | deaths of heart status 1B patients while on the heart-lung |
| Deaths | • , | waitlist |
| Status 2 Heart-Lung Waitlist | integer | deaths of heart status 2 patients while on the heart-lung |
| Deaths | • | waitlist |
| Inactive Heart-Lung Waitlist | integer | deaths of inactive heart status patients while on the heart- |
| Deaths | | lung waitlist |
| Deaths After Heart-Lung Wait- | integer | deaths of patients after removal from the heart-lung waitlist |
| list Removal | | |
| Deaths After Heart-Lung Re- | integer | deaths of patients after relisting for a heart-lung |
| listing | | |
| Total Heart-Lung Post-Graft | integer | deaths of patients after heart-lung transplant |
| Deaths | | |
| Status 1A Heart-Lung Post- | integer | deaths after heart-lung transplant of patients who were heart |
| Graft Deaths | | status 1A at time of transplant |
| Status 1B Heart-Lung Post- | integer | deaths after heart-lung transplant of patients who were heart |
| Graft Deaths | - | status 1B at time of transplant |
| Status 2 Heart-Lung Post-Graft | integer | deaths after heart-lung transplant of patients who were heart |
| Deaths | C | status 2 at time of transplant |
| | annotated su | mmary statistics example continued |

... annotated summary statistics example continues

annotated summary statistics example continued...

| Field Name | Data Type | Short Definition |
|------------------------------|--------------|---|
| Local Heart Transplants | integer | heart transplants in which patient and donor were in the same OPO |
| ZoneA Heart Transplants | integer | heart transplants in which patient and donor were not in the same OPO but were within 500 miles of each other |
| ZoneB Heart Transplants | integer | heart transplants in which patient and donor were not in the same OPO but were between 500 and 1000 miles of each other |
| ZoneC Heart Transplants | integer | heart transplants in which patient and donor were not in the same OPO but were between 1000 and 1500 miles of each other |
| ZoneD Heart Transplants | integer | heart transplants in which patient and donor were not in the same OPO but were between 1500 and 2500 miles of each other |
| ZoneE Heart Transplants | integer | heart transplants in which patient and donor were not in the same OPO but were more than 2500 miles of each other |
| Local Lung Transplants | integer | lung transplants in which patient and donor were in the same OPO |
| ZoneA Lung Transplants | integer | lung transplants in which patient and donor were not in the same OPO but were within 500 miles of each other |
| ZoneB Lung Transplants | integer | lung transplants in which patient and donor were not in the same OPO but were between 500 and 1000 miles of each other |
| ZoneC Lung Transplants | integer | lung transplants in which patient and donor were not in the same OPO but were between 1000 and 1500 miles of each other |
| ZoneD Lung Transplants | integer | lung transplants in which patient and donor were not in the same OPO but were between 1500 and 2500 miles of each other |
| ZoneE Lung Transplants | integer | lung transplants in which patient and donor were not in the same OPO but were more than 2500 miles of each other |
| Local Heart-Lung Transplants | integer | heart-lung transplants in which patient and donor were in the same OPO |
| ZoneA Heart-Lung Transplants | integer | heart-lung transplants in which patient and donor were not in the same OPO but were within 500 miles of each other |
| ZoneB Heart-Lung Transplants | integer | heart-lung transplants in which patient and donor were not in the same OPO but were between 500 and 1000 miles of each other |
| ZoneC Heart-Lung Transplants | integer | heart-lung transplants in which patient and donor were not in the same OPO but were between 1000 and 1500 miles of each other |
| ZoneD Heart-Lung Transplants | integer | heart-lung transplants in which patient and donor were not in the same OPO but were between 1500 and 2500 miles of each other |
| ZoneE Heart-Lung Transplants | integer | heart-lung transplants in which patient and donor were not in the same OPO but were more than 2500 miles of each other |

... annotated summary statistics example continues

8 Frequently Asked Questions

8.1 Data Input Parameters

Model Allocation Run Dates: 7/1/2009 through 7/1/2011 Organs available between 7/1/2009 and 6/30/2011 Wait List statistics as of 6/30/2009 New Patients added between 7/1/2009 and 60/30/2011 Status Updates between 7/1/2009 and 6/04/2012

8.2 Summary Report - Standard Deviation Calculation

Each iteration represents an independent sample from an infinite set of possible iterations. The variance around each statistic is thus given by the sum of the squared differences from the mean, divided by number of iterations minus one. The standard deviation is the square root of the variance.

8.3 Does Transplanted Organs include Retransplants?

Yes. It counts all organs that are transplanted, whether it was the patient's first transplant or not.

8.4 Does Patient Listings include Relistings?

No. Patient Listings includes only the initial listing.

8.5 Should the inputs and outputs balance?

Yes. This is the initial list + all entries to the list - all exits from the list.

- Initial Wait List
- + Patient Listings
- + Relistings
- Transplanted Organs
- Removed from Wait List
- Wait List Deaths
- Relisted Patient Deaths

Final Wait List

8.6 What records are included in Grafts.out vs GrPats.out?

Grafts.out contains a record for each organ transplanted. GrPats.out also contains one record for each transplant that occurs during the model run, but it contains information about the patient as well as the organ.

8.7 What are the types of Input/Output Errors?

Typically the TSAM program will not run with errors in the input files. Below are the most frequently encountered errors:

• If a value read from a text file does not conform to the expected format, an error message will be displayed during the model allocation run specifying the location of the error. The input data will have to be corrected and the model re-started.

| Thoracic Simulated Allocation Model |
|---|
| Error reading status update file> ', 12:56:33' is not a valid date and time |
| OK |

If an output file is in use by another program, i.e., Excel or Word, you will get "I/O error 32." Close the file in use and restart the model run. If a file you have selected in your input parameters does not exist, you will get "I/O error 103."

| Thoracic Simulated Allocation Model 🛛 🗙 | Thoracic Simulated Allocation Model |
|---|-------------------------------------|
| 1/0 error 32. | 1/0 error 103. |
| OK | ОК |

9 Additional Resources

OPTN maintains a glossary of terminology related to transplantation: <u>http://optn.transplant.hrsa.gov/resources/glossary.asp</u>

SRTR maintains summary information on organ allocation policy, including flowcharts and descriptive articles: <u>http://www.srtr.org/allocationcharts/Default.aspx</u>

The TSAM data input files are based on the SRTR Standard Analysis File (SAF), and the SAF data dictionary may be useful in understanding these fields in more detail: <u>http://www.srtr.org/data_request/saf.aspx</u>. Requests for SAF data may be made to the SRTR: <u>http://www.srtr.org/data_request/datause_policy.aspx</u>

Please send questions to SRTR: srtr@srtr.org or 1-877-970-SRTR.