

OPTN Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup**Meeting Summary****September 23, 2022****Conference Call**

Rachel Forbes, MD, Chair
Oyedolamu Olaitan, MD, Vice Chair
Martha Pavlakis, MD, Chair
Jim Kim, MD, Vice Chair

Introduction

The Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 9/23/2022 to discuss the following agenda items:

1. Kidney-Pancreas Simulated Allocation Model (KPSAM) Modeling Primer
2. Massachusetts Institute of Technology (MIT) Modeling Primer

The following is a summary of the Workgroup's discussions.

1. Kidney-Pancreas Simulated Allocation Model (KPSAM) Modeling Primer

The Workgroup received a presentation on Scientific Registry of Transplant Recipients (SRTR) KPSAM modeling in preparation for their review of modeling results.

Presentation summary:

The SRTR supports ongoing evaluation of the status of solid organ transplantation in the United States. The SRTR is currently administered by the Chronic Disease Research Group of the Hennepin Healthcare Research Institute and maintains an ever-expanding national database of transplantation statistics on the full spectrum of transplant activity – ranging from data on organ donation and waiting list candidates to transplant recipients and their outcomes.

The SRTR uses a software tool called Simulated Allocation Models (SAMs) to make predictions about how organ allocation rates and outcomes might change following the implementation of new allocation rules. SAMs take real candidate and donor information and use this to simulate allocation by applying new rules the Committee would like to explore. The software then outputs information on modeled results of new allocation rules, including the number of candidates transplanted, died waiting, and post-transplant deaths.

The models include some random components, reflecting uncertainty in acceptance decisions when an organ is offered to a potential recipient, and the unpredictable life expectancy that can result from undergoing or not undergoing transplant. To account for random variation, SRTR runs the models several times with the same set of allocation rules, organs, and candidates to determine average outcomes. SAMs rely on aggregate historical data and can't predict changes in organ acceptance behavior or identify trends over time. SAMs work best for modelling small allocation changes applied to large patient groups and are unlikely to give reliable predictions for small population subgroups, can't predict outcomes below an OPO level, and assume standardized behavior. Center- and OPO-level variation in policy or practice is not modeled, directed/expressed allocations are not modeled. Organ discard projections are unreliable as organs are discarded after a fixed number of declined offers,

regardless of organ and donor characteristics. Overall, SAMs are good tools to estimate the overall magnitude and direction of possible effects of policy change. However, some policy changes may be justified even in the absence of clear simulation results.

Committees considering changes to organ allocation may request modeling of allocation changes from SRTR. The SRTR then presents key findings from the report to the Committee and the Committee weighs information from modeling results as well as medical, ethical, and practical considerations in making a decision on whether to pursue an allocation change.

Summary of discussion:

A member asked how accurate the models are compared to real world scenarios. An SRTR representative answered for previous liver allocation models and thoracic organs, SRTR has looked at and published papers looking at accuracy of the models and their website contains publications on comparisons they've done for liver and thoracic modeling.

A Chair asked if there is a way to include more reflection of modeling for a center that is more urban versus (vs.) more rural to account for variability in geography. An SRTR representative commented modeling doesn't tend to look at a more granular level of center by center as it is difficult to ascertain data at that level. The representative further commented modeling does look at some metrics that try to get at the questions around regional variation. A member commented national policy affects individual centers and affects how individual programs care for patients and resources needed. The member further commented modeling at that level helps to fend off discussions and concerns. A staff member commented the smaller the population size modeling tries to predict, the less reliable the prediction may be. An SRTR representative further commented there is data available down to the DSA level, but getting the data to a more granular level makes the results less confident.

2. Massachusetts Institute of Technology (MIT) Modeling Primer

The Workgroup received a presentation on the MIT modeling efforts in preparation for their review of modeling results.

Presentation summary:

MIT mathematical optimization will help the Committees hone in on a range of acceptable policy options. MIT is augmenting KPSAM with machine learning to quickly and accurately predict outcomes by identifying policies (attribute weights) that achieve any set of pre-specified outcomes in near real-time. This mathematical optimization helps narrow the window of options to those with an acceptable equity vs utility balance. MIT did similar work for the lung continuous distribution project and helped inform the OPTN Lung Transplantation Committee's selection of weight for various attributes. The goal of the MIT analysis is to allow the committees to feel more confident about their chosen allocation policy options before SRTR conducts the final, confirmatory modeling.

Initially, MIT will model three optimizations to include:

- Transplant rate for pediatrics by pediatric attribute weight
- Variance in transplant rate by donation service area (DSA) by proximity efficiency weight
- Variance in median time from listing to transplant by DSA by proximity efficiency weight

Summary of discussion:

A member asked if it is possible to model all of the variables at once. Staff answered the modeling will look at multiple variables by comparing two at a time, and that constraints can be set to specify what the committees would want to optimize.

A member suggested the modeling evaluate discard rate. Staff answered the MIT modeling would be subject to the same limitations as SRTR modeling for discard rate. Organ discard projections are unreliable as organs are discarded after a fixed number of declined offers, regardless of organ and donor characteristics. Another member suggested evaluating longer term outcomes and survival.

Another member asked if modeling takes into account a projected bolus effect as has been seen post-implementation of other policy changes. Staff answered modeling is not meant to predict outcomes so much as it is a representation of what would have happened to a select cohort of candidates if policies had been different. The member further commented if modeling doesn't account for bolus, then the committees should take the bolus effect into account when conducting analysis.

Next Steps:

The Workgroup will review results of the KPSAM and MIT modeling once available.

Upcoming Meetings

- TBD

Attendance

- **Workgroup Members**
 - Martha Pavlakis
 - Rachel Forbes
 - Abigail Martin
 - Oyedolamu Olaitan
 - Bea Concepcion
 - Maria Friday
 - PJ Geraghty
 - Parul Patel
 - Rachel Engen
 - Todd Pesavento
 - Caitlin Shearer
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Representatives**
 - Bryn Thompson
 - Grace Lyden
- **UNOS Staff**
 - Joann White
 - Lindsay Larkin
 - Kayla Temple
 - Kim Uccellini
 - Alex Carmack
 - Ben Wolford
 - James Alcorn
 - Joel Newman
 - Kaitlin Swanner
 - Keighly Bradbrook
 - Lauren Mauk
 - Lauren Motley
 - Rebecca Fitz Marino
 - Ross Walton
 - Sarah Booker