OPTN Kidney Transplantation Committee
Meeting Summary
September 19, 2022
Conference Call

Martha Pavlakis, MD, Chair
Jim Kim, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 9/19/2022 to discuss the following agenda items:

1. Welcome and Announcements
2. Kidney-Pancreas Simulated Allocation Model (KPSAM) Modeling Primer
3. Massachusetts Institute of Technology (MIT) Modeling Primer
4. Continuous Distribution Project Timeline Check In

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

1. Welcome and Announcements

Staff and Committee Leadership welcomed the Committee members, and reminded members to book their travel for the upcoming in-person meeting in Chicago.

Summary of discussion:

There were no questions or comments.

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

The Committee 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/expedited 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:

The Chair asked if SRTR has done any analysis of predicted outcomes compared to actual one-year results after a policy is implemented. Staff commented the SRTR does review actual outcomes to improve future modeling. An SRTR representative also commented KPSAM 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.

Next Steps:

The Kidney and Pancreas Committees submitted the first KPSAM request in April 2022 and will review results once available.

3. Massachusetts Institute of Technology (MIT) Modeling Primer

The Committee 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 outcomesby identifying policies (attribute weights) that achieve any set of prespecified 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:

The Committee held a brief discussion on metrics that would be most important for measuring success of the new system, and what outcomes would not be acceptable.

A member asked if modeling can predict the impact of multi-organ transplant (MOT). Staff commented the SAMs as they exist now don't interact between organ types in a way that can predict the impact of MOT, however the modeling can give insight into the impact of kidney-pancreas and safety net policies. The member recommended evaluating transplant rates by MOT center availability.

Another member suggested a metric to look at cold ischemic time (CIT) and whether an unacceptable CIT threshold should be included. The Vice Chair commented proximity efficiency may help with efficiency factors such as CIT and suggested looking at CIT separately. Another member suggested evaluating how changes in CIT would affect graft survival. The member further suggested the modeling optimize longer graft survival beyond three years. An SRTR representative commented the new KPSAM modeling will include 10 year outcomes.

Next Steps:

The Kidney and Pancreas Committees will review MIT results along with the KPSAM modeling results once available. The Committee will continue to identify important metrics to include as part of MIT mathematical optimization.

4. Continuous Distribution Project Timeline Check-In

Staff presented an update to the project timeline an ongoing efforts across sponsoring committees and associated workgroups.

Presentation summary:

The Committees will be reviewing KPSAM and MIT modeling results, Public Comment feedback, and cross-committee feedback with the goal of submitting a second modeling request to SRTR in January of 2023. In order to accomplish this work, the Committee will be meeting more frequently. Additionally, committee leadership and staff have outlined a work plan to expedite work, enhance engagement, relieve volunteer time burden, and ensure stakeholder committee partners remain involved in discussions and decision making. With these goals in mind, two new workgroups have been created, and realigned project focus areas as follows:

- **Kidney and Pancreas Committees:** the Committees will be the primary sponsors of the continuous distribution projects and focus on the overall construction of the continuous distribution frameworks. Over the next few months the Committees will be dedicating their time to reviewing and adjusting these frameworks with the help of modeling and public comment feedback. The Committees will also be reviewing recommendations from other Workgroups for endorsement for inclusion in the eventual public comment proposals. The Committees consist of regional and at large representatives from transplant programs, OPOs, histocompability labs, and the patient community.
- **Operational Considerations Workgroup:** This new Workgroup will focus on operational components that fall outside of the composite allocation score and developing recommendations for Committee review and endorsement (ex. dual kidney allocation, kidney minimum acceptance tool, facilitated pancreas, etc.). This group includes representation from the Kidney, Pancreas, OPO, Transplant Coordinators, and Transplant Administrators Committees.
- **Review Boards Workgroup:** This new Workgroup will focus on the development of review boards for both kidney and pancreas. This group includes representation from the Kidney, Pancreas, Pediatric, and Data Advisory Committees.
- **Kidney-Pancreas Continuous Distribution Workgroup:** This existing Workgroup will continue to meet on a monthly basis and serve as a check-in meeting between the Kidney and Pancreas Committees and other stakeholder committee representatives to report out on project work and

collect feedback. This group includes representation from the Kidney, Pancreas, Pediatrics, Histocompatibility, Ethics, Minority Affairs, and OPO Committees.

Summary of discussion:

There were no questions or comments.

Upcoming Meetings

- October 14, 2022 – Chicago, IL
- October 24, 2022 - Teleconference

Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Beatrice Concepcion
  - Jesse Cox
  - Patrick Gee
  - Precious McCowan
  - Sanjeev Akkina
  - Stephen Almond
  - Asif Sharfuddin
  - Chandrasekar Santhanakrishnan
  - Jason Rolls
  - Marian Charlton
  - Marilee Clites
- **HRSA Representatives**
  - Jim Bowman
  - Adriana Martinez
  - Adrienne Goodrich-Doctor
- **SRTR Staff**
  - Grace Lyden
  - Ajay Israni
  - Bryn Thompson
  - Jonathan Miller
  - Nick Wood
  - Tim Weaver
- **UNOS Staff**
  - Lindsay Larkin
  - Keighly Bradbrook
  - Ben Wolford
  - Carly Layman
  - James Alcorn
  - Matt Belton
  - Melissa Lane
  - Rebecca Fitz Marino
  - Sara Moriarty
  - Sarah Booker
  - Stryker-Ann Vosteen