Minutes

SRTR Visiting Committee

Date: January 17, 2018 Time: 9:00 AM-12:00 PM CTD

First of Two Required Annual Teleconferences

Voting Members:

Susan Gunderson, MHA (Co-Chair) Ken Newell, MD, PhD (Co-Chair) Scott Biggins, MD, MAS Jonathan Chen, MD Richard Formica, MD Bethany Foster, MD, MSCE Walter Kremers, PhD Rachel Patzer, PhD Luke Preczewski

Ex-Officio Members:

Monica Lin, PhD (HRSA) Eric Engels, MD (NCI) Jennifer Milton, MBA (OPTN-POC) Jonah Odim, MD (NIH) Darren Stewart, MS (OPTN/UNOS)

Guests:

Joyce Hager (HRSA)
Chris McLaughlin (HRSA)
James Bowman (HRSA)
Raelene Skerda (HRSA)
Emily Levine (HRSA)
Janet Kuramoto-Crawford (HRSA)
Robert Walsh (HRSA)
Brian Sheppard (UNOS)
Ryan Ehrensberger, (UNOS)
James Alcorn, (UNOS)
Chad Southward (UNOS)
Cory Schaffhausen, PhD (MMRF)

SRTR:

Bertram Kasiske, MD Jon Snyder, PhD, MS Ajay Israni, MD, MS Laura Klein, MPH Nicholas Salkowski, PhD Andrew Wey, PhD Larry Hunsicker, MD Mona Shater, MA Bryn Thompson, MPH Alyssa Herreid, MPH Amy Ketterer Sommer Gentry, PhD

Welcome & Introductions

Co-Chair Susan Gunderson called the meeting to order at 9:05 AM CDT.

Dr. Jon Snyder roll-called the participants. All voting members of the committee were present. Non-voting members and guests also introduced themselves. Numerous staff members from HRSA and UNOS were present to listen to the discussion on geography.

Dr. Bert Kasiske informed the committee on the topic of conflicts of interest (COIs), Dr. Kasiske emphasized that SRTR must ensure management of any potential conflicts, and asked committee members to bring forward any potential COIs during deliberations and recuse themselves from related discussions.

Geography in Organ Distribution (Slides 6-18)

Dr. Snyder noted that the goal of this portion of the meeting was to inform SVC members about the new OPTN Ad Hoc Committee on Geography and the ideas that SRTR staff have been developing to

support the committee's deliberations. SRTR staff members may be asked to present these concepts to the Ad Hoc Committee in the future and were hoping to gain valuable feedback from the SVC members today.

Dr. Snyder began by discussing the history behind formation of the Ad Hoc Committee on Geography. He continued by presented key components of the OPTN Final Rule that have guided SRTR's thoughts regarding geography in organ allocation polices, both the "requirements" (slides 8-9) and the "performance goals" (slides 10-11). He noted SRTR's approach to delineating the differences between "individual equity" and "system equity" when evaluating the performance of any given solution and the inherent trade-offs that must be considered when balancing competing priorities (Slides 13-18).

The discussion thus far attempted to set the stage for presentation of two systems to be considered as alternative ways to handle geography in future allocation systems: adaptive circle boundaries and systems that use no set boundaries through use of a continuous proximity score.

Adaptive Circle Boundaries (Slides 19-35)

Dr. Sommer Gentry, SRTR Senior Staff, gave an overview of her work considering distribution circles based on population density as opposed to fixed circle boundaries based on nautical miles. In her examples, a circle would be drawn around the transplant center to include a certain population size, and any donor organ within that circle would be offered early in the allocation process to that center. The goal of such a system would be to balance donors per candidate to allow an equitable arrival rate of donor organs for candidates at different transplant programs. Dr. Gentry's summation stated the fixed population bubble did a better job of evening out the number of donors per candidate. When asked if she had considered designing the system based on supply vs. demand, Dr. Gentry affirmed it was certainly possible to design the bubbles in terms of "donors available" rather than population. She also noted that circles are centered on the transplant center in her current analysis, because that is where the patient is.

Systems without Geographic Boundaries (slides 36-56)

Dr. Snyder explained how a system could be constructed to use a continuous proximity score rather than fixed boundaries. It would combine a medical priority score with a proximity score. The proximity score would be based on factors that attempt to describe the ease and speed with which an organ could be moved from an available donor to a recipient, e.g., distance, cold-ischemia time, travel time, travel costs/logistics, etc. Dr. Snyder noted that "medical priority" scores are already in place for each of the organs, e.g., MELD, LAS, and heart tiers, and that the Final Rule allows for medical priority scores that are based on something other than medical urgency if a therapy exists to keep candidates alive following end-organ failure, e.g., dialysis or ventricular assist devices.

Dr. Snyder illustrated this concept in the context of liver allocation with a series of slides showing allocation priority vs. proximity (as measured in miles, for the sake of simplicity), with a proximity score function plotted that would be combined with medical priority to define final allocation priority. Dr. Snyder noted that the shape of the proximity slope function should be debated to best describe the values of the transplant community, i.e., the trade-off between shipping and medical priority. In addition, special considerations for donor characteristics, e.g., DCD vs. DBD, and recipient characteristics, e.g., adult vs. pediatric, could be incorporated into either the proximity score function or the medical priority function as appropriate.

There was a brief discussion and committee members generally supported the concept. Members supported the idea of separating individual equity and system equity. The committee supported bringing these concepts to the Ad Hoc Committee on Geography if requested to do so. Dr. Richard Formica serves as a member of both the SVC and the Ad Hoc Committee, and he was in agreement.

Update on the Recommended Changes to the SRTR Website (Slides 58-60 with AHRQ slides inserted.)

Dr. Snyder previewed a development version of the SRTR website that incorporated changes recommended by the SVC at the previous meeting, namely to include 5-tier evaluation systems for deceased donor transplant rate and waitlist mortality, separating living donor and deceased donor transplant volume, and including a "key" with the search results that provides metrics of expected outcomes at each tier level for the three metrics: waitlist mortality, deceased donor transplant rate, and first-year posttransplant graft survival.

Dr. Cory Schaffhausen gave an overview of previously presented feedback from participants in the current phase of the study, patient focus groups. To support the most recent SVC recommendations, he presented the website content to survey participants and asked a question to test their understanding of the information as displayed. This was to test whether the key with national data for each tier helped candidates better understand the content.

The key was presented in three different versions, including the current design shown on the devbeta site and a version similar to one shown to the focus groups. A final version allowed candidates to select the metric they were looking for from a drop down list (as previously suggested), and that seemed to be the most understandable version based on Dr. Schaffhausen's interviews. The version shown on the devbeta site produced slightly fewer correct survey responses; however, this difference was expected to be minimal on a functional website.

Overall, the greatest shared concern related to keeping the wording and presentation very simple, so patients can understand the information. One example is use of calculated metrics with units "per 100 person-years," which may be difficult for patients to understand and use. Links could provide access to more information describing what the displayed information means. Dr. Schaffhausen finished by discussing the intention to start including interviews with heart and lung patients.

Addressing the Recent Publication on the Utility of the 5-Tier Assessments by Dr. Jesse Schold (No Slides)

Dr. Andy Wey introduced an item not on the original agenda. A paper by Dr. Jesse Schold had been recently published in AJT, "Expanding clarity or confusion: volatility of the five-tier ratings assessing quality of transplant centers in the United States." This paper addressed the utility of the 5-tier assessment for patient decision making, concluding that tiered assessments vary substantially over time, limiting utility for patient decision making given the length of time between wait-listing and transplant for kidney candidates.

Dr. Wey presented a few slides showing preliminary thoughts in response to the arguments laid out in the paper. He noted that it was not surprising that centers change tiers. The "band width" of the tiers was designed to be thinner to reduce intra-tier variability in transplant program outcomes. The previous 3-tier system based on statistical hypothesis testing was arguably not variable enough since most programs were classified in the middle tier. Reduction in intra-tier variability leads to more programs being able to cross tier boundaries from cycle to cycle. Any system needs to balance the responsiveness to program changes with the ability to distinguish program performance. Dr. Wey also hypothesized that the relevance to future outcomes was likely best supported in kidney transplantation where wait times are longer; however, the paper did not evaluate other organ types.

There was considerable discussion among the committee members, particularly new members, about the tier system and whether it was necessary. Rather than revisit some of the decisions agreed upon by the SVC in the past, the committee decided to further explore issues raised by the Schold paper for presentation at its next meeting.

Closing business

There was a call for additional business. There was none and the meeting was adjourned at 12:16PM