

SRTR Review Committee Meeting Minutes

Teleconference

August 17, 2022, 12:00 PM – 3:00 PM CDT

Voting Members:

Roslyn Mannon, MD (Co-chair, '23)
Jeffrey Orlowski, MS, CPTC (Co-chair, '22)
Sumit Mohan, MD, MPH ('22)
James Pittman, RN, MSN ('22)
Chris Zinner ('23)
David Vock, PhD ('24)
Ginny Bumgardner, MD, PhD ('24)

Not in attendance:

Kiran Khush, MD, MA, MAS ('23)
Richard Knight, MBA ('22)

Ex-Officio Members:

Shannon Dunne, JD (HRSA)
Nicole Turgeon, MD, FACS (OPTN-
POC)
Jonah Odim, MD (NIH)
Laura Cartwright, PhD, MPH
(OPTN/UNOS)
Rachel Patzer, PhD (OPTN-DAC)

HRSA:

Adriana Martinez
Not in attendance:
Chris McLaughlin
Shannon Tait

SRTR Staff:

Ryutaro Hirose, MD
Larry Hunsicker, MD
Ajay Israni, MD, MS
Bertram Kasiske, MD, FACP
Grace Lyden, PhD
Jon Miller, PhD
Cory Schaffhausen, PhD
Jon Snyder, PhD, MS
Nicholas Wood, PhD
Not in attendance:
Allyson Hart, MD, MS
David Zaun, MS

Welcome and opening remarks

Mr. Jeffrey Orlowski called the SRTR Review Committee (SRC) meeting to order. He reviewed the agenda and conflict of interest management. Mr. Orlowski proceed with the first item.

Approval of the minutes

Mr. Orlowski asked the committee to approve or suggest changes to the minutes from April 28, 2022. Mr. Chris Zinner motioned an approval, and Dr. Roslyn Mannon seconded. The minutes were unanimously approved.

The 2022 SRTR consensus conference

Dr. Jon Snyder debriefed SRTR's People Driven Transplant Metrics Consensus Conference, which took place on July 18-20, 2022, in Bloomington, Minnesota. He highlighted attendance and steps SRTR is now taking to process the data collected at the conference.

The conference had 258 attendees (114 virtual, 144 in person). The target of 20%-25% patient participants was achieved. Patients, donors, caregivers, and patient advocates constituted 17% of attendees, and 7% identified as both patients and transplant professionals. Transplant professionals made up 76% of attendees. The patient participants consisted of 31 patients, 18 patient advocates, 14 caregivers, 13 living donors, and 6 deceased donor family members. The breakdown for professionals was as follows: 122 transplant professionals (physicians, surgeons, administrators), 48

researchers, 29 from organ procurement organizations (OPOs), 26 regulators, 14 from professional societies, 15 from universities, 8 from industry, and 7 payers. Organs represented included 143 for kidney; 98, liver; 70, pancreas; 60, heart; 16, intestine; 12, vascularized composite allograft; and 88, all organs. Dr. Snyder noted that attendees could indicate more than one affiliation and more than one area of expertise, so breakdowns do not sum to total attendees.

Day 1 of the conference focused on why each stakeholder group cares about transplant data. Day 2 was devoted to what information people would find most helpful. Day 3 focused on how SRTR could best address identified needs. Dr. Cory Schaffhausen's transplant system "subway map" was used to guide the conference discussions and was well received. The subway map and analogy are currently being used to help guide future developments. Dr. Snyder noted that the entire conference is now available in recorded form on srtr.org.

Dr. Schaffhausen gave an update on the consensus conference process, which spans the entire 5-year contract period. He mentioned that the conference agenda was intentionally broad to capture what all stakeholders thought was important, even if it was not currently in the scope of SRTR's contract. These broad discussions will be encapsulated into a manuscript and used to guide prioritization discussions with the SRC and the Health Resources and Services Administration (HRSA). Dr. Schaffhausen added it was important to continue with stakeholder engagement, particularly to give feedback on future reporting changes and website design. The final year of the contract calls for SRTR to reconvene the community to assess progress on initiatives undertaken following the conference.

Dr. Schaffhausen went into detail about recommendations collected at the conference. Data sources included summaries collected at the moderator dinner at the conclusion of day 2; breakout group "report backs," where moderators from virtual and in-person breakout groups summarized high-priority comments (already transcribed and to be compared with moderator day-2 notes); in-person participant worksheets; breakout group flip-charts that summarized and prioritized recommendations; virtual breakout sessions (recorded); and virtual chat comments in some cases. Focus groups with patients, donors, and family members were conducted prior to the conference to inform some of the conference work and results will be incorporated into conference recommendations. Once all data are processed, SRTR will work with the Task 5 Steering Committee and the SRC to summarize conference findings for submission in a peer-reviewed transplant journal.

Dr. Ryutaro Hirose reviewed the first draft of conference recommendations, largely taken from the summaries provided at the moderator dinner at the conclusion of day 2. He first reviewed the recommendations of patients and family members. There was an emphasis on the need for information and data, not just performance metrics. Patients wanted information about who has access to transplant listing, long-term outcomes following transplant, out-of-pocket costs, and survival benefit of transplant. Living donor concerns included acceptance criteria, access to exchange programs, center comparisons of the percentages of live donor procedures performed, recovery time, and quality of life. Deceased donor family members wanted to know what happened to loved ones' organs, predicted longevity of donor organs, donor criteria, and length of the donation process. Deceased donor family members also strongly disliked the term "discard" and suggested replacing this term with something perceived to be less derogatory.

OPO professionals were interested in donor hospital data and accountability, granular timestamp data on the organ offer process, and a metric for honoring first-person consent. For OPO metrics, it was agreed that eligible death was not a useful denominator, current Centers for Medicare & Medicaid Services (CMS) metrics are not adequately risk adjusted, and an accurate metric of true donor potential is needed.

Transplant professionals requested waitlist management and predictive tools, real-time risk and decision analysis tools for donor-recipient pairs, metrics of equity and effects of social determinants of health, and improvements in data definitions and completeness. They also recommend against metrics that drive risk-averse behavior or hinder innovation.

Payers and regulars were interested in referral, evaluation, and listing data; transplant center selection criteria; decision support to identify centers; staffing levels and staffing changes; patient-reported outcomes; patient satisfaction; and safety metrics.

Members gave additional comments and feedback. Dr. Nicole Turgeon suggested reaching out to patients and providers who are less engaged than conference attendees (as opposed to “professional patients”), as not getting these perspectives may lead to bias. Dr. Nicholas Wood asked if the family members’ disapproval of the word “discard” was due to the word itself or more so that a loved one’s organs were not used. Dr. Hirose surmised that both the word and the concept matter were reasons. Dr. Jonah Odim suggested the patient community might be open to the idea that a donated organ be used for research in the event it is not able to be successfully transplanted. Mr. Orlowski pointed out that this process already happens but that people may not realize it, which is why education is key. However, as OPOs differ in policies, not all OPOs will allow research for nonused organs.

Mr. Orlowski concluded the discussion of the consensus conference by noting that SRTR will continue to process the data from the conference. The SRC will be helping SRTR to prioritize efforts in response to conference recommendations.

Match-run complexity: Impact on organ allocation and utilization

Mr. Orlowski then introduced the next topic and turned to Dr. Snyder to introduce Dr. Wood, who would cover the work he is leading on match-run complexity and its potential association with organ utilization.

Dr. Wood said the motivation for this study was the paper by Adler et al,¹ which raised concerns over unintended consequences of complexity imparted by the new kidney allocation system. He demonstrated how broader definitions of “local” alter the complexity of organ allocation. Adler and colleagues were concerned that this increased complexity could cause strain on the transplantation system.

Dr. Wood defined the “complexity” of a particular match run focusing specifically on kidney offers. He reviewed an example of match run where, for any offer number, the cumulative number of unique transplant centers that would have received an offer by any point on the match run can be determined. Dr. Wood’s presentation focused on his chosen complexity metric of the center number at offer 50 (C50) (ie, the cumulative number of unique transplant centers on a match run by offer

number 50). Dr. Wood presented how the new allocation system that went into effect a year and a half ago affected the C50 metric. He then hypothesized that more transplant centers early on in the match run may increase the likelihood of delays, which may increase the likelihood of nonutilization of donated kidneys.

Dr. Wood presented a graph of the 1-year rolling average of the C50, highlighting the impact of allocation change to the 250-nautical-mile policy (KAS250). It showed that the average C50 for all match runs in the year prior to the new kidney allocation system was 5.5, which increased to 12 in the year after the allocation change. He then presented a map of the United States that showed the change in median C50 by Organ Procurement and Transplantation Network (OPTN) region. For donors recovered in regions 2, 9, and 10, the median C50 increased more substantially. Regions 5 and 6 in the west had little change. Dr. Wood noted that kidney programs are denser in the east compared with the west.

Dr. Sumit Mohan asked why 50 was used, as opposed to staying consistent with the hard-to-place organ threshold of 100 offers, or using median number of offers (about 7). Dr. Wood agreed that choosing 50 was arbitrary, but he found that the conclusions were not very sensitive to the choice of which offer number to focus the metric on. He thought 50 did a reasonable job of capturing match-run complexity and could be useful in comparing differences in allocation policies.

Dr. Wood moved on to the nonutilization rate of deceased donor kidneys. He presented a figure of the trend in the 1-year rolling average nonutilization rate, noting the declaration of a national emergency due to COVID-19 and when KAS250 went into effect. He showed that the nonutilization rate was 20.2% in the year prior to the pandemic and 21.4% in the year after the pandemic declaration, and that the rate increased to 25.8% as of June 2, 2022. Dr. Wood noted that, although not shown on the figure, the most recent data available showed a continued increase, surpassing 26% as of July 31, 2022.

Dr. Wood assessed the association between match-run complexity as measured by C50 and the kidney nonutilization rate. For this analysis, he considered all kidneys recovered for transplant from March 15, 2020, to March 14, 2022, 1-year pre- versus 1-year post-policy change. The primary predictors of nonutilization were the kidney donor risk index (KDRI) and the complexity metric C50. The resultant set was split into two data sets based on allocation era: the pre-KAS250 and KAS250 sets. Dr. Wood showed the results with two histograms, one with C50 pre and post allocation policy and the other KDRI. The KDRI histogram showed a similar distribution pre-KAS250 and post-KAS250. The distribution of C50 shifted substantially to the right after the implementation of KAS250, meaning more centers were involved early in the match run following KAS250. It was hypothesized that C50 might differentially affect probability of nonutilization depending on KDRI. After testing, a cut point of KDRI = 1 (representing a kidney donor profile index [KDPI] of approximately 25%) was chosen. Models were used to predict the number of nonutilized organs in the KAS250 era to estimate the impact of increased complexity, with the hypothesis being that any difference in the expected nonutilized kidneys could be attributable to the increase in complexity.

Results showed that the coefficient for KDRI in the logistic regression model was 2.81, meaning that as KDRI increased, the probability of nonutilized organs unsurprisingly increased. The predicted number of nonutilized kidneys in the KAS250 era was 5,816, for a rate of 22.3%. With a negative coefficient, as the center number increases and more centers are involved early on in match run, the

probability for nonutilized in both kidneys decreases. When KDRI ≥ 1 (KDPI $\geq 25\%$), the coefficient is positive, meaning as center number increases, the probability of nonutilized kidneys increases. However, when KDRI < 1 (KDPI $< 25\%$), the association was reversed (ie, as complexity increased, the likelihood of nonutilization decreased). Taking the model and applying it to predict the number of nonutilized kidneys in the KAS250 era totals 6,041, for a rate of 23.2% (difference of 225 nonutilized organs in 1 year). The actual nonutilization rate during this time was 25.4%.

Although C50 does not fully explain the increased nonutilization rate, Dr. Wood posited it could be influenced by increased regulatory pressure on OPOs to pursue marginal donors who are somehow not adequately explained by KDRI (eg, OPOs being more willing to recover COVID-positive donors). He noted that the relationship between C50 and the nonutilization rate existed prior to KAS250 implementation. Had this relationship been understood prior to KAS250, the expected nonutilization rate would have been predicted to increase by 1 percentage point (225 kidneys in the first year of KAS250).

Mr. Orlowski said OPOs were recovering much more aggressively from COVID-positive donors, although individual transplant practices vary and center nuance was complicated to measure. Dr. Hirose asked if the expected nonutilization rate varied by region, and Dr. Wood said there was no neat correlation. Nonutilization rate increased for all regions, but complexity as measured by C50 was not the sole cause of nonutilization. Mr. James Pittman asked about the association between match-run sequence number and allocation time. Dr. Wood said SRTR has been analyzing a new dataset supplied by the United Network for Organ Sharing (UNOS) with improved timestamp data and noted that sequence numbers are gone through more slowly in KAS250.

Dr. Wood revisited the US map displaying center density, noting that donation service area (DSA) sizes are generally smaller in the eastern United States, which correlates to population density. The old allocation, perhaps by accident, respected heterogeneity in population density. Dr. Wood noted that a well-designed continuous distribution algorithm could respect this heterogeneity in an effort to counter a negative effect imparted by match-run complexity. One hypothesis for why the effect of C50 different by KDRI may be that more centers can be seen as competition for the highest quality kidneys, but cause delay for lower quality kidneys for which programs may be more selective.

Dr. David Vock posited that Dr. Wood could look at whether centers that had the most changes in the complexity on the match run have the biggest changes in the nonutilization rates, leading to a stronger argument that increasing complexity might have unintended consequences. Dr. Mohan suggested to consider removing kidneys that got successfully placed under 50 in the inclusion cohort of the analysis, and seeing what impact that has on the analysis for predicting nonutilization. Also, the increase in selectivity may not be a factor of match-run complexity but a capacity issue at centers. Dr. Turgeon said it was important to consider the information from a policy perspective—specifically efficiency and equity. She cautioned against focusing too much on a complexity metric and the relationship to nonutilization while discounting other goals of allocation policies.

Before moving on to the next item, Mr. Orlowski introduced the new ex-officio member, Laura Cartwright, PhD, interim director of research at UNOS. Dr. Cartwright replaced Darren Stewart as the OPTN representative to the SRC.

A race-free kidney donor profile index

Dr. Jon Miller presented findings on the impact of Black race coefficient in the KDPI. Dr. Miller said the Kidney Committee has previously examined the estimated glomerular filtration rate (eGFR) and use of race in estimating kidney function and its effect on listing for kidney candidates. The race coefficient in the eGFR equations was hypothesized to be creating a barrier in access for Black candidates. OPTN has recommended a policy to use race-free eGFR equations. The KDRI, and the associated KDPI, is another algorithm that currently includes a modifier for black race. KDPI is used in kidney allocation and determines ordering of the match run. KDPI of 0%-20% is highest quality, while KDPI of 86%-100% has the highest risk of nonutilization and may have labeling effect.

The original analysis that estimated KDRI was from SRTR in 2009 by Rao et al.² The aim was to replace the expanded-criteria donor classification, a function of donor age and other underlying risks factors for determine a high-risk kidney. KDRI replaced this classification with a more nuanced approach to estimating donor quality. Several donor, recipient, and transplant factors were used in a survival model to establish the original coefficients, which were used to establish scores for individual donors. It was concluded in a 2019 reanalysis that there was not evidence that supported the need to update the original KDRI coefficients.

KDPI is a mapping of KDRI on a scale of 0%-100% and is based on all of the kidneys recovered the previous year. A KDRI to percentile mapping table is used for the subsequent year to determine the KDPI for donors recovered in that year. The mapping table is approved in the middle of the year (March-June), so donors in the first half of the year score on KDPI using a cohort that is 2 years old, and donors in the second half of year are scored on one that is 1 year old.

The study aimed to recreate the original KDRI analysis. Rather than doing original coefficient comparison, SRTR compared a recalculated coefficient without race variable to a replication of the original coefficients. SRTR aimed to estimate changes in the predictive value in the strength of other coefficients with and without donor race, and then estimate the changes that would occur in the donor KDRI in the proportion of donors classified in the highest risk (KDPI > 85%). All of the mapping tables were created using the OPTN process.

The cohort was from 1995-2005, with 69,244 kidney-alone transplant recipients. A Cox proportional hazards model was used, and donor and transplant variables were recreated, along with stratifying by transplant center, age in years, etc. A best match was achieved for recipient variables that were not described in the original publication, and then a refitting of the model without the variables for Black donor race was done, along with estimating some measures of model fit in a validation cohort from 2006-2010.

The OPTN process was used for mapping KDRI to KDPI, which scaled each year of KDRI to median and define percentiles, which were used to convert KDRI to KDPI for 73,000 deceased donors from 2015-2021. June was chosen as the point to move from one map to the next. The second half of year was based on 1 year prior, the first half based on 2 years prior. A model was created for nonutilization of kidneys under the race-free KDRI scenario. A cohort of 142,000 kidneys recovered from deceased donors in 2015-2021 was used.

The model recreating the original KDRI equation achieved a close approximation to the original coefficients. In removing the Black race variable, there was a relatively noticeable change in strength of the effect of donor serum creatinine. Dr. Miller pointed out that removing the Black donor race variable moved the Black donor population closer to parity with non-Black donors in terms of the proportion classified as KDPI > 85%. With Black donor race variable included, 31% of Black donors were classified above a KDPI of 85%, which decreased to 17.8% with the Black donor variable removed. For the non-Black donors, the proportion of donors classified as KDPI > 85% increased from 13% to 15.7% with the black donor variable removed. Even though the proportion moved towards equity with the Black race donor variable removed, the nature of KDPI was zero sum, meaning if a certain number of people move out of a KDPI > 85%, then that number from another group has to move into KDPI > 85%. The numeric decrease in Black donors with KDPI > 85% was almost exactly offset by an increase among non-Black donors. Given that approximately 80% of Black recipients matched with a kidney from a non-Black donor, and because KDPI is a zero-sum classifier, simply removing donor race from the calculation may not improve access for Black candidates, even though it does improve equity in terms of the number of donors classified above a KDPI of 85%.

The study also concluded there was no substantive impact on the predictive ability of the model by removing the variable. There was also no evidence of unintended harm from removing the Black donor variable from the KDRI and KDPI calculation. Removing the race variable may not be enough to improve equity for donors and recipients, although there is the opportunity to explore different ways of calculating donor risk using both contemporary data and newer methods and moving away from the zero-sum classification system. There is also opportunity in the future to get a better handle on nonutilization of kidneys by using the simulation modeling software.

Dr. Sumit Mohan suggested thinking about what models would look like without the hepatitis C variable, and getting rid of KDPI, as influences the labelling effect. Dr. Miller noted that the work is ongoing and a publication is in preparation. He will keep the SRC updated as the work progresses.

Report from the subcommittees

Dr. Snyder reported on behalf of Dr. Allyson Hart and Mr. Richard Knight that the Patient and Family Affairs subcommittee (PFAS) last met on June 1, 2022. Dr. Schaffhausen has been leading work with a patient group that attended the consensus conference to review design concepts for the SRTR public website.

Dr. Schaffhausen reported that the Human-Centered Design subcommittee last met in May 2022, with the next meeting scheduled for the end of September 2022. Dr. Schaffhausen said the September meeting will look at website concepts that are part of SRTR special projects. Work has begun with a contractor for the SRTR website redesign, and SRTR is obtaining patient feedback on the concepts as noted above.

Dr. Snyder said the last Analytical Methods Subcommittee meeting was in August, where three new members were welcomed. The topics were the race-free KDRI and modifying how risk-adjustment models are built, specifically having a relaxed least absolute shrinkage and selection operator (LASSO) fit procedure that would allow flexibility in terms of frequency for building risk models.

New MPSC metrics reporting

Dr. Snyder said the Membership and Professional Standards Committee (MPSC) decided at the December 2021 meeting that it would look at 90-day graft survival, 1-year graft survival conditional on 90 days, pretransplant mortality, and offer acceptance. SRTR already reports on the latter two, but the former two were not included on the public report. In July 2022, SRTR launched these new metrics on the SRTR public website following previous approval by the SRC to add these metrics. In addition, a new MPSC review criteria report is available on the secure site for transplant centers along with a CMS review criteria report.

COVID-19 updates

Dr. Snyder noted many SRC members participated in drafting a letter to the editor regarding the data carve out during the COVID-19 pandemic, which was published in the *American Journal of Transplantation* (AJT).³ AJT has also published Dr. Miller's analysis on COVID-19 previously presented to the SRC.⁴

Dr. Miller presented an updated analysis of the effect of the carve out on the July 2022 performance evaluations. Dr. Miller reviewed the effects of the carve out on 90-day and 1-year conditional outcomes evaluations. The results indicated that the 1-year evaluations were affected similarly to the January program-specific report (PSR), with a high correlation between the evaluations with and without the carve out. He noted the bigger impact on the 1-year conditional evaluations, due to more days being affected by the carve out. Considering MPSC flagging, there are slightly fewer flags in the current PSR compared to removing the carve out. There were no statistically significant differences in the change in average hazard ratio if the carve out was removed by region. There was not statistical evidence that any region disproportionately benefitted or was disadvantaged by having the carve out in or out of the July PSR.

Closing business

Mr. Orlowski said a few SRC members' terms were ending on December 31, 2022, with new members joining next year. Dr. Snyder said Dr. Mohan will be assuming the role Dr. Rachel Patzer currently holds as OPTN Data Advisory Committee chair and Mr. Pittman and Mr. Orlowski would be replaced (new members will be found in the coming months). Mr. Ameen Tabatabai will be assuming the role of chair of PFAS, subsequently replacing Richard Knight on the SRC.

With no other business being heard, the meeting concluded. The next meeting will be on November 29, 2022, 12:00 PM - 3:00 PM CST.

References

1. Adler JT, Husain SA, King KL, Mohan S. Greater complexity and monitoring of the new Kidney Allocation System: implications and unintended consequences of concentric circle kidney allocation on network complexity. *Am J Transplant*. 2021 Jun;21(6):2007-2013. doi: 10.1111/ajt.16441. Epub 2021 Jan 2.

2. Rao PS, Schaubel DE, Guidinger MK, Andreoni KA, Wolfe RA, Merion RM, Port FK, Sung RS. A comprehensive risk quantification score for deceased donor kidneys: The kidney donor risk index. *Transplantation*. 2009 Jul 27;88(2):231-236. doi: 10.1097/TP.0b013e3181ac620b.

3. Mannon RB, Khush KK, Mohan S, Vock DM, Knight R, Pittman J, Zinner C, Orlowski JP. Data carve out in the midst of the COVID-19 pandemic. *Am J Transplant*. 2022 Jun 29:10.1111/ajt.17132. doi: 10.1111/ajt.17132.

4. Miller J, Lyden GR, Zaun D, Kasiske BL, Hirose R, Israni AK, Snyder JJ. Transplant program evaluations in the middle of the COVID-19 pandemic. *Am J Transplant*. 2022 Jun 21:10.1111/ajt.17123. doi: 10.1111/ajt.17123.